UNITED NATIONS
INDUSTRIAL DEVELOPMENT ORGANIZATION

SUSTAINABLE DEVELOPMENT GOALS

SMART QUALITY INFRASTRUCTURE

Shaping a sustainable future

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FOREWORD

Modern manufacturing arrived in Europe in the 18th century in the first industrial revolution. Ever since then, industrial transformation has been deeply intertwined with the establishment and evolution of what we call "quality infrastructure" (QI), with metrology and standardization providing the foundational basis. QI is the system that ensures quality, safety and environmental soundness of goods, services and processes.

This symbiotic relationship got stronger and expanded over time, supporting and influencing industrial development. Today, industry is at a turning point with phenomenal forces transforming the sector to one driven by digitalization, new patterns of globalization, rapidly changing markets, consumer preferences and the social and environmental sustainability imperative.

A new industrial revolution is unfolding in such a profound way that it will likely surpass the scale and impact of previous ones. UNIDO's publication "Rebooting the Quality Infrastructure for a sustainable future" provides insights into how QI supports the achievement of the Sustainable Development Goals (SDGs). This publication highlights the intimate relationship between industry and QI and how it has evolved over time, with a view to present current trends and challenges and to also provide indications for future development. It addresses the subject from two perspectives:

» How digital transformation is reshaping QI into what we now call "Smart QI" and "Smart Quality".

» How is QI unleashing the fourth industrial revolution and how it supports and ensure adherence to the social and environmental sustainability paradigm.

For over 50 years, UNIDO has been supporting QI development to improve industrial and economic performance of developing countries. In order for QI to be effective and sustainable, QI must advance swiftly, underpinned by sustainable development.

We need to strengthen and expand QI institutions to help consumers make informed choices, encourage innovation and for lead businesses and industries to adopt fair production practices through sustainable technologies.

I hope that this publication will help promote "Smart QI" and show how it can support the 2030 Agenda for Sustainable Development, particularly for developing countries. This publication showcases that we have the solution to drive "progress by innovation" and achieve sustainable development.

Gerd Müller

Director General
UNIDO

EXECUTIVE SUMMARY

INTRODUCTION

The world has experienced three industrial revolutions with a fourth in progress and a fifth on the horizon. These transformations have brought major shifts to the way we work and live and major changes to the way industry functions. These changes have challenged not only industry, but also the quality infrastructure (QI) to respond and adapt in a manner that will ensure the benefits of the current transformation are realized. The publication also explores how quality and quality management (QM) are innovating in response to the challenges of digitalization and Industry 4.0.

THE FIRST THREE REVOLUTIONS

This publication briefly reviews the last three industrial revolutions. Each of which has given rise to many new technologies and inventions, which propelled us further down the road of industrialization. With these changes came the first monitoring and control activities indicating the emergence of the quality infrastructure.

During the second and third industrial revolutions (SIR and TIR) there were major developments in global critical infrastructure with the emergence of key sectors such as electrification, the railroads, the telegraph system and telephone networks. The World Wars gave rise to modern mass manufacturing and assembly lines. In parallel was the evolution of the QI in response to the demands of these transformations. Metrology saw the introduction of the Metre Convention and adoption of the metric system. Conformity assessment was initially centered on testing and inspection as a reflection of the risks associated with manufacture of pressure vessels and boilers.

Post-World War II electrification, telephone networks, automobile and road infrastructure all experienced exponential growth. The impact of this surge in economic activity was to elevate the need for QI to adapt and accommodate the new needs of industry.

By far the most important development of the TIR was the arrival of the information technologies including the first personal computers. With this dramatic evolution of technology came problems of incompatibility of equipment, software, and data. These incompatibilities were preventing industry from maximizing the benefits of the new technologies. In the same period the dissemination of wireless technology with the progression of the mobile sector (mobile phone and tablets) was a significant step change resulting in the smart phones we have today. This use of information and communication technologies gave us search engines, social media, electronic commerce, and digital media.

THE FOURTH INDUSTRIAL REVOLUTION

The fourth industrial revolution (4IR) saw an explosion of digitalization and new technologies. Digital production was driven by these advanced digital technologies including Industrial Internet of Things (IIoT), big data and analytics, advanced robotics, artificial intelligence (AI) and machine learning (ML), cloud computing, and additive manufacturing (3D printing). Advanced digital technologies brought a radical transformation of industry and specifically manufacturing.

SUSTAINABILITY IMPERATIVE

There was recognition that the earth cannot sustain the current level of production indefinitely unless something changed. The world needed a new model of industrialization and infrastructure development that would sustain the earth for future generations and hence the sustainability imperative was born. The sustainability imperative is a decoupling of economic growth from use of energy and the earth's resources. Slightly more recently, social responsibility-driven considerations around inclusiveness, representation, accessibility, and decent work, inter alia, have gained momentum in the discussion of the effects and uses of the 4IR and associated technologies and innovations. This publication examines how 4IR addresses the social and environmental sustainability imperative and how a "Smart QI" supports innovation and sustainability. The 4IR also supports a fairer and more circular economy which in turn supports sustainability and holds the potential to redress social inequalities.

SMART QUALITY INFRASTRUCTURE

The advent of the "advanced digital technologies", opened new opportunities for QI and its organizations. Likewise, QI needs of 4IR are re-defining the notion of "quality". This drives QI to transform itself to a more flexible "Smart Quality Infrastructure" (Smart QI). We explore in this document the adaptations and changes of each of the main components of the Smart QI (Smart metrology, Smart Standardization, Smart Conformity Assessment, Smart Accreditation).

SMART QUALITY

The publication also addresses the impact that digitalization is having on quality not only in the enterprise itself but also in the supply chain. The integration of these new technologies is placing significant pressure on Supply Chain Quality Management to not only keep pace with digitization but to also innovate. Quality responding to challenges of the new technologies has taken the designation "Smart Quality." The publication identifies the advanced technologies that can be used for each of the quality management system processes ranging from strategic management to risk management, marketing and customer processes, production and service provision maintenance, monitoring, measurement, and problem solving.

SMART QUALITY IN THE SUPPLY CHAIN

The difference between supply chains and value chains and the impact of advanced technologies on both are addressed. Digitalization together with smart sustainable value chains has facilitated the concept of smart manufacturing and smart factory. The smart value chain stakeholders need to review the governance and quality functions in their structures, and refresh and integrate the quality management system across the enterprise to facilitate enhanced quality management processes into the multi-tier supply chain.

ROLE OF THE QUALITY PROFESSIONAL

QM professionals will need to adapt to support digital transformation, and helping enterprises to design and redesign systems and processes, helping enterprises to translate big data into real value in terms of preventing failures and solving complex problems. The publication identifies the skills that quality professionals will need in the future.

FUTURE TRENDS IN THE SMART VALUE CHAIN

Looking to what the future holds is difficult as the speed of change will likely increase faster and faster as technology adapts and changes. The document identifies and discusses possible trends for the future.

LIST OF ACRONYMS

4IR	Fourth Industrial Revolution
AI	Artificial Intelligence
AM	Additive Manufacturing
ANN	Artificial Neural Networks
API	Application Programming Interface
AR	Augmented Reality
BIPM	Bureau International des Measures
CA	Conformity Assessment
CAD	Computer Aided Design
CAB	Conformity Assessment Body
CAM	Computer Aided Manufacturing
CEN	European Committee for Standardization
CENELEC	European Electrotechnical Committee for Standardization
CGMP	General Conference on Weights and Measures
CIPM	International Committee for Weights and Measures
DLT	Distributed Ledger Technology
DPP	Digital Product Passport
EOL	End-of-life
GHG	Green House Gas
GPU	Graphics Processing Unit
GSM	Global System for Mobile Communications
GVC	Global Value Chain
ICT	Information and Communications Technology
IEC	International Electrotechnical Commission

IMT	International Mobile Telecommunications
IEEE	Institute of Electrical and Electronics Engineers
IOE	Internet of Everything
IoT	Internet of Things
IIoT	Industrial Internet of Things
ISO	International Organization for Standardization
IT	Information Technology
MES	Manufacturing Execution System
ML	Machine Learning
NFPA	National Fire Protection Association
OEM	Original Equipment Manufacturer
OI	Quality Infrastructure
PLC	Programmable Logic Controller
QI	Quality Infrastructure
SC	Supply Chain
SI	International System of Units
SPC	Statistical Process Control
SVC	Smart Value Chain
TIC	Testing, Inspection, Certification
UNIDO	United Nations Industrial Development Organization
UUT	Unit Under Test
VC	Value Chain
VR	Virtual Reality
XML	Extensible Markup Language

1.
Three Industrial Revolutions and an Emerging Infrastructure

Modern industry has evolved over almost three centuries, undergoing significant step-changes linked to technological, organizational and economic factors. Three main "revolutions" or transformations of industry can be identified over this long period, with a fourth one in the making and a fifth on the horizon. Industrial transformations are nearly always accompanied by major shifts in the way we do things and how we live, and the first three transformations were no exception.

We will not delve too deeply into the history of the links between the industrial revolutions and quality infrastructure (QI) but rather set the scene for our focal point, the relationship between the fourth industrial revolution (4IR) and QI. We will examine how the new technologies of digitalization and Industry 4.0 are impacting QI and quality, enabling both to become more responsive and smarter.

We will start our journey with a brief look at the first and second industrial revolutions.

1.1
THE FIRST AND SECOND INDUSTRIAL REVOLUTIONS

The first industrial revolution (FIR) started in the United Kingdom and spread to Europe and the USA during the first half of the 19th century. The primary and most important element of the FIR was the invention of the steam engine. Steam power and fossil fuels were used to provide an unprecedented amount of energy in support of human activities. Other major achievements of the FIR concerned improvements in mining and in metallurgy and, most importantly from our perspective, the transformation of manufacturing by production from interchangeable parts.

Production from interchangeable parts brought extraordinary benefits, such as easier assembly and repair of products, specialization and competition among producers, all leading to cost reduction and increased quality. It took decades of effort and outstanding inventors to establish manufacturing based on interchangeable parts. However, it also opened a multitude of issues to be addressed:

- Accurate and trustable measurements regarding materials, product parts and various aspects of industrial processes.
- Specification regarding the quality of materials and parts (e.g. tolerances and dimensions).
- How to ensure compatibility/usability of products.
- How to ensure safety and fitness-for-purpose of end products.

The components of QI emerged and evolved in order to provide solutions to these issues.

The development of industry, outlined above, morphed into the second industrial revolution (SIR), leading to the transformation of economies and societies of what are today referred to as "industrialized countries".

The SIR covers a timeframe starting in the second half of the 19th century and ending at the start of World War I. We can identify four essential elements:

- Technological innovation.
- Changes in the modes of production and organizational structures.
- Development of critical infrastructures for industrialization.
- Emergence and consolidation of the modern QI as a key enabling element of industrialization.

Technological innovation

Innovation and invention had an extraordinary impact on the economic development and transformation of society during the SIR. A key aspect of technological innovation was the relationship between science and technology.[1] This period marked a series of fundamental "inventions" in a variety of fields, such as energy, chemistry, metallurgy, agriculture and food production, and medicine, resulting in the development of almost all modern industries.

[1] Joel Mokyr (1990) The Lever of Riches: Technological Creativity and Economic progress.

Changes in the modes of production and organizational structures of enterprises

Production from interchangeable parts allowed for substantial increases in productivity and output. This potential was captured by creating new processes based on a "systematic definition and specialization" of production tasks, along with monitoring and control activities—what was defined as "scientific management". These innovations gave birth to modern mass manufacturing with the development of the assembly line and other critical infrastructures for industrialization.

Railroads were the first example of organizations compelled to introduce administrative and organizational structures to manage the complexity of tasks involved in running a large and diverse business. These included specialized departments with defined responsibilities, chains of command, and detailed systems of reporting and inspection. This model eventually led to the establishment of dominant, large enterprises in almost all the US American sectors and industries.

Development of critical infrastructures including QI

Key infrastructures such as transportation, electrification and telecommunications were established during the SIR. Systems such as a national railway, telegraph network and the electrical infrastructure all involved a high level of complexity. Such systems required a great deal of coordination which was provided by market (and legal) dynamics, by voluntary standards, government institutions and intergovernmental organizations.

This period also saw the consolidation of metrology, standardization and conformity assessment (CA) as the main components of modern QI.

In metrology, the adoption of the metric system was ratified through an international treaty, the Metre Convention (in 1875) originally signed by 17 countries, and increased, on 19 January 2021, to 63 Member States and 39 Associate States and Economies. The treaty established the institutions[2] that to this day manage international metrology and provide a sound framework for measurement at the international level, providing an indispensable foundation for scientific and technical development and economic activities.

Enterprises that produced goods using machines and new sources of energy had to structure and manage their internal processes by introducing internal standards based on accurate measurement. This was vital for production from machine-made interchangeable parts as precise specifications for dimensions, tolerances, and other performance aspects were necessary to assemble or repair products, and to ensure the safety, durability and reliability of products.

These new processes built quality into every part produced and along the assembly line, ensuring quality, the identification of faulty items and that parts complied with specifications. All this gave rise to new roles in the manufacturing process (e.g. the role of inspectors).

The quest for efficiency, economies of scale and competition opened up the markets for materials and product parts. It was becoming evident that individual "company standards" hindered market development and "common specifications" (or standards) were required. Standardization became an essential aspect for the evolution of enterprises in their quest for economies of scale and broad market coverage. A similar story applies regarding CA and inspection which were beginning to play a role in manufacturing industries.

Annex 1 presents two cases that highlight the key role of standardization. The first case concerns the railways in the USA and comprises a mix of technical and business issues and the need for consensus among different stakeholders. The second case outlines the origins of CA.

1.2 STEADY EVOLUTION BETWEEN THE SECOND AND THE THIRD INDUSTRIAL REVOLUTIONS

The SIR created the basis for the extraordinary development of industry, for example, the case of electrification and the development of telephone networks. All the components of these two key infrastructures were invented, refined and deployed during the SIR, along with the business models necessary to support them.

Similar considerations apply to the development of the oil and gas sector after World War II which rapidly took a central strategic role in the world economic system. The SIR saw mass-production of automobiles with the development of road infrastructures progressing in parallel. Hydrocarbons have been essential to driving industrial development and economic growth, however, their role is one of today's biggest challenges, as climate change calls for rapid decarbonization.

[2] For more details see the web site of the International Bureau of Weights and Measures (BIPM) https://www.bipm.org/en/home

All components of QI (standardization, metrology and CA) evolved steadily in line with the development of economic sectors to reach national dimensions, with increasing levels of interaction with government's regulatory efforts.

Quality control and logistics are two areas that had a major impact on the development of industry over the decades following World War II, merging with and contributing to amplifying the third industrial revolution (TIR). Annex 2 presents two cases that describe the developments around quality and logistics.

1.3 THE THIRD INDUSTRIAL REVOLUTION MARKED A TIME OF MAJOR CHANGE

The concept "third industrial revolution" introduced in the 1980s mostly concerns the advent of information technologies and their impact on industry and society.

General purpose computers started to be extensively used during the 1960s for scientific and business applications. This impacted industry at various levels, including the development and use of real-time computer systems for monitoring and control of processes. However, the defining moment of the TIR concerns the invention of the PLC, programmable logical Controller. Prior to the PLC, the only way to control equipment in factories was by using electromechanical relay circuits. Modern factories needed dozens of actuators with ON/OFF switches to control machines. A major drawback was the lack of flexibility as it was a complicated procedure to modify a production process.

This all changed when General Motors very successfully replaced the "relay systems" with a device called the "Modular Digital Controller" (Modicon PLC). Following this success, many other companies entered the market and drove the rapid development and improvement of the PLC. However, the proliferation of incompatible equipment, data structures and programming languages created difficulties of integration of equipment from different manufacturers. With the advent of microprocessors and personal computers (PC) in the early 1980s, the challenge was for software programs to be designed to run on different systems.

The International Electrotechnical Commission (IEC) started the development of specification IEC 61131-3 in 1982 which gave a substantial contribution to the consistency of software products, improving interoperability and integration of solutions. Around the same time progress was also made using computer technologies to support product design as well as integration between digital design and manufacturing systems (Computer Aided Design and Computer Aided Manufacturing, CAD/CAM systems).

It soon became evident that the exchange of technical product data was becoming a potential problem. Manufacturers of complex products (e.g. in the aerospace and automotive sectors) established large and complex supply chain infrastructures that could involve thousands of suppliers and hundreds of customers. Companies began to use computer systems to maintain accurate and stable data that could be shared with suppliers and customers. Understanding the structure and format of such digital data was essential to exchange information across the supply chain and partners. All this led to the establishment of the ISO TC 184, Industrial automation systems and integration, which has delivered a set of fundamental standards (ISO 10303) in this field and facilitated the exchange of data.

2.
New Frontiers of Industrial Development

The foundations of the 4IR are based on the exponential development of information and communications technologies. Let us consider three aspects:

» The disruptive role of information and communication technologies.

» The rise of the 4IR.

» How does the 4IR address the "sustainability imperative"?

2.1
THE DISRUPTIVE ROLE OF INFORMATION AND COMMUNICATIONS TECHNOLOGIES

Here we explore the role that computerization, standardization and the explosion of information and communications technologies have played in the 4IR.

2.1.1
COMPUTERIZATION AND STANDARDIZATION BROUGHT ABOUT PROGRESS

The invention of the "transistor" and the birth of solid-state electronics in the early 1950s opened the digital era. The semiconductor industry and digitalization were driven by the need to miniaturize, and this had enormous consequences for electronics and information technology (IT). It greatly facilitated the ability to embed IT devices into products, services and processes of almost any sector and to use computers for any type of business application. This resulted in making ever-increasing computer power easily available and affordable, transforming the way we live and do business.

Generations of integrated circuits and RAM technologies have driven the exponential growth of digitalization, which has been maintained for over 50 years.

The development of the electronics and IT sector had a significant impact on the components of QI. The relationship with metrology is evident, given the miniaturization race and the need to ensure reliable and accurate measurement. At the same time, digitalization has contributed to transforming the standardization landscape. UNIDO addresses this in much more detail in its publication "Standards & Digital Transformation, Good Governance in a Digital Age".

Standardization played a key role in the exponential development of information and communications technologies. It is worth highlighting the three key aspects of the interaction between standardization and information technologies.

On the one hand, standardization has contributed to:

» Promoting the dissemination of technologies and the development of markets.

» Helping to consolidate/stabilize various layers of technologies, and to support interoperability among equipment and software.

On the other hand, the development of information technologies has led to:

» Establishing new ways for standardization to cope with their breathtaking speed of change.

Promoting the dissemination of technologies and the development of markets

The development of IT and digital media markets amplified the importance of "network effects" which significantly impact dissemination. Network effects become crucial when the value of a particular good or service for a customer is significantly influenced by the number of other customers using it. For example, for a digital device, the number and quality of available software applications (or "apps") is a critical buying decision factor, often more important than the characteristics of the device itself.

The dynamics of network industries and of their supply and demand behavior are strongly influenced by technical standards. This concerns both proprietary technologies (industry driven) that dominate, in the marketplace, referred to as "de facto standards"—as opposed to standards developed by formal standards organizations, referred to as «de jure». However, network effects and the substantial advantages they provide are also a key driver for collaboration among market players.

Consolidating various layers of technologies, and supporting interoperability

The IT sector initially developed through a set of enterprises covering the production of all the components of a computer system. Computers were fundamentally incompatible.

All changed with the introduction of personal computers, which were assembled using components and software provided by many different enterprises. This "unbundling" of the computer industry contributed to the transformation and explosion of the sector resulting in specialization of suppliers, furious competition on a global scale, and the dramatic driving down of price/performance.

There have been epic struggles in the IT market with the rise and fall and even resurrection of enterprises, and a complex interplay between the quest for market dominance through proprietary technologies and the need to support interoperability at the user level, through the development and implementation of open standards.

New ways to cope with the breathtaking speed of change of digital technologies

The information technology sector has modified the landscape of standards organizations, with the creation of "industry consortia" in the IT field and in areas impacted by digital technologies. They establish specifications ("standards") in very short time frames, while protecting the intellectual property of consortia and participating enterprises. Popular technologies in the IT field often carry the name of the parent consortium (e.g. HDMI, DVD video, Wi-Fi, USB, Bluetooth).

Another important phenomenon is the «open source» approach which is a form of standardization. It is an alternative model compared to the proprietary-based, « closed source » model. The open-source model consists of a cooperative and incremental approach to software and hardware development and is based on the contributions from a large number of participants, who have unrestricted access to the source code (and related documentation) and are required to make available in the same way their variations and improvements.

In summary, various forms of "standards" have been instrumental in supporting interoperability and facilitating the dissemination of technologies—partly through industry consortia and open-source projects, and partly through formal organizations such as the International Organization for Standardization (ISO), IEC, and Institute of Electrical and Electronics Engineers (IEEE).[3]

2.1.2 EVOLUTION AND DISSEMINATION OF TELECOMMUNICATIONS TECHNOLOGY

The evolution of the telecommunication world and the convergence with information technologies, created what we call today the "ICT" (information and communications technologies) sector. Its evolution is based on four fundamental aspects:

» The invention and implementation of the packet switching technology.

» The de-regulation of the telecommunication sector.

» The invention and broad dissemination of the world wide web (WWW).

» The improvement and broad dissemination of wireless technology.

Invention and implementation of packet switching technology

Packet switching represented a radical innovation when compared to the "circuit switching" networks of telephone companies, which were used to exchange data among computers. At that time, computer communications were realized by using dedicated telephone lines, with proprietary communication protocols running on top of them, different for each computer vendor. It became evident that there was a need to establish a more resilient telecommunication network and packet switching allowed for this. Packet-switching technology is a method to move data in separate, small blocks (packets) over a network, routed on the basis of the destination address contained in each packet, processed by small computers.

There was also need for "open standards" that could support software implementations at various levels, enabling the interconnection of computers. The most important ones were Transfer Control Protocol, TCP (a protocol for host-to-host internetworking), and Internet Protocol, IP (for packet routing).

The dissemination of PCs in the 1980s followed by the set-up of Local Area Networks based on TCP/IP (such as Ethernet), connecting PCs and other computers in offices, gave tremendous momentum to the dissemination of TCP/IP and the growth of the internet.

[3] IEEE Standards Association have an active portfolio of nearly 1200 standards.

De-regulation of the telecommunication sector

Prior to the 1980s the telecommunication sector was in most countries, composed of state-owned public telecommunications operators (PTOs) and in North America, of regulated private monopolies. Deregulation led to a complete reconfiguration of the telecommunication sector, with substantial transformation of former PTOs, the entry of new players, the introduction of new types of services (including that of "internet service provider") and business models. This de-regulation facilitated expansion of the sector.

Invention and dissemination of the world wide web

The world wide web (WWW) was invented by Tim Berners-Lee, while working at the European Organization for Nuclear Research (CERN) in 1990–1992. The WWW is one of the many services that use the internet and was the "killer" application that opened a new era in the convergence of information and communication technologies and the advent of the "information society".

Ben Segal, a colleague and mentor to Tim Berners-Lee, said, "....... *The idea behind this (WWW) was that hypertext, a document which contains links to other documents or parts of documents, should be structured in such a way that those links should be able to ride over networks between computers...*". Tim Berners-Lee also founded the World Wide Web Consortium (W3C) whose mission is to lead the WWW to its full potential by developing protocols and guidelines that ensure the long-term growth of the Web (as well as support W3C's vision of One Web).

Improvement and broad dissemination of wireless technology

Mobile networks experienced explosive growth during the 2000s. The development of the wireless/ mobile sector was organized and driven by telecommunication companies, IT companies and governments, following a "top-down" approach. The reason being mobile technologies use the radio spectrum, which is a scarce resource, and allocated by governments and international agreements to different sectors, including the military, broadcasting and mobile communications. At the international level, this matter is addressed by the ITU Radiocommunication Sector (ITU-R).

The first mobile phone was invented during the 1970s and was initially developed to be used in cars, with the first prototype tested in 1974. A few years later came the first generation (1G) of mobile networks, deployed in Japan in 1979 by Nippon Telegraph and Telephone Corporation and spreading to the US and Europe in the early 1980s.

The second generation (2G) was based on the Global System for Mobile Communications (GSM) standard developed by the European Telecommunications Standards Institute to enable the digital cellular networks used by mobile phones and other devices (e.g. tablets). The GSM standard played a key enabling role for the global dissemination of mobile phones and market take-up (reaching a global market share of about 75% in 2007).

The third generation (3G) of mobile communication was introduced to meet the evolving demand of mobile wireless systems to enable advanced, high-capacity information services (access to internet, data, and enterprise applications). With the introduction of 3G mobile communication systems, smart phones became popular, bringing the breadth and versatility of information technology applications and services to a mobile platform and allowing the mobile phone sector to expand substantially (from 1 billion units shipped in 2003 to 4.6 billion in 2009).

The fourth generation (4G) of mobile phone and internet access services refers to the ITU International Mobile Telecommunications-Advanced (IMT-Advanced Standard), which proposes a comprehensive and secure fully IP-based mobile broadband solution, including peak speed requirements of 100 Mbs (megabits per second) for high mobility communications (e.g. cars and trains), and 1 Gbs (gigabit per second) for stationary or low mobility users. Implementation of 4G gave smart phones the ability to take full advantage of the internet and multimedia services. In addition, 4G networks opened the possibility for the internet of things (IoT).

Currently, we have the fifth generation (5G) of mobile communication systems and the ITU IMT-2020 Standard. Based on the use of higher spectrum frequencies, 5G will significantly transform the telecommunication (and ICT) sector. 5G systems also provide the ideal platform to support the IoT and, particularly, the Industrial Internet of Things (IIoT).

ITU IMT-2020 and beyond is designed to support different, specialized scenarios, such as:

» Enhanced Mobile Broadband (eMBB) to manage hugely increased data rates, high user density and very high traffic capacity.

» Massive Machine-type Communications (mMTC) for the IoT, requiring low power consumption and low data rates for very large numbers of connected devices.

» Ultra-Reliable and Low Latency Communications (URLLC) to enable safety-critical and mission critical applications.

In summary, the developments of the last 10–15 years have changed the world including search engines, social media, e-commerce, dissemination and use of digital media in a broad variety of formats. It has given rise to the dominant, all-powerful companies of the information age, the so-called "GAFAM" (Google, Apple, Facebook, Amazon and Microsoft) and more. These transformations have created the foundations in terms of infrastructures, technologies, applications and services that are enabling the 4IR.

2.2
THE RISE OF THE 4IR

In this publication we use the term "Industry 4.0" when referring to the transformation of production related to factory automation, in a very broad sense, and 4IR when considering a more general perspective, related to the transformation of economy and society as a whole.

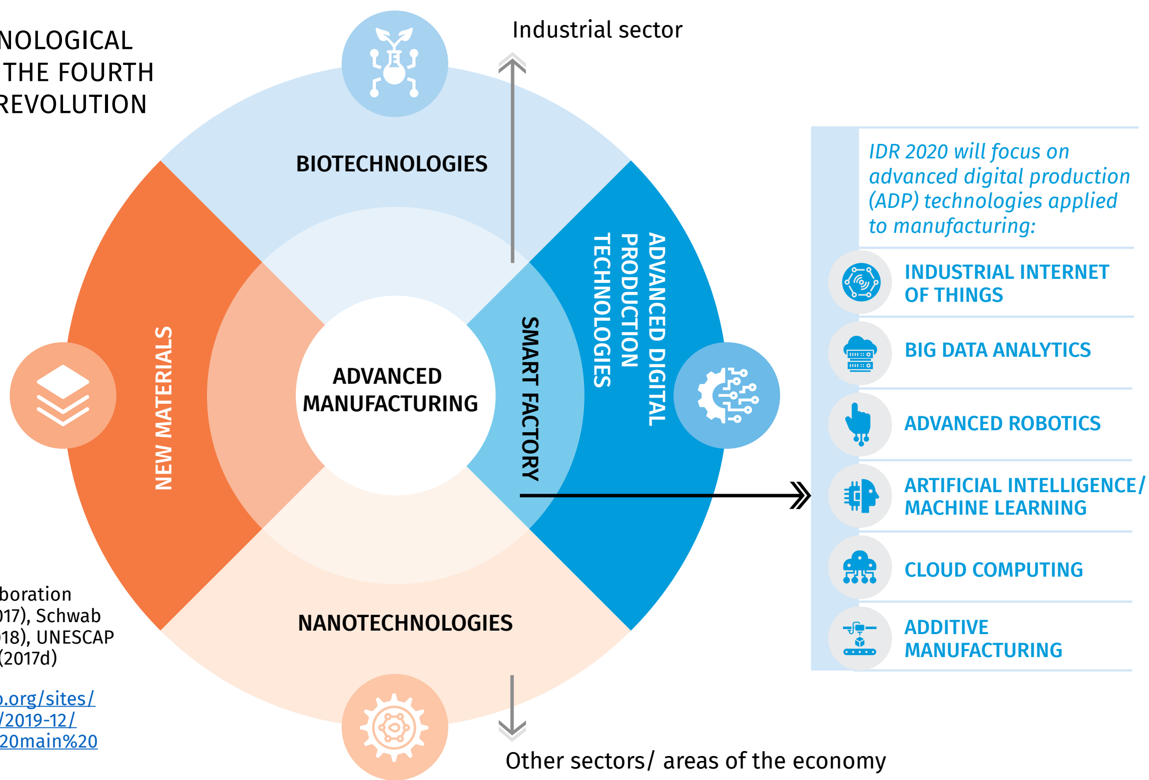
The term "Industrie 4.0" was coined by Prof Wahlster (Professor of Artificial Intelligence in Germany) who explained that to maintain its leadership role in manufacturing, it was essential for Germany to master the industrial revolution powered by the internet, and to understand the "bridge" between the digital and physical worlds. This idea soon spread with the publication of Klaus Schwab's (Chairman of the World Economic Forum) article "Mastering the Fourth Industrial Revolution" in 2015, and the selection of 4IR as the central theme for the 2016 World Economic Forum meeting in Davos, Switzerland. Schwab declared that *"When compared with previous industrial revolutions, the Fourth is evolving at an exponential rather than a linear pace. Moreover, it is disrupting almost every industry in every country. And the breadth and depth of these changes herald the transformation of entire systems of production, management, and governance".*

The phenomenal information processing power together with the capability of storing and moving information in unprecedented volumes and at ultrafast speed has opened entire new fields of application. Similar transformation has also taken place in fields that have developed in strong association with digital technologies, in particular biological science and technologies, materials science and the nanotechnologies.

The interaction and convergence of these developments is well represented in the figure below, taken from the UNIDO Industrial Development Report 2020.

These technologies (see figure 1) and their application have a significant impact on businesses and are already disrupting existing value chains (even before the impact of COVID-19). New models are emerging of production, use of materials and parts, and how to meet customer needs, modifying the way we create value. Business leaders and policymakers need to recognize and adapt to innovation running at an exponential rate, and to shape strategies, management approaches and policies accordingly.

FIGURE 1: **BROAD TECHNOLOGY DOMAINS OF THE 4IR**



Source: UNIDO elaboration based on OECD (2017), Schwab (2016), UNCTAD (2018), UNESCAP (2018) and UNIDO (2017d)

https://www.unido.org/sites/default/files/files/2019-12/UNIDO%20IDR20%20main%20report.pdf

In this publication, we focus our attention on the "advanced manufacturing" technologies and in particular on the "advanced digital production technologies" at the core of the 4IR and closer to the concept of "Industry 4.0". They are addressed within the next section, dedicated to highlighting the relationship between QI and the 4IR.

To complete the overview of "the new frontiers of industrial development", it is essential to highlight the **sustainability imperative**, which is of crucial importance to determine if the 4IR can deliver a positive contribution to humanity.

2.3 ADDRESSING THE SUSTAINABILITY IMPERATIVE THROUGH THE 4IR

Sustainable development came to the attention of the international community after the publication of the Brundtland report in 1987 ("Our Common Future", by the World Commission on Environment and Development, WCED) and the organization of the Rio Earth Summit (United Nations Conference on Environment and Development, UNCED) in 1992.

UNIDO's publication "Rebooting the Quality Infrastructure for a sustainable future" provides insights into how a QI supports and strengthens the implementation of the United Nations Sustainable Development Goals (SDGs). It describes how QIs support economies to meet the SDGs by creating prosperity, enhancing the well-being of people and protecting the planet. This document focuses on how the new technologies of 4IR address the social and environmental sustainability imperative within the industrial sector. It looks at how the Smart QI components are specifically supporting sustainability in relation to the industrial sector.

Sustainability concerns with respect to "corporate social responsibility (CSR) and responsible business conduct", as well as the importance of climate change and carbon emissions, were only fully recognized by the private sector in the 2000s. Concepts such as the "triple bottom line" (referring to economy, environment, and society) and "sustainability reporting" were introduced and first applied at that time, often based on private standards developed by multi-stakeholder initiatives. However, CSR and related concepts were mostly seen as "additional" constraints or targets concerning activities, without being fully integrated with the core objectives and essential nature of the business, manufacturing or otherwise.

The 4IR gives a unique opportunity to re-think and address manufacturing alongside sustainability- and social responsibility-related considerations. We give an overview of the subject, first, by providing a brief outline of the challenges, and then go on to describe, in general terms, some strategic directions that the 4IR should pursue to achieve and fulfil the sustainability imperative.

2.3.1 SUSTAINABILITY CHALLENGES

Industry, and notably the manufacturing sector, is recognized as a key driver of economic growth for both developed and developing countries. However, industrialization and infrastructure development take place in a radically different way today than previously. Humanity and our global economies are pushing the boundaries that the earth can sustain and this has enormous implications on how industrialization and infrastructure development should be pursued now and into the future. There are enormous consequences for our planet, people and prosperity if we do not get this approach right.

As noted by UNIDO (Structural Change for Inclusive and Sustainable Industrial Development, 2017): *"An increase in CO2 emission and material use was registered in the manufacturing sectors across all country groups, largely driven by the effects of increased volumes of production. This occurred despite the positive trend in the reduction in environmental intensity (environmental impact per unit of output) of production across all country groups, except for low-income economies. […]*

Efforts to reduce environmental intensity further still must be accelerated and the relevant technology diffused as widely as possible."

Faced with global demands for better working conditions and more diversity in the workplace, the industry is increasingly internalizing the concept of decent work – work performed in conditions of freedom, equity, security and human dignity. The importance of job quality as part of the sustainability imperative is highlighted in SDG 8, which aims to "promote sustained, inclusive and sustainable economic growth, full and productive employment and decent work for all".

The 4IR offers a tremendous opportunity to embrace diversity in the workplace. Many jobs are now more accessible than ever for people who suffer from discrimination and/or stigmatization. Excluding groups of people from jobs based on personal characteristics, such as ethnic origin, gender and special needs, is not only unethical and in many cases unlawful, but also bad for business.

On the question of gender equality, it has been observed that "[w]hilst globalization and the development of lengthy supply chains has created opportunities for female employment in export manufacturing, there is an ongoing debate as to how far recent trends in technological change and reorganization within firms generate a process of 'defeminization' and employment biases against women," further stating that "[t]echnological change inevitably affects and transforms employment opportunities. [...] Given the imperative to create jobs in order to meet inclusion objectives, the challenge is to ensure adequate growth of manufacturing production."[4]

All dimensions of inclusive industrial development, e.g. related to disability- or youth-inclusion, need to be analyzed and appropriate responses be derived to ensure equal opportunities, equal access, and equal enjoyment of benefits.

These are the core issues for industry, and it is appropriate to dedicate a few more thoughts to them.

There is no doubt the world economy is based on consumerism, for example, household consumption represents about 60 percent of global GDP (see TheGlobalEconomy.com). The problem is that the world economy is still structurally based on high throughput and producing ever more goods requires ever more materials and energy input. Additionally, because most consumer goods (including durables) have a relatively short lifetime, and the re-use of product components or materials at end-of-life is marginal, this generates increasing amounts of waste. To give an idea of the scale and complexity of the challenge, let us look at two sources of important data.

According to the Global Resources Outlook 2019 of the International Resource Panel, in 1900 the world consumed 7 billion tonnes of primary materials. In 1970 material consumption increased to 26 billion tonnes and by 2017 it reached over 90 billion tonnes. By 2030 primary material use is expected to reach 120 billion tonnes and by 2050, under a business-as-usual scenario, about 190 billion tonnes.

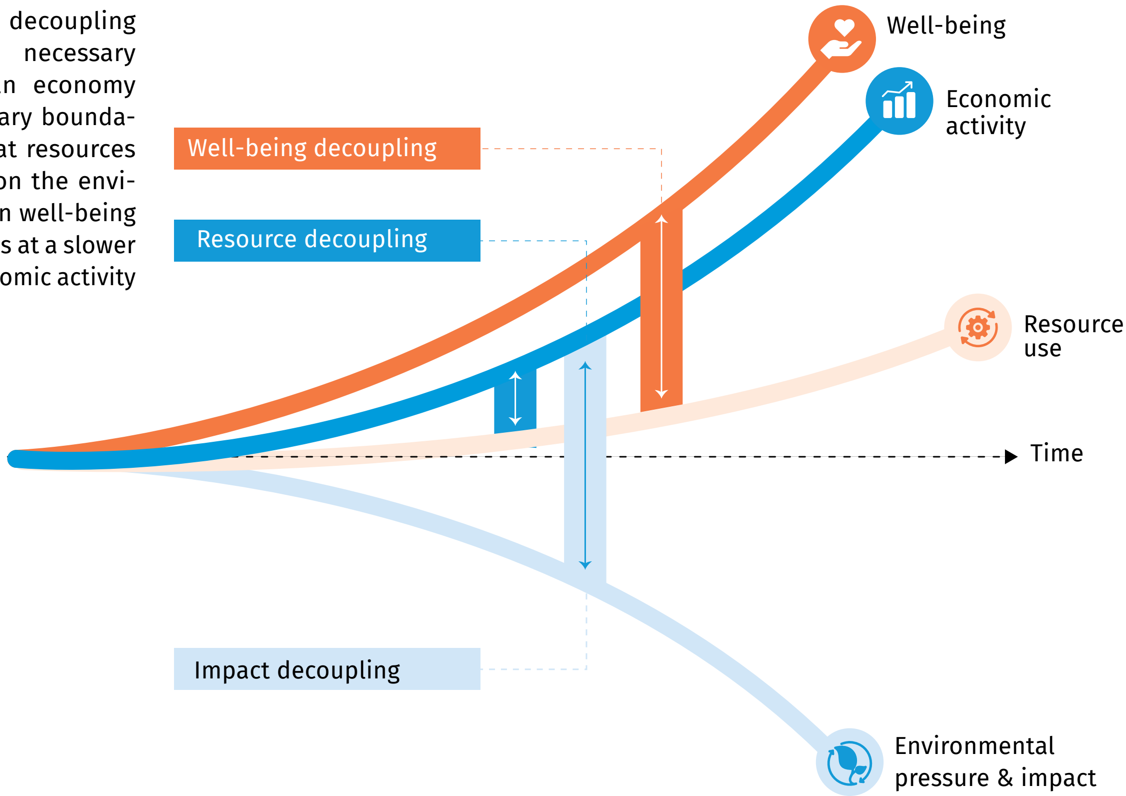
The Circle Economy Global Gap report (2020), based on the material flow analysis methodology, shows how material inputs of 100.6 billion tonnes (92 of primary materials and about 9 of recycled materials, in 2017) end up as outputs: only 31% result as "net added stock" of materials to the economy and 8.6% as recycled materials, while all the rest is dispersed into the environment (22.4%), transformed into emissions (14.6 %) or lost to the environment (24%), as collected but not-treated waste.

In order to maintain the ability of satisfying people's needs without compromising our future, it is imperative to achieve what the United Nations Development Programme (UNDP) has defined as "decoupling" (see figure 2).

[4] https://www.unido.org/sites/default/files/files/2018-06/EB-OOK_Structural_Change.pdf

FIGURE 2: **THE DECOUPLING CONCEPT**

The concept of decoupling describes the necessary conditions for an economy within the planetary boundaries. It means that resources use or pressure on the environment or human well-being decreases or grows at a slower rate than the economic activity causing it.



Economic activities need to dramatically increase their energy and material efficiency ("decoupling" economic growth from the use of materials and energy) and to stop their negative impact on the environment ("decoupling" the use of resources from environmental impact, targeting zero greenhouse gas, GHG, emissions). This should also result in limiting pollution, land use, and harm to biodiversity in order to not go beyond the environment's capacity of absorption and regeneration.

It is worth noting that, similarly to climate change-related consequences arising from industrial processes being unequally distributed between industrialized and industrializing countries, environmental and climate results caused by industrial operations also have gender differentiated impacts. For example, the International Organization for Migration (IOM) reports that gender constitutes a key differentiator when it comes to natural disaster response and environmental migration, as "vulnerabilities, experiences, needs and priorities of environmental migrants vary according to women's and men's different roles, responsibilities, access to information and resources, education, physical security, and employment opportunities".[5] Decoupling, therefore, not only has the potential to put a halt to environmental and climate degradation through effective and efficient use of natural resources and pollution management, but also signals opportunity to reduce and redress some of the gendered effects deriving from unsustainable production and consumption patterns.

Some key points need to be highlighted before looking at how the 4IR can contribute to "decoupling":

» Power generation plants based on fossil fuels, polluting and inefficient manufacturing plants, transportation/logistics based on aging and inefficient trucks and fleets create systemic conditions that are difficult to address in a short period of time.

» It is vital to consider the "material and energy footprint" of products, including the impact of extraction and processing of resources embedded into products. This is particularly important considering the structure of global supply chains. Production is based on the assembly of imported intermediate products and raw materials, and this transfers most of the environmental impacts to the countries where materials are extracted, and where intermediate products are created.

» As alluded to before, extractive industries are disproportionately governed and operated by men, and women and girls bear a disproportionate share of the negative social, economic and environmental impacts of the sector. E.g., extractive industries are reportedly aggravating dependencies related to land ownership (questions over access to land for subsistence agriculture; no compensation for women over land losses if men are the legal titleholders) and increasing women's care burdens due to pollution and health effects of extractive operations in close proximity to local communities.[6]

» We must also consider social and environmental impacts along the full lifecycle of products and services. We need to evaluate these impacts for aggregated data (e.g. for categories of products and sectors), and not only "per-unit" of output, which may provide misleading indications.

2.3.2 4IR STRATEGIC DIRECTIONS FOR ACHIEVING SUSTAINABILITY

Manufacturing has a fundamental role in the transition to a sustainable economy. This poses substantial challenges, regarding the entire process of designing, sourcing, producing, delivering, and servicing products. These challenges are broad and complex and go beyond the scope of this publication. Nonetheless, we can outline some essential issues.

There are four main aspects regarding the relationship between 4IR and sustainability:

» **Aspects directly related to the 4IR enabling technologies and infrastructures**: energy and material consumption of telecommunication infrastructures, server farms powering remote and local computing services, as well as energy/material consumption and waste of devices (computers, smartphones, sensors and other connected devices) used in the framework of the 4IR.

» **Aspects directly related to the 4IR and more specifically to the digital transformation**: regarding the social and environmental impacts of manufacturing processes (industrial safety, energy use, emissions, pollution and waste).

» **Aspects indirectly related to 4IR, regarding manufactured products**: how the technologies underpinning the 4IR and their business models contribute to reducing energy and material consumption and GHG emissions of products throughout their entire lifecycle.

» **Aspects regarding the social impacts of the 4IR**: in particular, how technologies and processes of the 4IR are affecting communities, the labor

[5] https://www.iom.int/sites/g/files/tmzbdl486/files/about-iom/gender/Gender-Approach-to-Environmental-Migration.pdf

[6] https://www.scribd.com/fullscreen/28872387?access_key=key-1jqxr250wrtppeois351

market, working conditions and the creation and distribution of wealth.

These aspects, which all relate in some way to people, planet and prosperity, need to be addressed to ensure a positive contribution of the 4IR to human well-being. For example, regarding the first aspect outlined above on the environmental impact of digital technologies, it is worth noting that:

- in 2019, the digital world was made up of 34 billion pieces of equipment with 4.1 billion users, the mass of this digital world amounting to 223 million tonnes.
- the network equipment comprises of 1.1 billion digital subscriber line (DSL)/fiber routers, 10 million GSM relays (2G to 5G) and about 200 million other active wide area network (WAN) equipment.
- there are a few thousand data centres with approximately 67 million hosted servers.

All this equipment is responsible for a significant share of global electricity consumption and carbon emissions. These are expected to grow substantially over the next years and *"by 2030, about 25% of the world's energy (most of which is produced by burning carbon-rich fossil fuels) could be consumed by electronic devices if nothing is done to make them more energy efficient".*[7]

If that is not enough, electronic waste is the fastest growing type of waste on the planet. According to the Global E-waste Monitor, over 53.6 million metric tons of e-waste were generated in 2019. Only 17.4% percent of this e-waste was formally registered, collected and recycled. E-waste has a significant social impact, as people involved in recycling activities are often exposed to health and safety hazards. According to WHO, as many as 12.9 million women are working in the informal waste sector, which potentially exposes them to toxic e-waste and puts them and their unborn children at risk. Children are often engaged by parents or caregivers in e-waste recycling. Other children live, go to school and play near e-waste recycling centers where high levels of toxic chemicals, mostly lead and mercury, can damage their intellectual abilities. Children exposed to e-waste are particularly vulnerable to the toxic chemicals they contain due to their smaller size, less developed organs and rapid rate of growth and development. They absorb more pollutants relative to their size and are less able to metabolize or eradicate toxic substances from their bodies.[8]

The environmental impact of digital technologies is an issue that has been recognized and is being taken into consideration. For example, the IMT-2020 Standard includes specific energy efficiency requirements for 5G networks, and there are many technological and organizational developments that aim to address the matter. Data centres have pursued efficiency improvement programmes, including the shift to hyperscale configurations, to curb energy intensity. New generations of chips are being designed to increase energy efficiency. New applications and development of power electronics can improve energy efficiency in various domains.

Rising energy costs will also dictate a more intense approach to energy saving technologies and strategies. However, from the perspective of the digital transformation, many other actions need to be taken to increase energy efficiency. A few critical directions include:

- Smarter and more energy efficient sensors.
- The need for lean and smart approaches for sensor connectivity.
- The need for advanced and highly efficient power electronics to control electric motors and other devices.

Regarding the environmental impact of manufacturing processes, energy and material efficiency are key drivers of innovation and the core 4IR technologies that can provide significant contributions. Energy use and emissions regarding the manufacturing process can be measured and tracked using digital technologies, while optimization of tasks and use of cyber-physical systems can reduce downtimes and use of energy. Additionally, additive manufacturing (3D printing) can be applied to the production of parts, saving materials and energy, and so on.

2.3.3 THE 4IR ENABLING A FAIRER AND MORE CIRCULAR ECONOMY

Developments such as those outlined above go in the right direction, however, much more needs to be done. Sustainability needs to become a strategic imperative for manufacturing and integrated at all levels in an enterprise's processes. In this respect, the most effective direction is the link between the 4IR and the circular economy. The "sustainability community" see the 4IR as a unique opportunity to establish a circular economy.

The circular economy is a production/consumption model that is:

"based on three principles, driven by design:

- *Eliminate waste and pollution*

[7] Theresa Duque, How Can Next-Gen Computer Chips reduce our Carbon Footprint? (2021)

[8] WHO (2021). Soaring e-waste affects the health of millions of children, WHO warns. [online] Who.int. Available at: https://www.who.int/news/item/15-06-2021-soaring-e-waste-affects-the-health-of-millions-of-children-who-warns [Accessed 7 Oct. 2022].

- *Circulate products and materials (at their highest value)*
- *Regenerate nature*

It is underpinned by a transition to renewable energy and materials. A circular economy decouples economic activity from the consumption of finite resources. It is a resilient system that is good for business, people and the environment" (Ellen MacArthur Foundation, Circular Economy Introduction).

Briefly, the circular economy indicates a strategic direction to meet SDG 12 (sustainable consumption and production patterns). Both circular economy and Industry 4.0 address the transformation of the world's production systems. In addition, the circular economy addresses the modalities of consumption and how to deal with products' end-of-life, (something that is not explicitly covered by Industry 4.0). To meet the sustainability imperative, they must go together. As understood by the "sustainability community", Industry 4.0—if properly directed (i.e. if strategists, engineers, production professionals, and marketeers are aligned on clear and concrete sustainability goals)—can play a key role in unleashing the circular economy. Although a complex matter, we outline some major aspects:

The first aspect (and arguably the most important) is product design

as products need to be designed considering the whole product lifecycle, generating circular and sustainability criteria design goals, including:

- Minimizing the materials and energy required for production.
- Minimizing the amount of non-renewable, "virgin" materials used.
- Eliminating hazardous materials, and finding suitable alternatives (or design changes).
- Extending durability, repairability and the possibility to upgrade products.
- Minimizing the energy required for usage.
- Maximizing the reusability of product components.
- Maximizing the recyclability of product components.
- Ensuring that renewable materials and recycled materials (or secondary raw materials) used as input are sustainable.
- Ensuring that product parts from the supply chain are produced according to the same criteria.

The second aspect is Industry 4.0 supporting technologies such as

The use of advanced design modelling (e.g. using "big data" and artificial intelligence, AI) to enable proof of concepts and simulations, aiming to incorporate an optimal combination of circularity criteria.

- "Digital twins"—i.e. digital "copies" of products (and parts) should be used to capture not only data about structure and properties, but also information on material composition and environmental footprint. This can be a key enabler for use of digital product passports (DPP), a fundamental tool supporting circularity at various levels of the product lifecycle.
- Establishing feedback loops between production and use phases of products and components, allowing to better understand behaviors and discover possible improvements. Additional, complementary research into and data collection on women's and men's differentiated user/consumer behaviours would be beneficial, as it would allow for the distillation of insights into gendered approaches to and philosophies on consumption.

The third aspect is establishment and operation of reverse supply chains for circularity

This is probably the area where the circular economy departs most significantly from the linear economy. Properly collecting products at end-of-life (EOL) is essential to valorize product components and materials, allowing to extend product life cycles and to reduce sourcing of virgin materials. Product collection initiatives, such as take-back programmes, or returns (e.g. through e-commerce platforms), already allow consumers to return products to retailers, service providers or manufacturers. Women should be capacitated to become key drivers of change in this regard, as "[w]omen are more likely to recycle, minimise waste, ... and engage in water and energy savings initiatives at the household level". Certain studies suggest that women appear to give preference to electronic products, that have an end-of-life feature.[9]

However, what is needed is a radical alignment of value chains. In essence, reverse supply chains require:

- An efficient, coordinated system of products collection (returns of new products and collection of EOL products).
- Centres for inspection and sorting to determine

[9] https://www.oecd-ilibrary.org/sites/7ff96708-en/index.html?itemId=/content/component/7ff96708-en

the recovery options for EOL objects (full products, product parts, or materials extracted from parts). Sorting and categorization determine which products are viable for reuse and which ones require repair, refurbishment or upgrading before reuse. Parts that are deemed non-reusable are then sent to specialized facilities for material recovery.

» Re-injection in supply chains of re-usable products and parts, and redirection of non-reusable components to recycling centres.

Some elements of this system are implemented by enterprises on an individual basis (for example Google has implemented an internal system for inspecting and sorting EOL computers used in its server farms, extracting and refurbishing disassembled components to make them available as spare parts in its warehouses). The real circular challenge is to organize such systems at the sector or sub-sector level. Depending on economies of scale, concentration of knowledge and transportation costs, these systems could be organized from a mostly local/national dimension to a fully international one.

Standards and regulations play a fundamental role here along with government and industry-led initiatives. In many countries, there is a trend to regulate extended producer responsibility (EPR) for products. This type of regulation aims to transfer the financial burden of waste collection and waste treatment from local authorities (and local tax payers) to manufacturers. Moreover, it encourages companies to repair and re-use products, reduce waste, and to embrace circularity.[10]

The fourth aspect is Industry 4.0, which can provide an essential contribution in this area

» DPPs and mechanisms for tagging parts would substantially facilitate inspection and sorting activities. Digital labelling after inspection, along with exchange of logistics information across the chain, would also allow the automation of various steps of the reverse supply chain.

» Digital twins would facilitate inspection of EOL products and refurbishing/remanufacturing of product parts.

» DPPs and other mechanisms providing detailed information about materials will be invaluable to feeding recycling plants.

Similar considerations apply to recycling and other aspects, and we have already outlined how Industry 4.0 can contribute to the sustainability of manufacturing processes.

[10] Cf. ISO (2022). [online] Available at: https://www.iso.org/obp/ui/#iso:std:iso:iwa:19:ed-1:v1:en:term:3.14 [Accessed 7 Oct. 2022].

The final aspect concerns the social impact of the 4IR

Some of the most social issues specifically those concerning labor, inequality and ethical aspects:

» Impact on the labor market: 4IR is likely to lead to job reductions in factories and the service sector. In many cases, technology adoption saves labor—for instance, when robots are deployed in manufacturing or when technology increases productivity so that fewer workers are required. At the same time, rising numbers of people are relying on digital platforms to generate income. Technological advances prompt labor substitution and create new jobs, but also break up existing work into smaller gigs and fundamentally restructure labor markets.[11] Moreover, research conducted by UNIDO has found that "technological upgrading is associated with the defeminization of labour in manufacturing industries, [...] attributable to the fact that many jobs typically held by low-skilled women consist of high non-routine manual skills that still represent bottlenecks to automation."[12] Furthermore, it is being postulated that a reduction of the digital gender divide, particularly in developing countries, could open up avenues for women to take on managerial roles and participate more in decision-making processes.

» Inequality: Digitalization and globalization have enabled services based on information that can be scaled up rapidly to the reach global dimension. Enterprises can grow using only a small fraction of the workforce. This generates enormous profits to the benefit of, primarily, the top managers and major shareholders of a restricted group of enterprises, with a rapid and massive concentration of wealth and power. In many of these enterprises, there is a loosening of the shared understanding of what it means to be a "worker" or "employer". The untethering of social protection from employment and the challenges of organizing workers who are self-employed and do not share the same work location (such as a factory floor) are issues that affect an ever-increasing number of people in the workforce. People and communities who do not have access to technology, or the skills needed to engage with it, or who are victim to biases embedded in certain algorithms are facing a significant disadvantage. This deepens the digital divide within and between countries.[13]

[11] ILO (2022). World Employment and Social Outlook: Trends 2022. [online] Available at: https://www.ilo.org/global/research/global-reports/weso/trends2022/WCMS_834081/lang—en/index.htm [Accessed 7 Oct. 2022].

[12] https://www.unido.org/api/opentext/documents/download/20105985/unido-file-20105985

[13] Ibid.

- Ethical aspects: for example, relating to autonomous machines that range from philosophical perspectives to legal aspects. And many other questions concern the use of autonomous or semi-autonomous systems in sensitive fields such as healthcare, security, information and media. Advance industrial production needs to ensure that (semi)-autonomous machines do not reproduce the unconscious biases and discriminatory beliefs of the people who make or program them. If this is not addressed, it can lead to greater inequality in society.
- Privacy: At the heart of the 4IR lies the free flow of data. This leads to concerns around privacy. New rules, regulations and standards are needed to protect businesses' intellectual property in a globally networked system, to protect citizens' and customers' sensitive personal information, and to make sure that self-optimizing systems are kept under control.[14]

[14] EY Global (2021). Four things to know about the Fourth Industrial Revolution. [online] Ey.com. Available at: https://www.ey.com/en_uk/digital/four-things-to-know-about-the-fourth-industrial-revolution [Accessed 7 Oct. 2022].

3.
Smart QI supporting Innovation and Sustainability

The 4IR is characterized by a deep interaction with QI. On the one hand, QI components are essential enablers of technologies and processes and on the other hand, innovations and transformations related to the 4IR have a significant impact on QI itself.

Digital technologies (including "advanced digital production technologies"), open new opportunities for QI and its organizations. Likewise, QI needs of 4IR are re-defining the notion of "quality". This drives QI organizations to perform differently and to provide new types of services. This transformation is often presented as "Quality Infrastructure 4.0" or as we prefer to it "Smart Quality Infrastructure" (Smart QI), to stress the importance of not only technologies, but also organizational and human factors.

We start with a description of the "advanced digital production technologies" component of Industry 4.0 and follow with an analysis of the emerging Smart Quality Infrastructure (Smart QI).

3.1 ADVANCED DIGITAL PRODUCTION TECHNOLOGIES OF INDUSTRY 4.0

The transformation of industry—and specifically of manufacturing—underpinned by Industry 4.0 aims at:

- Establishing flexible manufacturing operations that can easily be re-tooled to produce variations of existing products or entirely new products.
- Using cyber-physical systems (robots, actuators and sensors) able to autonomously manage factory shop-floor activities (including handling of materials and parts, the execution of tasks and monitoring and control activities).
- Implementing efficient and secure data, capturing and exchanging systems for all connected equipment, and allowing them to interact among themselves and with local or remote design and control centres.
- Producing digital copies ("digital twins") of product items at any relevant stage of the manufacturing process, copies that can be validated or modified by designers whenever needed, intervening directly into the process.

These developments are driven by the combination of advanced digital production technologies, such as **IIoT, big data and analytics, advanced robotics, AI/machine learning (ML), cloud computing, additive manufacturing (3D printing)**. These technologies are essential enablers for the 4IR and Industry 4.0.

The impact of each of the above is briefly described below.

Industrial Internet of Things

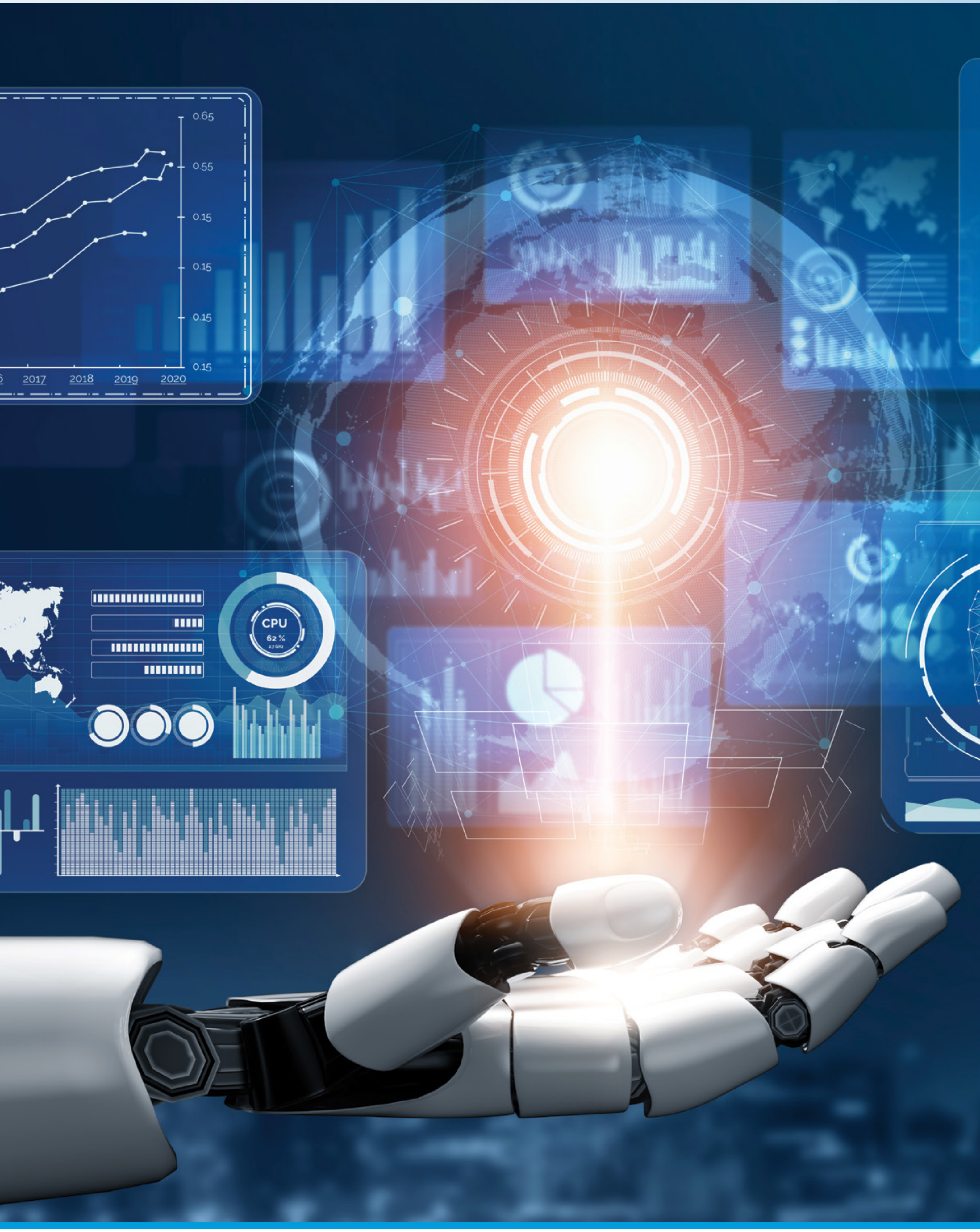
The IIoT is intended as an extension of the Internet of Things (IoT), specifically for the factory environment. It goes beyond the connection of "conventional" physical devices (e.g. wearable devices such as watches, smart home devices, simple healthcare devices). It is specialized to support wireless connection (through the cloud[15] and edge[16] computing systems) and interoperability of robots and industrial control systems. Strictly related issues concern speed, reliability, security and energy consumption.

Big data and analytics

ISO/IEC 20546:2019 defines big data as "*extensive datasets, primarily in the data characteristics of **volume**, **variety**, **velocity**, **and/or variability** — that require a scalable technology for efficient storage, manipulation, management, and analysis*".

Around 2010 new types of datasets began to be generated in very large and varied volumes (e.g. video, social media, streaming, mobile applications, IoTs) all having different needs in terms of velocity, which placed additional demands on technology. In the context of Industry 4.0, big data captured and shared by sensors (and other devices) is used to:

[15] Cloud computing refers to "on demand IT".
[16] Edge computing refers to distributed computing where data are stored and processed closest to where they originate.


0.65
0.55
0.15
0.15
0.15
0.15
2017
2018
2019
2020
CPU
62 %

» Ensure optimal coordination and synchronization of equipment.

» Perform virtual inspection and quality control of products.

» Analyze the production process (e.g. identify hidden or potential bottlenecks).

» Support automation through the analysis of historical data.

» Use artificial intelligence systems to generate changes that can be directly implemented by cyber-physical systems.

These applications are expected to drive the growth of data from about 10% of the total in 2020 to about 30% in 2025. In support of inclusive and sustainable development, data bias needs to be considered, as biased or incomplete representation can lead to the continuation and reproduction of social inequalities.

Advanced robotics

According to ISO 8373:2012, an **industrial robot** is an "***automatically controlled***, ***reprogrammable***, ***multipurpose*** *manipulator programmable in three or more axes, which can be either fixed in place or mobile for use in industrial automation applications*".

To align with the paradigms of Industry 4.0 and the 4IR, robotics is experiencing a rapid evolution, leading to a new generation of robots that are fully connected, smarter, more flexible and capable of movement and self-learning. They have a fundamental and enabling role in the 4IR. Robots and cobots (i.e. humans and robots collaborating together) are becoming more common in every aspect of life today with industry specifically benefitting greatly from both.

Artificial intelligence/Machine learning

The Merriam-Webster Dictionary defines artificial intelligence (AI) as:

1. *a branch of computer science dealing with the simulation of intelligent behavior in computers,*
2. *the capability of a machine to imitate intelligent human behavior.*

Over the last few decades, the applications and transfer of ideas from AI to many different fields have been incorporated into a variety of products and services, such as search engines, social media, automated translation, digital photography, digital assistants, autopilots, drones and robots, as well as emerging technologies, such as self-driving cars, unattended retail, and many more.

Machine learning, a term defined by Tom Mitchell (Machine Learning 1997) as "*the study of computer algorithms that can improve automatically through experience and by the use of data*", has become today's dominant field in AI. One of its branches, **deep learning**, defined by the Oxford dictionary as "*a type of machine learning based on artificial neural networks (ANN) in which multiple layers of processing are used to extract progressively higher-level features from data*" emerged following the increased processing power of computers and the introduction of GPUs (graphics processing units).

The use of machine learning and deep learning systems is of fundamental importance for Industry 4.0 as a key enabler of various functions, including:

» "Vision", for example, object detection and manipulation by robots and other devices acting on the factory shop floor.

» All the activities outlined under the "big data" section above, providing the intelligence needed to:

  - support automated product inspection and quality control (e.g. detecting product anomalies, such as scratches, wears, dirties, discoloration)
  - diagnostic analytics of machinery and other equipment (to check if bearings, rotors, gearboxes, etc., are working correctly and to identify and describe malfunctioning)
  - analyzing data in real time for process optimization (preventing bottlenecks and downtimes)
  - predictive analytics, working on historical data to suggest process improvement

» Assistance in product design, and particularly on simulations.

Cloud computing

Cloud computing refers to using the "on demand" availability of IT resources (notably processing power and data storage) by accessing data servers distributed at multiple locations and without direct active management by the user.

Cloud computing enabled the 4IR by giving rise to favorable price/performance trends of computing resources and telecommunication services. This opened up new possibilities for using global, scalable and secure services, with levels of performance tailored to customer needs, provided through data servers that provide optimized performance.

As another essential enabler for the 4IR and Industry 4.0, some of the most important functions provided by cloud computing are:

- Data storage and exchange among devices connected through the IIoT.
- Use of processing power and specialized applications (including AI services and analytics).
- Supporting the visibility and sharing of data by multiple parties along supply chains.
- Enabling location tracking of product items within factories and for logistics applications.

Additive manufacturing (3D printing)

ISO/ASTM 52900:2015 defines additive manufacturing as the "*process of joining materials to make parts from 3D model data, usually layer upon layer, as opposed to subtractive manufacturing and formative manufacturing methodologies*".

This concerns a digital model (usually created by a computer-aided-design, CAD, software, or a 3D object scan) and a computer-controlled process to create the 3D object.

3D printing is a form of additive manufacturing and in ISO/ASTM 52900:2015 it is defined as the "*fabrication of objects through the deposition of a material using a print head, nozzle, or another printer technology*". However, 3D printing is also used as a synonym for additive manufacturing (AM).

Chris Hull founded the 3D Systems Corporation that began to commercialize 3D printers in the late 1980s. It was only in the second half of the 2000s that substantial acceleration in the "use" of AM technologies (and particularly of 3D printers) took place. The evolution of AM also concerned engineering and manufacturing enterprises, going beyond simple prototyping, to the manufacturing of real product parts with adequate precision and reliability. In this respect, three other important aspects regarding the evolution of AM should be highlighted:

- First, the emergence of a repository of product designs (i.e. complete digital description of products, using different formats) available from the internet, and of 3D printing online marketplaces that offer a variety of services.
- Second, AM will have a significant impact on global value chains. The level of disruption will be different depending on the sector and specific characteristics of the global value chains (GVCs).
- Lastly, a major impact is the labor input for AM products is substantially lower than for conventional processes, and this will lead to increased small-scale, local production.

It is evident that AM is an important component of the 4IR. Some of the main aspects along with the potential impact on GVCs are:

- Faster and cheaper prototyping.
- Simplification and potentially huge increase of productivity in producing parts: parts that require complex processing steps can be produced in "one go", increasing overall productivity.

3.2 THE 4IR AND INDUSTRY 4.0 IMPACTING SMART QI

The scenario presented in the previous sections has a profound impact on QI. It is clear that services needed from QI and the way in which they are developed and delivered is different from the past, in particular in terms of speed, complexity, richness of information and ability to structure and deliver information to the appropriate targets (human or machine).

According to INetQI,[17] QI is a "system that combines initiatives, institutions, organizations (public and private), activities and people. It includes the policies, relevant legal and regulatory framework, and practices needed to support and enhance the quality, safety and environmental soundness of goods, services and processes. It is required for the effective operation of domestic markets, and its international recognition is important to establish its credibility in local and foreign markets. QI is a critical element in promoting and sustaining economic development, as well as environmental and social well-being". The key components of the Smart QI consist of institutions responsible for standardization, metrology, conformity assessment and accreditation (more detail is available in the UNIDO publication "Quality Infrastructure Building Trust for Trade").

Given the above, there are two major challenges in relation to the development of Smart QI:

- First, how process improvements, (driven by digitalization and the need to meet the evolving requirements of all stakeholders) are affecting all Smart QI organizations. This perspective is critical for standards developing organizations (SDOs), given that the standards development process is the cornerstone of their activities, but it is also of great importance for all the other QI organizations, in relation to the processes that they follow to develop their respective deliverables. **Annex 3** highlights a fundamental dichotomy facing SDOs. It also includes an outline of the process improvements that can be applied by all SDOs.

[17] https://www.inetqi.net/

» Second, the emerging new types of deliverables and solutions that different Smart QI organizations are developing to meet stakeholder needs, specifically in the framework of Industry 4.0 and 4IR.

3.2.1 SHIFTING FROM QI TO SMART QI INNOVATIVE PROCESSES AND DELIVERABLES

An outline of important emerging innovations is presented for each QI component showing how they adapt their processes in response to the demands of digitalization and Industry 4.0.

SMART METROLOGY

Metrology is experiencing phenomenal changes because of Industry 4.0 and the digital transformation. Starting with the redefinition of the International System of Units (SI) base units, recent developments include metrology in chemistry, biology and health sciences, the emergence of quantum metrology as well as the further development of metrology at the nanoscale (nanometrology).

Automation of test and measurement has made significant progress, with future trends ensuring and improving the quality of products and manufacturing processes. This has been done by capturing and combining manufacturing data with metrological inspection and evaluation data in "real time", and processing them, thus reducing the need for separate, offline operations.

An environment, characterized by a proliferation of interconnected devices, dramatic increase in data, use of advanced software and autonomous actions of equipment is pushing metrology to innovate in order to maintain its critical functions and value.

The major innovations of metrology in relation to digitalization and Industry 4.0 includes:

» **In-line/on-machine metrology**: These are measurements carried out within the process workflow, either on a production line or directly on the machine where the object is manufactured.[18] The idea is to embed inspections/controls in the process as opposed to perform them as a separate activity. This is based on the concept that maximum efficiency of quality control occurs when the measurement is carried out at the closest point to the manufacturing process. In-line and on-machine measurement speed up the process and allow for immediate adjustments. On-machine metrology is especially attractive because inspection can be performed simultaneously with the machining operations (machine in-process inspection), with maximum efficiency (no additional time is taken for the inspection) and other advantages (e.g. immediate comparison with design data driving the machine and compensation machining if anomalies are detected). In-line/on-machine metrology requires supporting technologies, at various levels, including improved non-contact metrology equipment, advanced software and, for on-machine metrology, integration of the measuring instrument with the machine tool.

» **Non-contact metrology:** This is high-resolution scanning of objects, usually combined with remote control of measuring instruments. Non-contact devices are increasing their level of accuracy by the day and provide substantial advantages. They are faster, allow a much larger set of data (from different perspectives), are able to capture complex surface shapes, do not interfere with the motion of a target and are ideally suited to support in-line measurements. Non-contact measurement instruments use various technologies, including vision systems, laser-based systems, computer tomography scanners, photogrammetry and confocal white light distance sensor. All these systems generate a massive amount of digital 3D.

» **Measurement-related data structures and models (supported by advanced software):** Measurement and control operations in the Industry 4.0 context require data to be efficiently organized. Data structures and software applications are therefore critical. For example, augmented reality/virtual reality (AR/VR) software using sensor data allows enhanced models of objects (e.g. small and intricate product parts) to be developed for which basic data are insufficient. CAD tools need to compare 3D model data and related dimensions and tolerances, with product information captured in the manufacturing process to assess conformity, evaluate defects and, if needed, trigger corrective actions.

» **Inspection technologies:** These are usually in proprietary formats, hindering user enterprises to develop integrated systems. However, contributions to address these issues are given, for example, by platforms based on the Quality Information Framework, published as ISO 23952:2020. The Quality Information Framework philosophy is: "All information models for transporting quality data should be derived from common model libraries so that common information modelling components can be reused throughout the entire quality measurement process and, as a consequence,

[18] Here we focus on discrete manufacturing and dimensional metrology.

the entire process will be inherently interoperable."

- **Touchless Calibration (TCal):** This is another important concept and trend to enable Industry 4.0. The idea is to establish a digital connection to the calibration laboratory, to provide a digital copy of the unit under test (UUT), and to receive relevant calibration data from the laboratory and carry out calibration on the manufacturing premises. This is another way to improve the efficiency of the process, product quality and prevent possible production downtimes. With TCal, the calibration reference standard remains in the calibration laboratory, while the UUT remains on site. This process, however, introduces new sources of uncertainty that need to be managed.

Enabling the provision of these services in a structured and consistent way is a key driver of metrology innovation. An underlying element concerns the transposition of SI into the digital world. The effort is led by the International Committee for Weights and Measures (CIPM) Task Group on "Digital SI" (TG "Digital-SI"), which published the "Grand vision of the SI Digital Framework" in 2020, highlighting the goals to be achieved.

"*The long-term aim of the TG "Digital SI" initiative is to establish a framework that meets FAIR (Findable, Accessible, Interoperable, Reusable) principles (respecting business and privacy constraints) and allows all aspects of the international measurement system—measurement results, uncertainties, traceability and provenance—to be accessed and interpreted digitally, enabling machine-to-machine communication and analysis.*

The framework will allow more information to be represented digitally, not only measurement results, but also the system being measured, how the measurements were made, and the workflow (data, models, software) associated with establishing the measurement results. The framework will increase the level of machine readability from basic capabilities to full machine actionable knowledge representation."

The development of the SI Digital Framework is taking place in two phases.

- The first phase concerns the development of interoperable data and metadata models for quantities and SI units and the representation in digital form of the knowledge embedded in the primary SI reference documents.
- The second phase will concern the digital representation of measurement processes (including measurement procedures, workflows, methods of analysis, provenance, and traceability chains) to allow machines to access complete measurement data and act autonomously.

The SI Digital Framework provides a clear, unifying reference for the initiatives undertaken by National Measurement Institutes and the broader metrology community in support of digitalization usually defined as "Metrology for Digital Transformation (M4DT)".

Given the proliferation of low costs sensors and their critical role in driving 4IR, the international metrology community is responding to the challenge of ensuring that calibration data is both human and machine readable. Currently, calibration certificates present the results of a calibration process in a format that must be evaluated by a human and interpreted for use. However, machines do not presently have the intelligence to be able to understand context and therefore must rely on other methods to interpret the data. The Digital Calibration Certificate (DCC), currently being designed, aims to provide universal exchange formats for calibration results that are both human and machine readable and interpretable.

SMART STANDARDIZATION

The dominant subject regarding new types of deliverables enabled by digitalization is that of "machine readable standards". This is a primary strategic direction for many SDOs, such as ISO, IEC, CEN and CENELEC.

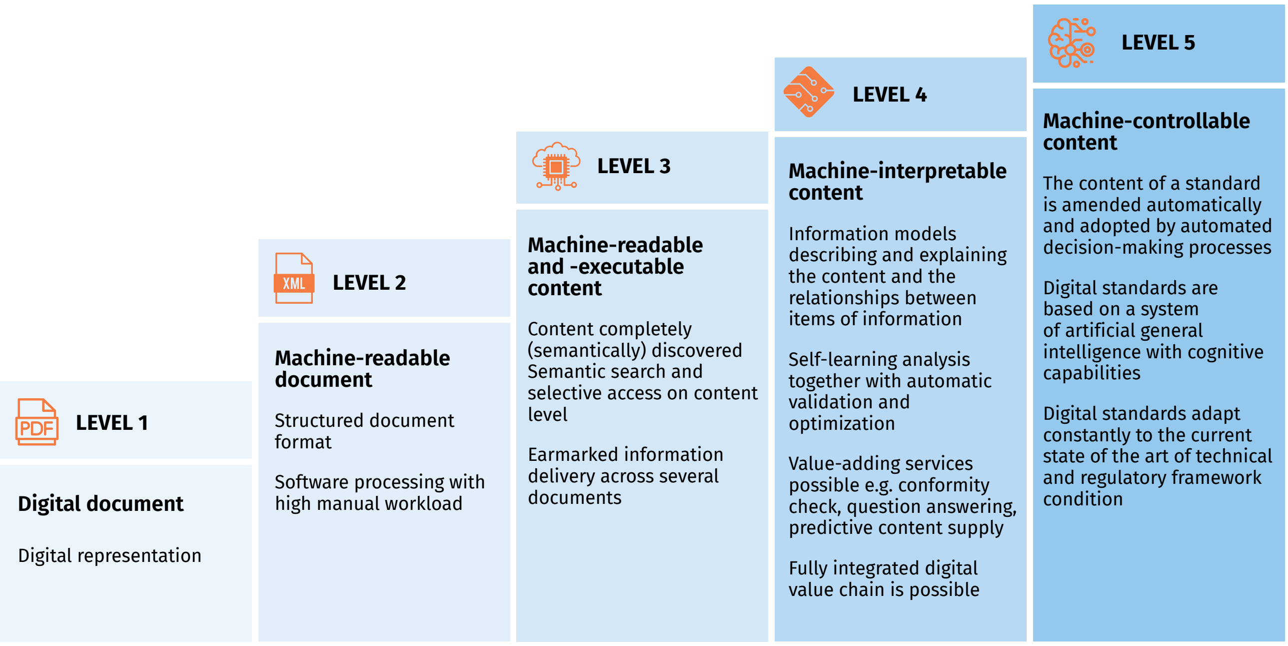
For decades standards have been produced first as paper documents then later as electronic versions of paper documents, typically in PDF format. They have been developed to be read by human eyes.

The idea behind machine readable standards concerns the possibility of transforming the standards' content, i.e. the knowledge embedded in standards, into appropriate digital formats that can be "understood" and "acted upon" by machines. This would clearly be invaluable for Industry 4.0 (and for many other domains encompassed by the 4IR). It gives us the possibility of embedding requirements and other relevant "granular" information included in standards into the software driving the operation of machines, or the analysis of product and process data for monitoring and control functions or process optimization. ISO and IEC call this transformative programme SMART (Standards Machine Applicable, Readable and Transferable). This joint ISO and IEC programme will drive the digital evolution of international standards to address the needs of citizens, societies and economies. There is a consistent and continuous sharing of information with CEN/CENELEC who have a similar SMART programme.

A model developed by the IEC SMB – Strategic Group 12, Digital Transformation and Systems Approach, revised and extended by the German standardization bodies DIN and DKE,[19] is shown in figure 3.

[19] DIN/DKE, Scenarios for the digitalization of standardization and standards.

FIGURE 3: **SCENARIOS FOR THE DIGITALIZATION OF STANDARDS**



https://www.dke.de/resource/blob/2076816/facc9bde1806e2194a3d26a60c79bf77/idis-whitepaper-en---download-data.pdf

Figure 3 gives a useful representation of the various levels of machine readability and "actionability" of mostly future digital standards. Level 1 represents printed paper documents and level 5 represents standards that can be read, understood and acted upon by machines. Although these SMART levels were key initial input into the ISO/IEC SMART programme, they are currently under review in order to have a central alignment of terminology to avoid confusion and misunderstanding.

ISO, IEC and CEN have started to publish standards in the NISO STS (Standards Tag Suite) Extensible Markup Language (XML) format. "*NISO STS provides a common XML format that developers, publishers, and distributors of standards...can use to publish and exchange full-text content and metadata of standards.*" This partly covers level 2 above. However, it is worth noting that the NISO format (and the ISO and IEC implementations based on it) are mainly designed to facilitate the automation of publishing processes.

Some content elements (such as tables and formulas) can be extracted but, in general terms, the markup is limited to entire clauses as single items. This means that applications to embed granular standards content, such as requirements and reference values, in automated processes still require substantial ad hoc, manual work.

Applications using standards' content to feed industrial automation applications and systems have been developed by some SDOs and private enterprises, but these are mostly project-based or vendor specific solutions. In addition, there are already standards that offer deliverables in formats suitable to be processed by a computer.

SMART Projects are underway in ISO and IEC as well as in CEN/CENELEC to design standards for the future (digital standards meeting the requirements of the higher SMART levels described in figure 3), understanding that these would target those sectors and application areas that need more "data-centric" vs. "document-centric" standards.

The matter is complex and requires significant efforts and coordination among experts. A critical aspect concerns how to capture and represent the granular elements of information included in standards with their semantics. A simple example (concerning the IEC 60376 standard) is proposed to sketch the type of issues to be addressed.[20]

Consider the **requirement** on the environmental impact:

*"SF6, CF4 and SF6 mixtures with N2 and/or CF4 have a **certain** environmental impact. Due to this impact, SF6, CF4 and their mixture gas shall be handled **carefully** to prevent **deliberate** release of SF6 and CF4 gas into the atmosphere.*

The use of bolded words presupposes that the persons reading the requirement will "understand" and "interpret" them in a consistent and repeatable manner. For example, what do the terms "**carefully**," "**certain**" and "**deliberate**" mean in this case and how does each user of the standard understand or interpret them? Should we anticipate the possibility of a deliberate malicious action? And if so, should it be anticipated and how should it be "dealt with"?"

[20] Taken from Hélène De Ribaupierre, et al. (2021) Automatic extraction of requirements expressed in industrial standards: a way towards machine readable standards?

It is evident even for human understanding, let alone machines that requirements need to be expressed in a univocal, unambiguous way. For this, various techniques and tools from information science and natural language processing are needed that can be used to support the authoring of machine-readable standards.

Another issue (probably unavoidable, considering the huge number of published standards) concerns the extraction of information from existing standards. This could be done by using methods and tools of natural language processing and applying ML/deep learning methods. It is worth noting that annotated (or labelled) data sets are not yet available and should gradually be developed.

SMART CONFORMITY ASSESSMENT

Digital transformation is also substantially impacting conformity assessment (CA), driving innovation for all the organizations providing testing, inspection, and certification (TIC) services.

Maintaining the focus on Industry 4.0 and the impact of digitalization, the most important evolutions concern:

- Automation of testing and inspections activities.
- Remote inspections and audits.
- New roles and skills required for inspectors/auditors.
- Use of blockchain technologies for product certification and traceability over supply chains.

Automation of testing and inspection services

Regarding the automation of testing and inspection activities, providers of CA services address many of the issues regarding accuracy and integrity of measurement. They are concerned with in-line and contactless measurement and use of advanced software, including big data and AI/ML techniques to aggregate and analyze data. Additionally, "predictive maintenance" is another area capturing particular attention.

As there always will be various levels of automation implemented by manufacturing enterprises, providers of CA services need to adapt, and offer CA services tailored to the needs of enterprises. In general terms, what can be considered common threads are:

- Development of competence in technologies, equipment, software, and systems supporting advanced forms of measurement, data capture and methods of analysis. Some conformity assessment bodies (CABs) are already offering solutions based on these technologies, partnering with vendors of specialized systems.
- The ability to provide a combination of on-site support with remote inspections and services, using a cloud-based business model. Customers submit relevant data over the cloud to be processed by the CA service provider and can obtain online the results of the activities performed.

Remote audits and inspections

Remote audits represent another major development that have experienced spectacular growth due to lockdown measures during the COVID-19 pandemic. Most of these activities are conducted in substitution to the corresponding "conventional" ones (requiring on-site intervention). Remote audits and inspections allow the auditors/inspectors to use a variety of visual and electronic aids.

These activities are based on the use of various technologies with levels of specialization depending on the scope and context. For example, inspections of products or plants in locations that are dangerous or difficult to reach (e.g. inside a pipe or an engine or within a manufacturing unit using hazardous substances), may require the use of special video probing equipment (inspection cameras, videoscopes, borescopes, fiberscopes), closed circuit TV, virtual and augmented reality systems and other tools. Additionally, the UNIDO publication "Remote Conformity Assessment in a Digital World" provides an overview of the ways in which remote assessment/audit techniques have developed in recent years and have been applied in different CA contexts, including their implications for the future.

For more customary activities regarding both audits and inspections, typical technologies used include:

- Videoconferencing, with related functionalities (document sharing, on-screen chats, etc.).
- Livestream videos from body and equipment-mounted cameras or other devices (e.g. drones).
- Video and audio recordings purposely taken for audits.
- Relevant documentation (documents and data) in electronic formats.

Successful execution of remote audits and inspection require the adoption of accepted good practices to ensure trust and acceptance of results.

With regard to remote audits, specific standards and guidelines have been published by ISO and the International Accreditation Forum (IAF), including ISO 19011:2018, Guidelines for auditing management systems, and IAF MD 4 - IAF Mandatory Document for the Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes. A useful document providing comprehensive information on the subject is the joint ISO/IAF Guidance on: REMOTE AUDITS developed by the ISO 9001 Auditing Practices Group[21] and published in 2020.

For remote inspections, in general terms, good practices like those established for audits are applied. Specific guidelines and related information have been developed by public authorities in several countries for specific sectors (e.g. the medical sector), and by organizations such as the International Code Council who developed *Recommended Practices for Remote Virtual Inspections*. Other documents are under development, including guidelines for remote inspection ("survey") of ships by the International Maritime Organization's Maritime Safety Committee. Additionally, the National Fire Protection Association (NFPA) NFPA 915 - Standard for Remote Inspections establishes minimum requirements for remote inspections to deliver an equivalent or improved result as that which would be obtained with other inspection methods.

A joint IAF/ILAC/ISO survey[22] of more than 4000 participants concluded in August 2021 that a majority of respondents (about 80%) prefer remote or blended audits (mixed remote and on-site), assessments, and evaluations. The same majority agreed that remote procedures give the same confidence as on-site audits and over 90% felt that a substantial increase in remote techniques will stimulate the use of new processes. Based on these encouraging results, the three organizations are planning new developments to make further progress in this area.

Briefly, the transformations related to digitalization require that auditors and inspectors develop new skills and approaches to be able to continue to maintain the integrity of the conformity assessment services.

New roles and skills required for auditors/inspectors

Auditors and inspectors need to acquire knowledge and expertise in many of the technologies outlined above and their application to establish more advanced, embedded measurement and control processes. CABs will be increasingly called upon to play a role in relation to the set-up of automated systems and supervising and monitoring their correct operation, ensuring compliance with reference standards and good practices.

Uses of blockchain technology

A final note on the role of blockchain technology for conformity assessment. Blockchain is defined by ITU-T as "A type of distributed ledger which is composed of digitally recorded data arranged as a successively growing chain of blocks with each block cryptographically linked and hardened against tampering and revision".

Blockchain is another fast evolving technology that has captured attention in different areas and has the potential to support phenomenal changes ("*...the technology is still maturing, and many challenges, including technical, interoperability and legal issues, need to be addressed before the technology can be used to its full potential*" (WTO Report, 2018 "Can Blockchain Revolutionize International Trade?").

That said, blockchain is already impacting CA. At least in the nearer term it concerns, at a minimum, three important areas:

- Verifying conformity of products at each step of the supply chain and ensuring full traceability (hence, providing exceptionally strong and complete forms of certification).
- Marks of conformity, used to give confidence to the market by demonstrating a product or service meets the specified requirements.
- Databases of certified companies, ensuring up to date, verified information about companies and their certifications.

Other areas particularly important for Industry 4.0 include, for example, the precise identification of products and assemblies, incorporating detailed information about product components, their properties, origins, and more.

Smart Accreditation

Many of the areas highlighted for CA are also relevant for accreditation. Use of digital technologies by accreditation bodies is primarily related to:

- Remote assessments ("auditing" in CA).
- Use of blockchain technology for real-time verification of assessment data.
- Accredited certification of services supporting electronic transactions (such as electronic signatures, registered delivery services and certificates, website authentication).

In this respect, the considerations presented for CA apply. However, accreditation bodies have an increased responsibility in regard to verifying the accuracy and integrity of activities performed by CABs. This includes the reliability, certainty, and unambiguity of the technologies used by CABs. Therefore, accreditation bodies need a better understanding of the robustness of technologies and their fitness for purpose when assessing conformity.

[21] https://committee.iso.org/home/tc176/iso-9001-auditing-practices-group.html.
[22] https://ilac.org/latest_ilac_news/use-of-remote-techniques-supported-by-iaf-ilac-iso-survey/

In addition, a fundamental role traditionally played by accreditation bodies concerns the interaction with public authorities regarding regulatory aspects related to the development of digital solutions, requiring various forms of CA, provided by accredited certification bodies. Remote audits and inspections, and application of blockchain technologies in a variety of sectors are important examples.

3.3 KEY SMART QI CONTRIBUTIONS TO THE 4IR

Section 3 has outlined how the Smart QI is intimately linked to the information and communications technologies underpinning the 4IR. To complete the picture regarding the synergy between QI and 4IR, we present two examples of key contributions that the Smart QI is making to the 4IR and to Industry 4.0.

Example 1: Development of advanced digital production technologies

All the technologies previously mentioned (IIoT, big data, advanced robotics, AI, cloud computing and additive manufacturing) have specific standardization and CA needs that are extremely important for their development and integration into a broad variety of fields and applications.

These matters are highly specialistic, rapidly evolving with hundreds of organizations deeply involved, at various levels, we can give an idea of some of the issues being addressed.

The issue of **big data**.

It covers a broad variety of data. The enormous data sets captured in unstructured form tend to be aggregated using ad hoc mechanisms by information providers and user companies, creating data silos that may not be put to good use and might be hard to exchange.

Standardization is providing an important contribution to address this. Technology standards exist and support the distributed processing of large data sets across clusters of computers. They have been set up and disseminated through open-source initiatives (such as Apache Hadoop) and embedded in the solutions offered by vendors or implemented directly by user enterprises.

Guidance on big data, potentially very important to promote harmonization, can be found in the ISO/IEC standards series 20547. These standards define a “Big Data Reference Architecture” (BDRA) that provides a common language for use by all stakeholders, a conceptual model of big data including a description of components, processes, and systems and a categorization of roles and activities within the big data “ecosystem”.

However, more standardization efforts are still needed to support real-time data capturing and streaming functions, enabling processing and analyzing large amounts of data in real time, or to define domain-ontologies (e.g. terminology, definitions, classification) that would facilitate data sharing across enterprise functions.

The issue of **advanced robotics.**

Another example is the rapid development of advanced robotics, which has triggered important standardization initiatives. The growing use of industrial robots has highlighted reliability, safety, and security issues. Robots may malfunction due to mechanical failures, power outages, and software failures. These issues are being addressed by standardization projects from various organizations (examples include ISO TC 299, Robotics).

Major trends related to Industry 4.0 and digitalization are pushing robots from performing specific routine tasks to “autonomous” behavior, based on self-learning, to becoming adaptable, mainly through the interconnection with the IIoT. It is clear that more standardization efforts are needed to:

- support substantial improvements in robot software, i.e. the programming languages and software tools required to instruct a robot to perform mechanical tasks, trigger actions or to interact with electronic systems.
- define ontologies for robotics and automation.
- facilitate the development of software libraries and categorized datasets, supporting robot’s multitasking, remote control, connection with AI-deep learning systems and more.

Example 2: Enabling interoperability

This is an area where Smart QI can contribute significantly to Industry 4.0.

Industry 4.0 is driving a proliferation of devices, machines, and applications from different vendors, used by enterprises in factories over multiple locations and exchanging with partners across supply chains. Interoperability across heterogeneous systems is therefore a key factor for Industry 4.0 to succeed.

Smart QI can contribute significantly to three major topics in this regard:

- Reference model architectures for Industry 4.0.
- Exchange of data among interconnected devices.
- Consolidation of data sets from the cyber-physical world, making them available and suitable for use by AI systems.

Reference models:

They provide a general structure and terminology to describe and specify system architectures. They offer a reference base for defining the relevant entities and understanding their relationships in each domain (in this case, smart manufacturing), promoting clarity, consistency of concepts, a common language and a basis for the interoperability of systems.

At present there are some leading reference architecture models and work is underway to pursue harmonization among them:

- RAMI4.0 (Reference Architecture Model Industry 4.0) developed by the German initiative Industry 4.0.
- The evolving ISA-95 model (based on the ANSI/ISA suite of standards for developing an automated interface between enterprise and control systems).
- The IIRA (Industrial Internet Reference Architecture Model).

Exchange of data:

The exchange of data among interconnected devices is another essential aspect of Industry 4.0. Some important standards already available are MQTT (Message Queuing Telemetry Transport), OPC UA (Open Platform Communications United Architecture), and AutomationML (Automation Markup Language).

Consolidation of data sets into suitable forms:

The third aspect, the consolidation of data sets in suitable forms for use by AI systems is not fully realized yet but is important to fully enable “Industrial AI”. This would allow digital data to be analyzed in context and to automatically drive process and product improvements. These developments require innovative and reliable data infrastructures to be used, where data and services can be made available, collated and shared in an environment of trust.

3.4 SMART QI CONTRIBUTING TO SUSTAINABILITY

As outlined earlier, it is essential for the 4IR to align with the social and environmental sustainability imperative. In this respect, the contribution of Smart QI is invaluable provided that Smart QI itself undertakes a transformation, as described in the UNIDO publication “Rebooting Quality Infrastructure for a Sustainable Future”. There are positive signs such as the “London Declaration”,[23] titled “ISO’s Climate Commitment”, approved by the ISO General Assembly in 2021, and the joint “Call to Action” on standards supporting sustainable development, subscribed by ISO, IEC and ITU at the International Standards Summit for People, Planet and Prosperity, organized in conjunction with the G20 meeting in October 2021. However, a lot more needs to be done.

The QI in the 4IR needs to provide enterprises with systems, methods and tools to ensure that products are manufactured under social and environmentally friendly conditions and can be used by different individuals and groups that take part in society. Some groups face barriers that prevent them from participating in economic activities fair terms. By understanding and addressing the causes of structural exclusion and discrimination, the Smart QI can support inclusive growth and reduce poverty. Many standards already include useful strategies and tools to this end. Examples of efforts to further responsible production and consumption are promoting open-source systems and countering planned obsolescence. Endeavors like these ultimately result in quality products for everyone, which can be used, repaired at reasonable cost, and eventually reused in the manufacturing process of other products.

Here we list a few important areas where Smart QI can support Industry 4.0 to meet the sustainability imperative. We are referring to standards and conformity assessment frameworks (with the understanding that metrology is implicitly involved in various ways). We also need to clarify that in this field, there are other organizations that provide essential contributions, including those responsible for private and voluntary sustainability standards. These types of standards, such as certification schemes, codes of conducts and product labels, are developed and implemented by companies, non-governmental organizations, intergovernmental organizations, industry bodies and multistakeholder initiatives.

[23] https://www.iso.org/ClimateAction/LondonDeclaration.html.

For all the areas outlined below, the potential synergy between Smart QI and Industry 4.0 is substantial, with many possibilities to support fair and sustainable practices.

» Definitions, models and criteria to evaluate the material, energy and water footprint of products (including intermediate products) and projects, communicating and reporting about that in various contexts.

» Increasingly detailed frameworks for assessing, monitoring, communicating and reporting about greenhouse gas emissions.

» Definition of properties of and test methods for secondary raw materials (for a broad variety of materials—aiming to support appropriate information and trust, including CA certification schemes).

» General criteria and good practices, and sector-specific requirements for the set up and operation of reverse supply chains (this area also requires updates of intergovernmental agreements, to revise existing regulations for trade of cross-border "waste", with the understanding that EOL products are not "waste"). Sound international standards and CA practices would be an important enabler, contributing to building trust and removing suspicions of malpractice.

» Ecodesign approaches and criteria, with related test methods and CA frameworks, aiming to support "circular products".

» Standards, CA, and metrology frameworks supporting "sustainable activities and products" (for example there are already portfolios backing renewable energy technologies, much more needs to be done for other types of goods).

» Stakeholder engagement, inclusiveness, gender equality and diversity are key aspects in the development of smart QI. They help industry to meet societal expectations, as well demonstrate corporate responsibility.

4. Future Outlook for QI with regard to Industry 4.0 and 4IR

Phenomenal transformations are occurring in industry and society. The disciplines, organizations and activities that collectively constitute Smart QI are inextricably linked to the transformation. They are key enablers of change and, in turn, the innovation underpinning the 4IR are contributing to reshape QI itself.

In this section we highlight key takeaways, especially from the perspective of developing countries.

The learning imperative

In the context of transformation and digitalization it is vital for developing countries to build a reliable knowledge base. At a minimum, they need to identify and understand key trends and their implications in the near and long term. They also need to get directly involved and develop the capabilities to be able to participate in the process, at least in selected areas that are crucial to their own economies.

In this respect, it is vitally important to support the education of younger generations. The same digital technologies that are shaping the 4IR offer in various ways substantial informative and educational resources that can be leveraged by a variety of programmes.

Capture the opportunities

Starting from the current baseline (in particular, components of the global supply chains that already operate), investigate opportunities to connect with relevant sectoral initiatives driven by other players of the value chain. Select and follow initiatives taking place in the international Smart QI system to capture knowledge and build network relationships.

Select and leverage the huge opportunities offered by open-source platforms in many important areas, to acquire knowledge. We have seen, for example, that in the field of additive manufacturing, open hardware initiatives allow us to implement solutions in relatively simple ways and at low cost which can be instrumental to gaining knowledge in the field. Similar opportunities exist in a broad variety of software domains.

Take advantage of support programmes provided by UNIDO and other international organizations targeting Industry 4.0 at various levels.

Integrate digital technologies and sustainability

Sometimes, the absence of a significant base of manufacturing plants and use of older technologies is an opportunity. Developing countries can leapfrog to the higher levels of digitization by not repeating the learning curves of the more developed countries and instead they can leapfrog to the newer technologies.

The ability of combining the use of digital technologies with goals and criteria of the "sustainability imperative" highlighted in the publication can be extremely important and rewarding. Not only for establishing industrial systems that, overall, will give a much stronger contribution to the well-being of people, but also from a short-term perspective, related to strict economic and financial objectives.

Today the combination of sustainability and digital technologies represents a very attractive proposition and being able to implement projects with this combination can give a significant competitive advantage in attracting foreign investment.

"Sustainable finance and responsible investing" i.e. investment in activities and projects that meet certain environmental, social and governance (ESG) criteria,[24] are already a substantial component of international finance and the fastest growing form of investment. It is strongly supported by institutions such as the European Investment Bank and the World Bank, but increasingly by funds managed by a broad variety of private sector entities.

[24] Cf. ISO (2022). ISO/TR 32220:2021(en) Sustainable finance — Basic concepts and key initiatives. [online] Available at: https://www.iso.org/obp/ui/#iso:std:iso:tr:32220:ed-1:v1:en [Accessed 8 Oct. 2022].

5.
Smart Quality

This part of the publication explores the relationship between digitalization, Industry 4.0 and the impact on quality.

As technologies have become ever-more sophisticated, culminating in the 4IR and Industry 4.0, the latest approaches to quality that embrace such technologies have taken on the designation "Quality 4.0" (what we shall call "Smart Quality"). It is appropriate to try to understand what we mean when we talk about Smart Quality in enterprises today.

5.1
SMART QUALITY IN ENTERPRISES

Enterprises rely on their supply chains to deliver a quality product or service, on-time to the end customers, with some of them having many of their product's components provided by external suppliers. The integration of new technologies is placing significant pressure on Supply Chain Quality Management to not only keep pace with Industry 4.0 and digitization but to also innovate, using methodologies compatible with these new technologies within a smart multi-tier value chain approach.

5.1.1
DEFINING "SMART QUALITY"

Very simply put, ***quality*** is *"the ability to meet needs and expectations".* These needs and expectations might be for a product or a service, for a process, a system, a person or an organization, and are typically defined by customers, regulators or other interested parties.

In today's high-tech and increasingly socially and environmentally conscious world, the traditional "inherent quality" of products and services alone is not enough. Consumers are more demanding in terms of the ways in which those products and services are provided. This means, for example, they have concerns about sustainability that include carbon or water footprint, product life-cycle, contributions to climate change, use of socially unacceptable practices such as child labor or forced labor and overall corporate governance. If any one of these factors is found to be deficient, it can result in consequences for the organization concerned, although the "inherent quality" of their product or service may be impeccable. This has caused a shift by more progressive organizations in recent years from a "narrow" approach to quality (focused almost exclusively on the quality of the products and services they provide) to a more holistic "broad" quality philosophy that extends along the value chain and addresses the many different dimensions of quality that are important for today's consumers. Some of these are mentioned in the UNIDO publication on "Good Governance in a Digital Age" and include topics such as trustworthiness, inclusiveness, sustainability, social responsibility, interoperability, safety and security and data privacy.

5.1.2
ROLE OF QUALITY MANAGEMENT IN SMART QUALITY

The most widely used global set of criteria for enterprises that wish to implement a quality management system is ISO 9001:2015 (Quality management systems – Requirements), which focuses on an organization being able to demonstrate that it is capable of *"consistently providing products and services that meet customer and applicable statutory and regulatory requirements".*

In the context of Smart Quality, it is important to recognize that ISO 9001 is a performance-based standard, written in a way that defines *what* must be done but not *how* to do it. It is up to individual organizations to decide how to manage their processes and process interactions (including the degree of documentation, automation, digitalization) for them to be *effective* within their own unique context. This means that enterprises can choose (or not) to implement the latest Smart Quality philosophies and methodologies as long as they are able to demonstrate that these provide confidence in their "ability to consistently provide conforming products and services".

Although ISO 9001 does not set out to address some of the wider sustainability-related issues, it does provide a sound basis for such initiatives and is the usual point of entry for most organizations in developing economies wishing to embark on their "quality journey".

5.1.3 TRENDS DRIVING SMART QUALITY

Two key trends have emerged to drive what we now know as Smart Quality:

» Quality professionals have a huge array of sophisticated technologies, many of them brought about by Industry 4.0, that enable real-time process controls, predictive analytics, trend analyses, problem-solving methodologies and other tools that allow them to manage quality in a way that was impossible before. This is true regardless of whether the sectors in which they are working have adopted an Industry 4.0 approach.

» Businesses that have embraced Industry 4.0 will need to rethink their approach to quality, and those professionals that are involved in "traditional" quality management activities will have to make paradigm shifts in the way they work to remain relevant and to keep abreast of both the opportunities and challenges that digital transformation can bring.

Smart Quality is not only about technology—all the social, economic and environmental dimensions mentioned earlier need to be incorporated into our ideas about quality in the context of the 4IR.[25] The most pragmatic and succinct concepts behind Smart Quality is that proposed by Oakland,[26] "*... Quality 4.0 (sic. Smart Quality) is the leveraging of technology with people to improve the quality of an organization, its products, its services and the outcomes it creates*".

5.2 SMART QUALITY AND INDUSTRY 4.0 WORKING TOGETHER

Some of the core enabling technologies for Smart Quality are the same as those used in Industry 4.0, though with a different emphasis. These technologies have already been described earlier in this publication and will not be repeated here.

The ways in which Smart Quality and Industry 4.0 interact depend on the specific context in which enterprises are situated. This involves both internal and external factors. Figure 4 outlines the different approaches to quality, depending on the degree of digital transformation of the enterprises concerned.

We can see that there are four combinations as follows:

Combination 1: (Traditional quality methodologies in traditional organizations)

In some regions or economic sectors that have not yet fully embraced the digital transformation, many enterprises continue to use traditional manufacturing and service-delivery models supported by traditional quality methodologies.

Combination 2: (Traditional quality methodologies in Industry 4.0 organizations)

In more developed regions or more sophisticated economic sectors where enterprises have implemented an Industry 4.0 approach, it will no longer be feasible to try to use "traditional" quality tools and methodologies that are not fully integrated into the production or service delivery processes. These are unlikely to be able to keep pace with the real-time (often automated) decision-making processes that are key to the Smart Quality concept.

Combination 3: (Smart Quality methodologies in traditional organizations)

In enterprises that have not yet embraced Industry 4.0 and the digital transformation, there can be many benefits to using Smart Quality as a driver for technological change. Although it may not be feasible to leverage the full benefits in the production and service delivery processes (which are likely to require interactive real-time controls and data analysis), Smart Quality tools and methodologies can be used, for example, to predict user needs and expectations, to design better products and services, to provide agile customer support in call centres, or as part of systematic problem-solving and quality improvement initiatives.

[25] https://www.bcg.com/publications/2019/quality-4.0-takes-more-than-technology

[26] Oakland, J and Turner, M - "Defining Quality 4.0". Quality World, Summer 2021 – The Chartered Quality Institute – see https://www.quality.org/quality-4-point-0

Combination 4: (Smart Quality methodologies in Industry 4.0 organizations)

In more developed regions or more sophisticated economic sectors enterprises can leverage the synergies that will be realized by using Smart Quality approaches as an integral component of Industry 4.0 strategies. Indeed, in these cases, it is likely that there will be a coalescence of Smart Quality and Industry 4.0 with no discernible differences between the two components and each one providing opportunities for and driving improvements in the other.

5.3 DIGITALIZATION AND SMART QUALITY

Process Approach

According to ISO 9001:2015, "Understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its intended results. This approach enables the organization to control the interrelationships and interdependencies among the processes of the system, so that the overall performance of the organization can be enhanced."

The ultimate goal of quality management at the enterprise level is to reduce process variation to levels that provide total confidence in the resulting products and services and their ability to meet customer needs and expectations, whilst at the same time minimizing the associated costs for the organization.

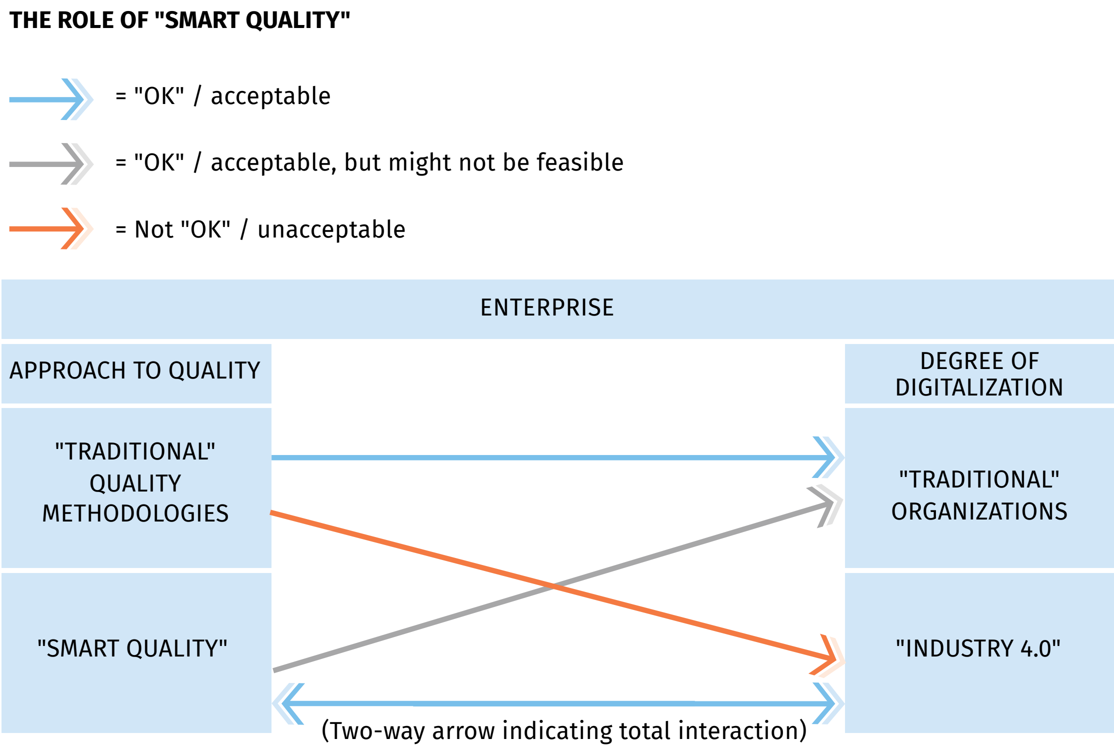
PDCA Cycle

Every process (from strategic to the more mundane, day-to-day operational processes) can be managed using the "Plan-Do-Check-Act" (PDCA) cycle to drive continual improvement. Digital technologies for Smart Quality can revolutionize all these processes, resulting in real-time process control and feedback loops, shorter cycle times, lower rejection rates, greater productivity and efficiency and improved customer satisfaction.

For example:

"Plan 4.0" can make use of social media, big data, and predictive analytics to look at global trends, including the identification and prioritization of risks and opportunities for the enterprise.

FIGURE 4: **VARIOUS COMBINATIONS OF APPROACHES TO SMART QUALITY AND INDUSTRY 4.0**



"Do 4.0" can take advantage of robotics (including chat-bots) for product and service delivery, as well as AI and ML to make real-time decisions. Distributed ledger technology (DLT) can provide unprecedented levels of traceability for processes, products and services that might be required by customers and regulators, or that can enable future problem-solving or improvement initiatives.

"Check 4.0" includes real-time process control, the use of remote inspection technologies (drones and remotely operated sensors, cameras, or vehicles) to provide data from hard-to-access sites, video streaming, VR and AR to facilitate remote audits as well as social media and big data to analyse trends in customer satisfaction.

"Act 4.0" is greatly facilitated by the velocity of data-driven decision-making processes, based on the provision and analysis of accurate and timely data and the often-instantaneous feedback loops achieved via interconnected equipment (IoT, IIoT and IoE, for example) together with AI and ML.

5.4 SMART QUALITY TOOLS FOR TYPICAL QMS PROCESSES

We can explore the ways in which recent technological advances provide opportunities for Smart Quality by examining some examples of typical processes that apply to just about any enterprise, and the latest technological advances that can support them (independently of whether the processes are themselves digitalized).

Table 1 shows a summary and cross-reference between the tools and some typical QMS processes, each of which will be discussed further in this section.

TABLE 1 : **EXAMPLES OF THE USE OF SMART QUALITY TOOLS IN SOME TYPICAL QMS PROCESSES**

TECHNOLOGIES / TOOLS	STRATEGIC MANAGEMENT	RISK AND OPPORTUNITY MANAGEMENT	MARKETING AND CUSTOMER-FACING PROCESSES	DESIGN & DEVELOPMENT OF PRODUCTS AND SERVICES	PRODUCTION AND SERVICE PROVISION	MAINTENANCE	MONITORING AND MEASUREMENT	PROBLEM-SOLVING
VR and AR			✓	✓	✓	✓	✓	
Remote data transfer (including video streaming)			✓			✓	✓	
Robotics					✓	✓	✓	
AI / Machine learning		✓	✓	✓	✓	✓	✓	✓
IoT, IIoT, IoE		✓		✓	✓	✓	✓	✓
Big data analysis	✓	✓	✓	✓	✓	✓	✓	✓
Predictive analytics	✓	✓	✓	✓	✓	✓	✓	✓
Real time process control					✓		✓	
Remotely operated vehicles						✓	✓	
Blockchain / DLT						✓	✓	✓

Strategic planning

Strategic planning is a process used to define an organization's strategy, or direction, and making decisions on allocating the resources to pursue this strategy. In the context of quality management, it can also include establishing policies, objectives and key performance indicators that are then deployed throughout the organization to the appropriate functions, levels, and processes.

It is unlikely (in the near future) that the digital transformation of enterprises and, for example, the use of AI will substitute the human element of strategic planning. What it does is greatly facilitate data identification, collation, and analysis on which the strategic planning is based. Data that provides inputs into the strategic planning process are typically gathered from a multitude of sources from both inside and outside the enterprise. Typical methodologies to support the strategic planning process include "SWOT" ("Strengths, Weaknesses, Opportunities and Threats") and "PESTEL" ("Political, Economic, Social, Technological, Environmental, and Legal") analyses.

Smart Quality can, through extensive computer-based modelling, allow for the analysis of these various scenarios to support the strategic decision-making process and provide for rapid reaction when the organization's business context changes.

Smart Quality tools that can support the strategic planning process include:

- Social media
- Big data analysis
- Predictive analytics/modelling
- Risk and opportunity management

The analysis and treatment of risks and opportunities is a core component of all management system disciplines, including quality. There are several well-proven methodologies and techniques that can be used to support the analysis of risk, and IEC 31010 (Risk management – Risk assessment techniques) provides excellent examples. Whilst some of these are relatively simple (for example traditional brainstorming or "Structured What-if?" approaches), others can be highly complex and demanding in terms of mathematical and statistical analyses (such as Bayesian analysis, or Monte Carlo simulations), lending themselves to the sophisticated techniques that are now readily available with the latest computing capabilities.

If we consider the high-level strategic risks that enterprises face, many of these will have been analysed and addressed as part of the strategic planning process, using the Smart Quality tools mentioned earlier. At the more operational level, however (and particularly in an Industry 4.0 environment), the factors that give rise to opportunities and risks can be changing at lightning speed, requiring almost instantaneous treatment or mitigation. In these cases, interconnected sensors (IoT and IIoT) can detect changes in the statistical stability ("uncertainty") of processes and, together with AI and ML capabilities, make adjustments to mitigate undesirable outcomes. Examples include risks and opportunities associated with the use of robotics in production lines, or driverless vehicles that might be pre-programmed to address specific emergency situations in changing driving conditions. In these "operational" situations, it becomes impossible to make a distinction between Industry 4.0 and Smart Quality methodologies, and the two concepts coalesce into a single symbiotic relationship.

Another important factor is the need to incorporate feedback loops into the risk management process, particularly when problems occur. Important inputs into these feedback loops can include information obtained by data mining of social media to look for trends that might not be immediately apparent from a local, narrow perspective. Examples include the use of statistical data mining algorithms to detect trends in adverse events in a healthcare setting[27] or product-related defects identified by big data analysis of multiple sources such as those from hospital emergency room visits.

Smart Quality tools that can support the risk and opportunity management process include:

- Social media
- IoT, IIoT and IoE
- AI/Machine learning
- Big data analysis
- Predictive analytics

Marketing and customer-facing processes

The traditional marketing and sales processes of most enterprises is often described in terms of a "sales funnel" which starts by seeking to attract as many people as possible, before narrowing them down until only those who buy the product or service are left. With the widespread digital transformation of local and global economies in recent years, this "digital sales funnel" is now an integral part of the ways in which enterprises are planned and operated, and closely interlinked with all operations from strategic planning, through product, service and process design and development, resource and supplier management,

[27] Coloma, P and de Bie, S "Data Mining Methods to Detect Sentinel Associations and Their Application to Drug Safety Surveillance" Current Epidemiology Reports volume 1 (2014) https://link.springer.com/article/10.1007/s40471-014-0016-2

operations planning and many more. All of this is facilitated using digital technologies that include a structured approach to social media, big data analysis, predictive analytics that look at customer and consumer trends and innovative use of AR/VR to enhance the customer experience.

As the world moves more towards remote (e-commerce) transactions for just about everything (including B2B, B2C, G2C and C2C interactions), the ways in which customer satisfaction (one of the key objectives of quality management) is achieved and measured also must change. Today's customers want not only a "quality product or service", but also the overall customer experience (from first contact through product and service delivery, payment, and after-sales support) becomes important, as do the social, environmental, and ethical considerations related to the product and service. Digital transformation facilitates the effective interlinkage of the entire process to ensure this is achieved in a seamless way, both within the various parts of an enterprise and at the numerous "touch-points" between an enterprise and its customers.

Smart Quality tools that can support marketing and customer-facing processes include:

» Social media

» VR and AR

» Remote data transfer (including video streaming)

» Big data analysis

» Predictive analytics

Design and development of products and services

In the context of quality management "design and development" involves a process of transforming the needs and expectations of customers (and other interested parties) into characteristics of the product or service to be provided in such a way that these are clearly defined (with acceptance criteria) for those in production and service delivery processes. The activities associated with design and development are often non-linear and depend on multiple inputs and interactions with other processes if they are to be successful. This is where Smart Quality techniques and methodologies can be immensely useful to manage these complexities and other (often conflicting) requirements, to achieve an optimum solution, regardless of whether or not they are associated with an overall Industry 4.0 approach to production or service delivery.

Key inputs into design and development include:

» Customer needs and expectations (typically outputs from the marketing and customer-facing processes mentioned earlier).

» Needs and expectations of other interested parties (for example requirements of regulators or expectations from civil society for environmental, social, and ethical considerations).

» Production and service provision capabilities.

» Availability of resources (material, human, technological and infrastructure, among others).

» Competitive landscape (including the "unique selling proposition" of the product or service under development).

» Many of the traditional design and development methodologies employed by enterprises for many years continue to be applicable but can be significantly enhanced by the use of modern technology to consolidate and analyze the wealth of information that is available. Examples include:

  - Quality Function Deployment (QFD)[28] used to transform the "Voice of the Customer" into product or service characteristics.
  - Failure Mode and Effect Analysis (FMEA) to examine key characteristics of the product or service that can adversely affect customer satisfaction.
  - Design of Experiments (DoE) using (for example) Taguchi statistical techniques.[29]
  - Design verification and validation (which can benefit, for example, from VR and AR simulations as well as focus groups working remotely, with real-time feedback and interactions with the design team).

Smart Quality tools that can support the design and development process include:

» Social media

» VR and AR

» AI/Machine learning

» IoT, IIoT and IoE

» Big data analysis

» Predictive analytics

Production and service provision processes

These are the core processes of any organization, and it is here where there are major and revolutionary benefits to be obtained by adopting a simultaneous and synergistic Smart Quality/ Industry 4.0 approach.

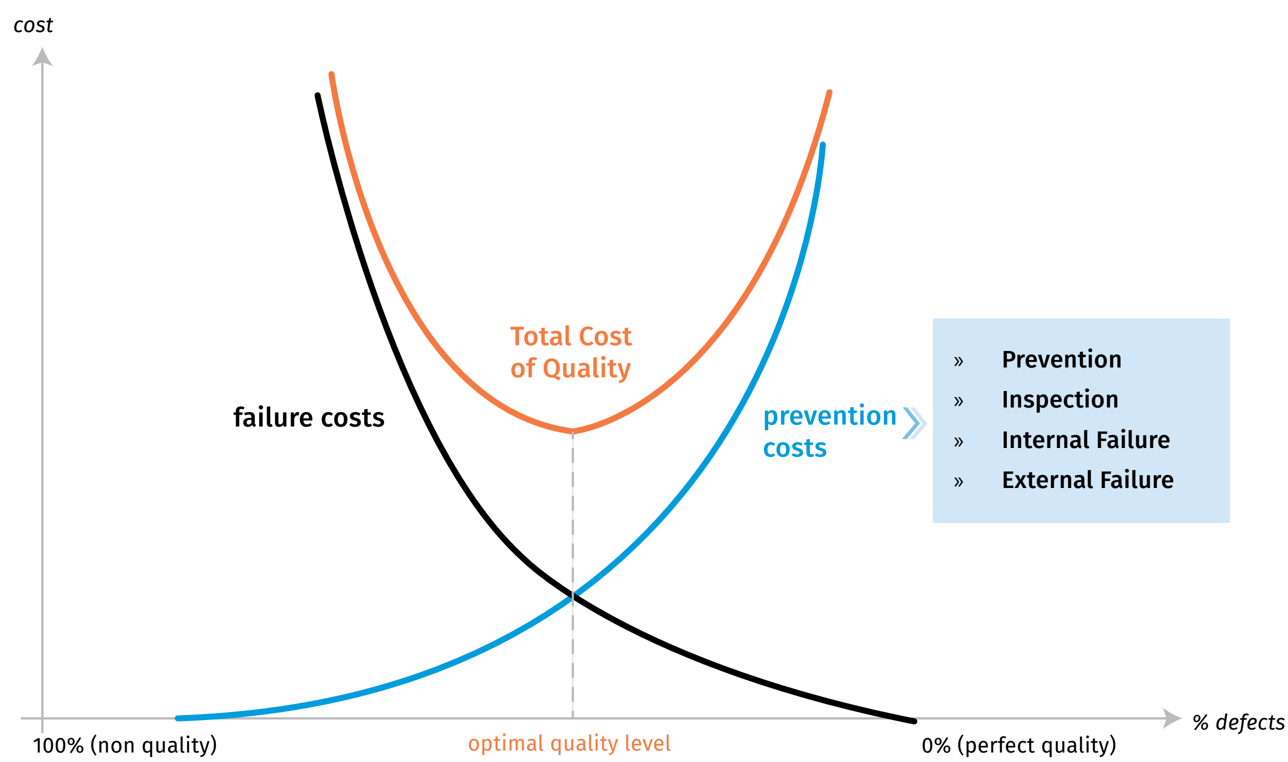
[28] https://en.wikipedia.org/wiki/Quality_function_deployment
[29] https://en.wikipedia.org/wiki/Taguchi_methods

The "quality" function of companies evolved over time to become responsible for quality assurance (and, later, quality management), with a greater focus on ensuring process stability and overall quality planning, control, and improvement activities. As we saw in the previous section, Smart Quality takes this entire approach to the next level, with the use of advanced robotics (in a "Smart Factory" manufacturing environment as well as in the administration of "Smart Cities"), with sensors providing real-time monitoring and measurement with instantaneous feedback loops and pre-programmed corrections/corrective actions performed automatically via the IoT, IIoT and IoE. This is further augmented by machine learning, predictive analytics, and AI to continually improve the "automatic" decision-making processes, supported by blockchain/DLT for the purposes of traceability and the provision/tracking of data for continual improvement purposes.

This specific convergence of Industry 4.0 and Smart Quality technologies in the production and service provision arena is worthy of further discussion here. The commonality from the quality management perspective is the combination of a "process approach" and use of the PDCA cycle as a basis for process control, which is inherent in all cybernetic systems. Of course, there is still a human element to all this, and the extent to which cybernetics alone can operate in an IoT and IIoT environment without human intervention will depend significantly on the context of the enterprise, as well as the risks associated with the control of its processes and the opportunities. This is particularly relevant in a service-provision environment, where different users may have very different needs and expectations. Whilst some more "tech-savvy" users welcome the speed and agility provided by (for example) AI-driven chat-bots to provide information and solutions, others may still prefer human interactions. In many cases, however, the consumer is unaware of the various complex technologies that are operating quietly in the background to support such human interactions.

Within a manufacturing or service provision context, Smart Quality approaches can contribute very significantly to achieving the "zero defects" goal. Whilst this concept was typically viewed pragmatically as a quest for perfection to improve quality in the manufacturing process, another important consideration for enterprises that seek to implement such an approach is the so-called "cost of quality". This is shown in its simplest form in Figure 5. Investments in cybernetic systems, AI, and ML and others that are associated with both Industry 4.0 and Smart Quality can be significant, particularly for SMEs, so it is appropriate for enterprises to conduct a cost/benefit analysis in terms of the "costs of quality" (defect prevention) and the "costs of poor quality" (failure costs) when making their investment decisions.

FIGURE 5: **CONCEPTUAL SCHEMATIC DIAGRAM SHOWING THE TOTAL COST OF QUALITY APPROACH**



Smart Quality tools that can support production and service provision processes include:

- VR and AR
- Robotics
- AI/Machine learning
- IoT, IIoT and IoE
- Big data analysis
- Predictive analytics
- Real time process control
- Blockchain/DLT

Maintenance

Maintenance processes (in their broadest sense) warrant a special mention in this analysis because of the concept of total productive maintenance (TPM). The TPM philosophy empowers those who operate equipment to take care of its routine maintenance themselves. This morphing together of "operations and routine maintenance" is like the tendency to agglomerate "production and inspection" into a single, integrated activity, and both are facilitated by a number of Smart Quality approaches and initiatives.

Predictive maintenance (one element of TPM) uses several tools and techniques to monitor the condition of machines and equipment to predict when problems are going to occur by identifying the symptoms of wear and other failures. This traditionally includes the use of sensors (for example to monitor temperature or vibration) that can then be coupled into an interactive cybernetic feedback loop to avoid the need for unnecessary preventive maintenance whilst at the same time avoiding the additional (lost time) costs associated with breakdowns and corrective maintenance.

Other Smart Quality methodologies that can be of use include AI and ML to interact (via IoT and IIoT) with inventory management and purchasing processes (for example to avoid maintaining unnecessary stocks of expensive spare parts), big data analysis and predictive analytics (to process multiple sources of data as part of a predictive maintenance approach) and blockchain/DLT to provide traceability (for example) of tool usage and associated wear. Robots and remotely operated vehicles or equipment can also be used to access difficult or hazardous areas where maintenance is needed, and to transmit the appropriate data (or consult specialist assistance using video streaming) in real time.

Smart Quality tools that can support maintenance processes include:

- VR and AR
- Remote data transfer (including video streaming)
- Robotics
- AI/ML
- IoT, IIoT and IoE
- Big data analysis
- Predictive analytics
- Remotely operated vehicles
- Blockchain/DLT

Monitoring and measurement

In an Industry 4.0 context, it becomes increasingly difficult to try to separate process monitoring and measurement activities from the operational process controls themselves. There are, however, several other monitoring and measurement processes that are required for an effective quality management system, which make good use of modern technologies without necessarily operating in an Industry 4.0 environment. The following are three such examples:

CUSTOMER FEEDBACK

ISO 9001:2015 requires an organization to monitor customer feedback, and notes that examples can include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, warranty claims and dealer reports. All of these can be conducted or supplemented using methodologies such as the use of social media, video streaming (to facilitate feedback from focus groups), IoT and IoE for automatic feedback on outages and breakdowns, as well as big data analysis.

INTERNAL AUDIT

As we have seen in the previous sections the use of remote assessment methodologies has evolved significantly in recent years. Smart Quality applied to auditing includes the use of methodologies such as remote data transfer (including video streaming), VR and AR, remotely operated vehicles (for observations in hazardous or difficult-to-access locations) as well as providing the ability to consult real time process data, and the use of big data analysis to look for trends. Blockchain/DLT tools can also be used to track root-cause analyses and corrective action plans when nonconformities are encountered.

MANAGEMENT REVIEW

Management review involves a determination of the suitability, adequacy, and effectiveness of the quality management system to achieve its stated objectives. It can necessitate the collation and evaluation of complex information and data from multiple sources, so the use of Smart Quality methodologies can facilitate the analysis of "information on the performance and effectiveness of the quality management system".

Smart Quality tools that can support monitoring and measurement processes include:

» VR and AR

» Remote data transfer (including video streaming)

» Robotics

» AI/ML

» IoT, IIoT and IoE

» Big data analysis

» Predictive analytics

» Remotely operated vehicles

» Blockchain/DLT

Problem-solving

The final example provided here relates to improvement processes. These can include methodologies ranging from correcting and taking corrective action on process, product, service, or system nonconformities (what we will call here "systematic problem-solving"), small-step continual improvements, breakthrough change and innovation.

When anomalies occur, in whatever circumstances, they may result in process, product, service or system nonconformities (they are only characterized as such if they result in a specific requirement not being met). Most traditional approaches to quality management have tended to focus on those anomalies that result in nonconformities or have a clear potential to do so. This is primarily because of the lack of resources and the "technical fire-power" to try to deal with all cases. Within a total quality management philosophy, however, anomalies should not simply be ignored, because they can have the potential to result in such nonconformities if they are not adequately addressed.

This typically involves intuitive or more formal risk assessment followed, if necessary, by a root cause analysis as part of a systematic problem-solving process. This is known by several names, including the Japanese "QC Story"[30] or "8D Problem-solving Methodology"[31] (widely used in the automotive industry).

Traditionally, there are a number of quality (statistical) tools that are used in a root-cause analysis, collectively known as the "Seven Basic Quality Tools for Process Improvement", as follows:[32]

» Cause-and-effect diagram

» Check sheet

» Control chart

» Histogram

» Pareto chart

» Scatter diagram

» Stratification

Whilst all these tools were developed and implemented in the mid-20th century, all of them lend themselves to a digitalized Smart Quality approach, which can enhance the ways in which data is collected, collated, and analysed. The quantum leaps in computing power over recent years provide unprecedented opportunities to address all anomalies using the IoT, IIoT and, eventually, the IoE, and—by using big data analysis and predictive analytics—to untangle the often-complex relationships between the many potential causes. In doing so, enterprises can begin to truly prevent nonconformities before they occur and move closer to the ultimate goal of achieving "zero defects".

Smart Quality tools that can support problem-solving processes include:

» AI/Machine learning

» IoT, IIoT and IoE

» Big data analysis

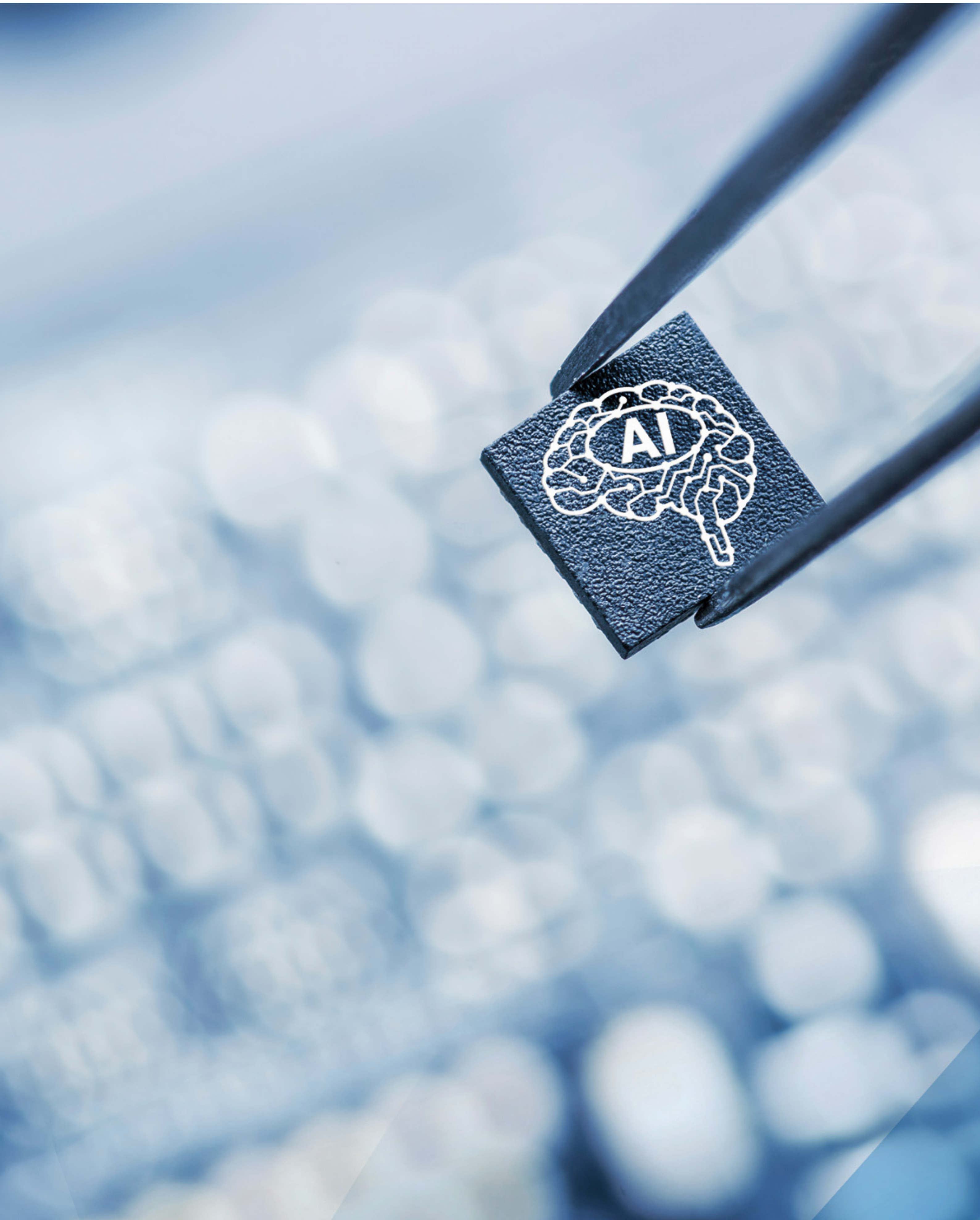
» Predictive analytics

» Blockchain/DLT

[30] See, for example, Dhumal et al "Problem Solving Methodology by Quality Control Story - A Review", https://www.researchgate.net/publication/317873255_Problem_Solving_Methodology_by_Quality_Control_Story_A_Review/link/594fe11ea6fdccebfa69ea34/download

[31] See https://asq.org/quality-resources/eight-disciplines-8d

[32] https://asq.org/quality-resources/seven-basic-quality-tools


AI

6.
Smart Quality in the Supply Chain

According to a 2015 survey by Gartner,[33] only 22% of manufacturers reported to have quality management functions integrated into their supply chain management and many of those only have visibility into their first tier of suppliers. The consequence of this is more than 50% of the high-profile quality failures of the past decade, ranging from flawed product launches, customer and patient safety incidents, and product recalls, are rooted along the supply chain management. The main reason is the lack of understanding and weak capabilities to integrate quality management along the supply chain.

During the last decade changes have been observed that aim to increase the visibility in the supplier value chain, including:

» **Identification of critical suppliers in the multitier-supplier network,** especially those categorized as critical due to the importance of its raw material/component/service: i.e. spare parts or tooling critical to production, being the only supplier available, owners of a unique intellectual property.

» **Identification of inspection and verification requirements** able to be moved down to the supplier, facilitating earlier detection of out of specification supplies, especially those critical-to-quality component provided by lower tier suppliers.

» **Setting up simple metrics** along the supplier value chain used to communicate conformance to schedule, quality and collaboration goals. Visibility of manufacturing progress to scheduled dates on long cycle time made-to-order components. Perhaps even in-process verification of critical-to-quality characteristics as the components are manufactured at the supplier site.

» **Verification Results.** The earlier there is visibility of any issue with components the better. It is desirable to move more inspection and verification to the supplier site whenever possible. Inspection results should be available electronically along with product delivery date updates. Some critical characteristics might even be verified in-process. In-process and delivered product inspection results can be provided by the supplier via supplier portals or transmitted electronically via B2B interfaces up the supply chain. Inspection results reported by suppliers and gathered through source and receiving inspection allows calculation of the real capabilities of each supplier to hold the required tolerance levels in specifications.

» **Nonconformance Documentation.** Whether defects are found before the supplier ships a component, at receiving inspection, or at production, it is necessary to have visibility of defects, nonconformances, and the root-causes identified for those issues. Containment and corrective actions can be initiated with specific suppliers to avoid further shipment of units with critical problems until they are resolved.

» **Supplier Audits.** Suppliers must be reassessed periodically via supplier audits for compliance to regulatory and contractual requirements. Companies need to maintain visibility of supplier audit history and ongoing audit scheduling arrangements.

» **Corrective Actions.** Whether tied to poor performance, specific product defects or audit findings, supplier management must maintain visibility of all corrective actions open with suppliers, their respective root-cause investigation, and resolution implementation plans.

» **Regulated industries** including automotive, food, drugs, medical devices, and aerospace have additional accountability interests into their supply chains. These industries have been adding these types of requirements to the industry specific ISO9001 extensions, including TS 16949, ISO 2200 FSC, ISO13485 and AS9100 and several others.

As can be seen for the above, quality management has been experiencing several changes in the last years, transforming its role in the supply chain. Nevertheless, with the introduction of the new technologies known as Industry 4.0, these changes

[33] "Supply Chain is Missing the Mark on Quality", Jacobson, Suleski, Barger, Chadwick, Stevens and Dorman, Gartner, 2015

will pale in comparison to those that are coming to maintain the quality of products and services in the innovative supplier value chain.

Industry 4.0 with the integration of new technologies, like IoT, AI and ML, blockchain, 3D/AM, big data, VR/AR, cyber-physical systems (CPS), is completely reshaping the industrial net and placing significant pressure on quality management to innovate their processes coming out with new methodologies compatible with the new technologies to ensure quality throughout the manufacturing process and the smart value chain.

Supply value chain stakeholders need to review the assignment of quality functions and governance in their organizational structures, and refresh and integrate the quality management systems across the enterprise to facilitate enhanced quality management processes into the multi-tier supply chain.

6.1 FROM ENTERPRISES TO SUPPLY CHAINS TO SMART VALUE CHAINS

6.1.1 SUPPLY CHAIN

The concept of supply chain (SC) or supply change management was born in the 1980s at Chrysler Corporation, when they decided to establish long-term relationships with suppliers that were an essential part of product design and development.

A SC is the sequence of processes involved in the production and distribution of a commodity. In its simplest form a SC is the set of activities required by the organization to deliver goods or services to the consumer. A SC is focused on the core activities the organization requires to convert raw materials or component parts through to finished products or services. It is comprised of all the contributors involved in creating a product, from raw materials to finished merchandise. In other words, the SC includes all functions involved in receiving and filling a customer request. These functions include at least:

- Product development
- Marketing
- Operations
- Distribution
- Finance
- Customer service

The supply chain comprises the flow of all information, products, materials, and funds between different stages of creating and selling a product to the end user. The concept of the supply chain comes from an operational management perspective. Every step in the process—including creating a good or service, manufacturing it, transporting it to a place of sale, and selling it—is part of a company's supply chain.

While many people believe logistics—or the transportation of goods—to be synonymous with the supply chain, it is only one part of the equation. The supply chain involves the coordination of how and when products are manufactured along with how they are transported. The primary concerns of supply chain management are the cost of materials and effective product delivery. Proper supply chain management can reduce consumer costs and increase profits for the manufacturer.

6.1.2 VALUE CHAIN

The value chain (VC) is a process in which a company adds value to its raw materials to produce products eventually sold to consumers. The SC represents all the steps required to get the product to the customer. The VC describes the full range of activities that enterprises and workers do to bring a product from its conception to its end use and beyond. This includes activities such as design, production, marketing, distribution and support to the final consumer. The main stakeholders in VC are shareholders and investors, while supply chain partners are crucial stakeholders in the SC.

The idea of the VC is searching for opportunities to add value to the business, for example, cutting back on shortages, preparing product plans, and work with others in the chain to add value to the customer, providing companies a competitive advantage in the industry.

Five steps are identified in the VC process that give a company the ability to create value exceeding the cost of providing its goods or services to customers. The five steps are:

- **Inbound Logistics**: Receiving, warehousing, and inventory control.
- **Operations**: Value-creating activities that transform inputs into products, such as assembly and manufacturing.
- **Outbound Logistics**: Activities required to get a finished product to a customer. These include

warehousing, inventory management, order fulfillment, and shipping.

- **Marketing and Sales**: Activities associated with getting a buyer to purchase a product.
- **Service**: Activities that maintain and enhance a product's value, such as customer support and warranty service.

Maximizing the activities in any one of the five steps allows a company to have a competitive advantage. To help streamline the five primary steps, the value chain also requires a series of support activities. These include procurement, technology development, human resource management, and infrastructure.

A profitable VC requires connections between what consumers demand and what a company produces. Simply put, the connection or sequence in the VC originates from the customer's request, moves through the value chain process, and finally ends at the finished product. VC places a great amount of emphasis on things such as product testing, innovation, research and development, and marketing.

6.1.3 VALUE CHAIN VS. SUPPLY CHAIN

A supply chain involves all parties in fulfilling a customer request and leading to customer satisfaction, however, a value chain is a set of interrelated activities a company uses to add value and create a competitive advantage.

While in the first supply chains the flow was from the supplier to the customer pushed by production, in the value chain the flow goes from the customer to the supplier pushed by the demand. Moving from the concept of supply chain considered as a cost of providing product/service to the customer, the value chain is viewed as a source to generate extra value to the customer. This change had its correlation in moving from quality control to quality assurance and quality management.

6.1.4 SMART VALUE CHAIN

A smart value chain (SVC) looks holistically at the entire supply chain and focuses on delivering value to the end customer. The SVC aims at bringing awareness for efficient decision-making, by tapping the data gathered by IoT devices and providing detailed visibility of products, all the way from manufacturer to retailer.

SVC are the result of the introduction of new technologies in the manufacturing cycles that are completely reconfiguring the way manufacturing companies produce and sell. Manufacturing has switched from mass production to mass customization. Scale and volume are no longer the key success factors, flexibility and production close to customers are now the winners.[34] It manufactures on demand and no longer creates inventory, adapting itself to needs. Its logic is now focused not on the product but on the usage, switching also from Taylorism to a flexible labor model.

TABLE 2 **COMPARISON OF THE DIFFERENT SUPPLY AND VALUE CHAIN CONCEPTS**

	FOCUS ON
SUPPLY CHAIN	» Cost reduction and effectiveness » Operation driven
VALUE CHAIN	» Value creation » Innovation » Demand driven
SMART VALUE CHAIN	» Introduction of new technologies » Process digitization » Faster response to customers » Improved communication throughout the chain
SUSTAINABLE VALUE CHAIN	» Environmental, social and governance practices measured at all tiers » Trust, transparency and full traceability » Net zero carbon » Circular processes minimizing waste

Smart manufacturing or smart factory is a broad production concept that has emerged to optimize the manufacturing process. It is a technology-driven approach that utilizes internet-connected machinery, modelling, big data and other automation to monitor the production process and increase manufacturing efficiency. The goal of smart manufacturing/smart factory is to

[34] Demartini et al. Digitization of manufacturing execution systems. The core technologies for realizing future smart factories, 2017. Proceedings of the Summer School Francesco Turco.

identify opportunities for automating operations and use data analytics to improve manufacturing performance. Smart manufacturing/smart factory are at the centre of the SVC.

Examples of smart manufacturing/smart factory around the globe are:[35]

Schneider Electric, France: Schneider Electric's le Vaudreuil facility is a shining example of a smart factory, having been recognized as one of the world's most advanced production sites, employing 4IR technology at scale. The factory has incorporated the most up-to-date digital technologies, such as the EcoStruxureTM Augmented Operator Advisor, which allows operators to use augmented reality to speed up operation and maintenance, resulting in a productivity boost of 2% to 7%. The company's first application of EcoStruxureTM Resource Advisor saves up to 30% on energy and adds to long-term improvement.

Johnson & Johnson DePuy Synthes, Ireland: The DePuy Synthes medical device manufacturing facility, which opened in 1997, has undergone a multi-million-dollar upgrade in recent years to better incorporate digitalization and Industry 4.0. The IoT was one of Johnson & Johnson's most significant investments. The factory employed IoT technology to produce digital representations of physical assets (known as digital twins) that resulted in advanced machine insights by connecting equipment. The organization was able to cut its operational costs while also lowering machine downtime as a result of these insights.

Bosch, China: Combining IoT and big data, Bosch drives the digital transformation of its Bosch Automotive Diesel System factory in Wuxi, China.

The corporation connects its devices to keep track of the complete production process at its plant's heart. This is accomplished by embedding sensors in the factory's machines, which are then utilized to collect data on the machines' state and cycle time. When the data is acquired, complex data analytics systems evaluate it in real-time and notify workers when bottlenecks in the production process are discovered. This method aids in the prediction of equipment breakdowns, allowing them to plan maintenance procedures well ahead of time. As a result, the manufacturer can keep its equipment running and operational for extended periods of time.

Adidas Speed Factory, Ansbach, Germany: With robots assisting humans, the company focused on sneaker-production processes in a single space, thereby completing production in a couple of days and proving their speed theory. Focusing on mass customization with shorter lead times, they use 3D printing technology to easily create digital replicas or mock-ups. Prototypes are quickly printed, facilitating an appropriate response to shifting consumer demands and satisfying customer's needs within days.

Haier, China: The SmartFactoryKL was created to pave the way for the "intelligent factory of the future". It is the world's first manufacturer-independent Industry 4.0 manufacturing plant, serving as a demonstration of the value of high-quality, flexible manufacturing and how it can be applied effectively. SmartFactoryKL has been led by specific strategic goals that have driven innovation for the past four years; the goal is to see AI implemented in manufacturing. An 'order-to-make' mass customization platform and a remote AI-enabled, intelligent service cloud platform to foresee maintenance needs before they occur are two examples of AI-driven transformations.

Infineon, Germany: Infineon's smart factory in Dresden dazzles the world with its intelligent networked manufacturing. Over 200 robots aid employees at the company, which has a 92% automation level. For all four of the company's segments, Infineon produces over 400 different products based on 200mm and 300mm wafers in a timely and high-quality manner. The factory's 200mm line is the most automated in the world, and its 300mm line was designed to achieve fully automated manufacturing, increasing productivity by 70%.

6.2 DIGITALIZATION AND QM IN SMART VALUE CHAINS

New technology introduced by the 4IR is creating new ways of interaction and new relationships among stakeholders of the SVC, generating new business models.

These new technologies, while increasing productivity and efficiency, are challenging quality management which must keep pace with the changes new technologies are making in processes and services but without neglecting the level of quality required by customers.

Product complexity, smart value chains with multiple actors around the globe, mass customization of products and shorter time to market all impact on the level of quality, (especially in some global industries like the automotive). The introduction of software and electronic components into products increases a product's complexity. As an example,

[35] https://www.threadinmotion.com/blog/smart-factories-all-around-the-globe

compare the number of electronic components in automobiles today with one 10 years ago. All these components sourced from different suppliers and you appreciate the complexity of the quality management required to keep pace with new technologies in the SVC. Aligning the quality management systems among all the participants of the SVC is a challenging task.

Product development cycles have also been shortened, placing high tech industries under enormous pressure to introduce new gadgets and features in their products, sometimes with insufficient testing resulting in poorer quality.

This new quality management paradigm known as Smart Quality is already impacting the SVC at all levels.

The technology enablers for Smart Quality are the same as those for the advanced digital production technologies described in section 3.1. However, we will focus on them from the perspective of Smart Quality.

The following are some of the technology's enablers for Smart Quality:[36]

Internet of Things and the Smart Value Chain

IoT enables manufacturers to dive deep into product data that is being generated from devices to know about product quality. IoT enabled connected products provide real-time data about the actual usage pattern of the product. This data can be compared with the actual design data to minimize the risk of product failure. Connected product usage data can be further used for remote diagnostics of the product and reduce the customer service request handling time. This will enhance the customer experience and capture the exact requirements of the customer.

IoT devices use sensors to measure specific aspects of the world around them. With the IoT it is much easier to understand where goods are, how they are being stored and when they can be expected at a specific location. A device could be attached to the product or its container and its position to track how the product moves through the SVC. This can trigger other administrative tasks like supplier payments or onward shipping requests.

In the supply chain, IoT devices can also monitor the storage conditions of products which enhances quality management throughout the supply chain. All actors in the SVC can prepare to receive the product, reducing handling times and ensuring the efficient processing of materials. Furthermore, for goods like food and chemicals that need to be stored in ideal conditions, IoT devices allow temperature, humidity, exposure to an atmosphere, light intensity and other environmental factors to be monitored. These devices may even trigger an alarm if certain thresholds are breached. This makes it easier to track the quality of goods through the supply chain and to reduce spoilage.

When integrated with more traditional supply chain management systems, the IoT has the potential to enable unprecedented levels of effectiveness, connectivity, security and communication. Adding AI and blockchain to the mix can introduce an innovative and even more powerful element to this tech-stack.

The data gathered by IoT and IT systems can provide greater transparency into logistics and supply operations, highlighting inefficiencies and opportunities to reduce costs, foresee future market trends and get an edge. A well-optimized and secure supply chain can also help you save on administration overhead and costs, while IoT devices and apps can play a big role in achieving this.[37]

Examples of IoT use in the supply chain:

- Farmers can use IoT devices to monitor soil moisture and decide the optimum time to plant or harvest.
- Manufacturers can use IoT enabled cameras to spot defects and reject faulty products.
- Chemical manufacturers can ensure that raw materials stay safe by monitoring and triggering an alarm if they are exposed to high temperatures.
- Manufacturers can take advantage of "just-in-time" manufacturing by preparing to produce goods just as they are scheduled to arrive.
- Food retailers can monitor the temperature and humidity of goods in storage or transportation to ensure they reach stores in optimum condition.
- Retailers can work with specialist logistics fleets to track products as they are "en route" to distribution centres.

Internet of Things and quality management

Quality control is fundamental in every industry, but in manufacturing, it is vital. With the advent of IoT gradually in manufacturing, quality management is an area with transformational opportunities.

Effective quality management relies on the ability to constantly monitor and control machines and

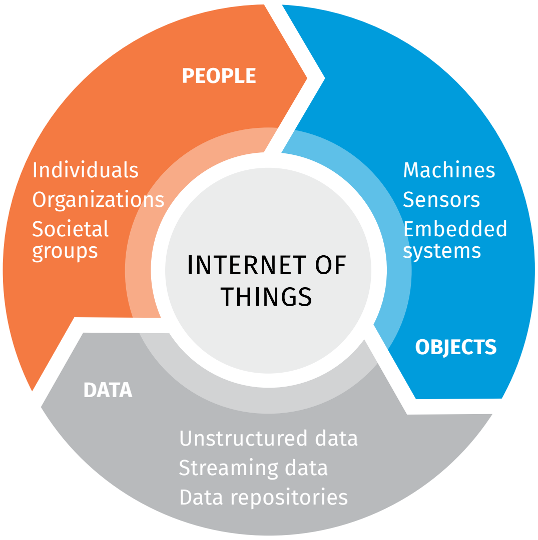
[36] Quality Management in the age of industry 4.0 – White paper by Y. SatyaNarendra, L&T Group

[37] IoT in smart supply chains, Pegasus Digital, May 2020

process parameters that impact product quality. However, time-sensitive automation tasks and wired communications lack the flexibility and affordability needed to capture telemetry data at scale and beyond the machine level. Typically, factors like environmental conditions, despite their major influence on quality variability, are often not studied and controlled. For example, in auto manufacturing, unfavorably low room temperature can reduce the quality of 3D printed components by causing them to cool too quickly.

As most of these systems have been designed in the last century, they are not suitable for connecting with external partners in an SVC. This creates disconnected islands of data that cannot be used to enhance production efficiency and output. Systems designed under Industry 4.0 with a proactive approach to IoT connectivity, deliver not only industry-grade reliability and secure dependable communications, but also a high level of scalability, cost-efficiency, and interoperability needed to overcome the manufacturing inertia.[38]

IoT, to whatever degree it is implemented in an organization, will facilitate connections between 3 important agents.



These connections will provide transformative performance enhancements, including increased innovation, stronger organizational and societal relationships, more resilient processes, and more critical decision-making in real time.[39]

[38] https://behrtech.com/blog/how-to-level-up-quality-control-in-manufacturing-with-iot/
[39] Radziwill N., Connected, Intelligent, Automated: the definitive guide to digital transformation and Quality 4.0. Quality press. 2020

Wireless IoT networks that can capture vast, granular data points along the production line render manufacturers with unprecedented control over their operations and product outputs. Beyond reactive, end-of-run quality inspection, IoT data empowers a proactive quality assurance approach to diagnose and prevent defects much earlier in the process for peak production output and repeatability alongside reduced costs and waste. Concurrently, it provides valuable insights to achieve and maintain storage best practices.

IoT will play a critical role in optimizing manufacturing quality as robots and machine controls increasingly become an integral part of the plant floor, serving to accelerate output and improve repeatability. Yet, equipment will wear and eventually experience failures over months and years of operation. Meanwhile, people involved in manufacturing processes as well as material handling, maintenance, and manual data capture can introduce mistakes. By capturing, analyzing and communicating data from IoT sensors in real time, manufacturers can identify and even predict issues before they become problematic.

Furthermore, when it comes to industries like pharmaceuticals or food and beverage, quality management does not stop at the end of the manufacturing line. Temperature, humidity, shock and other factors during storage all have an impact on the product shelf life. IoT sensor networks can thus help monitor and achieve ideal storage and transport conditions.

The IoT technology available for production facilities now enables direct connections to programmable logic controllers and smart sensors on process equipment and tooling to monitor operating parameters, such as speed, cycle time, temperature, pressure, flow rate, current, and voltage. This makes it feasible and affordable to capture both process and product measurements for each work piece in the overall measurement scheme. Moreover, when automated monitoring of process parameters is combined with in-line measurements of product characteristics, the information flow and real-time analytics assures an effective transactional quality management system.[40]

The steady stream of measurements (data) from the production floor enables the information loop to be closed in an enduring way. With real-time analytics built on SPC (statistical process control) methods applied to upper and lower control limits, quality specialists and operations managers can access up-to-the-minute metrics to predict product quality and receive alerts for looming quality issues. With this automated lean information flow, they are also able to predict when equipment will need maintenance prior to impacting product quality or interrupting production schedules. This in turn helps to assure maximum uptime and equipment utilization in support of efficiencies, consistent quality, and on-time deliveries.

AI/ML and the SVC

AI-enabled supply chain management has the potential to supercharge demand forecasting, revolutionize end-to-end transparency and boost integrated business planning. According to the Association for Supply Chain Management's Research, Innovation and Strategy Committee Sensing Subcommittee, AI and ML are among the 10 supply chain trends to watch in the next few years. "McKinsey's Succeeding in the AI Supply Chain Revolution" estimates that AI and ML's ability to support better decision-making through the analysis of massive volumes of data has enabled early adopters to improve logistics costs by 15%, inventory levels by 35% and service levels by 65%. There is no doubt about the significant impact AI/ML has for the performance of the SVC.

In the industrial sector, AI application is supported by the increasing adoption of devices and sensors connected through the IoT collecting an enormous amount of data. AI enables the use of such data for high value-adding tasks such as predictive maintenance or performance optimization at unprecedented levels of accuracy. Hence, the combination of IoT and AI has begun the next wave of performance.

Furthering this automation, AI uses the historical IoT data to analyze trends that can help in streamlining and improving the supply chain process through innovative solutions such as AI-driven operations scheduling. This provides recommendations to humans as to the optimal scheduling sequence, substantially reducing error and inefficiencies. AI is not replacing humans but partnering with them to increase efficiency and accuracy. Through integrated workflows, much of the supply chain process can be intelligently automated. These types of AI-driven capabilities have the potential to redefine the business supply chain process.

Early adopters of AI have deployed these technologies on-premises, in the cloud, at the edge, and through many types of hybrid architectures. AI itself is not one thing but comprised of several technology types, including neural networks, deep learning, natural language processing, computer vision, unsupervised machine learning, supervised machine learning, reinforcement learning, transfer learning, and others. These various types of AI are applied in different ways throughout the industrial world to create targeted solutions provided as descriptive, predictive, and prognostic analytics.[41]

AI/ML and Quality Management

The convenience quality professionals have today in capturing data compared with a decade ago is substantial. Thanks to IoT and cloud computing, an enormous amount of data is available for decision making and quality improvement. Nevertheless, every advantage always has some disadvantages. In this regard, we are referring to data quality. Machine learning has an important role to play in improving data quality. An example will illustrate how ML can be utilized to improve data quality.[42]

» Problem statement: Let us say a large bank deals with Credit Risk (CR) Financial. Sometimes, CR Financial is written as "CR", "CR Financial," or, rarely, "Credit Risk Financial" in official records. The time has come to reconcile all these entries, though managers agree the task is labor-intensive and tedious. Moreover, if a human were to carry out this job, he or she might miss an entry.

» Approach: This is where ML comes in. A computer program can scan all of the bank's information in a matter of hours, and then deliver a report that shows how many times the variations of CR Financial show up. With this information, the bank can get a sense of its exposure to CR Financial.

Improving Quality of Data after Every Run: What happens if there are some mistakes in the scan—for example, the computer program brings back false positives? The machine learns from its errors; once it receives feedback, it incorporates the corrections into its memory. It will apply those rules to the next data set it reviews.

AI/ML could be used in different ways to improve data quality.

[40] Capitalizing on the Convergence of Manufacturing Quality, IoT and Lean, Quality Magazine, Ed Potoczak, October 17, 2017

[41] https://supplychaindigital.com/technology/unlocking-value-supply-chain-ai-driven-processes

[42] Phani Akkineni, Role of AI & ML in DATA QUALITY MANAGEMENT, August 27, 2021

» Automatic data capture: Data are gathered by the machine without human engagement (error free).

» Identifying duplicate records: AI can be used to eliminate duplicate records in an organization's database.

» Detecting anomalies: An accidental and small error may cause a significant loss down the road. An AI-enabled system can remove a defect in a system.

Likewise, AI/ML, when used in the SVC, optimizes the quality management processes. The following are possible advantages AI/ML could provide to QM processes:

» Reuse Templates and Checklists

» Intelligent Analytics

» Simplified Investigation

» Proactive Problem-Solving

» Improved Visibility

» Reduced Process Cycle Time

» Faster and Smarter Decision-Making Process

Examples of the above are the use of AI/ML techniques to automate testing and inspection processes that, on top of the data gathered by some devices, require the interpretation of the data to take a pass/no pass decision. Final visual inspection of packaging quality, some organoleptic properties of food and beverage are examples where AI/ML can be applied with high degree of effectiveness to automate the process.

Likewise, the analysis of the root causes of quality problems considering the large number of internal parameters that need to be considered (man, machine, material, method, and measurement) is another field in which AI/ML can provide valuable assistance, finding correlations from large sets of information, which is exactly what is needed in root cause analysis.

3D printing/additive manufacturing and the SVC

In a 2017 study by PwC, 74% of participants agreed that companies investing in 3D printing today will have a significant competitive advantage.[43]

Today, the impact of 3D/AM on the product life cycle is indisputable, as industry moves towards SVC, 3D/AM is being integrated in various processes;[44] product and technology development is an example. Businesses that embrace 3D printing leverage unparalleled speed in product development, iterating faster with 3D printing's tool-less manufacturing and reduced production times. Instead of viewing AM as a replacement manufacturing method for components that were designed with another process, in AM components are designed for function rather than manufacturability.

3D/AM shrinks the supply chain as there is no need to look around the globe for reliable suppliers with low labor rates. 3D/AM allows for fewer suppliers and local production equipped with a fleet of 3D printers. Local suppliers reduce transportation costs, there are minimal or no tooling costs, components are made-to-order, there are no warehousing costs with significant capital immobilized on shelves and delivery is faster.

3D/AM and traditional manufacturing processes can coexist together complementing each other, maximizing benefits while increasing manufacturing flexibility, reducing time to market, an opening new design opportunities and product features.

3D printing/additive manufacturing and Quality Management

Although 3D printing is getting faster, thanks to the solutions provided by CAD software providers, quality remains the main barrier to massive adoption of 3D printing throughout the SVC.

If you are a warehouse operator with an asset-intensive business, then your primary focus will be to aggressively manage spare part inventories to reduce the tie-up capital while ensuring your customers will have the required spare part on time to avoid any disruption in the operation's processes. In this scenario 3D printing is viewed as the game-changing solution to this challenge. But here is when quality shows up, providing a real challenge for companies that do not have experience with the manufacturing processes. Customers will be delighted if they can have the required spare part on time at a minimum cost, but if the spare part is not in conformance with quality requirements, 3D printing advantages vanish.

Under traditional operating models, quality is inherent in the manufacturing of spare parts. But quality of spare parts produced by 3D printing is anything but certain. For spare part 3D printing to be considered reliable, the quality must be:

» Proven and repeatable under stable production processes—similar printers, materials, operators, etc.

» Consistent across locations and operations, under any conditions.

[43] Why quality is the obstacle to mass adoption of 3D printing, Matt Bellias, IBM Business Operation Blog, February 5, 2018
[44] Demartini et al., Quality Management in the industry 4.0 era, XXIII summer School Francesco Turco

» Guaranteed without input from the part's designer.

Here are three risks when an asset-intensive business shifts from spare part procurement and management to manufacturing parts themselves.[45]

Quality of source materials

Anyone in the manufacturing business knows the famous "garbage in-garbage out" saying, and management of suppliers is key to ensure that only supplies that meet the quality criteria get into the process. However, this is not the case for 3D printing equipment and solutions vendors, who have little to no experience with manufacturing. The burden for sourcing input materials for AM falls on the business producing the spare parts with their printers. Unknown quality of the source materials presents a large potential operational risk. This is especially true if the parts are used in mission-critical equipment or have a role in the production of quality-sensitive products such as medical devices, food products, and many others.

Quality in the manufacturing process

Quality management in manufacturing process has come a long way to ensure the quality of the goods we have today but for spare parts manufacturers it is not the case. While providing 3D printing solutions with consistent quality standards may be a disruptive model for supply chains and solve many operational challenges, manufacturing on their own may be constrained—at least for the near future—to a fraction of their spare parts inventory that is not mission critical. For the time being ensuring quality in the manufacturing process of the parts with AM is very difficult.

Quality control

Every traditional manufacturing process has quality control built into it, that varies from manual inspection to the application of AI and ML to advanced manufacturing operations. Because the industry is just emerging, there are no clear solutions to quality control. This is especially complicated for certified spare parts if they are coming from a manufacturer. We know a series of procedures and testing has been carried out to ensure conformity with requirements and the whole process is under the surveillance of an accredited certification body (CB). But that would not be the case with a 3D manufactured spare part. In this case, how could conformity to requirements be checked? One emerging idea is to apply visual inspection to the 3D printing process. This option is relatively cheap if done at scale. As it only relies on software and a high-definition camera, it can be done at the printing site. However, it requires the parts designer to train the ML algorithms and the CB to approve them. Industry has started to see solutions in this regard.

[45] Why quality is the obstacle to mass adoption of 3D printing, Matt Bellias, IBM Business Operation Blog, February 5, 2018

Blockchain and the SVC

Blockchain, the digital record keeping technology, is mainly seen as applicable in the financial world in relation to Bitcoin and other cryptocurrencies. However, in the last few years it has become more evident that blockchain can also be a highly valuable technology to improve supply chains.

Delivery of products, traceability, coordination between partners and aiding access to financing could be faster and more cost-efficient through blockchain technology.

In the financial world blockchain is an open system enabling unlimited number of anonymous parties to transact privately with one another without a central intermediary. However, within a supply chain it allows for the interaction of a limited number of known parties to protect their business operation against malicious actors while supporting better performance in a closed system. This is a critical and basic difference between both fields of application of this technology.[46]

As it is a new application of a new technology, the development of new standards to represent transactions on a block, and new rules to govern the system, are in different stages of development.

The advantages of using blockchain technology in the supply chain is reflected in the visibility it provides. A transaction between two parties in the supply chain involves financial flow, inventory flows and information flows. Blockchain integrates all three types of flow in the transaction by a chronological string of blocks. Moreover, each block is encrypted and distributed to all participants, who maintain their own copies of the blockchain. Thanks to these features, the blockchain provides a complete, trustworthy and tamperproof audit trial of the three categories of activities in the supply chain.[47]

Despite these promising benefits, this technology is still at a very early stage in the supply chain. According to a APQC 2018 survey only 1% of organizations are using blockchain in the SVC and another 30% are exploring their use, while more than 50% are neither using nor exploring its use. However more than 7% of organizations are intending to invest in blockchain in the near

[46] Vishal Gaur and Abhinav Gaiha, Building a transparent Supply Chain, HBR, June 2020
[47] Vishal Gaur and Abhinav Gaiha, Building a transparent Supply Chain, HBR, June 2020

future with almost 49% still unsure about the technology.[48]

Blockchain and quality management

Blockchain technology has created tremendous transformation in multiple industries, bringing more transparency and visibility into the way business processes are operating. The secure, distributed ledger has numerous possibilities, which are still evolving but more and more industries are embracing this new technology. Blockchain technology has a lot of potential in Smart Quality initiatives.

The technology can be used for better handling of product recalls which can be time-consuming, and more importantly, hamper the image of the enterprise. In certain factories like automobiles or food products, a single system to handle product recalls by identifying the origin of faulty parts saves time and money. Warranty management in the automobile industry involves multiple stakeholders and multiple transactions making it a more complex process to handle. The distributed ledger would provide secure transparency to various stakeholders and can be a better business opportunity for manufacturing firms. The figure below shows some examples of how blockchain technology can be applied within the SVC and some quality management processes.

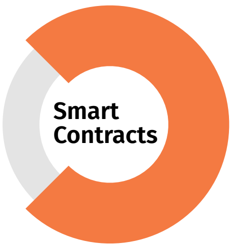
[48] Supply Change management Review, by APQC, January 5th, 2018

Although blockchain is one of the new technologies encompassed under the umbrella of Industry 4.0 it still has a long way to go to be part of the supply chain quality management toolbox.

6.2.1 ADDITIONAL TECHNOLOGIES IMPACTING QUALITY MANAGEMENT

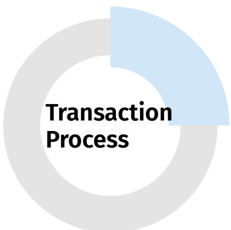
Mobility

Mobility has disrupted the traditional manufacturing patterns and created new business models for them. Mobility has reduced the boundaries that existed and is connecting various supply chain stakeholders in real-time. Mobility is also transforming the traditional quality systems towards digital quality control systems by means of mobile-based applications. Mobile apps can be used to create notifications for the operations personnel or to create digital quality control instructions.



- Automate the moving of material based on predefined conditions
- Automate the purchasing process
- Ensure the quality, authenticity, and availability of goods
- Prevent from accepting bad products or goods without verification
- Release correct payments to the appropriate parties
- Verify delivery and agreed conditions

- Give the visibility on the shipment origin handling conditions
- Record product status at each stage of production
- Trace the entire process steps
- Track purchase orders, changed orders, receipts, shipment notifications, or other trade related documents



- Document every transaction
- Offer transaction transparency possibilities
- Reduce the need for manual input
- Visualize recorded transactions on a blockchain

- Communicate loads, geo-waypoints and basic compliance information with carriers
- Provide more visibility across the supply chain
- Register the parties involved, price, quality, locations and state of the product
- Secure insurance and conformity documents, DOT numbers, and pickup documentation

Social Media Analytics

Social media has become inevitable for any customer, and companies have used this opportunity to enhance their customer outreach. Social media platforms capture the voice of the customer in terms of product performance and can be used to determine the success of a product. These platforms are huge sources of unstructured customer feedback and can be used to draw useful insights. Analytics can be used to determine data patterns and correlate data with similar situations to accelerate root-cause analysis. These same platforms can also be used to make the customers aware of existing and potential problems with the product.

Data Analytics

The amount of data generated across an organization is huge, and utilizing this data effectively is a challenge for them. With improvements in advanced computing and intelligent algorithms, valuable business insights can be obtained from the data, all of which can act as a key competitive advantage for the enterprises. Modern quality management systems can utilize data analytics to predict failure rates of the product which can be a challenge for manufacturing enterprises. Predictive quality and predictive maintenance are some of the important uses for data analytics.

Augmented and Virtual Reality

Traditional quality management systems are more paper-based and require human intervention. Specialized skills of shop-floor personnel are required during manual quality inspections on the shop floor. The operating people must manually inspect the product from a lot and then must identify whether it conforms to the quality specification or not. The amount of time consumed, skill level of the operators and the number of operators required are huge, which are the potential bottlenecks in this process. AR and VR can smoothen these operations by guiding operators sequentially about the process. This will reduce the dependency on the highly skilled operators and reduce the time for operation.

Typical features of this new SVC are vertical networking based on CPSs to build reconfigurable factories that are flexible and react rapidly to changes in customer demand. Resources and products are networked and materials and parts can be located anywhere and at any time. Additionally horizontal integration via global SVC provides high levels of flexibility, enabling the enterprise to respond faster. The transparency within the SVC allows the manufacturer to identify changes.

Quality Management Standardization and Conformity Assessment

Quality management and standardization are two components of the SVC that should work together to mitigate the risks that arise from the introduction of these new technologies and processes. Traditional conformity assessment methodologies and processes must be adapted to the requirements of the SVC, e.g. costly and time-consuming physical testing utilized in product certification can be replaced by modelling and simulation. The efforts to extend and adopt standards for the exchange of quality information in the supply chain are far from complete. Industry leaders need to engage in these activities to ensure their needs are represented and that standards continue to evolve.

Regulatory and conformity assessment bodies shall consider how to certify products and services that have not been physically tested. A recent example of this is the development of a digitalized test rig to test PPE face masks to international standards while delivering validated data for digital certification.[49] The physical and digital test methods developed provide direct feedback to the design process, while assuring the quality of data throughout to provide traceability of the decisions made. While implementing this new process the need for end-of-line physical testing is significantly reduced, as is the time to market and testing cost. As SVC continues its globalization, conformity assessment services are required to ensure quality management can maintain the level of quality as an enterprise digitalizes its processes (see figure 6).

As mentioned in the previous sections, international and national standardization bodies have to accelerate the process of making standards "machine readable" so that they can easily be processed by a computer to better accommodate the needs of the SVC.

Another example is the use of digital technology to improve and deliver accreditation, including the use of blockchain technology. The United Kingdom Accreditation Service has begun using blockchain technology in its own processes with the introduction of new e-Certificates, allowing quick and easy verification of the authenticity of accredited certification status by simply scanning a QR code.

As start-ups, SMEs and multinationals integrate their products and services in a seamless SVC providing new products and services, new international standards will be required to support the adoption of the new Industry 4.0 technologies. SVC stakeholders, including innovators in SMEs who

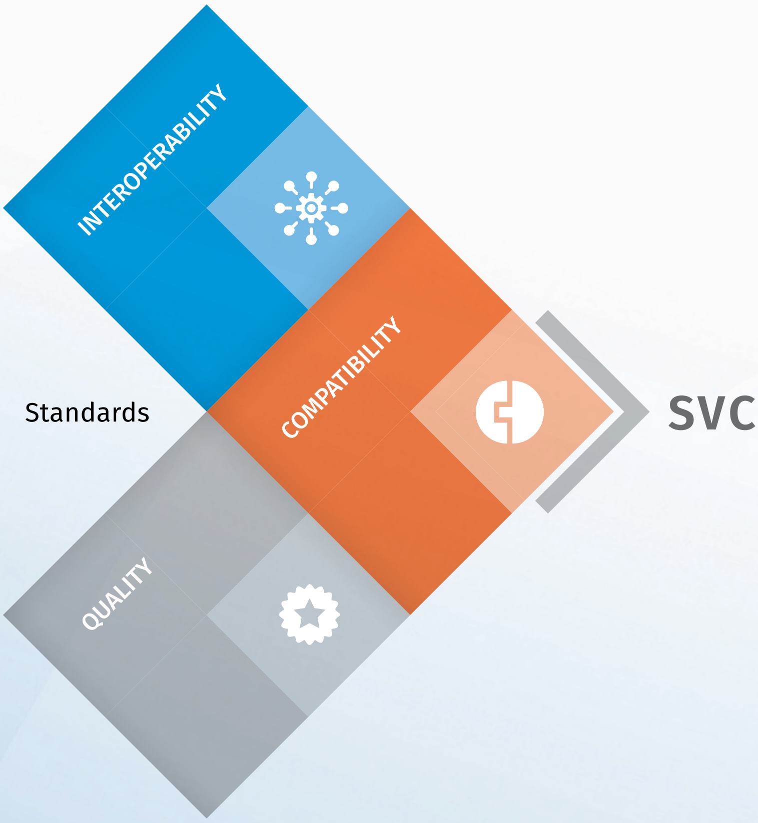
[49] Standards for the Fourth Industrial revolution- Department for Business, Energy and Industrial Strategy, July 2021, www.gov.uk/beis

are at the heart of the innovation community and often struggle to sustain effective participation in the standard development process, need to contribute to their development. This will facilitate the adoption of new technologies without building barriers to the introduction of new technologies, product and services.

FIGURE 6: **QI STRUCTURES MAINTAIN TRUST IN NEW TECHNOLOGIES OF THE SVC**

FIGURE 7:

Achieving a common language about the new technologies throughout the SVC will facilitate the interoperability and fast adoption of the new technologies as well as the knowledge transfer among SVC stakeholders.



6.3
CHANGES FOR THE QUALITY MANAGEMENT PROFESSIONAL

But not everything is about new technologies and business models—human beings working within the SVC, QM professionals among them, are also affected. The changing landscape of geopolitics, markets and supply chains, including international standardization of product and management systems, is significantly changing the role of QM within the organization. QM professionals will need to operate in an increasingly complex and fast-moving global context, dealing with new markets, new compliance requirements, and new supply chain challenges. QM professionals will need to adapt to support digital transformation, helping enterprises to design and redesign systems and processes, helping enterprises to translate big data into real value in terms of preventing failures and solving complex problems. Consequently, the skills needed by QM professionals working in SVC are very different from those previously when QM was an in-house discipline. Although it is very difficult to predict the necessary skills for the future QM, we can at least identify the following:

» Smart Quality professionals will need skills, such as creative thinking, leadership, and communication, and will need to collaborate not only within the enterprise but throughout the whole SVC.

» They must understand the role of new technologies that are cyber-physical production systems and combine with the best quality management practices, where their decisions are based on big data. The profession will need to embrace technology in the design of business models and systems, building in digital control and assurance.

» They must motivate their work teams, be open to change, know how to make decisions and how to manage conflicts. It must also be highlighted that in the future, the exchange of ideas will take precedence over the exchange of goods.

7. Future trends for Smart QI

7.1 SMART QUALITY IN ENTERPRISES

Although the 4IR is here to stay, there is already talk of "Industry 5.0" which builds on some of the concepts of Quality and Smart Quality that were discussed in previous sections of this publication. According to the European Commission, "Industry 5.0 provides a vison of industry that aims beyond efficiency and productivity as the sole goals and reinforces the role and the contribution of industry to society."[...] "It places the wellbeing of the worker at the centre of the production process and uses new technologies to provide prosperity beyond jobs and growth while respecting the production limits of the planet". [50]

There are vast disparities in the pace at which enterprises (and in particular developing economies) will implement Industry 4.0 and Smart Quality philosophies to meet the needs and expectations of their customers and other interested parties. Much will depend on the context in which they operate. According to ISO 9001:2015, this includes both the internal context (for example issues related to values, culture, knowledge, and performance) over which the organization can be expected to exert some influence and control, and the external context (including legal, technological, competitive, market, cultural, social, and economic environments) which are largely outside their control.

It is therefore reasonable to assume that there will be a co-existence of high-tech, sophisticated approaches to quality management (which we call "Smart Quality") together with more traditional approaches that can remain relevant depending on the markets in which individual enterprises operate

[50] European Commission, Research and innovation. (2022). Industry 5.0. [online] Available at: https://research-and-innovation.ec.europa.eu/research-area/industry/industry-50_en [Accessed 11 Oct. 2022].

or aspire to operate. As we have seen in section 5.2 figure 4, the only imperative is that a traditional approach to quality management will no longer be appropriate or effective for those enterprises that have made the digital transformation to an Industry 4.0 approach. For those who have not done so, traditional approaches to quality management may suffice, so long as they continue to provide confidence in the organization's ability "to consistently provide conforming products and services", though this will not guarantee long-term sustained success. The quality management system can, however, also act as a driver to stimulate enterprises to adopt more modern (Industry 4.0 type) approaches not only internally, but also throughout their supply/value chains.

As far as quality management system standards are concerned, there has been significant debate in the last two years about whether there is a need to revise ISO 9001:2015 (the world's major quality management system requirements standard, used as a basis for certification on a global level). The conclusion was that ISO 9001:2015 remains fit for purpose and is considered (at least for now) to be sufficiently flexible to allow enterprises to use both low-tech and high-tech (Smart Quality) approaches and tools to meet their performance-based requirements. A decision was made in 2020 by ISO's Technical Committee on Quality Management and Quality Assurance (ISO/TC176) to reconfirm ISO 9001:2015 for a further five years. However, a revision process could still be initiated before 2025 if it is deemed necessary after further consultations or developments in the global socio-economic context.

It is also relevant to consider the implications of the concept of "Broad Quality". That does not mean that the scope of ISO 9001 is likely to change to address issues that go beyond the traditional focus regarding the quality of products and services that an enterprise provides. What it does mean is that enterprises may need to look beyond ISO 9001, to standards such as ISO 9004 ("Guidelines for sustained success"), ISO 14001 (Environmental Management), ISO 45001 (Occupational Health and Safety Management), ISO/IEC 27001 (Information Security Management) , ISO 26000 (Guidance on Social Responsibility) and others, if they are to fulfil their commitments to interested parties other than just "the customer", but also to society as a whole, in preparation for an "Industry 5.0". This requires an increased awareness of environmental, social and governance issues and the contributions that enterprises can make to achieving the 2030 SDGs.

ISO now has an extensive suite of harmonized management system standards that can be implemented using an integrated, business-oriented approach.

7.2
QUALITY MANAGEMENT AND SMART PRODUCTION IN SMART VALUE CHAINS IN DEVELOPING COUNTRIES

Integrating Quality Management into Smart Value Chains

As manufacturing evolves from the perspective of an individual manufacturing enterprise to the SVC, quality management must also adapt and change its role. Many industries with in-depth knowledge of quality management have focused on measuring defects, complaints and other negative performance attributes of their products for which achieving zero defects and reducing warranty and complaint costs was the main goal. Industry 4.0 is changing the way data are captured and interpretated, not only defect, complaints and other QM KPIs, but also more complex data that is now available through a variety of digital channels. This expands the scope of quality management in the SVC to include the capture and interpretation of customer intelligence.

Quality management can be effective to ensure consistent treatment of intelligence data across different functions, the rapid identification of regional and other trends, and a consistent focus on the customer, ensuring a positive customer experience at every touch point. This allows quality management to evolve into the role of a value-adding business partner. This in turn will demand a change in strategy, processes, organization and culture as well as in the set of skills required by the QM professional that will not only be oriented on assurance and compliance, but also include business-oriented capabilities. Quality management is no longer the "quality policeman" but rather a SVC business partner and considered a key strategic asset.

There are some good illustrations of this evolution in the automotive sector. For example:

» Volkswagen's quality management function initiated the People's Car Project in the company's main market, China. Using a web-based platform, Chinese customers can express their ideas for product features and become actively involved in the creation of new cars.

» During the past 10 years, BMW has made huge progress in reducing the number of warranty cases by more than 50 %, through integration of quality within the entire value chain. Each quality programme, from purchasing through to production, sales and after sales, contributed to this success.

7.3 FUTURE TRENDS IN THE SMART VALUE CHAIN

Several trends are reinforcing the integration of smart manufacturing into the SVC,[51] including:

Product manufacturing and services are converging based on new market demands

For many products, the market is switching from buying a mass-produced product off-the-shelf to buying a custom configured product as-a-service. These new blended manufacturing-service business models require more customer interaction and elevate the value of the digital data that accompanies the product during its service life. These ecosystems are forced to evolve to deliver the required data services.

Manufacturers are redefining their processes and services around new enabling technologies

New technologies are not just enabling optimization of existing processes, companies are rethinking their processes, value chains, and business models.

Hybrid human-machine processes are on the rise

Robots, rather than replacing humans, have resulted in a collaborative work environment with a balanced distribution of responsibility. Technologies like cobots, exoskeletons, AI and AR will augment, assist and empower the future worker.

Manufacturing ecosystems are achieving higher levels of connectivity and transparency

There has been much progress in engineering, production automation, and enterprise business systems in the last few decades. Manufacturing operations management systems and paperless operations are the new norm in the manufacturing environment. Machines are getting smarter with embedded computers, AI, and application programming interfaces (APIs) ready to exchange data with manufacturing execution systems and cloud platforms. Smart Manufacturing eliminates manual steps and inconsistencies bringing silos of information together and finally links them in a full digital thread of automated data exchanges.

[51] https://www.manufacturing-operations-management.com/manufacturing/2020/02/six-trends-accelerating-the-smart-manufacturing-future.html.

The Smart Factory becomes a node in a connected smart ecosystem with API requirements for partner and customer interaction. The required data exchanges go beyond purchase order, shipment and warranty data if the ecosystem is delivering new data services with the product. For example, if a company is including a product digital twin as an additional service, it must be ready to make accessible, to the ecosystem and customer, 3D and simulation models of the product along with each unit's unique as-built and operational data.

Manufacturing systems are incorporating more automated intelligence

The availability of low-cost sensing, pervasive connectivity and cloud computing services has made it practical to access and holistically analyze data across integrated systems. Unstructured datasets such as images, natural language, and even messages in social media have become part of the data available for analysis. More integrated data and AI capabilities are bringing us closer to systems with automated routine decisions where humans intervene only when necessary.

Manufacturing culture is embracing digital

Manufacturing companies are investing more into their organizational culture. There is a recognition that technology plays a key role in the company image and in attracting talent. National governments have incentives for companies to adopt Smart Manufacturing and are supporting efforts to educate the workforce with the required new skills. Staffing services are evolving to fill the demand for highly specialized skills.

7.4 SMART VALUE CHAINS IN DEVELOPING COUNTRIES

In principle everybody agrees on the potential benefits Industry 4.0 can bring to all kinds of industries. However, empirical data at enterprise level about the real benefits obtained from the application of Industry 4.0 technologies are scarce. This lack of data is even more significant in developing countries.[52] For ITC technologies, that have been in the market already for a couple of decades, the amount of empirical data is significant and valuable analysis can be made, but for Industry 4.0 new technologies it is not the case. This is an important issue for developing countries since we know that Industry 4.0 positively influences the competitiveness of any country. It would be

[52] "Does value chain participation facilitate the adoption of Industry 4.0 technologies in developing countries?" Michael Delera et al., World Development, 2021, Elsevier Ltd.

interesting to know at enterprise level what are the factors stimulating the adoption of Industry 4.0 technologies in developing countries.

Quite often, the adoption of these new technologies come together with the acquisition of specific platforms, services, royalties or software. Factors that hinder the adoption of these technologies in developing countries is often due to unavailability of resources and sometimes services providers.

Nevertheless, the participation of enterprises from developing countries in global smart value chains are an important factor to facilitate the flow of technology from developed countries to the developing ones.

Data analysis from the UNIDO database on the adoption of production technology by manufacturing firms[53] indicates that enterprise participation in global SVC facilitates the adoption of Industry 4.0 technologies.

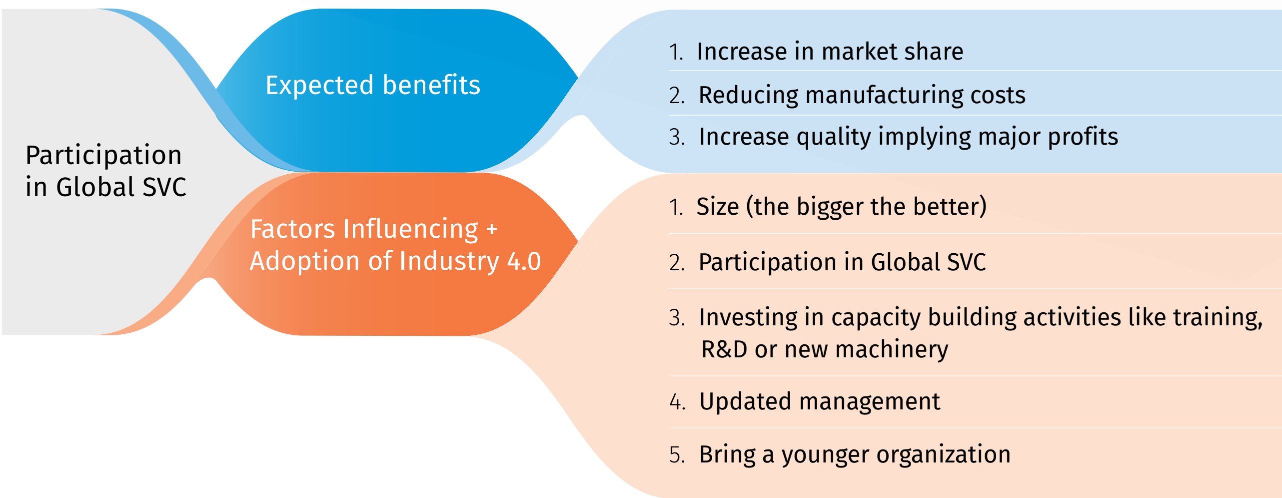
An enterprise takes up new technologies when the expected benefits exceed its costs. Some expected benefits from Industry 4.0 new technologies are shown in figure 8 below together with those factors that positively influence the adoption of Industry 4.0 technologies in developing countries.

In developing countries there is a high heterogeneity among industries, and within an industry, regarding the adoption of Industry 4.0 technologies. Only a small percentage of enterprises have adopted the state-of-the-art digital technologies, but the vast majority still have some way to go.

Industry 4.0 technologies keep pushing the technological frontier further, raising the level and quality of management capabilities required to adopt those technologies. This widening of the capability gap is one of the major obstacles for the adoption of Industry 4.0 technologies in developing economies. There is a risk of turning a technology upgrade opportunity into a digital industrialization bottleneck.

[53] UNIDO, 2019, International Yearbook of Industrial Statistics, Edward Elgar Publishing

FIGURE 8: **EXPECTED BENEFITS FROM INDUSTRY 4.0 NEW TECHNOLOGIES**



8. Conclusions

In response to the digital transformation and the 4IR, business leaders and policymakers need to recognize and adapt to innovation and change, progressing exponentially and shaping adequate strategies and polices accordingly. Enterprises need to change and adapt the way they operate to take full advantage of the new technologies.

The components of the Smart QI are critical factors, enabling the progression of industrialization and digitalization. Many if not most of the advanced technologies have specific standardization and CA needs that are necessary for their integration into manufacturing and other aspects of industrialization. Smart QI components are addressing these needs, resulting in a more efficient integration of the new technologies.

The advantages and benefits of the 4IR and the digital transformation will not be fully realized without taking the sustainability imperative into account. Social and environmental sustainability must become a strategic imperative for business, and specifically manufacturing, if it is to succeed. Advanced production technologies (IoT, IIOT, AI/ML, 3D printing robotics cloud computing big data and analytics, etc.) are enablers for the 4IR and the digital transformation. Likewise, the digital transformation and the 4IR enable a fairer and more circular economy which is turn supports the sustainability imperative. They are also opportunities for manufacturers to meet their obligations in terms of corporate responsibility. Smart QI and Smart Quality are therefore enablers of the sustainability imperative. Smart Quality is an integral part of the 4IR and has a key role to play in its success. It involves the "leveraging of technologies with people to improve the quality of an organization, its products, its services and the outcomes it creates".

Whilst the underlying principles of quality management remain as relevant today as they were over 30 years ago, the technologies that were traditionally used to support the various quality management processes, tools and methodologies are no longer capable of keeping pace with the rapid technological developments associated with Industry 4.0. The implementation of such new Smart Quality technologies can either go hand-in-hand with Industry 4.0 or can be used within traditional enterprises and value chains that have not yet made the digital transformation and act as a driver for them to do so.

Smart Quality means that quality professionals have a huge array of sophisticated technology available that support the quality processes like never before and allow them to manage quality in a more effective and efficient manner. Business must adapt to take advantage of what these tools are able to provide.

Both Smart QI and Smart Quality are integral parts of the 4IR and are vital to their success. However, the sustainability imperative must be taken on board if any of this is to benefit humanity, otherwise nothing will succeed. We have a unique opportunity before us to leverage all of the knowledge gained through the industrial revolutions in order to ensure that the ongoing transformation contributes to the three pillars of sustainable development: the planet, people and their prosperity.

Annexes

ANNEX 1

Two Cases to highlight the Key Role of Standardization

Annex 1 presents two cases to highlight the key role of standardization. The first case concerns the rail tracks in the USA because it comprises an ideal mix of technical and business issues and shows the importance of the quest for consensus among different stakeholders. The second case is an outline on the origin of conformity assessment, focused on the needs that led to its establishment.

CASE 1 – RAIL TRACKS

Railroads represent an ideal bridge between the FIR and SIR. The construction of railroads started in Britain and had an explosive growth in the first half of the 19th century. However, rail tracks at the time were made with wrought iron—a material superior to cast iron, but still far from perfect.

But then came steel, whose production had been made affordable by the invention of the Bessemer process in 1856 and improved in the following years by other inventors and steelmakers. Steel rails were made for the first time in 1857 by the British steelmaker Robert Forester Mushet. Steel is clearly a superior material and rapidly replaced iron for use on rails, allowing much longer lengths of rails to be rolled with substantially improved performance (reliability and duration).

However, the evolution and stabilization of the composition of materials for steel rails was a lengthy and complex process that required several decades.

The situation of American railroads at the end of the 19th century is well summarized by the American Society for Testing and Materials:[54] "*The industrial revolution opened a new chapter in the history of material specifications. Locomotive builders, steel rail producers, and steam engine builders who used revolutionary new materials such as Bessemer steel could no longer rely on craft experiences of centuries past. The new materials and techniques invented during this period required new technical expertise. Moreover, manufacturers encountered numerous quality problems in end products such as steel rails because suppliers furnished inferior materials. American rails were so poorly made, in fact, that many railroad companies preferred British imports, which were more expensive but reliable.*"

An effort to address this difficult situation—destined to have profound and lasting implications well beyond the railroad sector—was undertaken by Charles Dudley of The Pennsylvania Railroad, one of the largest corporations of the 19th century. In 1878, Dudley analyzed properties and performances of different types of steel, recommending an improved formula for steel to be used for steel rails. Dudley's report was met with fierce opposition by steel producers, who criticized his technical arguments and were adamant on claiming their right to maintain full control over their products.

Dudley realized that a constructive dialogue between suppliers and customers was needed to resolve the issue. It took about 20 years and the relentless effort of Dudley to overcome the antagonistic attitudes dominating the relationships between Pennsylvania Railroad and its suppliers—in particular, through the creation of committees where the parties had the possibility to discuss every aspect of specifications and testing procedures.

During this period Dudley extended the dialogue to representatives of the engineering community involved in the American Chemical Society and the International Railway Congress. This intense work led to the establishment in 1898 of the American Society for Testing and Materials (ASTM), one of the first SDOs in the world.

The same year, the first ASTM standard was published: A-1, 1898, On Steel, Stainless Steel and Related Alloys. This standard (to be followed by several others) marked a turning point in the relationships between suppliers of materials and manufacturers and gave a clear example of the essential role of standardization for the development of industry. Dudley was shortly after appointed president of ASTM, a position that he covered from 1902 to 1908.

[54] The History of ASTM International, Chapter 1

CASE 2 – ORIGINS OF CONFORMITY ASSESSMENT

Conformity assessment, or verifying the compliance of products, processes, and services to rules of reference—mandatory requirements or voluntary standards, good sector practices, etc.—has ancient roots, but it is in conjunction with the industrial revolution (late FIR and SIR) that it took its modern form.

The first sector affected by embryonic forms of conformity assessment (well before the industrial revolution) is probably the maritime sector. Since its inception, navigation (particularly high seas navigation) has been considered an extremely risky practice—not by chance associated, for centuries, to adventurers and intrepid captains.

Measures aimed at mitigating the risks of maritime trade were introduced as early as the late Middle Ages. For example, Venice, in 1255, made it illegal to charge ships excessively and Genoa, in 1330, not only defined detailed rules on authorized maximum loads, but also introduced inspection procedures and specific penalties for offenders. These forms of control extended in the following centuries, following the gradual growth of the importance of maritime traffic in volume and value, including periodic inspections aimed at verifying the conditions of suitability of empty and full cargo vessels and preventive rules to be observed in the construction and operation of ships.

Despite these initiatives, risk prevention remained a rudimentary practice for centuries: the protection of the risks of maritime trade was primarily addressed in financial terms, through the legal system—including compensation for ship owners and cargoes, and various mechanisms of sharing economic risk, including the introduction of a third figure, the insurer, as a risk underwriter in place of the parties directly concerned (discussed in detail below).

Innovations resulting from the industrial revolution (steam propulsion, metal hulls, etc.) made a decisive contribution to the further expansion of maritime traffic at the end of the 18th century. This gave a decisive boost to the introduction of measures to ensure greater safety on the seas and reduce risks—giving rise to modern forms of conformity assessment.

London merchants, owners and captains, all Edward Lloyds' coffee-clientele—a famous place where ships, travel and business were discussed—introduced the practice of "underwriting", or signing an agreement that established the commitments of different parties to cover losses in the event of a shipwreck, in exchange for profit shares if the voyage was completed successfully. The "underwriters" soon realized the importance of assessing the reliability of the ships to be insured. In 1760, the Register Society (later renamed Lloyds Register) was founded as the first classification company involved in the annual publication of a register of vessels, including a classification of vessels based on the assessment of their suitability (e.g. hull and equipment conditions).

Several other classification companies were founded in the following years, for example, the Bureau Veritas (BV) in Antwerp, Belgium, in 1828 (later transferred to Paris, France), and the RINA (ITALIAN NAVAL REGISTER) in Genoa, Italy, in 1861 by the Association of Mutual Maritime Insurance; while the adoption of common rules concerning the construction and operation of ships by Norwegian insurance companies led to the establishment of Det Norske Veritas (DNV) in 1864.

Beyond the maritime sector, the link between technological innovation determined by the industrial revolution, the risks associated with its large-scale applications and the role of insurance companies involved in covering those risks, can be considered a common pattern at the basis of modern conformity assessment.

The case of boilers and pressure vessels shows considerable similarities. Given the enormous potential and versatility of steam, in the second half of the 19th century the use of such devices grew enormously. However, for several decades, the engineering and use practices of these devices were significantly misaligned with the state-of-the-art design safety and operating modes, causing a huge number of accidents and thousands of fatalities per year.

Suffice it to say that the worst disaster in U.S. naval history is the sinking of the Sultana, a typical side-wheeler of the Mississippi river with two decks. On 27 April, 1865, steaming along the river above Memphis, the Sultana met a catastrophic end when three of its four boilers exploded for reasons never determined. Within 15 minutes, it had burned to the waterline, with a death toll that varied in later reports from 1,200 to more than 1,500—the USA's worst marine disaster in history.

"The Hartford Steam Boiler Inspection and Insurance Company" (now part of the Munich Re Group) was founded in Hartford, Connecticut, USA, in 1866, shortly after the explosion of the Sultana. This company was the first in the world to combine inspection and insurance—ensuring boilers only after an inspection had been carried out by qualified technicians and then to renew the insurance policies only if the results of the periodic checks provided for the insured devices were deemed satisfactory.

Similar developments have occurred in other industrialized countries. In Germany, the Technischers Überwachungsverein (TÜV, Technical

Inspection Associations), organizations that provide product inspection and certification services, were born in a similar way at the end of the 1800s.

Following the explosion of a steam boiler at the Zum Grossen Mayerhof brewery in Mannheim in 1865 and other similar accidents, on 6 January 1866, 22 Baden entrepreneurs launched the “Gesellschaft zur Ueberwachung und Versicherung von Dampfkesseln mit dem Sitze Mannheim” (Association for inspection and insurance of boilers, based in Mannheim). The main objective was to prevent future incidents with regular inspections, and the initiative was later supported by the government of the Grand Duchy of Baden. Similar associations were created in the following years in many other German cities, and these were merged into the “Deutscher Verband von Dampfkessel berwachungsvereinen” (German Union of Steam Boiler Inspection Associations) in 1873.

In both cases (ships and boilers), during the SIR the evolution of engineering practices and inspection activities gradually led to the definition of standards and regulatory codes spread on a large scale, to be used:

» on the one hand, as a foundation for the design, production and use of equipment and machinery activities, and

» on the other hand, for inspection, testing and certification practices carried out by specialized personnel (with adequate technical background and qualifications acquired through appropriate training programmes).

ANNEX 2

Two Cases to highlight Developments around Quality and Logistics

Annex 2 presents two cases that describe the developments around quality and logistics—two areas that had a major impact on the development of industry over the decades following World War II, merging with and contributing to amplifying the TIR.

CASE 3 – QUALITY

Prior to the war only a few companies in the USA were using statistical methods for quality control. However, given the serious concern about quality for many of the products supporting the war effort, high-level representatives from hundreds of companies supplying the US Government were requested to follow extensive training in the discipline.

A primary source of knowledge was embedded in three standards developed by the American Standards Association (ASA, the predecessor of ANSI) at the request of the US War Department: the "Guide for Quality Control" and the "Control Chart Method of Analyzing Data", published in 1941 and followed in 1942 by the "American War Standard" and the "Control Chart Method of Controlling Quality During Production".

Shortly after, a similar development took place independently in the United Kingdom, with the British Standards Association (the predecessor of BSI) publishing the standards BS 1008-1942, Quality Control, and BS 600 R-1942, Quality Control Charts.

It is important to underline that statistical quality control represented a very important innovation for manufacturing, given the practical impossibility of performing inspections on each finished product in a mass-manufacturing context (as previously done).

These early developments constitute the basis for the establishment of the modern discipline of quality management, which had an enormous impact on manufacturing worldwide. It was only after the enormous influence of Edwards Deming's lectures and Joseph M. Juran's courses in Japan after the war, and the impact on western's economies of the competitiveness of quality-oriented Japanese manufacturing, that the quest for quality exploded in the late 1960s to 1970s, leading to major developments of the field in the 1980s.

CASE 4 – LOGISTICS

Logistics is another field that experienced significant development during and after the SIR. The first trucks were invented at the end of the 19th century and trucks with diesel engines were introduced in the mid-1920s. Forklift trucks were designed prior to 1930, but their use grew only after the invention of pallets in 1925, probably the major development in supply chain storage supporting the earlier evolution of logistics.

In the 1930s the concept of "freight container" started to become an economic reality: in 1933 the International Container Bureau (French: Bureau International des Conteneurs, B.I.C.) was established in Europe and set obligatory parameters for containers used in international traffic. However, these containers were primarily intended for land transport (based on railway and truck) and their role was eclipsed by the advent of the shipping container in the following decade.

World War II brought new, phenomenal logistical challenges, given the need of supplying millions of troops and materials over long distances and overseas. It is in this period that the US Navy started to use small, standardized boxes full of war material to optimize capacity to deliver wartime necessities. After the war, in 1947 the US Transportation Corps developed the Transporter, a rigid, corrugated steel container that was later used effectively in the Korean War and evolved in 1952 into the CONtainer EXpress or CONEX box system.

These developments were well noted by the private sector, and particularly by Malcom McLean. Other than being the first businessperson to "bet the house" on containerization, he gave ISO a royalty-free license to use his patents for the upcoming international standards, a factor that contributed dramatically to accelerate and strengthen their development. From the perspective of this publication, there are some essential points to retain:

» International standardization was a critical factor (perhaps "the" critical factor) for the development of the world transportation infrastructure that we know today. In fact, standardization facilitated a coordinated effort of players as diverse as cargo, railway, and truck transportation companies; public authorities responsible for transportation in many countries; along with port and railway operators. Something that no company or country could have ever achieved alone.

» The impact of containerization was phenomenal. According to the OECD, today over 90% of traded goods are moved by cargos and over 60% of that by containers. The increase in productivity has been unprecedented.

» Reshaping world transportation, containerization was responsible for the greatest revolution in supply chains. In fact, the set-up of modern supply chains would have not been possible without the versatility, efficiency and low cost brought by "the Box". It was only because of the Box that materials and parts for products could be purchased and delivered from the world over, ever more rapidly and at affordable costs.

» These developments, combined with computerization that shaped the third industrial revolution, as we will see in a moment, created the foundation for today's "just in time" approach to global manufacturing. The transformation brought by these two forces (containerization and computerization) allowed the import of products cheaper to make abroad (e.g. garments, toys, consumer electronics). Individual companies could specialize in niche components which could be exported everywhere, assembled in other countries, and then shipped as finished products to the target markets.

ANNEX 3

A Fundamental Dichotomy facing Standards Developing Organizations

Standards developing organizations (SDOs) wishing to be recognized by the World Trade Organization's Committee on Technical Barriers to Trade (WTO TBT) must adhere to internationally recognized principles for standards development, notably the "six principles": transparency – openness – impartiality and consensus – relevance and effectiveness – coherence – development dimension.

The dichotomy is that the principles of "relevance and effectiveness", which in digital technologies and other fast-moving fields means rapid development of deliverables, may conflict with "transparency, openness and consensus". On the one hand, it is essential to deliver on time to stakeholders what they need; on the other hand, standards have value only if the concerned and affected parties are involved. This is critical to give standards the degree of legitimacy required to be linked to public policies and particularly technical regulations.

Many SDOs, such as ISO, IEC and ITU, are committed to comply with the six principles[55] for standardization activities and they need to strike a balance between the conflicting implications of these principles. However, this is not necessarily the case for industry consortia and other types of organizations, which may involve a limited number of actors or adopt faster processes that do not necessarily guarantee a broad level of openness and consensus.

In certain cases, the interaction between consortia and "formal" SDOs represents a possible path to accelerate standards development. There are many examples of technical standards developed by consortia taken up by standards organizations, such as ISO, IEC and ITU, refined (if needed) and legitimized through a process compliant with the six principles.

Process improvement for QI organizations

That said, in what follows we try to outline process improvements that can be applied by all types of SDOs—and do not necessarily require closed groups or limited levels of consensus to create deliverables in short timeframes.

[55] TBT Committee Decision on principles for Development of International Standards, Guides and Recommendations (November 2000G/TBT/9).

There are three main established and emerging directions, already being applied by SDOs:

» Use of IT platforms in support of the standards development.

» Adaptations of the general standards development process rules to increase flexibility.

» Tailored solutions addressing rapidly evolving technologies (maintaining compliance with the general rules).

Use of IT platforms

The possibility of downloading and exchanging documents over the internet represented a step change in terms of access to information and efficiency of document exchange.

Since then, IT platforms have played an important role to increase the efficiency of standards development. Taking the IT platforms implemented by ISO and IEC as examples, it is possible to outline some of the most important services to the community of standards developers:

» Access to standards project data and documents through internet-based applications.

» Electronic workspaces for technical structures (committees, sub-committees, working groups) supporting technical work.

» Notifications and tools to support the online execution of key standards development process tasks (e.g. submission of documents, electronic balloting, management of comments, notification services).

» Management of data regarding experts and related roles in technical structures.

» Management of meetings (virtual and physical).

The most important developments currently taking place concerns two additional important aspects:

» **Collaborative authoring of standards in structured form.** For example, the joint ISO and IEC Online Standards Development platform facilitates the collaborative authoring of standards documents, providing easy access to specific document elements, managing contributions and comments, and allowing to structure documents consistently with the standardized formats used for publishing it.

» **Virtual meetings.** Almost all the meetings of standards organizations were conducted virtually in 2020/21 as a result of COVID-19. Organizations have developed a variety of good practices and services to support the effectiveness and efficiency of virtual meetings. The trend is evolving, with the integration of meeting management and other IT committee tools into comprehensive platforms.

The second direction addresses adapting the standards development process rules to give more flexibility to technical committees.

Standards organizations have a variety of deliverables that allow for the publication of documents with lower levels of consensus in shorter timeframes. The goal of new initiatives promoting flexibility is to allow standards committees to determine and apply how best to organize the work within the committee.

The third direction concerns the adoption of tailored solutions to address specific fields.

This is particularly important for rapidly evolving technologies, such as those related to Industry 4.0.

Some elements of the approach followed by the ISO/IEC Technical Committee (TC) for the Coding of Moving Pictures and Audio (known as MPEG) can translate to other areas and are worth noting:

» Standards should anticipate the future. This is crucial for rapidly moving fields. Standards should not be designed to “adapt to” or “consolidate” existing technologies but provide for possible future developments.

» Standards should be able to drive the best performance, no matter if some technologies incorporated by the standard are covered by patents—there are ways to deal with this issue, satisfactory for patent holders and all the other players.

» Standards should be “toolkit-based”, not all enterprises, from different industries, are interested in the same functions or levels of performance. Standards can be structured in a variety of ways that provide maximum flexibility of implementation to companies from different industries.

» Standards have to be “industry-friendly” and leave room for companies to compete “within” the standard, and not by promoting competing standards.

To apply these and other principles requires a carefully balanced combination of competition and cooperation among the participants in the group.

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