

Industry 4.0

Assessment 2 – Introduction to Industry 4.0 Essay

The Use of Industry 4.0 Technologies within Medical Device SMEs in Wales

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1 Introduction

The 4th Industrial Revolution commonly referred to as Industry 4.0 (I4.0) is defined as an intelligent manufacturing process which incorporates technologies such as Internet of Things (IoT), Robotics, Machine Learning, Big Data, and Cyber-Physical Systems to enable the development of a smart factory (Golan, et al., 2020). Such technologies enable the implementation of I4.0 to boost the efficiency and productivity of factories as well as enabling companies to effectively respond to new demands and requirements of the market (Yeeles, 2022). Medical device companies in Wales have slowly implemented I4.0 technologies adopting fully automated production processes, while some are still making use of methods which can be classified as semi-automatic production processes.

Small and medium-sized enterprises (SMEs) have been facing tremendous challenges due to the emerging I4.0 technologies (Cotrino, et al., 2020). Challenges currently faced by SMEs in Wales is in understanding the impact of I4.0 as well as the uncertainties that comes with investment in such technologies. To explore this, two medical device SMEs in Wales and the differences between their manufacturing processes, competencies, and struggles with the adoption of I4.0 will be investigated. The benefits of implementing I4.0 will also be explored as well as providing a proposed solution on how SMEs in the medical device industry can further consider the adoption of new technologies and systems within their manufacturing facilities. Comparisons between two different SMEs in different position within their adoption of I4.0 will be made to provide a proposed resolution on how SMEs in Wales can further their knowledge of I4.0, and how companies who have adopted such systems and technologies have improved the efficiency and productivity of their manufacturing systems.

2 Case Studies

The medical device industry is a highly regulated sector where quality, safety and clinical efficacy are key requirements that companies need to adhere to (Borland, 2021). To better understand the current manufacturing capabilities of SMEs in Wales, two case studies based on two medical device SMEs will be looked into to assess their different manufacturing competencies. The companies in both Case Study A and B are leading manufacturers in their own sectors and both develop Class 1 medical devices in the medical device healthcare market. Although Company A and B produce different types of devices, the manufacturing processes used to fabricate their products use comparable systems and technologies. Case Study A consists of a medical device SME which is owned by an investment company with over 200+ employees. Case Study B is a privately owned company with over 300+ employees.

2.1 Case Study A – Company A

Company A is a medical device manufacturer which specialises in pressure relieving devices in the healthcare market, and their products are manufactured in their facility in Wales.

The manufacturing processes of Company A currently does not consider nor apply any I4.0 manufacturing systems. They currently heavily rely on experienced cell workers and

operators who have been in the company for a long time. The machines used to fabricate their devices are mostly manually driven and controlled machines operated by their skilled work force - Figure 1 illustrates the process flow of a product fabricated by Company A. The processes to which the raw materials are processed and prepared is operated through three semi-automated welding and cutting machinery which prepares the material to its required dimensions. Other raw materials required for the products are manually processed and assembled using manually controlled machineries and jigs. Each process is manually quality checked to ensure that assemblies and sub-assemblies at each stage of the process are manufactured in the required quality and standard. Two semi-automatic machines are also used to fabricate the final products which are also controlled by skilled operators. As a result, the product throughput of Company A is not as high as it can be since most of their products are manually manufactured. The production scheduling and target throughputs of the company varies depending on the most on demand line of products, such priority is then given to those lines to be manufactured and ensures a targeted stock is made during a production day.

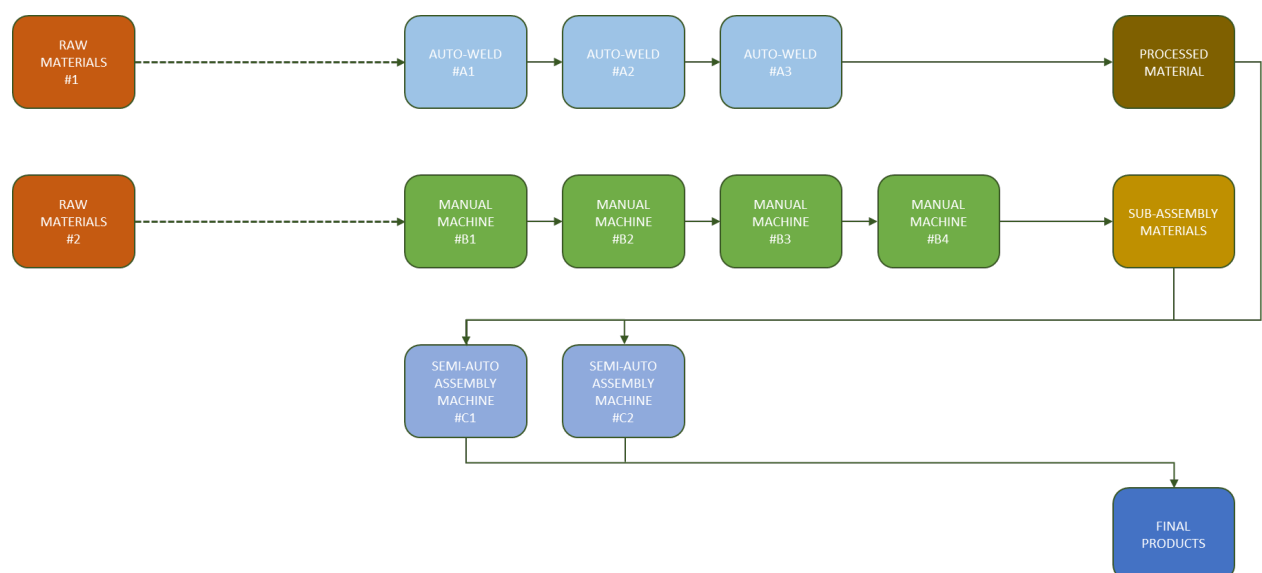


Figure 1 Manual Production Process - Simplified Process Flow

2.2 Case Study B – Company B

Company B is a medical device manufacturer which specialises in ostomy care devices in the healthcare market. Their products are manufactured in their facility in Wales.

The manufacturing processes of Company B uses automated machinery and robotics to process raw materials and assemble sub-components for their products. They have established their expertise in ensuring excellent production efficiency for their products and have welcomed I4.0 by establishing a smart factory which utilises a good balance of automation, robotics and IoT while considering human interaction with their operations to build a successful I4.0 production process (Yeeles, 2022). As shown in Figure 2, the systems

setup within the production processes of Company B are all automated machineries which uses programmed robots to interact and fabricate the raw materials into products. They have invested in designing machines which automatically feeds through raw materials from one process to another without the need for human intervention and interaction. They do not rely on the experiences or expertise of their workforce but ensure that their operators are trained to ensure that they are skilled in the setup of the automated machineries at the start of each shift. Since Company B utilises a fully automated smart factory, the production throughput of products which are fabricated within the processes are high. This allows the company to run their production schedule for 24 hours, enabling them to ensure that they have a good quantity of products in stocks and provides products in the market on time to compete with their competitors.

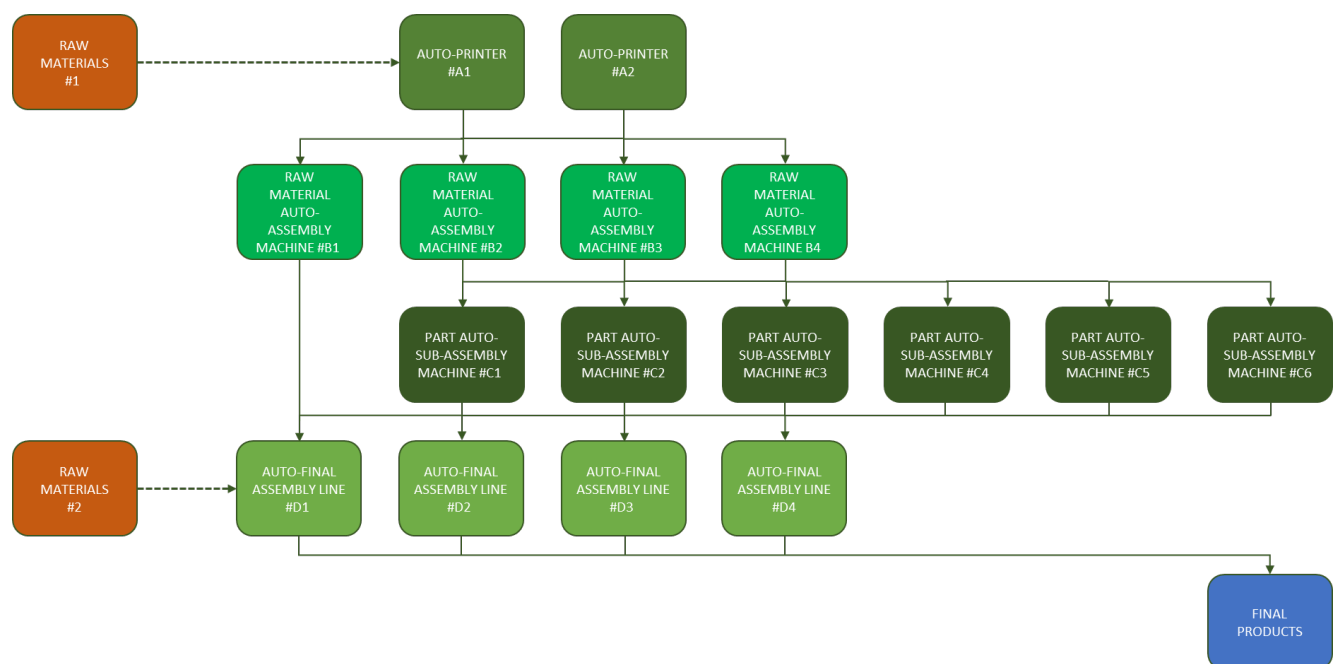


Figure 2 Automated Production Process - Simplified Process Flow

3 Adoption of Industry 4.0 Systems within SMEs

SMEs face challenges in adopting I4.0 technologies as they are less capable of managing the financial and technological challenges of implementing such systems compared to larger companies (Cotrino, et al., 2020). Welsh SMEs all have varied manufacturing capabilities and expertise and adopting I4.0 systems can cause companies to have uncertainties around which technologies to invest in and in understanding how investment in such systems will impact their businesses. There are a large array of I4.0 systems which can be adopted by SMEs, but the lack of standardisation provides difficulties in knowing which technologies to adopt and which will provide the required efficiency improvements for the company (Cotrino, et al., 2020).

In recent years, the medical device industry has been under pressure to meet the increasing demands of customers and the market to ensure affordability and accessibility of medical devices (Yeeles, 2022). Such pressure from the market has pushed SMEs like Company B to adopt innovative technologies within their manufacturing processes to meet the demands of the market. Villa & Taurinoa, (2019) stated that experiences and success stories provided by the application of I4.0 within SMEs helps in providing confidence in considering such systems. Compared to Company B, SMEs like Company A face challenges from top management regarding investing and considering the adoption of I4.0 systems due to the lack of knowledge on which technologies to consider and how it may impact their business. Another problem is how companies like Company A grow comfortable, and subsequently stagnant, with their current processes and capabilities as well as the growing uncertainties that their skilled work force may not accept such new advances in production technologies.

3.1 Feasibility of Industry 4.0 Systems in SMEs

Applying I4.0 systems and technologies within SMEs is achievable once the key challenges the company faces are addressed. The two SMEs emphasised within the case studies are both medical device SMEs in Wales and the size of both companies are comparable with each other. Although on the surface they are similar, the main difference between the two companies lies within the way their manufacturing processes are set up to fabricate their products.

Company A lack the technical and economic means of considering I4.0 systems which is seen in how their current production processes are based on their current competencies as well as the technologies that they have traditionally built their proficiencies on (Pinto, et al., 2019). It is possible for Company A to consider the transfer of their manual production processes (Figure 1) to build a smart factory similar to Company B (Figure 2) as the basis of automation is already set up with the processing of their raw materials. Additionally, investing in automated and robotic machinery can further aid with fully automating their manufacturing processes and increasing output.

The feasibility of adopting I4.0 technologies is only possible if the top management, as well as the current financial strategy of the company, matches the financial requirement of such systems. The adoption of I4.0 for Company A can be proposed and included in the corporate strategy of the company which drives the decisions and action of an organisation. This highlights the importance of improving corporate performance in the long term while considering any uncertainties which arise with the adoption of I4.0 (Agrawal, et al., 2018).

3.2 Complexity of considering Industry 4.0 within Welsh SMEs

Understanding which I4.0 systems to adopt as well as how much investment to put into such technologies can be complicated for a company that do not have enough knowledge in the I4.0 methodologies. Aside from the unknowns of which systems can provide production improvements, a company's top management also needs to understand the risk of investing in new technologies. Given the promising advantages of I4.0, many companies are making

the move in considering substantial investments in the future of their businesses (Agrawal, et al., 2018). The example of Case Study A – Company A illustrates where and how SMEs can consider investment in their manufacturing capabilities as it can drive the company to improve production and output and therefore make the company more competitive in the market. Agrawal, et al., (2018) indicated that the capability of production needs to be aligned with the corporation resources and strategy to create a sustainable competitive performance. Evaluating the potential gains of such new systems before implementation can aid with alleviating the complexity of considering such technologies (Pinto, et al., 2019). There is a room for growth within the medical device industry to continue product innovations that make devices easier to use and improve healthcare, and consideration of I4.0 systems will only become more needed as the interest rises for the development of new generation devices (Lewis, 2020).

4 Challenges of Adopting Industry 4.0 Systems

With the complexity of considering I4.0 systems, comes the challenges of adopting such systems within SMEs.

At present, medical device manufacturers are facing challenges and uncertainties as new standards and regulations emerges in the healthcare industry. As a result, these new evolving challenges are pushing medical device SMEs to consider manufacturing capabilities that will help meet evolving regulatory requirements (Lewis, 2020). The existing highly regulated industry of medical device development is a challenge for medical device SMEs like Case Study A – Company A and Case Study B – Company B. Companies like Company B who have already adopted and continuously improved their production systems only faces the challenge of clearly defining and documenting their current process flows as well as how such data are reported i.e., production failures, and material scraps.

On the other hand, I4.0 for most SMEs like Company A is a major challenge to adopt (Matt, et al., 2018). The strict regulations that continuously change prevents the consideration of I4.0 systems especially for companies like Company A who have not yet adopted such I4.0 technologies as the work around implementing new complex systems as well as ensuring that products and technologies meets regulatory requirements requires huge investments.

Aside from regulatory requirements, as already discussed, understanding which technologies as well as considering the financial requirements of I4.0 are also challenges currently faced by SMEs when it comes to considering adopting I4.0.

4.1 Barriers of Industry 4.0 Systems

SMEs do not have the economic resources to implement I4.0 technologies compared to large companies who have teams of experts dedicated to successfully implementing I4.0 systems. SMEs do not have such capabilities as they are normally structured as a single-layer company (Elhusseiny & Crispim, 2022). This knowledge barrier is proving to be one of the

biggest challenges with the consideration of I4.0 systems as there are a wide range of technologies that can be designed for different manufacturing requirements and blindly absorbing new technology may increase risks of investment failure (Agrawal, et al., 2018).

SMEs like Company A have grown comfortable with their current manufacturing systems as the company has relied on building the knowledge of their workforce to be internal experts on their manually controlled machineries and systems. As a result, this has built a barrier in welcoming new systems and technologies as the workforce are comfortable in working with their current competencies and are more hesitant to change. This poses a big business risk as this skilled workforce can leave the company and subsequently cause gaps in the business thus creating more challenges for the company.

To combat this, time and effort into training new employees can be substituted with hiring talented engineers who have comprehensive knowledge of designing smart systems (Hopali & Vayvay, 2018). Technical barriers and organisational barriers are the main two obstacles that SMEs such Company A needs to overcome as the room for implementation of I4.0 systems can provide more development and growth opportunities for their business (Elhusseiny & Crispim, 2022). SMEs like Company B who have adopted the integration of I4.0 systems with the development of their manufacturing facilities have the simple barrier of overcoming new technology advancements. Despite already having an established smart factory, upgrading such machinery with new technologies must be considered by the top management and be considered as part of their corporate strategies.

4.2 Uncertainty on the Success of Implementing Industry 4.0 Systems

One of the biggest uncertainties of the success of I4.0 is the successful integration of the different systems and technologies that can be implemented by companies (Pinto, et al., 2019).

In the medical device industry, the uncertainty of being ruled out by large companies that currently demonstrate the knowledge and flexibility of adopting new systems can greatly become an ambiguity with SMEs adopting I4.0 systems (Borland, 2021). Many SMEs struggle with the overwhelming number of technologies which are constantly developing (Masood & Sonntag, 2020). Despite already adopting several I4.0 systems and technologies, SMEs like Company B still fall behind in comparison to their large competitors which have multinational offices and factories which are constantly evolving. Investing in new automated machines to increase the number of product throughputs or developing new products lines alone will not allow SMEs like Company B to catch up with large company competitors. Thus, despite already having established a smart factory, uncertainties in not knowing whether new machines and systems will provide the desired impact on the market contributes to the slower growth of SMEs when compared to larger companies. I4.0 projects are cost driven initiatives especially in SMEs - companies like Company A are tied to their original technical knowledge and therefore resist the acceptance and implementation of new systems and technologies to their business (Villa & Taurino, 2019). Therefore, the ambiguities for companies like Company A to invest in I4.0 technologies due to the uncertainties around its

impact on business performance remains, although adopting I4.0 systems will subsequently force competitors to participate in similar financial strategies thus lowering the margins of production for the medical device industry (Agrawal, et al., 2018).

5 The Benefits of Adopting Industry 4.0 Systems

I4.0 provides automatic and flexible adaptation to a company's production process as it allows them to track parts and products, and enables communication among parts, products, and machines (Masood & Sonntag, 2020). I4.0 presents significant opportunities for SMEs which enhances their ability to innovate and enter new markets (Elhusseiny & Crispim, 2022). Company B has already acquired some benefits of converting its production processes to a smart factory, such as the ability to not rely heavily on a skilled workforce which provides the benefits of having a system that can be controlled and automatically started to fabricate products. New product development projects are easily put through the stages of development as existing manufacturing capabilities exist to implement products to manufacture.

This shows how the evolution of I4.0 is incremental but leaves a disruptive impact on the performance, and productivity of companies (Agrawal, et al., 2018). Product throughput is a key benefit to the application of I4.0 systems in smart factories, as mentioned above which when not implemented as is the case for Company A, leads to struggles in planning specific product targets to manufacture since high selling products are put to priority in production. Company B enables better management in production scheduling as a quantity of each line of products can be manufactured automatically in a day's worth of production. The benefits of a I4.0 production system provides increase in efficiency and reliance which allows manufacturers to thrive in the increasingly competitive market (Yeeles, 2022), and also provides reduction in costs as well as ease of use for operators and cell workers (Hanson, 2022).

5.1 The impact of adopting industry 4.0 systems

The impact of implementing I4.0 systems and technologies can significantly help eliminate unnecessary tasks and integrate information into the company's production management system (Pinto, et al., 2019). It reduces the application of manual processes in an automated process and integrated IoT systems within machines that allows the transfer of key datasets which allows better management of raw material usage, number of fabricated products, as well as quantity of defected products to be automatically reported. Machine setup time also decreases as part of the integration of I4.0 systems which in turn increase product quality of products. Automated detection of machine breakdown also prevents delays in production and aids in quickly identifying which machine requires maintenance (Hopali & Vayvay, 2018). An example is the use of an Andon system by Company B with each of their automated machinery. Andon is a term that refers to a system that notifies users of a quality or processing problem (Cotrino, et al., 2020). Such system provides a big impact in knowing

which machine require maintenance and further adjusts the production scheduling of products while the machines are being fixed. It makes it easier to ensure processes are carried out efficiently and productively as the Adon system aims to work as an early warning device giving operators and managers time to resolve machine errors (Cotrino, et al., 2020). Company A can benefit from the impact of I4.0 technologies as seen in Company B - the concept of a smart factory which is already implemented by Company B is a logical technological advancement to the future and can provide the same positive impacts seen in Company B's production facilities (Matt, et al., 2018).

5.2 How industry 4.0 systems can benefit Medical Device Welsh SMEs

As stated, regulatory compliance is a key element of medical device manufacturing. I4.0 benefits medical device companies by having all the relevant documentation requirements available to the regulatory bodies using IoT systems (Rahman, 2019). Both Company A and Company B uses IoT with the same purpose of ensuring the required documentations for the products are built within a Quality Management System that is secure. The requirements of tracking product information are also a key benefit to medical device SMEs as products can be tracked at the start of the process from the raw materials up to the delivery of the devices to the users (Rahman, 2019). Other benefits that I4.0 can provide medical device SMEs includes cost reductions, improvements in quality, efficiencies, flexibilities, and productivity which ultimately aids in making the company become more competitive in the market (Masood & Sonntag, 2020). As an example, Company B as an SME in Wales can grow to compete with larger companies in the market despite being smaller in size as seen in the fact that Company B can develop new products that can be manufactured within an automated line that enables the product to be readily available in the market. Their application of machine-to-machine systems and consideration of human-machine-interaction is a vital process that have benefitted their adoption of I4.0 systems (Gildchrist, 2016). Medical device SMEs in Wales are continuously growing and I4.0 further enables them to increase their innovation with new products. Welsh medical device SMEs can benefit with the never-ending advancement of new technologies and systems. It is expected that the medical device industry will see improvements in smart manufacturing solutions which focuses on value propositions such as improved manufacturing agility, optimising end-to-end manufacturing costs digitalising validation practices, compliance management and production operations (Yeeles, 2022).

6 Conclusion

The case studies explored here are a good example of the current competencies of two SMEs in Wales. The two companies are currently in different positions in terms of where the two businesses are at with considering I4.0 methodologies which was investigated in the feasibility, challenges, and benefits of adopting I4.0 systems. The two companies mentioned in the case studies are key examples of how it impacts their business and specifically their manufacturing and production processes. Adopting I4.0 systems for Welsh SMEs in the medical device industry provides benefits in enabling such businesses to compete with larger companies in the market, as explored with investigating the smart factories established by Company B. The way they have established a smart factory has enabled a fully automated process of fabricating their products as well as being able to keep their production running for 24 hours a week. On the other hand, SMEs like Company A who struggle and are more hesitant in adopting such methodologies due to being comfortable with their current competencies fall behind in comparison.

The acceptance of the top management to include I4.0 systems within their financial strategy is also a factor for such SMEs; providing success stories and guidance for SMEs to consider investment in such systems will allow benefits and support for SMEs to further reflect on investing in I4.0 technologies. Furthermore, Welsh SMEs who have successfully established knowledge in I4.0 can support and share guidance to other SMEs on considering the adoption of I4.0 technologies. One of the key problems identified is in establishing confidence with I4.0 technologies as well as successfully implementing an I4.0 system that can further help drive a company's strategy in evolving their production facilities into smart factories.

In principle, this essay has demonstrated the current state of two Welsh SMEs in the healthcare market in adopting I4.0 systems respectively. Despite the two companies having different production methodologies, there are lessons to be learnt in I4.0 technology approaches in the effective development of a smart factory. The journey of implementing I4.0 systems will always start with the investment a company is willing to put into such systems. Through successful case studies, businesses can learn from one another in how to implement such technologies successfully and give confidence on the benefits of capitalising in a fully smart manufacturing system.

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