



An Overview of the Future of Manufacturing and the Fourth Industrial Revolution

Opportunities for Malta-Based Manufacturers

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1.0 | Executive summary

The world is currently witnessing Industry 4.0, the fourth industrial revolution. The first took place in the 18th century, with the arrival of mechanical weaving looms. The second, between 19th and early 20th century, was characterized by mass production using electric conveyor belts. The third came in the 1970s with automation of production using information technology and computerized control. The current industrial revolution started at the start of this millennium with production monitoring and automation using cyber-physical systems and the Internet of Things (IoT) together with a host of other technology drivers. Its philosophy is that “manufacturing systems are vertically networked with business processes within factories and enterprises and horizontally connected to dispersed value networks that can be managed in real time – from the moment an order is placed right through to outbound logistics.”

This report shows how disruptive particular technologies such as additive manufacturing can be. In addition, Industry 4.0 will also transform business models and supply chains.

In reviewing the impact of Industry 4.0, we would like to propose a number of key considerations for exporting Malta-based SMEs and manufacturers:

- Industry 4.0 is a reality which has already started. Although investment plans of large conglomerates are extremely ambitious, early investors are already moving ahead. We believe that Industry 4.0 holds the potential for clearer differentiation in global competition.

- Industry 4.0 strategies can be developed along the three major digitisation directions:
 - o Digitisation and integration of vertical & horizontal value chains
 - o Digitisation of product & service offerings
 - o Innovative digital business models
- Companies expect to reduce costs and increase revenues through the adoption and harnessing of Industry 4.0 technologies.
- Industry 4.0 will drive change across the entire business and trigger significant disruption to both companies and sectors. But to win, companies will need to develop a strong digital culture.
- Industry 4.0, through a host of technologies, will bring the customer at the core of production processes. However, it becomes integral for companies to have oversight and capacity to analyse the customer through big data.
- Data analysis will be the necessary pre-requisite for the successful implementation of Industry 4.0.



2.0 | Introduction

The scope of this report is to provide an overview of the future of manufacturing and the fourth industrial revolution and its impact on Malta-based manufacturers. Economies and manufacturing systems have in the past gone through revolutionary phases thanks to new technologies that had a large impact on productivity and efficiencies. The fourth industrial revolu-

tion is the result of deep changes and the coming together of various technologies. These are transforming companies, manufacturing processes, products and also services. Industry 4.0 is ushering in a new factory of the future which is bringing to fore new challenges and opportunities. The fast pace of change that is happening in the industry cannot be denied, and this



new, dynamic phase is bringing new opportunities for the manufacturers. Recent changes in various technologies and market realities will have an impact on the future of manufacturing and we believe that these can be distilled in three main themes:

- Faster, more responsive and closer to customers;
- More sustainable; and
- Increasingly dependent on highly skilled workers.

In addition to these changes, we are also on the verge of welcoming the fourth industrial revolution in the history of manufacturing, which is based on a number of related technological drivers. Although different technologies, they are all based on bridging the gap between the cyber or digital and physical worlds. In essence, these systems mean that physical production plants are linked together in an open network whereby devices are all connected to each other across different sources and locations. This interplay can drive the physical act of doing business in an ongoing cycle. Throughout this cycle, real-time access to data and intelligence is driven by the continuous and cyclical flow of information and actions between the physical and digital worlds. This flow occurs through an iterative series of three steps. To achieve this process Industry 4.0 combines relevant physical and digital technologies. Industry 4.0 goes beyond automation and

digitisation. For many firms, the components of the value chain are already highly automated. What separates Industry 4.0 from past technological advances is an emphasis on integration. In the next Section, the Report looks at the future of manufacturing before moving on to the section that specifically deals with Industry 4.0. The following two sections look at 5 some applied elements of Industry 4.0 with a focus on additive manufacturing and the impact of Industry 4.0 on business models. The report then moves on to exploring the factories of the future before concluding with some considerations for Malta-based manufacturers.



3.0 | Manufacturing

The manufacturing of goods has always formed a big part of economies worldwide, and its relevance does not seem to reduce in the near future, but the way manufacturing works keeps changing. Even though we have seen radical changes from the first industrial revolution to our current days, when we look ahead, we still see countless changes coming our way that are aimed at continuously improving the pace and the efficiency of production. Manufacturing in 2050 will look very different from today and will be virtually unrecognisable from that of 30 years ago. Successful firms will be capable of rapidly adapting their physical and intellectual infrastructures to exploit changes in technology as manufacturing becomes faster, more responsive to changing global markets and closer to customers. Successful firms will also harness a wider skills base, with highly qualified leaders and managers whose expertise combines both commercial and technical acumen, typically in science, technology, engineering or mathematics. Constant adaptability will pervade all aspects of manufacturing, from research and development to innovation, production processes, supplier and customer interdependencies, and lifetime product maintenance and repair. Products and

processes will be sustainable, with built-in reuse, remanufacturing and recycling for products reaching the end of their useful lives. Closed loop systems will be used to eliminate energy and water waste and to recycle physical waste.

These developments will further emphasise the key role of physical production in unlocking innovative new revenue streams. Traditionally we understand manufacturing as the larger scale processing of raw materials and/or other components by hand or machine into a final product that is then sold to customers. However, recently this understanding has changed, and now we understand that this production process is part of a wider manufacturing value chain.

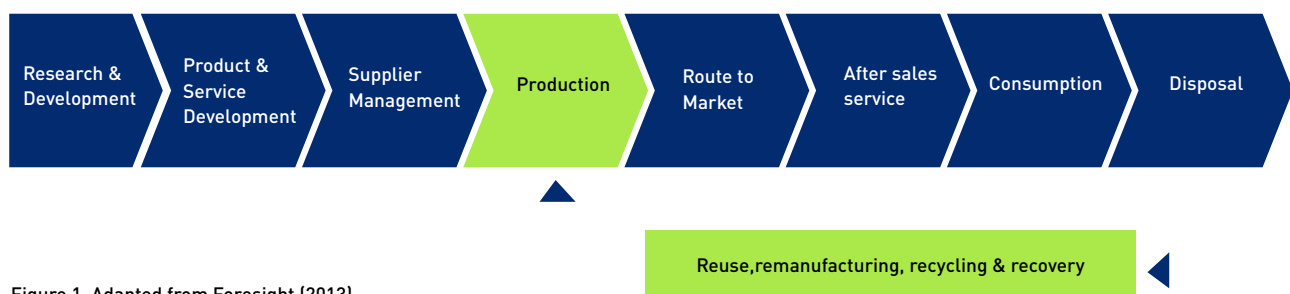


Figure 1. Adapted from Foresight (2013)

Note: Within this value chain some elements are repeated many times, for example as components come together to build a complex product. There are also feedback loops which may vary for different sub-sectors.

The players in this sector are using the above model more and more to generate new and additional revenue, with production being the centre of the value chain, allowing the emergence of other value - creating activities.

The business model for manufacturing is already changing to explore new revenue sources and value creating services. The new sources of revenue will likely include:

- Increasingly extensive service packages with the products;
- New information sources on the usage of products with built-in sensors that will provide the data;

- Becoming a “factoryless goods producer” capturing value by selling technological knowledge and leaving production to others;

- Becoming “remanufacturer” with end of life products remanufactured and returned to original specifications;

- Aiming at collaborative consumption, where no one customer owns a product outright;

- Creating value from new forms of strategic alliance within and across sectors;

- Exploiting new technologies at a higher pace through greater operational capability together with entrepreneurial knowledge.

3.1 | The future of Manufacturing

The fast pace of change that is happening in the industry cannot be denied, and this new, dynamic phase is bringing new opportunities for the manufacturers. Recent changes in various technologies and market realities will have an impact on the future of manufacturing and we believe that these can be distilled in three main themes:

- Faster, more responsive and closer to customers;
- More sustainable; and
- Increasingly dependent on highly skilled workers.

We believe that these forces, together with the big technology changes that are taking place, we will see the emergence of the Fourth Industrial Revolution, or Industry 4.0, which will be discussed in the next section.



3.1.1 | Faster, more responsive and closer to customers.

There are numerous technologies, such as 3D printing or robotics, that already have started shifting the whole industry at a pace that could not have been anticipated. This trend is likely to continue in the coming years. Manufacturers will have to keep looking out for these new technologies that are changing the way how products are designed, made, sold and eventually used by the customers. Historically there has always been a clearly distinguishable gap between the low-cost products of mass production and the more expensive, customized products. This gap will

likely be significantly reduced across a wide range of products. With technologies like 3D printing – also known as additive manufacturing, coupled with augmented and virtual reality, becoming more available, having personalized products is less of a luxury and part of the normal production process. Customization offers a great opportunity for Malta-based operators and customisation is possible due to two other trends which are largely influenced by Industry 4.0.



Distributed production

The production landscape will be completely transformed by the new trends, like additive manufacturing or advanced robotics. Future factories will be more varied and more distributed, producing complex products and their units are going to be integrated with their supply chain partners. Due to the developments, factories in the future could be urban sites close to their customers.

Digitised manufacturing value chains

IT and computing will go much further in the transformation of value chains, where they improve customer relationship management, process control, logistics, product traceability and safety systems. Customers will be able to have more of their input in the designs of the products, and the suppliers are going to be able to take bigger parts in the complex produc-

production processes. Table 1 presents some of the main technologies that will shape the future of manufacturing. These are also the main drivers of Industry 4.0 which will be discussed in further detail in the next

Table 1. Important pervasive and secondary technologies for future manufacturing activities. Adapted from Foresight (2013)

PERSUASIVE TECHNOLOGY	LIKELY FUTURE IMPACTS
Information and communications technology (ICT)	Modelling and simulation integrated into all design processes, together with virtual reality tools will allow complex products and processes to be assessed and optimised, with analysis of new data streams.
Sensors	The integration of sensors into networks of technology, such as products connected to the internet, will revolutionise manufacturing. New data streams from products will become available to support new services, enable self-checking inventories and products which self diagnose faults before failure, and reduced energy usage.
Advanced & functional materials	New materials, in which the UK has strong capabilities, will penetrate the mass market and will include reactive nanoparticles, lightweight composites, self-healing materials, carbon nanotubes, biomaterials and 'intelligent' materials providing user feedback
Biotechnology	The range of biotechnology products is likely to increase, with greater use of fields of biology by industry. There is potential for new disease treatment strategies, bedside manufacturing of personalised drugs, personalised organ fabrication, wide availability of engineered leather and meat, and sustainable production of fuel and chemicals.
Sustainable/green technologies	These will be used to reduce the resources used in production including energy and water, produce clean energy technologies, and deliver improved environmental performance of products. Minimising the use of hazardous substances.

SECONDARY TECHNOLOGY

Big data and knowledge-based automation

These will be important in the on-going automation of many tasks that formerly required people. In addition, the volume and detail of information captured by businesses and the rise of multimedia, social media and the internet of things will fuel future increases in data, allowing firms to understand customer preferences and personalise products.

Internet of Things

There is potential for major impacts in terms of business optimisation, resource management, energy minimisation, and remote healthcare. In factory and process environments, virtually everything is expected to be connected via central networks. Increasingly, new products will have embedded sensors and become autonomous.

Advanced and autonomous robotics

Advances are likely to make many routine manufacturing operations obsolete, including health-care and surgery, food preparation and cleaning activities. Autonomous and nearautonomous vehicles will boost the development of computer vision, sensors including radar and GPS, and remote control algorithms. 3D measurement and vision will be able to adapt to conditions, and track human gestures.

Additive manufacturing (3D printing)

This is expected to have a profound impact on the way manufacturers make almost any product. It will become an essential 'tool' allowing designs to be optimised to reduce waste; products to be made as light as possible; inventories of spare parts to be reduced; greater flexibility in the location of manufacturing; products to be personalised to consumers; consumers to make some of their own products; and products to be made with new graded composition and bespoke properties.

Cloud Computing

Computerised manufacturing execution systems (MES) will work increasingly in real time to enable the control of multiple elements of the production process. Opportunities will be created for enhanced productivity, supply chain management, resource and material planning and customer relationship management.

Mobile Internet

Smart phones and similar devices are positioned to become ubiquitous, general purpose tools for managing supply chains, assets, maintenance and production. They will allow functions such as directed advertising, remote healthcare and personalisation of products. Linked technologies include battery technology, low energy displays, user interfaces, nano-miniaturisation of electronics, and plastic electronics.

3.1.2 | Sustainability

Thinking more about a sustainable way to produce things and provide services, has been on the rise with trends, like CSR gaining more and more attention. However, shifting towards sustainability is not only a communication trend anymore, but increasing demand from customers to think and act differently.

The below table outlines the expected changes that environmental sustainability will have on production processes in the coming decades.

2013-2025: Efficiency and Resilience	2025-2050: Experimentation with new systems	2050 and beyond: A resource constrained world
• Minimised material input • Waste management • Increased energy efficiency • Reduced water usage • Improved efficiency in land usage	• New forms of value associated with products including sustainability • Products reused, remanufactured, recycled and redesigned with recovery in mind • More durable products designed for shared ownership • Spare capacity built into supply chains to ensure resilience	• Products use smaller amounts of materials and energy • Material is not landfilled but kept in a 'productive loop' • Cleaner and quieter factories close to consumers, suppliers and academic institutions • Supply chains with spare capacity at all stages

Table 2. Three phases in the shift to sustainable manufacturing. Adapted from Foresight (2013)

3.1.3 | Increasingly dependent on highly skilled workers

In recent years the manufacturing sector has started to see a positive, though cautious, turnaround from the 2009 recession. The improvement in activity is also reflected in employment, which has started to recover from the steep decline recorded in previous years. Notwithstanding the increased availability of foreign workers, sentiment indicators suggest that the

industry is not immune to labour shortages. Demand for technical specialism combined with commercial and problem-solving abilities will become critical going forward. In addition, the emergence of the new technologies discussed earlier and their importance to the future of manufacturing will require a host of specialist skills.



3.2 | Conclusion

Several forces and trends are going to be influencing the global manufacturing sector. With global integrated supply chains, Malta is not immune to these changes. In addition, the biggest challenge yet opportunity arises from a new wave of productivity improvements dubbed the fourth industrial revolution. As will be seen

from the next section, the fourth industrial revolution is already disrupting manufacturing sectors around the world and for Malta's manufacturing firms to remain competitive, they need to examine how to harness these changes and to find the opportunities in the challenges that such a new era will bring about.

4.0 | Industry 4.0

The Fourth Industrial Revolution, commonly known as Industry 4.0, appears to be changing the way businesses function, and by extension the stakes by which they are forced to compete. Maltese manufacturing entities are no exception. Organisations must decide how and where to invest in these new technologies and identify which ones might best meet their needs. Without a full understanding of the changes and opportunities Industry 4.0 brings, companies and also countries risk losing ground.

The basis for a technological revolution is well established with the cost of bandwidth and processing power decreasing dramatically. At a time when blockchain, big data and artificial intelligence are claiming the headlines, a lot has been happening in the manufacturing world which has not received enough of the attention it deserves. In fact, Industry 4.0 is fast gathering pace as traditional production lines merge with cutting-edge technologies, factory floors smarten up, while production plants scale down.

4.1 | A brief history of manufacturing

Manufacturing revolutions have always ushered major productivity booms.

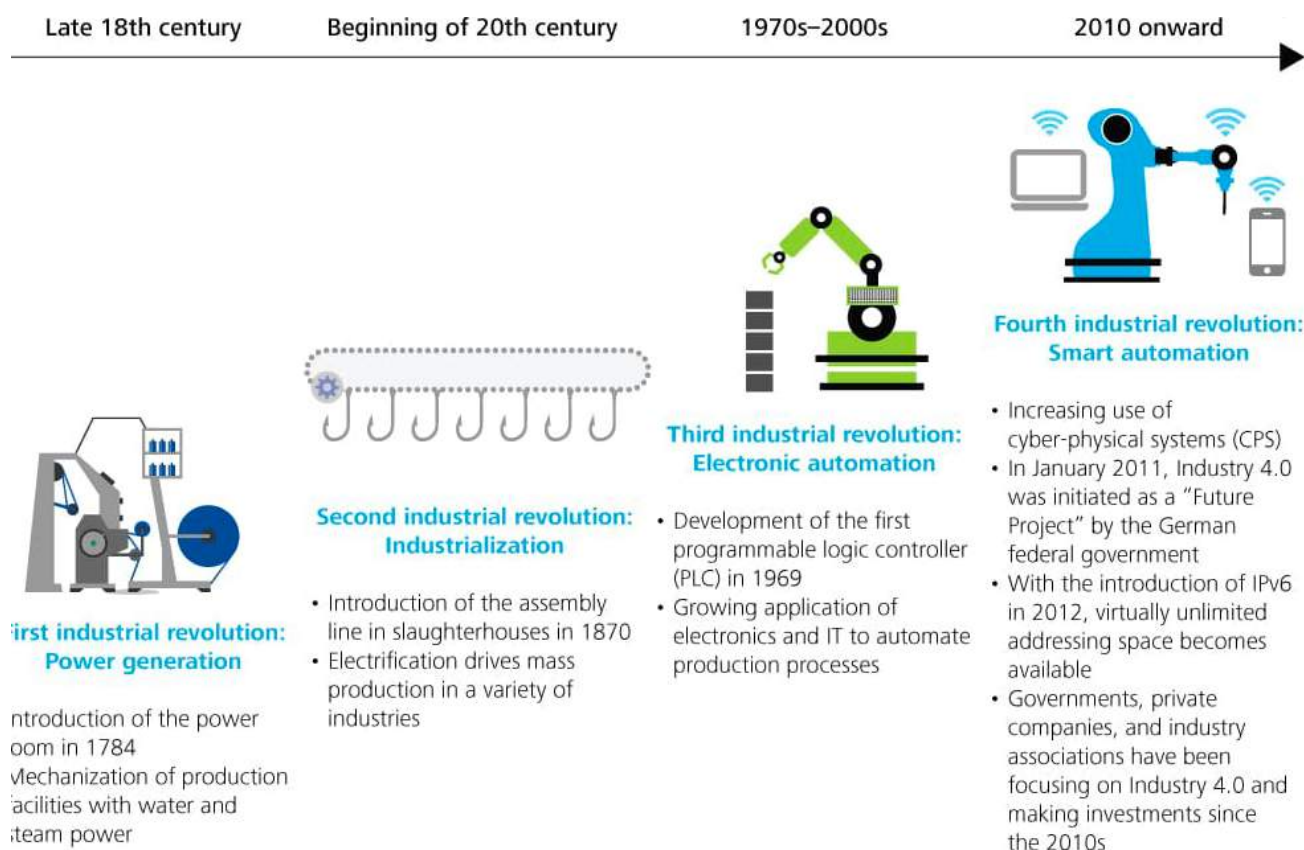


Figure 2. A history of industrial revolutions: Industry evolution with key developments
Sourced: [Deloitte, 2016]

The First Industrial Revolution started in Britain in the second half of the 18th century and lasted till the early 19th century, during which time the manufacturing shifted from the time-consuming hand-made products to using mainly steam powered machines. This has brought the emergence of mechanization which resulted in industry overtaking agriculture as the economic structure of society.

The Second Industrial Revolution took place a century later, and unlike the first revolution where the focus was on new technology, the second revolution was more about the advancement of the existing technologies, which also initiated the use of new energy sources. Gas, oil and electricity replaced the water and steam-powered engines as the primary power source in factories, which allowed for assembly lines and mass production to appear. Methods of communication were revolutionized with the invention of the telegraph and tele-

phone, as well as the new means of transport such as the automobile and the plane. With the development of new machines and different use of the existing ones, a new era started in the industrial world affecting every major economy.

The Third Industrial Revolution happened a century later when the new source of energy was discovered, the nuclear energy, and new disruptive technologies were introduced, such as the computer and automation. It started around 1960-1970, when the use of computers enabled a new level of accuracy and precision, which led to the production of miniaturized materials and helped the rise of electronics.



Now we are on the verge of welcoming the fourth industrial revolution in the history of manufacturing, which is based on a number of technological drivers. However, in essence, it is based on cyber-physical systems. In essence, these systems mean that physical production plants are linked together in an open network whereby devices are all connected to each other across different sources and locations. This interplay can drive the physical act of doing busi-

ness, in an ongoing cycle. Throughout this cycle, real-time access to data and intelligence is driven by the continuous and cyclical flow of information and actions between the physical and digital worlds. This flow occurs through an iterative series of three steps. To achieve this process Industry 4.0 combines relevant physical and digital technologies. The flow is referred to as the physical-to-digital-to-physical (PDP) loop and is presented below.

Physical to digital	Capture information from the physical world and create a digital record from physical data
Digital to digital	Share information and uncover meaningful insights using advanced analytics, scenario analysis and artificial intelligence.
Digital to physical	Apply algorithms to translate digital-world decisions to effective data, to spur action and change in the physical world.

Table 3. The Physical-to-digital-to-physical loop

As one can imagine, the loop is based on a number of related and connected technologies that have allowed this loop to close and function. An exploration of the key drivers behind Industry 4.0 is given in the next section.

Industry 4.0 goes beyond automation and digitisation. For many firms, the components of the value chain are already highly automated. What separates Industry 4.0 from past technological advances is an emphasis on integration.

4.2 | The technology drivers

The advent of Industry 4.0 is the combination of a number of technological changes that are happening and merging together. This coming together of these different

technologies is in essence Industry 4.0. One can highlight 9 main technology drivers which will usher in a new era and act as a revolutionary force.

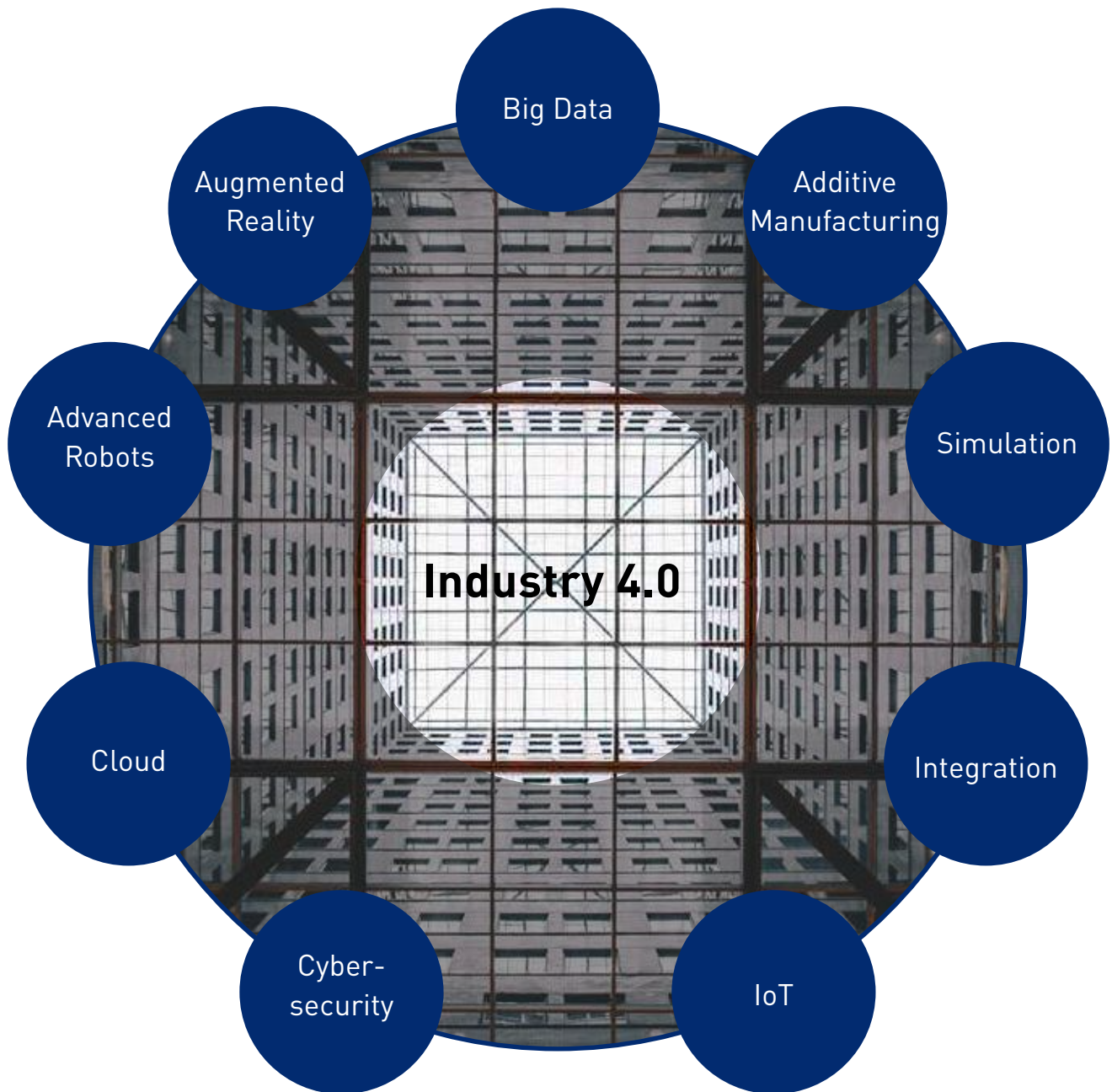


Figure 3. Technology drivers behind Industry 4.0

DRIVER	DESCRIPTION
Advanced Robotics	Today's robots are blunt instruments surrounded by cages in order to prevent workplace accidents. In the future, these robots will be replaced by what are touted as 'cobots', a breed of intelligent robots that collaborate seamlessly with other robots and humans.

Additive manufacturing	If one had to ask a traditional factory to manufacture a single, customised component, the bill would be prohibitively expensive. However, for a 3D printer, scale is irrelevant.
Augmented reality	By displaying supported information through a pair of glasses, this technology allows even inexperienced workers to perform highly complex tasks. More generally, it can be used successfully used for training purposes.
Simulation	Simulation is already a widely-used tool for testing and optimisation, eg. for products, materials and production processes. It is even used for factory design. However, in the future, this technology will also be used for advanced real-time simulation of the physical world in a virtual model. This will allow firms to test work processes even before factories have been erected.
Integration	Horizontal and vertical integration of the supply chain will bring crosscompany, universal data integration. This is a prerequisite for a fully automatic value chain that extends from suppliers to customers.
Internet of Things (IoT)	Above all, IoT, and in particular Industrial IoT embodies the spirit of Industry 4.0. This breed of technology promises to link machines, products, processes and systems together in real-time. More devices will be embedded with sensors and computing. This helps to decentralise analytics and decision-making, enabling real-time responses.
Cyber security	On the flipside, open and integrated networks are vulnerable to malicious attacks. As a result, factories will have to emphasize cyber security in order to protect industrial systems and manufacturing lines.

The cloud	Cloud systems will manage huge volumes of data in open systems, allowing instantaneous communication with production systems. Software can be hosted in the cloud, rather than locally, for easy, continuous upgrading and backup.
Big data and analytics	Meanwhile, analytics powered by 'Big Data' will mature to deliver comprehensive evaluations of many available data sources, such as ERP, and CRM systems. This will provide fresh insights and real-time decision-making support.

Table 4. The technology drivers behind Industry 4.0

The interplay and coming together of all of the above technologies will leave to tangible benefits to every bit of the production process. We believe that the main benefits can be summarised below however more detail on the impacts of Industry 4.0 will be covered in another section of the report.

Quality	The quality of products benefits from additional sensors that monitor production in real time. In the event of errors, useful information is quickly dispatched to the appropriate stakeholder.
Productivity	Productivity increases not only because automation reduces production time, but also because assets are better used, and inventory is better managed.
Speed	Manufacturers can shorten time-to-market by quickly prototyping new ideas and simulating various scenarios.
Flexibility	All of this happens flexibly with machines and robots that are easily retooled to work on a large variety of products, which can be produced in a one-piece flow.

Table 5. Benefits of Industry 4.0

Apart from the above benefits, others come about in areas such as safety, working conditions, accessibility and environmental protection. For example, advanced robots help to reduce the physical burden for many workers, allowing older employees to stay in the workforce for longer.

In a traditional sense, Industry 4.0 improves production by lowering costs. Labour costs have the potential of being decreased through the introduction of advanced robots, logistics costs are also expected to decrease through optimised supply systems and operational costs decrease through lower setup costs in the event of sudden changes. More generally, costs are

also expected to decrease through reductions in waste, bottlenecks and information flow disruptions.

Conversely, new business models will also emerge, and we believe that this is one of the biggest challenges and at the same time offers unique opportunities if handled and managed correctly. This will be the focus of a specific section in the report. In essence, we believe that Industry 4.0 has the potential of increasing revenue through the ability to offer customised and locally manufactured products, from an enhanced focus on value creation and innovation and from targeted sales through the power of data.



4.3 | Conclusion

The next industrial era will offer an opposing world to what we got used to in the manufacturing sector. Through the combination of the different technology drivers, factories have the potential of returning to home markets with trade flows focusing on regions. Firms, including the ones in Malta, will need to respond to these changes. In the coming sections we will look into

further detail of the effects of Industry 4.0 and we will look at two main areas which we believe add value to the Maltese manufacturing ecosystem. These two main areas are additive manufacturing and the integration of value chains. These we believe can be key challenges for Malta-based companies, though they can be harnessed into the opportunities.

5.0 | Additive manufacturing

5.1 | Introduction

Additive manufacturing (AM), also known as 3D printing (3DP), refers to a group of technologies that create products through the addition of materials (typically layer by layer) rather than by subtraction (through machining or other types of processing).

3D Printing has been around for a number of years and has been mainly used for rapid proto-typing. However, improving production techniques and processes together with the advances in other technologies, has made 3D printing of final products a reality. This section will look at the advancements in additive manufacturing and will present a number of case studies which will show how such printing technologies can challenge traditional firms unless these firms harness the technology themselves.

Crossing the threshold from 3DP-produced prototype to final product has largely been confined to specialized, low-volume and customized products. Half of the manufacturers said that it is “likely” or “very likely” that 3DP will be used mostly for Low-vol-

ume highly specialized products over the next three to five years; 20% believed the technology would be used for high-volume production, according to the PwC Innovations Survey. Adopters are finding that it reduces wasted material in parts that are difficult and complex to make through traditional processes, especially for parts with internal structures that add strength, reduce weight and increase functionality. A burning question is how much of the future 3DP has for the production of final parts.

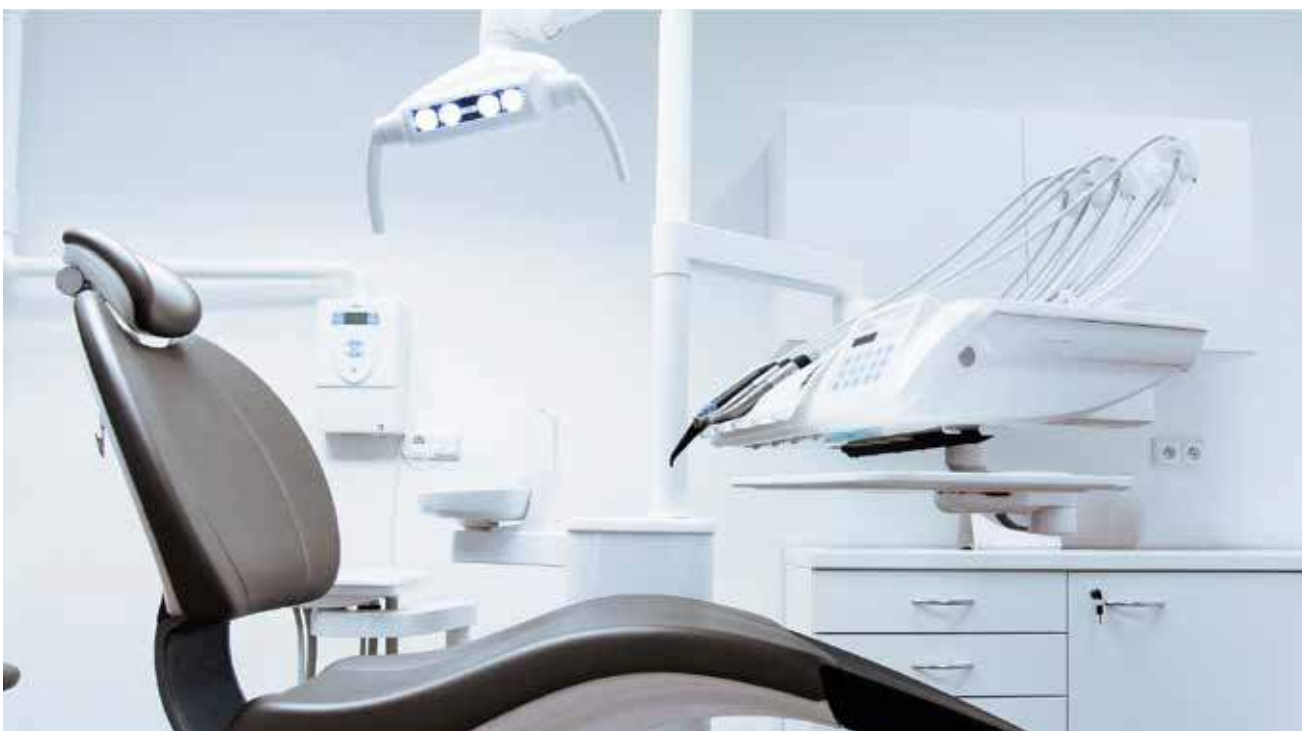
3DP printer maker, Stratasys, whose Redeye division, which operates as a sort of contract manufacturer for manufacturers and entrepreneurs, has already seen a dramatic shift in the last several years as its orders go from “virtually” all being proto-type product to “about 65%” being manufactured product (final end-use product or a final mould or fixture), according to the Stratasys executive vice president for corporate affairs, Jon Cobb.

Case Study 1: 3D printing medical devices

The technology has gained adherents in the medical devices industry for uses that include advanced prosthetics, and potentially, even printed living tissue. Hearing aid makers, such as Denmark’s Widex, have been printing final product for decades, and are continuing to use more advanced printers to make ever-smaller hearing aids. An estimated 10 million “in-the-ear” hearing aids (where the ear canal is scanned and hearing aid shells are printed) are currently in use.

From Case Study 1, it becomes evident the disruption such technologies can have on manufacturing outfits in a host of sectors, in this case medical devices. Malta has a strong medical device exporting manufacturing sector. Therefore, the advent of additive printing for final products might disrupt such players through customisable medical

devices. The technology is also simplifying design. It is enabling designers to print products that might otherwise be created via the assembly of numerous parts, thereby consolidating them in a product that has fewer parts.



Case Study 2: 3D printing in aviation & automotive sectors

GE, for example, which is printing fuel nozzles in one piece-rather than assembled in 20 parts through traditional means-for its LEAP engines. It has plans to print as many 45,000 annually with cost savings of up to 75%. The company is developing a “micro factory” to roll out the printed parts, adding to one already in use devoted to 3DP rapid prototyping. Boeing already makes about 300 different smaller aircraft parts using 3DP, including ducts that carry cool air to electronic equipment. Some of these ducts have complicated shapes and formerly had to be assembled from numerous pieces, boosting labour costs. The company noted that it can save up to 30% through printing compared to traditional manufacturing.

For some industries and some products, the concept of “on-demand” manufacturing could radically change business models and supply chains. Consider the homeowner needing a spare part for a dishwasher. He orders the part online from the manufacturer, receives a bar code for the part and then gets it printed at a local 3DP centre, perhaps at a library, post office or a big retailer. Or an airline carrier that needs a spare part for a jet in Singapore prints it on a printer installed at the airport for such needs. These scenarios shrink the supply chain to almost one link-eliminating those connecting development, prototyping, production, delivery, and warehousing of parts.

Looking ahead, 3DP could potentially make significant inroads in the after-market of products, particularly for manufacturers of products with long lives and a high demand for parts replacement and repair and even for obsolete parts. Beneficiaries of this model could include industries such as aerospace, consumer appliances, electronics, transportation, power and utilities, and energy.

3DP can bring a number of benefits across a number of sectors. The following Table tries to summarise the benefits that can accrue from this technology.

Table 6: Benefits of 3DP

Manufacturers poised to benefit through 3DP	
Near Term	Long Term
Original equipment/parts manufacturers of: • Low-volume and/or new designs not economically attractive through subtractive production methods (e.g. aerospace) and/or more customized products such as hearing aids or knee replacements (e.g. medical devices), goods and products that are frequently updated and re-designed. • After-market goods production, including aerospace MRO firms that can limit or eliminate buffer inventory with ondemand and production at local maintenance facilities. • Complex and older generation products with many parts, and obsolete parts that are still in demand (e.g heavy machinery, energy, agricultural equipment makers). • Products that incur high fuel and/ other operating costs 3DP can make possible new, and potentially more efficient, product designs.	Possibly, 3DP could break more into other sectors such as auto manufacturing for some higher-end/low volume equipment, as well as after-market sales for older vehicles. White goods/appliances also could benefit in the after-market. Additionally, companies offering 3DP inks/ feedstock, such as plastics, polymers, metals, and ceramics, cement, carbon, composites, graphene (e.g. Chemicals and metals sectors) could also benefit. Retailers that offer 3DP services (big box, large online retailers) particularly those with wide geographical networks of printers or “printer farms.”

5.1.1 | The use of AM in medical device manufacturing

The medical technology (medtech) industry has been a leader in the use of additive manufacturing (AM), also known as “3D printing.” In 2017, medical applications accounted for over 20% percent of the total system-related revenue for the AM market. A key reason for this is that AM capabilities align well with the needs of medtech’s medical device segment.

For example, the medical device segment serves a broad, geographically distributed population of service providers that in turn serves an even larger end market of health care consumers. Many medical devices, such as hearing aids, dental crowns, and surgical implants, are relatively small in size and therefore suitable for the production envelope sizes available through

common AM systems. Furthermore, these products are value-dense — that is, they combine relatively high value with relatively small physical volume — and the high level of customization available with AM makes this technology well suited for custom-fitting products to individual patients, an important factor in clinical efficacy.

Given the strong alignment of AM capabilities with the medical device segment’s needs, and the medtech industry’s ability to support investment in new technologies, it is perhaps no surprise that AM has made substantial inroads with health care practitioners and service providers. Our goal here is to investigate ways that AM may influence the trajectory of the medical device segment.



AM has historically been used within the medical device sector to improve performance in product modelling and prototyping, thus positioning most companies along path I of our framework. Companies on this path have used AM to improve product quality, reduce cost, and reduce time to market. The pursuit of these goals requires little alteration to a company's existing supply chain or products, thus offering a significantly lower-risk entry point for firms looking to apply this technology across their operating model.

As an example, consider **Kablooe Design**, an invention, design, and engineering firm that helps companies evolve ideas from the concept stage through manufacturing. For Kablooe, creating products that help advance the medical industry is nothing new. Nearly 75 percent of the firm's creations are medical devices. In one case, Kablooe was tasked with creating a device that would treat benign prostatic hyperplasia (BPH), commonly known as an enlarged prostate, in a less invasive way. More traditional BPH treatment is highly invasive and usually involves surgery (and thus a short hospital stay), bleeding, and scarring.

While developing the BPH device, Kablooe turned to the flexibility and short turnaround times of AM-enabled rapid prototyping to take the product from concept to end-product manufacturing. Kablooe estimated that it would take 10 iterations to perfect the device's design. With this in mind, the company concluded that using traditional tooling and injection moulding for prototyping would be too costly and time-consuming. By turning to rapid prototy-

ping using AM, Kablooe was able to save more than \$250,000 and 12 weeks of development time over the cost and time of using traditional manufacturing techniques. As an added benefit, the shorter development timeframe allowed Kablooe to collect feedback from practicing physicians and "tweak" designs in order to better meet their preferences.



Orchid Design (Orchid) offers another example of the application of AM for rapid prototyping. A division of Orchid Orthopaedic Solutions, Orchid is dedicated to working with medical professionals to prototype and test new orthopaedic solutions. The development process, from initially sketching a proposed device through end-unit production, can take months of highly detailed design and process work, capped with the uncertainty of approval by the US Food and Drug Administration (FDA). Historically, Orchid had minimized its use of prototypes because of the high cost and time-consuming nature of orthopaedic design, relying instead on computer-aided design (CAD) drawings. But the reliance on CAD meant that design flaws sometimes went undiscovered until later in the production process, when they were expensive and time-consuming to fix.

Pursuing a higher-performing development process, Orchid turned to AM to print high-resolution prototypes in-house. This allowed the company to increase the quality and manufacturability of its designs as well as reduce the development timeline, enabling Orchid to drive more revenue and increase repeat business. Rapid prototyping has also been helpful to Orchid in determining the functional requirements of small parts commonly used in the medical field. Through the use of AM, Orchid is now able to print parts at five to ten times their actual size to analyse how they will function, enabling the company to make adjustm-

ents to the design if necessary. Most medical device companies currently apply AM in the basic applications described above. This low-risk approach has allowed these firms to begin to adopt this technology without employing an overly aggressive strategy.

By streamlining a product's supply chain, companies can reduce production costs, decrease the time it takes for a customer to receive the end product, and simplify multi-step production processes. Firms concerned about their supply chain competitiveness may use AM to serve existing customers more efficiently and improve their service delivery capabilities.

For example, AM has already significantly changed the way in which custom hearing aids are delivered. Relative to conventionally manufactured hearing aids, hearing aids made with digital imaging and AM technology are believed to be more comfortable and reliable. They can also be produced more efficiently, and they can reduce the number of repeat ear impressions needed in order to correct fit issues. Siemens, one of the world's largest manufacturers of hearing aids, is switching completely to using AM to produce them at several of its factories. Drivers for the change include AM's ability to shorten the manufacturing process for customized devices by 50–80 percent, localize the distribution of the end product, and significantly reduce labour costs.

The market for custom dental crowns provides another example of AM's impact on supply chains in the medical device segment. In contrast to traditional hand-moulding approaches, modern dental technicians can now use scanned data and dental software to design a CAD model of a patient's crown. A key benefit of using AM in the custom crown creation process is increased speed of production. EOS, an AM system manufacturer in the aerospace and medical device printing space, asserts that a dental technician who uses traditional production methods can produce around 20 dental copings per day. In comparison, the use of AM allows for up to 450 crowns and bridges to be created in one 24-hour production run. In 2013, dental labs used EOS

AM machines to create more than 1.5 million direct metal copings and bridges. AM is also influencing medical device supply chains through its ability to impact inventory and distribution. A key function of inventory is to buffer against demand uncertainty when product lead times are long. Organizations may pursue the use of AM in their supply chains in order to reduce offshore manufacturing and inventory. AM may also reduce the steps and the number of components required to produce end products, resulting in a lower need to maintain subcomponent inventory. Finally, firms employing AM in their supply chains may be able to stay closer to end-product point of use, developing a leaner, more cost-effective supply chain that relies less on safety stock and requires less of a working capital commitment.

Protaico, a provider of surgical guides in Latin America, has been able to move its

production of dental surgical guides in-house by incorporating AM into its supply chain.

Facing increased demand, Protaico realized that it needed to achieve faster throughput without compromising standards or significantly increasing the size of its staff or inventory. Whereas prior to its use of AM for in-house manufacturing, Protaico cited a historic need to reject orders or outsource the production process, with AM, the company believes it can now quickly fulfil customer orders. Protaico also claims that its investment in AM delivered returns in the form of higher revenues and lower operating costs. The firm can now offer customers dental appliances with very short lead times at increasingly competitive prices.



While many organizations are still assessing the use of AM in their supply chains, in the long run, supply chain evolution may represent a strong growth opportunity for AM as companies look to use AM to decrease unit cost and delivery time as well as to improve product delivery precision.

Because AM can improve product fit and alter the end-product build, current applications within the medical device space typically focus on enhanced customization. Examples can be seen in AM applications related to improving visualization (in preparation for surgical procedures) and increasing the clinical efficacy of implants and other devices. To limit surgical risk, it is vital that surgeons have ample practice, much of which comes from performing trial runs on patient-like models. As surgical procedures grow in complexity, many doctors are turning to AM to help create personalized guides for detailed procedures. Surgical guides help doctors understand key structural attributes of the anatomy that they are likely to encounter during surgery.

Surgical guides created using AM are typically of human organs such as livers and kidneys, body cavities, and bones. For example, kidney or liver models based on CT or MRI scans of a patient can be constructed out of a translucent material composed of acrylic resin.

These models allow surgeons to see and understand organs' internal structure, such as the location of a tumour or the path of blood vessels. They can also allow surgeons to plan for different operating approaches

Demand for low-volume, highly customized products with life-dependent outcomes creates strong conditions for alignment between the medical device space and AM. Although few companies have pursued AM for product evolution in depth, it is anticipated that as the technology continues to establish itself, more companies will see AM's potential benefits for product development and apply it to future production.



Mass customization combines the low unit costs of mass production with the flexibility of individual product customization. The use of AM to mass-customize medical devices offers an example of ways that product evolution and supply chain modification can work in concert to deliver an improved product more efficiently.

A relatively new application of AM in the medical device space is the creation of custom insoles to reduce foot pain and improve posture. Custom insole creator Sols plans to offer a completely customized product using a novel production process.

In traditional custom sole manufacturing, the process generally involves taking casts of the patient's feet and then sending them to a lab for analysis. The multiple human touchpoints in the traditional process leave room for error. With AM, Sols has replaced the need for these error-prone touchpoints, streamlined the production process, and created a product with unique opportunities for customization.

Using AM in a firm's supply chain and product development life cycle can allow manufacturers to rely less on standard customization techniques, maintain lower safety stock in inventory, and lower their commitment of working capital. As custom products move to a just-in-time inventory model, manufacturers will spend less money on the overhead required for inventory and warehousing.

For example, surgeons who today use standard "off-the-shelf" knee implants for replacement surgeries must choose from a

range of fixed sizes and then make necessary adjustments in the operating room to determine the implant's final fit. Because standard implants are not tailored to each patient's specific anatomy, surgeons often must compromise on implant fit. In the future, AM may be used to scan a patient and immediately produce a more nearly perfect implant on site, offering doctors the ability to better manage inventory and reduce procedure time.

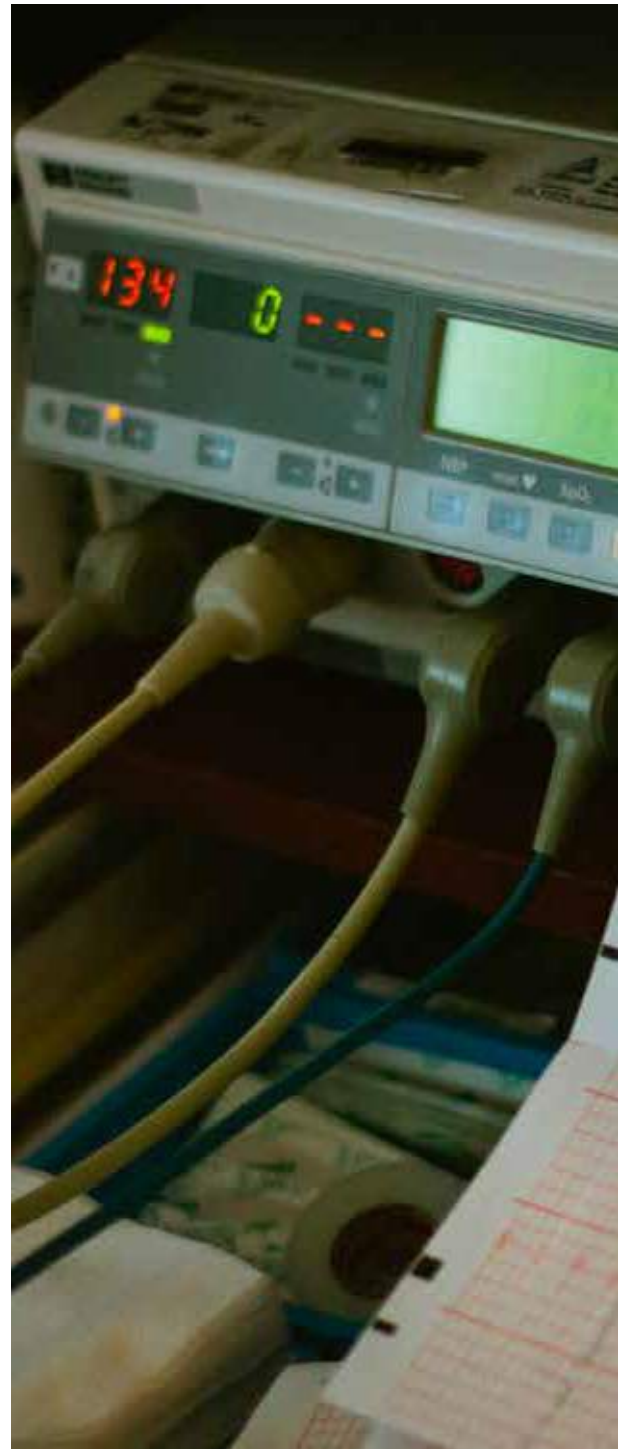
Conformis, a company that focuses on the image-to-implant process, offers a knee replacement system that it believes offers unique advantages not possible with off-the-shelf implants, including a more individualized fit that virtually eliminates the sizing component during procedures while enabling just-in-time delivery of the end product. At Conformis, the process starts with a 3D scan of the patient's knee, which is used to create a model that corrects for imperfections related to bone spurs, cysts, or joint flattening.

The design is then produced using AM and delivered on-site to a surgeon just days before surgery, relieving hospitals of the need to keep inventory on the shelf for extended periods of time. Although Conformis does not currently offer on-site implant printing, its process highlights the opportunity for customized knee implants to be printed on-site or delivered quickly to the site. While advancements in customized, on-site implant production with AM remain limited at this time, many companies are exploring this avenue to realize the potential cost savings available through AM's inventory management capabilities.

AM is anticipated to have a significant impact on the medtech industry – in particular, the medical device sector. Adoption of AM is likely to increase as more firms come to appreciate its potential benefits across their supply chains and products. Industry participants should closely monitor the evolution of business models based on the deployment of AM technologies. The possibility of rapid change in key markets – as has occurred with devices such as hearing aids and dental crowns – is real. Additionally, medical device firms should begin to develop a long-term strategy surrounding AM.

Although not all companies will want to make substantial strategic investments at this time, leaders should consider devoting attention to where the industry and the individual segments they serve are moving. In some cases, a “wait and see” strategy may be appropriate.

As the advantages AM can offer over traditional supply chain and production methods become more evident, companies in the medical device sector will likely become more open to the use of AM. The constant need to innovate and grow will give medical device companies the impetus to continue to explore and adopt AM technologies. And for the Maltese medical device sector to remain relevant, this is not a luxury.



6.0 | Supply-chain integrations & business models

Industry 4.0 can transform organizations' processes and operations. Below, we explore some key insights that can enable business leaders to visualize the ways in which the Fourth Industrial Revolution could affect their worlds.

The digitization of operations, manufacturing, supply networks, and products enables companies to combine learnings from humans, machines, analytics, and predictive insights to hopefully make better, more holistic decisions.

Fully connected processes present huge opportunities: Rather than monitoring processes in a linear fashion, as has always been done, and operating reactively, companies can take learnings along the way and feed them back into the process, learn from what they are seeing, and adjust accordingly in real or near real time. This should lead to smarter decisions, better-designed products, service and systems, potentially more efficient use of resources, and a greater ability to predict future needs.



The digital thread represents one such end-to-end Industry 4.0 solution, linking the entire design and production process with a seamless strand of data that stretches from the initial design concept to the finished part. Beyond the digital thread, the use of the digital twin can enable organizations to gain insight into the inner workings

of systems or facilities, simulate possible scenarios, and under-stand the impacts of changes in one node on the rest of the network.

It is not just about the supply chain or manufacturing, it is about business operations and revenue growth.

6.1 | Impacts of Industry 4.0

Whatever their sector or industry there three key areas in which Industry 4.0 can have the most impact and below is a brief summary of such impacts before expanding on to the transformation in business models and supply chains this will also bring about.

6.1.1 | Products

Industry 4.0 technologies can transform the way products are designed and developed. Connected technologies can also lead to completely new products and services. The use of sensors and wearables, analytics and machine learning, and advanced manufacturing in the form of additive manufacturing, advanced computer numerical control, and robotics can enable product improvements in various ways, from enabling rapid prototyping and testing to adding connectivity to previously unconnected products, to innovative new offerings.

Finally, they can lead to new business models, as companies can sell data and services in addition to physical objects. Data from products out in the field could also be very important. Digital signals from customer interactions with fielded assets—or from the assets themselves—can enable better service, improved warranty claims, visibility into usage patterns, and data to monetize.

6.1.2 | Supply chain

Every company has a supply chain, although the shape it takes is unique depending on operational needs. Whether the chain comprises materials, parts, and other physical matter or data, information, and expertise, organizations depend on external inputs to operate. Industry 4.0 can enable the smart factory, connect supply network and logistics capabilities, and inform planning and inventory processes, along with a host of other capabilities, enabling organizations to know things they didn't know before.

These capabilities can become particularly salient when viewing the changes that Industry 4.0 brings to all stakeholders in an ecosystem. Smart, connected, digital technologies would change how consumers and other parts of the business landscape expect to experience whatever it is they are going to experience when they interact with a company or its products and services. This, in and of itself, would create challenges and opportunities in the supply chain, some of which can be realized by leveraging Industry 4.0 solutions.

6.1.3 | Customers

Across all stages of the customer journey, Industry 4.0 can create new opportunities for innovation and growth. Data gathered through intelligent products and services can enable a deeper understanding of customers. Information from connected systems can enhance the customer experience, direct selling and marketing strategies, and better enable companies and their partners to offer post-sales support to customers, strengthening the customer relationship.

Customer experience in the age of Industry 4.0 would be driven not just by the physical object but by the information, analytics, and customization that make the customer's interaction with that object more transparent, and the ways the company takes action on the insights they gather. In this way, organizations can use the principles of the PDP loop to better engage their audiences, maintain a stronger degree of connection both internally and throughout their network, and better monetize products and services.

6.2 | Transformational impact of Industry 4.0

The effects of Industry 4.0 can be felt at multiple levels: across entire ecosystems, at the organizational level, and at the individual employee and customer level. Given the scope of this report, attention will be given to the transformation of supply chains and business models.

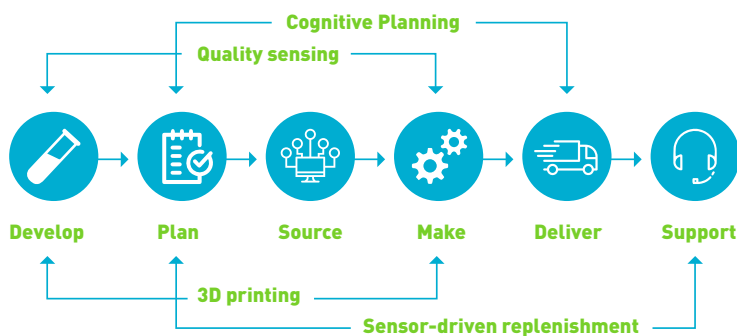


6.2.1 | Supply Chains

At its broadest level, Industry 4.0 portends a shift not only in how companies would operate, and goods would be produced, but how ecosystems—the suppliers, customers, regulatory considerations, investors, and other third-party experts and influencers—would function and interact. Industry 4.0 technologies create the potential for interactions between every point of a network. Thus, stakeholders can work together more effectively, using a constant stream of data from connected systems to learn and adapt to new conditions, and even begin to predict rather than react.

While the supply chain is not the only application of advanced, Industry 4.0 technologies, it seems to provide a useful illustration of the ways in which Industry 4.0 can connect an ecosystem, enabling stakeholders to integrate information from many different sources and make more holistic decisions. This shift from linear, sequential business operations to an interconnected, open system can change industries and lay the foundation for how companies operate, collaborate, and compete in the future as shown in Figure 4.

Traditional supply chain



Digital supply networks

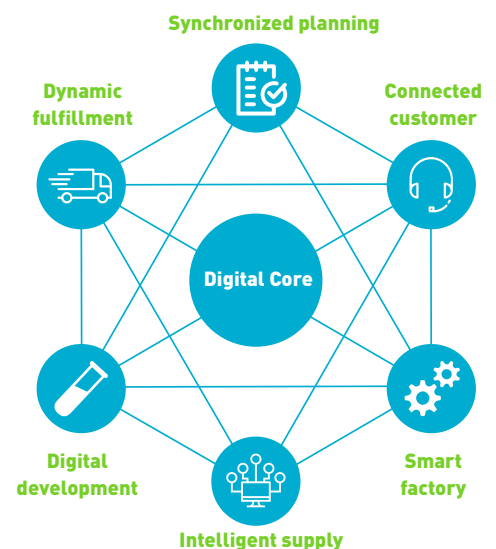


Figure 4. Supply-chain evolution

6.2.2 | Business Models

Most organizations continue to contend with a host of organizational and ecosystem-wide changes exerting pressure on their operations, including:

- Rapidly evolving technological capabilities
- Increased supply chain complexity and global fragmentation of production and demand
- Growing competitive pressures from unexpected sources
- Organizational realignments resulting from the marriage of digital and physical technologies
- Ongoing talent challenges

Industry 4.0 offers ways that can potentially address some of those issues. The ability to adjust to and learn from data in real time can make organizations more responsive, proactive, and predictive, and enables the organization to possibly avoid operational downtime and other productivity challenges.

Within the organization itself, the impacts of Industry 4.0 could be perhaps most distinct and specific. New business outcomes may emerge from the integration of digital and physical technologies in Industry 4.0. Broadly speaking, those outcomes can be divided into two key areas: operations improvements and revenue growth as seen in Figure 5.



Operational improvements can focus on enhancements to productivity

(such as improving labour efficiencies and managing costs and schedule accuracies) and reduction to risk (such as mitigating vendor, data, and geographic risks and ensuring availability of supplies).

For its part, revenue growth can include incremental revenue improvements (su-

ch as finding new efficiencies in the core business, and using customer data to deepen customer understanding and integration) and wholly new revenue streams (such as using data from connected systems to create new products and services or using demand data and digital technologies to expand more easily into new markets).

Depending on where a company's focus lies, leaders may pursue different opportunities within both areas. This is the focus of the next sections.

Product impact	Key objectives	Transformational plays
 BUSINESS OPERATIONS	Productivity improvements	• Maximizing asset utilization and minimizing downtime • Driving direct and indirect labor efficiency • Managing supply network costs and synchronization • Ensuring schedule and plan stability and accuracy
	Risk reduction	• Ensuring raw material price and availability • Managing warranty and recalls effectively • Mitigating geographic risks
 BUSINESS GROWTH	Incremental revenue	• Finding sources of growth for the core business • Growing aftermarket revenue streams • Deepening customer understanding and insights • Strengthening customer integration and channels
	New revenue	• Creating new products and service offerings • Expanding internationally and in emerging markets • Identifying attractive M&A opportunities

Figure 5. Business model evolution

6.3 | Business growth through Industry 4.0

On either end of the manufacturing value chain, Industry 4.0 technologies can enable business growth. In particular, in the R&D and design, sell and deliver, and support stages, various physical-to-digital, digital-only, and digital-to-physical connections can transform engineering, customer interaction, and even the products themselves.

Products in the age of Industry 4.0 run the technological gamut. The use of IT such as sensors and wearables and OT such as advanced manufacturing in the form of additive manufacturing, advanced computer numerical control, and robotics can enable product improvements in various ways. Indeed, manufacturers are already using advanced technologies (such as additive manufacturing) and advanced IT (in the form of scanning and embedded sensors) to create new products and improve upon old ones - delivering new levels of value to customers, along with new data products.

At its 3D Medical Applications Centre (3D-MAC), the Walter Reed National Mili-

tary Medical Centre manufactures prosthetics by scanning the patient's individual anatomy, enabling it to use additive manufacturing technologies to fabricate a fully customized fit.

Similar applications can be envisioned in business-to-business settings where the application of scanning/digital design, digital manufacturing, and field sensors will change the value proposition for industrial products. Indeed, General Electric's power and water division is implementing digital twinning for the parts it supplies to power plants, wind farms, and electrical grids. Using sensors and controls, signal aggregation, and highperformance computing, it is developing real-time digital simulation models of its reallife, physical parts operating within the plant. These cloud-based "digital power plant" models will enable plant operators to know the condition of parts, optimize power, determine the right time for machinery maintenance, and simulate various conditions to understand how they might impact the plant.



Data and information gathered through intelligent products and services can enable manufacturers to better understand their customers. Indeed, customer experience in the age of Industry 4.0 is driven not just by the physical object, but also by the data and information - and analytics - that make the customer's interaction with that object more transparent and impact the customer-manufacturer interplay in various ways.

The information gathered from customers can be used to price and sell products and services more intelligently. Industry 4.0 can potentially drive product and service improvements, as well as bring about more intelligent asset utilization. Further, this data can work both ways: Not only can information be sent to the manufacturer and its partners, but also back to the customer via smart apps that offer user-experience enhancements.

At the start of the manufacturing value chain, products are developed and designed.

Various Industry 4.0 technologies can come into play to impact the process in several key ways. The use of digital-to-physical manufacturing technologies such as additive manufacturing in rapid pr-

ototyping can speed up the design process as well as the production of end-use products, thus reducing supply chain dependencies. Ford estimates that its use of rapid prototyping during vehicle design can save it weeks, with additively manufacturing prototypes taking hours to fabricate rather than the 4 to 6 weeks taken by typical machine tooling approaches, bringing automobiles to market months earlier. Using advanced manufacturing technologies can also enable engineers to optimize manufacturability, as they can evaluate product design options based on the eventual assembly process.

Industry 4.0 technologies can drive improved engineering effectiveness via digital design and simulation. This can take the form of virtual product development and testing.

Malta-based manufacturing outfits need to ensure that their plants and processes are Industry 4.0 ready. The impact of such technologies can be enormous and the capacity to harness such technologies needs to be built. Having the skill-set and also the investment in technologies is important for this to materialise. Not harnessing these changes can make Malta-based manufacturing plants lose their place in the value chain.

6.4 | Business operations

Industry 4.0 technologies also enable improved operations. In the “plan,” “source,” and “make” stages of the value chain, various physical-to-digital and digital-to-physical connections can transform planning, support, and factory operations.

When planning for production, manufacturers often encounter a host of uncertainties across the manufacturing value chain. Information Technology (IT) and Operational Technology (OT) can support several transformations in this area. Demand sensing and planning using IT (for example, sensors, signal aggregation, optimization, and prediction) enable manufacturers to gather data throughout the value chain. Data can be analysed to uncover patterns, track movements, and, ultimately, understand what customers want, and where - so they can better plan to provide it at the right time and place. For example, Ridgeline Pipe Manufacturing, a manufacturer of polyvinyl chloride (PVC) pipes, dealt with constantly changing customer demand and short lead times. The company needed to anticipate and plan in the face of uncertain demand, rapidly adjust to unforeseen changes, and reduce production change-over time. Using legacy systems, waste, costs, and inflexibility had risen to unacceptable levels. The company adopted a flexible production platform, in which automated production controllers managed the manufacturing equipment while

providing access to information on diagnostics and performance. The system also analyses production data to offer predictive failure analytics.

Perhaps no other segment better encapsulates the physical-to-digital transformation inherent in Industry 4.0 than the intelligent factory. The industry 4.0-enabled factory utilises physical-to-digital technologies such as augmented reality, sensors and controls, wearables, and the Internet of Things to track movement and production, monitor quality control, and manage the tooling life cycle, among other capabilities. In this way, Industry 4.0 on the factory floor can enable enhanced capability effectiveness, production asset intelligence, and activity synchronization and flow.



Learning the causes behind a failure can enable manufacturers to more effectively address the root of the problem, rather than its symptoms. For example, **Schneider Electric** examined both maintenance and historical data collected over the course of one year for a 110 MW steam model turbine which had required regular, ongoing maintenance for an escalating series of ongoing breakdowns, realizing that technicians had been addressing symptoms rather than root causes for a quality issue. Analysis enabled Schneider to address the root cause - thermal expansion problems - before they led to "symptoms" - bearing vibration - that caused equipment shut-downs. The company estimates that predictive maintenance offers millions of dollars in potential savings along with far fewer days of equipment downtime.

In another predictive analytics example, **Caterpillar** is partnering with a company named Uptake, analysing data gathered through telematics devices in its machinery to predict failures and engage in proactive repair. The companies see future opportunities to monetize this capability by offering new data products and services to customers.

When responding to field failures, wearables and augmented reality can allow remotely located technicians to walk users through maintenance procedures.

An industrial equipment manufacturer, for example, faced challenges as it expanded its operations to China, including increased operational costs and more frequent downtime of machinery.

These issues were, in large part, rooted in a shortage of seasoned talent to train employees within the new manufacturing facilities. The manufacturer piloted a smart-glass, wearable technology so that remote experts could see alongside the equipment operators in the facility and offer step-by-step instructions and training. These improvements were also accompanied by risk reductions in the overall production process due to better quality management.

Malta-based manufacturing plants need to be ready to embrace changes that these technologies can bring about. They need to build the capacity to understand the transformational changes it will bring about in their respective supply-chains and management need to see how to build the resilience of the Malta-based operation in this regard. Other companies that will embrace it, might transform themselves into more productive enterprises with the end result of being more efficient, cost-effective and competitive on global export markets.

7.0 | The smart factory

Automation has always been a part of the factory to some degree, and even high levels of automation are nothing new. However, the term “automation” suggests the performance of a single, discrete task or process. Historically, situations in which machines have made “decisions” have been automation based and linear, such as opening a valve or turning a pump on and off based on a defined set of rules. Through the application of artificial intelligence (AI) and increasing sophistication of cyber-physical systems that can combine physical machines and business processes, automation increasingly includes complex optimization decisions that humans typically make. Finally - and perhaps most crucially - the term “smart factory” also suggests an integration of shop floor decisions and insights with the rest of the supply chain and broader enterprise through an interconnected landscape. This

can fundamentally change production processes and enhance relationships with suppliers and customers.

Through this description, it becomes clear that smart factories go beyond simple automation. The smart factory is a flexible system that can self-optimize performance across a broader network, self-adapt to and learn from new conditions in real or near-real time, and autonomously run entire production processes. Smart factories can operate within the four walls of the factory, but they can also connect to a global network of similar production systems, and even to the digital supply network more broadly.



It is important to note, however, that the smart factory as defined and described in this paper should not be considered the “end state,” given the rapid pace of technological development. Rather, it represents an ongoing evolution, a continuous journey toward building and maintaining a flexible learning system - rather than the “one and done” factory modernization approach of the past.

The smart factory is a flexible system that can self-optimize performance across a broad network, self-adapt to and learn from new conditions in real or near-real time, and autonomously run entire production processes.

The true power of the smart factory lies in its ability to evolve and grow along with the changing needs of the organization - whether they be shifting customer demand, expansion into new markets, development of new products or services, more

predictive and responsive approaches to operations and maintenance, incorporation of new processes or technologies, or near-real-time changes to production. Because of more powerful computing and analytical capabilities - along with broader ecosystems of smart, connected assets - smart factories can enable organizations to adapt to changes in ways that would have been difficult, if not impossible, to do so before.

7.1 | Features of the smart factory

As many manufacturers grapple with the myriad organizational and ecosystem-wide changes exerting pressure on their operations (see the sidebar “The smart factory: Why now?”), the smart factory offers ways that can successfully address some of those issues.

The ability to adjust to and learn from data in real time can make the smart factory more responsive, proactive, and predictive, and enables the organization to avoid operational downtime and other productivity challenges.

As part of its efforts to implement a smart factory while producing air conditioners, a leading electronics company used a fully automated production system, three-dimensional scanners, Internet of Things (IoT) technologies, and integrated machine control. The benefits of this automation included lower lead times for customers and lower overall costs, along with production capacity improvement of 25 percent and 50 percent fewer defective products.

Connected	• Continuously pull traditional datasets along with new sensor and location-based datasets • Real-time data-enabling collaboration with suppliers and customers • Collaboration across departments (e.g., feedback from production to product development)
Optimized	• Reliable, predictable production capacity • Increased asset uptime and production efficiency • Highly automated production and material handling with minimal human interaction • Minimized cost of quality and production
Transparent	• Live metrics and tools to support quick and consistent decision making • Real-time linkages to customer demand forecasts • Transparent customer order tracking
Proactive	• Predictive anomaly identification and resolution • Automated restocking and replenishment • Early identification of supplier quality issues • Real-time safety monitoring
Agile	• Flexible and adaptable scheduling and changeovers • Implementation of product changes to see impact in real time • Configurable factory layouts and equipment

Table 7. Characteristics of a smart factory

Table 7 lists the smart factory's major features: connectivity, optimization, transparency, proactivity, and agility. Each of these features can play a role in enabling more informed decisions and can help organizations improve the production process. It is important to note that no two smart factories will likely look the same, and manufacturers can prioritize the various areas and features most relevant to their specific needs.

Perhaps the most important feature of the smart factory, its connected nature, is also one of its most crucial sources of value. Smart factories require the underlying processes and materials to be connected to generate the data necessary to make real-time decisions. In a truly smart factory, assets are fitted with smart sensors so systems can continuously pull data sets from both new and traditional sources, ensuring data are constantly updated and reflect current conditions. Integration of data from operations and business systems, as well as from suppliers and customers, enables a holistic view of upstream and downstream supply chain processes, driving greater overall supply network efficiency.

An optimized smart factory allows operations to be executed with minimal manual intervention and high reliability.

The automated workflows, synchronization of assets, improved tracking and scheduling, and optimized energy consumption inherent in the smart factory can increase yield, uptime, and quality, as well as reduce costs and waste.



In the smart factory, the data captured are transparent: Real-time data visualizations can transform data captured from processes and fielded or still-in-production products and convert them into actionable insights, either for humans or autonomous decision making. A transparent network can enable greater visibility across the facility and ensure that the organization can make more accurate decisions by providing tools such as role-based views, real-time alerts and notifications, and real-time tracking and monitoring.

In a proactive system, employees and systems can anticipate and act before issues or challenges arise, rather than simply reacting to them after they occur.

This feature can include identifying anomalies, re-stocking and replenishing inventory, identifying and predictively addressing quality issues, and monitoring safety and maintenance concerns. The ability of the smart factory to predict future outcomes based on historical and realtime data can improve uptime, yield, and quality, and prevent safety issues. Within the smart factory, manufacturers can enact processes such as the digital twin, enabling them to digitize an operation and move beyond automation and integration into predictive capabilities.

Agile flexibility allows the smart factory to adapt to schedule and product changes with minimal intervention. Advanced smart factories can also self-configure the equipment and material flows depending on the product being built and schedule changes, and then see the impact of those changes in real time. Additionally, agility can increase factory up-time and yield by minimizing changeovers due to scheduling or product changes and enable flexible scheduling.

These features afford manufacturers greater visibility across their assets and systems and allow them to navigate some of the challenges faced by more traditional factory structures, ultimately leading to improved productivity and greater responsiveness to fluctuations in supplier and customer conditions.

For example, an apparel, accessories, and shoe company is exploring ways to address some of the challenges manufacturers typically face, including global fragmentation of production and rapidly shifting demand (see the sidebar “The smart factory: Why now?”), by building one new smart factory each in Europe and North America. Traditional factories and supply chains can face challenges in keeping up with ever-shifting fashions. Located close to the point of customer demand, the new smart factories can better adapt to new trends and allow shoes to reach customers faster - an estimation of less than a week, compared with two to three months with traditional factories. Both smart factories will leverage multiple digital and physical technologies, including a digital twin, digital design, additive manufacturing machines, and autonomous robots. The company plans to use lessons learned from the two initial smart factories as it scales to more facilities in other regions, such as Asia.”

7.2 | The Drivers

While automation and controls have existed for decades, the fully smart factory has only recently gained traction as a viable pursuit for manufacturers. Five overarching trends seem to be accelerating the drive toward smart factories:

- Rapidly evolving technological capabilities
- Increased supply chain complexity and global fragmentation of production and demand
- Growing competitive pressures from unexpected sources
- Organizational realignments
- Ongoing talent challenges



7.2.1 | Rapidly evolving technological capabilities

Until recently, the realization of the smart factory remained elusive due to limitations in digital technology capabilities, as well as prohibitive computing, storage, and bandwidth costs. Such obstacles, however, have diminished dramatically in recent years, making it possible to do more with less cost across a broader network. Further, the capabilities of technologies themselves have grown more sophisticated: AI, cognitive computing, and machine learning have enabled systems to interpret, adjust to, and learn from the data gathered from connected machines. This ability to evolve and adapt, coupled with powerful data processing and storage capabilities, allows manufacturers to move beyond task automation toward more complex, connected processes.

7.2.2 | Increased supply chain complexity and global fragmentation of production and demand

As manufacturing has grown increasingly global, production has fragmented, with stages of production spread among multiple facilities and suppliers across multiple geographies. These shifts, coupled with the increased demand for regional, local, and even individual customization; strong demand fluctuation; and increasingly scarce resources, among other shifts, have made supply chains more complex. Due to these changes, many manufacturers have found it important to be agile, connected, and proactive to address ever-shifting priorities.

7.2.3 | Growing competitive pressures from unexpected sources

The rise of smart digital technologies has ushered in the threat of entirely new competitors who can leverage digitization and lower costs of entry to gain a foothold in new markets or industries in which they previously had no presence, sidestepping the legacy of aging assets and dependence on manual labour encumbering their more established competitors.

7.2.4 | Organizational realignments

Factory automation decisions typically occur at the business unit or plant level, often resulting in a patchwork of disparate technologies and capability levels across the manufacturing network. As connected enterprises increasingly push beyond the four walls of the factory to the network beyond, they are beginning to have greater visibility into these disparities. The increasing marriage of IT and OT has made it possible for organizations to move many formerly plant-level decisions to the business-unit or enterprise level.

This can illuminate where inefficiencies exist or where changes in one plant have resulted in complications in other facilities. It has also made the notion of the smart factory more of a reality than an abstract goal. While connectivity within the factory is not new, many manufacturers have long been stymied about what to do with the data they gather—in other words, how to turn information into insight, and insight into action. The shift toward the connected digital and physical technologies inherent in Industry 4.0 portends solutions to this challenge: the ability to not only gather data, but to now analyse and act upon them in the physical world.

7.2.5 | Ongoing talent challenges

Multiple talent-related challenges - including an aging workforce, an increasingly competitive job market, and a dearth of younger workers interested in or trained for manufacturing roles - mean that many traditional manufacturers have found themselves struggling to find both skilled and unskilled labour to keep their operations running. Deloitte has estimated that the US manufacturing industry could face a 2 million worker shortage over the next decade. Many companies are making investments in smart factory capabilities to mitigate the risk associated with this possibly pervasive labour shortage. However, this move can create a new set of talent-related consequences, as automated assets typically require highly skilled personnel to operate and maintain; even the location of manufacturing facilities would need to take into account factors such as this.



7.3 | Benefits

The decision on how to embark on or expand a smart factory initiative should align with the specific needs of an organization. The reasons that companies embark or expand on the smart factory journey are often varied and cannot be easily generalized. However, undertaking a smart factory journey generally addresses such broad categories as asset efficiency, quality, costs, safety, and sustainability. These categories, among others, may yield benefits that ultimately result in increased speed to market; improved ability to capture market share; and better profitability, product quality, and labour force stability. Regardless of the business drivers, the ability to demonstrate how the investment in a smart factory provides value is important to the adoption and incremental investment required to sustain the smart factory journey.

7.3.1 | Asset efficiency

Every aspect of the smart factory generates reams of data that, through continuous analysis, reveal asset performance issues that can require some kind of corrective optimization. Indeed, such self-correction is what distinguishes the smart factory from traditional automation, which can yield greater overall asset efficiency, one of the most salient benefits of a smart factory. Asset efficiency should translate into lower asset downtime, optimized capacity, and reduced changeover time, among other potential benefits.

7.3.2 | Quality

The self-optimization that is characteristic of the smart factory can predict and detect quality defect trends sooner and can help to identify discrete human, machine, or environmental causes of poor quality. This could lower scrap rates and lead times and increase fill rates and yield. A more optimized quality process could lead to a better quality product with fewer defects and recalls.

7.3.3 | Lower Cost

Optimized processes traditionally lead to more cost-efficient processes - those with more predict-able inventory requirements, more effective hiring and staffing decisions, as well as reduced process and operations variability. A better-quality process could also mean an integrated view of the supply network with rapid, no-latency responses to sourcing needs - thus lowering costs further. And because a better-quality process also may mean a better-quality product, it could also mean lowered warranty and maintenance costs.

7.3.4 | Safety & Sustainability

The smart factory can also impart real benefits around labour wellness and environmental sustainability. The types of operational efficiencies that a smart factory can provide may result in a smaller environmental footprint than a conventional manufacturing process, with greater environmental sustainability overall. Greater process autonomy may provide for less potential for human error, including industrial accidents that cause injury. The smart factory's relative self-sufficiency will likely replace certain roles that require repetitive and fatiguing activities. However, the role of the human worker in a smart factory environment may take on greater levels of judgment and on-the-spot discretion, which can lead to greater job satisfaction and a reduction in turnover.

7.3.5 | Impacts of the smart factory on manufacturing processes

Manufacturers can implement the smart factory in many different ways - both inside and outside the four walls of the factory - and reconfigure it to adjust as existing priorities change or new ones emerge. In fact, one of the most important features of the smart factory - agility - also presents manufacturers with multiple options to leverage digital and physical technologies depending on their specific needs.

The specific impacts of the smart factory on manufacturing processes will likely be different for each organisation. Deloitte has identified a set of advanced technologies that typically facilitate the flows of information and movement between the physical and digital worlds. These technologies power the digital supply network and, by extension, the smart factory - creating new opportunities to digitize production processes. Table 8 depicts a series of core smart factory production processes along with a series of sample opportunities for digitization enabled by various digital and physical technologies.

Process	Sample digitization opportunities
Manufacturing Operations	• Additive manufacturing to produce rapid prototypes or lowvolume spare parts • Advanced planning and scheduling using real-time production and inventory data to minimize waste and cycle time • Cognitive bots and autonomous robots to effectively execute routine processes at minimal cost with high accuracy • Digital twin to digitize an operation and move beyond automation and integration to predictive analyses
Warehouse Operations	• Augmented reality to assist personnel with pick-and-place tasks • Autonomous robots to execute warehouse operations
Inventory tracking	• Sensors to track real-time movements and locations of raw materials, work-in-progress and finished goods, and high-value tooling • Analytics to optimize inventory on hand and automatically signal for replenishment

Quality	• In-line quality testing using optical-based analytics • Real-time equipment monitoring to predict potential quality issues
Maintenance	• Augmented reality to assist maintenance personnel in maintaining and repairing equipment • Sensors on equipment to drive predictive and cognitive maintenance analytics
Environmental, health, and safety	• Sensors to geofence dangerous equipment from operating in close proximity to personnel • Sensors on personnel to monitor environmental conditions, lack of movement, or other potential threats

Table 8. Digitisation in smart factories



It is important to note that these opportunities are not mutually exclusive. Organizations can - and likely will - pursue multiple digitization opportunities within each production process. They may also phase capabilities in and out as needed, in keeping with the flexible and reconfigurable nature of the smart factory.

It is important for manufacturers to understand how they intend to compete and align their digitization and smart factory investments accordingly. For example, some manufacturers could decide to compete via speed, quality, and cost, and may invest in smart factory capabilities to bring new products (and product changes) to market faster, increase quality, and reduce per-unit costs. Others may choose to focus on “lot size of one” product customization and fulfilment models and invest in other technologies to fulfil those goals.

7.4 | Areas for consideration

Just as there is no single smart factory configuration, there is likely no single path to successfully achieving a smart factory solution. Every smart factory could look different due to variations in line layouts, products, automation equipment, and other factors.

However, at the same time, for all the potential differences across the facilities themselves, the components needed to enable a successful smart factory are largely universal, and each one is important: data, technology, process, people, and security. Manufacturers can consider which to prioritize for investment based on their own specific objectives.

7.4.1 | Data and algorithms

Data is the lifeblood of the smart factory. Through the power of algorithmic analyses, data drive all processes, detect operational errors, provide user feedback, and, when gathered in enough scale and scope, can be used to predict operational and asset inefficiencies or fluctuations in sourcing and de-mand. Data can take many forms and serve many purposes within the smart factory environment, such as discrete information about environmental conditions including humidity, temperature, or contaminants. How data are combined and processed, and the resulting actions, are what make them valuable. To power the smart factory, manufacturers should have the means to create and collect ongoing streams of data, manage and store the massive loads of information generated, and analyse and act upon them in varied, potentially sophisticated ways.

In order to move to higher levels of smart factory maturity, the data sets collected will likely expand over time to capture more and more processes. For example, implementing a single use case might require the capture and analysis of a single data set. Implementing further use cases or scaling an operation to an industrial level will typically require expanding the capture and analysis of greater and different data sets and types (structured vs. unstructured), leading to considerations around analytical, storage, and management capabilities.

Data might also represent a digital twin, a feature of an especially sophisticated smart factory configuration. At a high level, a digital twin provides a digital representation of the past and current behaviour of an object or process. The digital twin requires cumulative, real-world data measurements across an array of dimensions, including production, environmental, and product performance. The powerful processing capabilities of the digital twin may uncover insights on product or system performance that could suggest design and process changes in the physical world.

7.4.2 | Technology

For a smart factory to function, assets - defined as plant equipment such as material handling systems, tooling, pumps, and valves

- should be able to communicate with each other and with a central control system.

These types of control systems can take the form of a manufacturing execution system or a digital supply network stack. The latter is an integrated, layered hub that functions as a single point of entry for data from across the smart factory and the broader digital supply network, aggregating and combining information to drive decisions. However, organizations will need to consider other technologies as well, including transaction and enterprise resource planning systems, IoT and analytics platforms, and requirements for edge processing and cloud storage, among others. This could require implementing the various digital and physical technologies inherent in Industry 4.0 - including analytics, additive manufacturing, robotics, highperformance computing, AI and cognitive technologies, advanced materials, and augmented reality - to connect assets and facilities, make sense of data, and digitize business operations.



7.4.3 | Process and governance

One of the most valuable features of the smart factory - its ability to self-optimize, selfadapt, and autonomously run production processes - can fundamentally alter traditional processes and governance models. An autonomous system can make and execute many decisions without human intervention, shifting decision-making responsibilities from human to machine in many cases, or concentrating decisions in the hands of fewer individuals. Additionally, the connectivity of the smart factory may extend beyond its four

walls to include increased integration with suppliers, customers, and other factories. This type of collaboration may raise new questions about processes and new governance models. With a deeper, more holistic view across the factory and the broader production and supply network, manufacturers could face new and different questions. Organizations may want to consider - and perhaps redesign - their decision-making processes to account for these shifts.

7.4.4 | People

People are expected to still be key to operations. However, the smart factory can cause profound changes in the operations and IT/OT organizations, resulting in a realignment of roles to support new processes and capabilities. As mentioned earlier, some roles may no longer be necessary as they may be replaced by robotics (physical and logical), process automation, and AI. Other roles might be augmented with new capabilities such as virtual/augmented reality and data visualization. New, unfamiliar roles will likely emerge. Managing changes to people and processes will require an agile, adaptive change management plan. Organizational change management could play an important role in the adoption of any smart factory solution. The successful smart factory journey will require a motivated workforce that embraces the greater impact of their roles, innovative recruiting approaches, and an emphasis on cross-functional roles.

7.4.5 | Cybersecurity

By its nature, the smart factory is connected. Thus, cybersecurity risk presents a greater concern in the smart factory than in the traditional manufacturing facility and should be addressed as part of the overall smart factory architecture. In a fully connected 45 environment, cyberattacks can have a more widespread impact and may be more difficult to protect against, given the multitude of connection points. Cybersecurity risk seems to only grow more pronounced as the smart factory scales and potentially moves beyond the four walls of the factory to include suppliers, customers, and other manufacturing facilities. Manufacturers should make cybersecurity a priority in their smart factory strategy from the outset.

7.5 | Case studies of smart factories

The below provides some case studies from around the world showcasing best practice when it comes to smart factories.

7.5.1 | Whirlpool

Appliance manufacturer Whirlpool set itself a goal of eliminating the waste that its factories send to landfills by 2020. To help meet that objective, the company began using an analytics platform across all of its facilities to reveal the amounts of waste they generate, along with usage data about electricity, water, and more. This data is available via customisable, Web-based dashboards. In addition to retrieving local information, the company can check the sustainability performance of its plants worldwide. This is a prime example of how a company looked for the right intelligent tools to match its strategic goals: strategy first, followed by supporting technology. Whirlpool also demonstrates that having a global presence is no obstacle when linking plants together. Via the IoT and its analytics platform, the company can measure how close any factory is to the zero-waste milestone, no matter where it may be in the world.



7.5.2 | Hirotec

Hirotec is a global auto parts manufacturer with annual revenues of over \$1 billion. As a result, the company is well aware that planned downtime is a major challenge: one that can cost up to \$361 a second. Hirotec wanted to reduce downtime and the IoT helped it to achieve just that. Hirotec has employed a mix of IoT and cloud-based technologies, along with small, robust servers on its factory floors. These generate analytics data without sacrificing physical space. Meanwhile, machine learning helps the company to predict and prevent systems failures. After running three pilots of its IoT platform and reviewing the data, Hirotec was able to achieve a 100 percent reduction in manual inspection time for its systems.



7.6 | Conclusion

Industry 4.0 is happening and is also transforming factories ushering them into a new era whereby manufacturing robots are connected to each other and big data is analysed and used to improve production efficiencies and lower costs. It is expected that such factories will transform the traditional factories. To this end, Malta-based manufacturers that are focused on exporting need to internalise the effects of Industry 4.0 and see with the parent companies on how Industry 4.0 will transform their Malta operation in view of changing global supply chains too.

8.0 | Conclusion

Manufacturing processes and business models are undergoing huge transformational changes. Various forces of change are coming together, and different technologies are maturing together to drive the Fourth Industrial Revolution. It is expected that Industry 4.0 will bring about transformational changes in business models, factories and manufacturing processes.

This report has given a general introduction on Industry 4.0 with a focus on how this new industrial era will evolve. We have seen in detail the role of additive manufacturing with a particular focus on medical devices and life sciences. This is of interest to Malta given that it has a well-developed manufacturing based of medical devices. The impact such a new technology can have on business models and supply-chains is important to consider and it is crucial that companies in Malta start looking at these developments to ensure they retain their competitive edge.



Focus was also given to the role business models are changing in line with changing supply chains. This is extremely important for the Maltese manufacturing base which is very much value-chain driven and component focused. Shrinking supply chains can have a tangible impact on manufacturing companies which are transforming themselves into the factories of the future whereby big data is powering production processes.

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In reviewing the impact of Industry 4.0, we would like to propose a number of key considerations for exporting Malta-based SMEs and manufacturers:

- **Industry 4.0** is a reality which has already started. Although investment plans of large conglomerates are extremely ambitious, early investors are already moving ahead. We believe that Industry 4.0 holds the potential for clearer differentiation in global competition
- **Industry 4.0** strategies can be developed along the three major digitisation directions:
 - o Digitisation and integration of vertical & horizontal value chains
 - o Digitisation of product & service offerings
 - o Innovative digital business models
- **Companies** expect to reduce costs and increase revenues through the adoption and harnessing of Industry 4.0 technologies
- **Industry 4.0** will drive change across the entire business and trigger significant disruption to both companies and sectors. But to win, companies will need to develop a strong digital culture.
- **Industry 4.0**, through a host of technologies, will bring the customer at the core of production processes. However, it becomes integral for companies to have oversight and capacity to analyse the customer through big data
- **Data analysis** will be the necessary pre-requisite for the successful implementation of Industry 4.0

Although Industry 4.0 might appear to be exclusively for the large firms, we believe that even SMEs can harness some of the technologies that will shape the future of manufacturing. We believe that it is critical for their own survival and competitiveness to start embracing a digital transformation and to assess the impacts, challenges and opportunities of Industry 4.0. It is a reality and one that is happening fast.

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