IT and OT Convergence: The case of implementing the connected enterprise

SIMBARASHE PAGIOUS WEKARE

A dissertation submitted to the University of Dublin in partial fulfilment of the requirements for the degree of M.Sc. in Management of Information Systems.

1st September, 2016

Declaration

I hereby declare that this is entirely my own work and that is has not been submitted as an exercise for the award of a degree at this or any other University. I further declare that this research has been carried out in full compliance with the ethical research requirements of the School of Computer Science and Statistics.

Signed: ______________________________

Author

1st September 2016

Permission to lend and/or copy

I agree that the School of Computer Science and Statistics, Trinity College may lend or copy this dissertation upon request.

Signed: ______________________________

Author

1st September 2016

Acknowledgements

I would like to thank my dissertation supervisor Anthony Niland for his guidance and encouragement throughout the course of this research study.

I would also like to thank my work colleagues and other professional acquaintances who participated in this research study.

Finally, I would like to thank my family for their patience and understanding over the past few months as I undertook the research study.

Abstract

This research study is motivated by the research question, *'how has the evolution of Operational Technology (OT) supported the implementation of the connected enterprise for an Irish pharmaceutical manufacturing company?'* Literature on the evolution of OT has focussed on the development of the Programmable Logic Controller and the Fieldbus. Notwithstanding this fact, there has been little international research on how this evolution in OT and its subsequent convergence with Information Technology (IT) has supported the implementation of the connected enterprise. This research study advances understanding on how the successful convergence of IT and OT results in the establishment of the connected enterprise. This understanding is becoming of utmost importance as organisations are now spending millions of Euros on such initiatives. For instance the case organisation is spending €3 million on a project to implement a Manufacturing Execution System.

A cross sectional case study of a significant player in the Irish pharmaceutical manufacturing industry was conducted as part of this research. A simple mixed method research approach underpinned by the interpretivist philosophy was undertaken to explore the factors affecting the implementation of the connected enterprise. The research utilised an online questionnaire as the data collection method.

The findings offer insights into the case study participants' perceptions of the connected enterprise as well as the participants' own understanding of the various facets of the connected enterprise. The data from the pilot study demonstrates that the research data can be used as inferential data for similar healthcare manufacturing companies in Ireland.

The findings from the research show that the evolution of OT and the convergence of this technology with IT is a technical antecedent for the successful implementation of the connected enterprise. The findings from the research also show that the human factor is an equally important consideration for this successful implementation.

Table of Contents

Table of Figures

List of Tables

List of Abbreviations

Acronym	Definition
BR	Batch Record
CoE	Centre of Excellence
CPS	Cyber Physical System
CPwE	Converged Plant-wide Ethernet
DCS	Distributed Control System
DMS	Document Management System
EBR	Electronic Batch Record
EMEA	Europe, the Middle East and Africa.
ERP	Enterprise Resource Planning
FDA	Food and Drug Administration
GAMP	Good Automated Manufacturing Practice
GMP	Good Manufacturing Practice
GDP	Good Documentation Practice
GEP	Good Engineering Practice
GxP	Good Anything Practice
HPRA	Irish Health Products Regulatory Authority
IAAS	Infrastructure As A Service
IACS	Industrial Automation Control System
IPC	In Process Control
IP DECT	Internet Protocol Digital Enhanced Cordless Telecommunications
ISA	International Society of Automation
ISPE	International Society for Pharmaceutical Engineering
IT	Information Technology
KPI	Key Performance Indicator
LMS	Learning Management System
MBR	Manufacturing Batch Record
MES	Manufacturing Execution System
MOE	Margin Of Error
MOM	Manufacturing Operations Management
MNC	Multinational company
OEE	Overall Equipment Efficiency and other
OEM	Original Equipment Manufacturer
OPC	• Open Platform Communications, • Open Productivity Connectivity, • OLE for Process Control (Object Linking and Embedding for Process Control).
OT	Operational Technology
PERA	Purdue Enterprise Reference Architecture
PLC	Programmable Logic Controller
QMS	Quality Management System
SAAS	Software as a Service
SCADA	Supervisory Control and Data Acquisition
SCSS	School of Computer Science and Statistics
SIPOC	Suppliers, Input, Process, Output, Customers
SMS	Short Message Service
US	United States (of America)
VLAN	Virtual Local Area Network
WMS	Warehouse Management System

1. Introduction

1.1. Background to the study and context

This research is a case study of the implementation of the connected enterprise by a significant player within the Irish healthcare industry. Over the last few years, health care manufacturing companies have begun deploying information technology and operational technology which deliver management's strategic, informational and transactional objectives. (Gartner, 2013, p. 1), states that, *"Operational technology (OT) is the hardware and software that detects or causes a change through the direct monitoring and/or control of physical devices, processes and events in the enterprise"*.

Companies are adopting these technologies to ensure sustainability and competitiveness. Enterprise Ireland states that one of the growth areas in the pharmaceuticals is the, *"development of new product offerings based on the convergence of multiple technology platforms involving collaboration between innovative pharmaceutical, medical technology, diagnostics and ICT companies"* (Enterprise Ireland, 2010, p. 1). Based on this current trend, it can therefore be argued that it is now not a question of why nor a matter of when the connected enterprise should be implemented but rather a matter of how can the connected enterprise be successfully implemented. OT and Information Technology (IT) have traditionally existed as different entities within the same organisation. The evolution of OT and the resultant convergence of this technology with IT has been proved to be key to the establishment of the connected enterprise.

"The Connected Enterprise helps operations managers profitably manage and improve manufacturing and industrial processes. It helps IT executives reduce network complexities and exposure to information security risks. It shares productivity-improving information to workers across the organisation in a context that is meaningful for each role" (Rockwell Automation, 2015, p. 1).

This research study aims to add to the body of knowledge which currently exists in relation to the convergence of IT and OT resulting in the establishment of the connected enterprise. Notwithstanding the fact that there are several literature sources which theorize the concept of the connected enterprise, there has been little international research on how the evolution in OT and its subsequent convergence with IT has supported the implementation of the connected enterprise in the healthcare manufacturing industry.

1.2. The research question

The research question that this dissertation aims to address is as follows;

How has the evolution of Operational Technology supported the implementation of the connected enterprise for an Irish pharmaceutical manufacturing company?

1.3. Importance of the research

New and existing companies have to transform their manufacturing operations to adopt to the digitalisation era. *"This transformation into a digital enterprise requires positive disruption in the business models, value chains, processes and operating models, key performance indicators as well as the strategic use of Information Communication Technologies (ICT)"* (Weichhart, et al., 2015, pp. 1-13). The deployment of these technologies should be done in a safe and secure environment, thus facilitating integration of the factory floor systems and the enterprise systems. By utilising this secure integration, strategic business objectives such as ensuring a safe product for the patient; which should be the primary business objective for any pharmaceutical manufacturing company, can be achieved. Integration of factory floor systems and the enterprise systems also results in improved responsiveness to problems on the factory floor through the use of smart phones, smart tablets and SMS with IP DECT or Wi-Fi phones.

Another important strategic business objective which the pharmaceutical manufacturing companies have to consider is the issue of data integrity. Computer systems such as SCADA systems, which by nature utilise some form of database, have become prevalent in pharmaceutical manufacturing processes. The requirement to ensure that the data on these systems is stored in a secure environment and retains accuracy and consistency implies that companies have to embrace digital data integrity.

Other management strategic initiatives which are aided by the establishment of the connected enterprise include; lean manufacturing, asset performance management and product life cycle management. The common envisaged results for this connected enterprise are increased economic profits, increased customer satisfaction, lean and agile operations as well as regulatory compliance.

The fact that the FDA is the federal agency of the United States Department of Health and Human Services implies that compliance with its guidelines on, data integrity, 21 CFR Part 11 (Part 11 of Title 21 of the Code of Federal Regulations; Electronic Records; Electronic Signatures), general principles for software validation and GAMP amongst others cannot be understated. The main revenue generated by most Irish based pharmaceutical manufacturing companies is from the US market. Furthermore, "*it is the main market for the foreign/MNC sector and the second most important market for the indigenous sector*"

(Fitzgerald, et al., 2014, pp. 1-27). In addition, the goal to achieve and maintain compliance with guidelines from EU regulations such as the EudraLex - Volume 4 GMP guidelines and the HPRA guidelines is another factor which needs to be considered. The EudraLex - Volume 4 GMP guidelines state that, *"production operations must comply with the principles of Good Manufacturing Practice in order to obtain products of the requisite quality and be in accordance with the relevant manufacturing and marketing authorisations"* (European Commission Health Consumers Directorate General, 2014, p. 3).

1.4. The scope of the study

This dissertation will analyse and evaluate how to implement the connected enterprise which is established as a result of the successful convergence of IT/OT within the Irish healthcare industry. This convergence is key to ensuring a company's abidance with the principals of GAMP, GDP, GEP and other GxP requirements. Compliance with FDA, EU and HPRA guidelines then becomes achievable once there is abidance with the aforementioned practices.

Although the research is limited to one significant player in the healthcare manufacturing industry in Ireland, it is hoped that the research findings will be consistent with any future research studies which utilise a multiple-case study research approach.

1.5. Overview of the research methodology

To answer the question as to how the evolution of OT has supported the successful implementation of the connected enterprise for an Irish pharmaceutical manufacturing organisation and how this can be sustained to ensure that the organisation achieves its strategic business objectives, a case study on the implementation of the connected enterprise forms the basis of this research study. The case study will be carried out on a multinational pharmaceutical company based in Dublin, Ireland which has recently implemented the connected enterprise and is in the process of enhancing this connected enterprise further. Secondary data will be derived from a pilot survey study involving participants from other healthcare manufacturing companies in Ireland.

1.6. Chapter roadmap

Chapter 1: This introduction chapter provides a summary on the background to the study, context and relevance of this research study. The research question is also presented and an overview of the research methodology is provided.

Chapter 2 will provide a review of relevant literature. There will be three main parts to the literature review. The first part will be an analysis of the evolution of operational technology from the development of the Programmable Logic Controller (PLC) in the late 1960's to the 1980's. Taking into account the varied nature of the subject and the number of players (vendors and designers) involved, this dissertation will not include too much detail on the subject but will instead focus on the key milestones in the evolution of PLC technology.

The transformation of machine networks or Fieldbuses with a view to evaluating the role that machine networks have played and continue to play in enabling the convergence of IT and OT (thus facilitating the establishment of the connected enterprise) will be investigated as part of the review of the evolution of OT. Challenges such as a lack of standardisation associated with legacy and current Fieldbus technology as a potential inhibitor to the connected enterprise will be discussed. Potential solutions to address this lack of standardisation will be explored.

The second part of the literature review will focus on the analysis of the existing OT and IT applications or systems associated with Irish pharmaceutical manufacturing companies. The case of the pharmaceutical company based in Dublin will be considered as part of this analysis. The pharmaceutical company was originally an indigenous company. After several acquisitions, the company is now owned by a large multinational organisation. The acquisition by the multinational organisation resulted in capital injection into the existing company which in turn resulted in new manufacturing facilities being established. The existing facility represents legacy pharmaceutical manufacturing systems and the new manufacturing facility represents an example of the connected enterprise.

As part of this literature review, the challenges and opportunities presented by legacy and existing OT will be considered. Challenges presented by OT in some pharmaceutical companies such as legacy hardware for instance Siemens' S5 controllers or Rockwell Automation PLC-5 controllers will be evaluated with a view to establishing what needs to be done to successfully set up the connected enterprise. The relationship between the opportunities presented by legacy and existing OT and the establishment of the connected enterprise will be assessed.

The third part of this dissertation's literature review will look at what the future holds for manufacturing within Irish pharmaceutical manufacturing firms. Concepts such as Germany's Industrie 4.0 will be introduced. There will be an evaluation of any fundamental differences or similarities between the terms Industrie 4.0 and the connected enterprise. Technological developments such as the internet of things and big data will be briefly discussed in the third part of the literature review. The subjects of the internet of things and big data are expansive topics. It is therefore not the intention of this dissertation to discuss these topics in great detail. Instead this dissertation will introduce these subjects and evaluate the envisaged role for these technologies in future Irish pharmaceutical manufacturing. The roles that OT and IT play and the importance of the convergence of these two seemingly disparate systems will be examined to determine its influence on a company's preparedness for future manufacturing.

Chapter 3 details the research methodologies considered and explains the rationale behind the research strategy adopted. The research onion as posited by Saunders et al, 2016 will be the technique used to collect the research data and provides the procedural approach for data analysis. This is outlined in *Figure 3.1 - Adaptation of the research onion for this research*. The role of ethics, the limitations of the research methodology and learning outcomes are also discussed in this chapter.

Chapter 4 presents the research findings and analysis of the data. The chapter provides the results of the online surveys. Triangulation to check the validity, credibility and authenticity of the parent survey data is achieved by means of a pilot survey. Open ended questions provide additional unstructured data from the participants.

Chapter 5 concludes the dissertation by providing a summary assessment of the research findings and providing recommendations on the findings. The chapter also provides the strengths of the research study and proposes future work.

2. Literature Review

2.1. Introduction

This chapter begins with a review of the history of automation. Particular focus will be on the history of PLCs and Fieldbus technology. The period under review will be from the late 1960's to the 1990's. Since the subject of the history of PLCs and Fieldbus technology is varied, this dissertation will only concentrate on the key milestones in the development of these anchors of automation technology. Upon completion of this automation history review, an analysis of the present status of manufacturing technology comprising of OT and IT will be undertaken. The case of the Dublin pharmaceutical manufacturing company is considered. This is followed by a review of the future status of OT and IT. The hope is that at the end of the literature review, this dissertation will have provided a critical analysis of how the convergence of the two technologies (IT and OT) is paramount to the establishment of the connected enterprise.

2.2. Paying homage to the early developments in Automation.

Automation by definition involves the use of systems and technology to reduce the requirement for human beings in the execution of any number of tasks. (Guarnieri, 2010, pp. 42-43), posits that, *"Hellenistic engineers were the first to make steps in the direction of automation"*. For instance, Ctesibius (285–222 BC) is credited with the development of the first feedback system which was a water clock capable of compensating for reduced water flow rate. The Greek mathematician and engineer Hero of Alexandria is also credited with coming up with some of the earliest forms of automation such as the first automated vending machine. *"When a coin was introduced through a slot at the top of the machine, a set amount of holy water was dispensed"* (Norman, 2015, p. 1).Other early developments included the dancing "automata" which simulated various movements made by man or animal. Dancing "automata" began to take shape as mechanical devices that could accomplish a series of movements. (Norman, 2015, p. 2), points out that, *"this type of technology is an excellent example of open loop control systems"*.

2.3. Winds of change in Automation in the early 20th century

The key drivers for automation in the 20th century were the industrial revolution, World War I and World War II. These factors necessitated the requirement to mass produce vehicles and military equipment to meet the demands of the war effort. "*Starting in the second half of the 1940s, if not before, members of many overlapping communities – technical, scientific, government, military, business, industrial, and organized labour – began to discuss the industrial implications of wartime developments, particularly new scientific* *disciplines and technologies connected to mechanization and automatic control"* (Brock, 2012, p. 378).

(Assante & Conway, 2014, p. 7), mention the benefits of automation as, *"that it reduces the amount of labour, can save energy through efficiency gains, reduces the amount of materials needed, and improves quality, accuracy, predictability, and precision"*. These benefits would explain why there was a drive to implement automation in manufacturing for the production of armaments during the two world wars. As would be expected, the original systems required significant manual interventions. Safety systems such as the use of emergency stops were not available at the time implying that these manual interventions often resulted in injuries or death.

It was also during this early to mid-20th century period that disposable incomes meant that there was a growing demand for American businesses to produce automobiles. This increased the levels of automation in industries, albeit with inflexible manufacturing systems. The inflexibility of these earliest forms of automation is summed up by Henry Ford (creator of the Ford Motor Company) when describing his automobiles that were undergoing mass production at the time: *"Any customer can have a car painted any colour that he wants so long as it is black"* (goodreads.com, 2015, p. 1).

2.4. The labour conundrum impacting the development of Automation.

The development of automation in the early to mid-20th century was not all smooth sailing. Workers in the automotive industry were naturally concerned that the introduction of new technology would have an adverse impact on their livelihoods resulting from the loss of factory jobs. *"Historians have slighted the importance of automation both as a cause of organized labour's decline in America and as a lively issue among labour leaders in the early post-WWII period"* (Steigerwald, 2010, p. 429). Automation involves the use of automatic equipment in the manufacturing operations hence the scepticism displayed by the union leaders and the factory workers. "*American unions never launched a militant attack on those technological changes that were gathered under the name 'automation', even though automation undeniably contributed to the relative decline in manufacturing employment between 1955 and 1965…"* (Steigerwald, 2010, p. 429).

During this period, unions such as the United Auto Workers (UAW) were actively involved in collective bargaining to protect the interests of the workers who were faced with potential job losses as a result of the introduction of automation. On the other hand, the auto companies were keen to adopt automation to gain competitive advantage as well as to remove the unionised work force. (Steigerwald, 2010, p. 431), posits that, *"If there is no smoking-gun evidence that the automakers saw automation as a means for ridding* *themselves of the UAW, there is cause for suspicion”*. (Mayer, 2004, p. 1), mentions that, *“As a percent of wage and salary employment and a percent of total employment, union membership peaked in 1954 at 34.8% and 28.3%, respectively”.* The trend in union membership in the US, which shows a gradual decline from the 1940’s, is shown in Figure *2.1*.

Figure 2.1 - USA Union Membership as a Percent of Employment, 1930-2003

Source taken from, (Mayer, 2004).

2.5. Industrial Control System (ICS).

2.5.1. What are industrial control systems?

An ICS refers to a control system that is used during the industrial manufacture or production of goods. This includes the following; DCS, SCADA Systems and PLCs. These aforementioned systems are fundamental building blocks for OT. *“SCADA systems are generally used to control dispersed assets using centralized data acquisition”* (Stouffer, et al., 2011, p. 1) . (Theorin & V.R., 2012), defines a PLC as, *“an industrially hardened computer based unit that performs discrete or continuous control functions in a variety of processing plant and factory environments”.*

OT is effectively automation implying that the two terms are interchangeable. Examples of some of the ICS components in use within the Irish pharmaceutical manufacturing are as follows:

a. Programmable Logic Controllers

Today the PLC is used much more than just for performing arithmetic and logic operations for the automation of manufacturing systems. PLCs now play an integral part in the storage, retrieval and transmission of manufacturing data from the factory systems. *Figure 2.2* shows an example of a powerful Elau C600 PLC which is in common use within the pharmaceutical industry.

Figure 2.2 - Example of modern PLCs – The Elau C600 PLC

The wide selection of communication interfaces available on most PLCs today is testament of the ease of connectivity which can now be achieved. *Table 2.1* shows the communication interfaces available on the Elau C600 PLC.

Table 2.1 - Elau C600 communication protocols

Category	Parameters	Value
Interfaces	Serial interfaces	COM1: RS232 (**X17**)
		COM2: RS485 (**X18**)
	Network connection	Ethernet (10/100 Base-T) (**X10**)
	Field bus connection	PROFIBUS DP Master/Slave (12 MBaud) (**X20**) and
		CAN (2.0A) or CANopen (**X19**)
		DeviceNet Slave (cable adapter required)
		EtherNet/IP Slave (optional hardware module required)
		EtherNet/IP Scanner (optional hardware module required)
	Real-time bus interface	SERCOS interface (16 MBaud) (**X14**, **X15**)
	PacNet interface	2 PacNet interfaces (**X12**, **X13**)
	Master encoder interface	1 SinCos master encoder or
		1 incremental master encoder (**X11**)
	HMI interface	RS485 (Modbus or PROFIBUS DP)
		HMI software tools: OPC server (for Windows NT/2000/XP or Windows CE)
	Diagnostic interface for remote maintenance	Modem
	Communications protocols	Http
		Ftp
		SMTP (E-Mail)
	Iintegrated trace recorder (soft-ware oscilloscope)	8 channels, resolution 1 ms
	Integrated data logger for diag-nostic messages	27 kB

Source taken from, (Elau GmbH, 2009).

b. Industrial Control Networks (ICNs)

ICNs are an important feature of ICSs. "*An industrial control network is a system of interconnected equipment used to monitor and control physical equipment in industrial environments"* (Galloway & Hancke, 2013, p. 860). The key component of an industrial control network is the Fieldbus. IEC (International Electrotechnical Commission) 61158 is the standard which has been developed for ICNs or Fieldbuses and defines a Fieldbus as *"a digital, serial, multidrop, data bus for communication with industrial control and instrumentation devices such as but not limited to transducers, actuators and local controllers"*.

This dissertation discusses the history of the PLC which is the control system of choice for the Dublin pharmaceutical manufacturing company. It should be noted that most manufacturing companies use either a combination of PLC(s) with SCADA(s) or a DCS on its own for both control and visualisation. It is common to find hybrid systems in use within the same manufacturing facility.

2.5.2. A brief look at the evolution of the Programmable Logic Controller

The birth of the PLC can be traced back to the 1960's. Prior to this period, control systems comprised of relays executing the control functions for machinery. Depending on the complexity of the operations, there could be complete walls or cabinets filled with these relays. These systems were inflexible, required a lot of time to troubleshoot problems and generally the effort to maintain or establish these systems was cumbersome.

"In 1968 Bill Stone, who was part of a group of engineers at the Hydramatic Division of General Motors Corporation, presented a paper at the Westinghouse Conference outlining their problems with reliability and documentation for the machines at this plant" (Theorin & Segovia, 2012, p. 3). The specifications presented as part of the design criteria were provided to the machine builders including Bedford Associates.

When this proposal from Bill Stone was pitched, engineers at Bedford including Richard Morley were already working on the design of a device which had the following characteristics*, " a modular and rugged design, the use of no interrupts for processing, as well as direct mapping into memory"* (Theorin & Segovia, 2012). The design of this unit which was named the 084 and subsequently re-named the programmable controller resulted in the birth of the PLC as we know it today.

From that time onwards, when the collaboration between Bedford Associates and Modicon (company formed by Richard Morley et al) presented this programmable controller design, the race was on as different manufacturers and machine designers started introducing their own programmable controllers. The term PLC was introduced by Allen Bradley when the Bulletin 1774 PLC was developed in 1971. *"This relay replacer has taken on many faces over the past 45 years, growing from a simple logic solver to a true multitasking central core for many automated systems"* (Control Engineering, 2015, p. 26).

Developments in PLC technology in the late 1960's to early 1970's are illustrated in *Figure 2.3*.

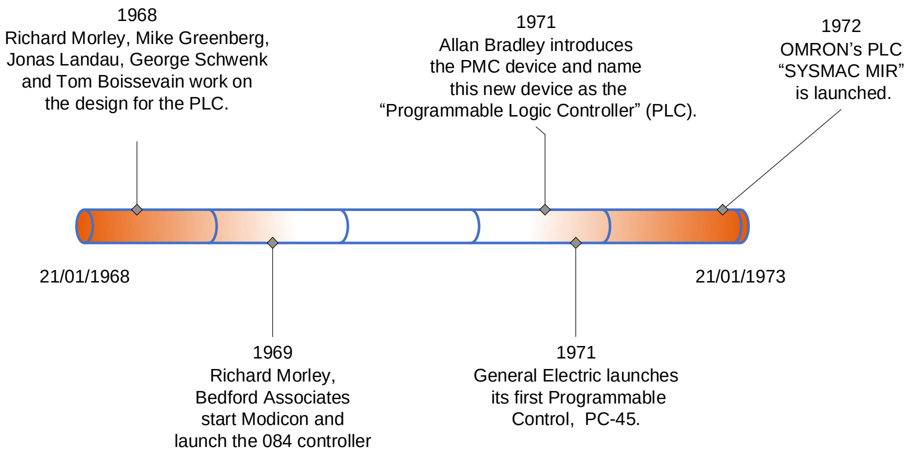


Figure 2.3 - Early PLC development timeline

Source adapted from, (Theorin & Segovia, 2012).

The period 1972 to 1979 saw other players such as Square D enter the fray. In 1983, Siemens, who will turn out to be a significant player, introduced the S5 PLC. *"The early 1980s saw a cross pollination between PLCs and distributed control systems (DCSs), where PLCs already begun incorporating distributed control functions so they could be linked much in the way that DCSs were linked"* (Theorin & Segovia, 2012, p. 7).

2.5.3. Then there was the Fieldbus

Device connectivity is a primary requirement for the successful implementation of the connected enterprise in a manufacturing environment. *"Several precursors to what are now known as Fieldbus systems were originally in development as early as the 1970s"* (Galloway & Hancke, 2013, p. 865). The development of the PLC significantly contributed to the development of Fieldbus technology. (Thomesse, 2005, p. 1076), suggests that, "*Perhaps the most important reason for Fieldbus development was the awareness that it could become the backbone of the future distributed and real-time systems for automation (and then the bone of contention for the competition between automation companies)"*.

The proliferation of Fieldbuses began in the 1980's as many players entered the field. *"In the second half of the 1980s, at the beginning of the IEC efforts in the technical committee TC65C, the development of Fieldbus systems was mainly a European endeavour, thrust forward by research projects that still had a strongly academic background as well as many proprietary developments*" (Felser, 2002, p. 1). The IEC solution was to drive towards standardisation of the proprietary Fieldbus protocols. This is because, *"the overwhelming number of different systems appalled rather than attracted the customers, and what followed was a fierce selection process where not always the fittest survived, but often those with the highest marketing power behind them"* (Felser & Sauter, 2002, p. 73). *Figure 2.4* shows the Fieldbus development timeline.

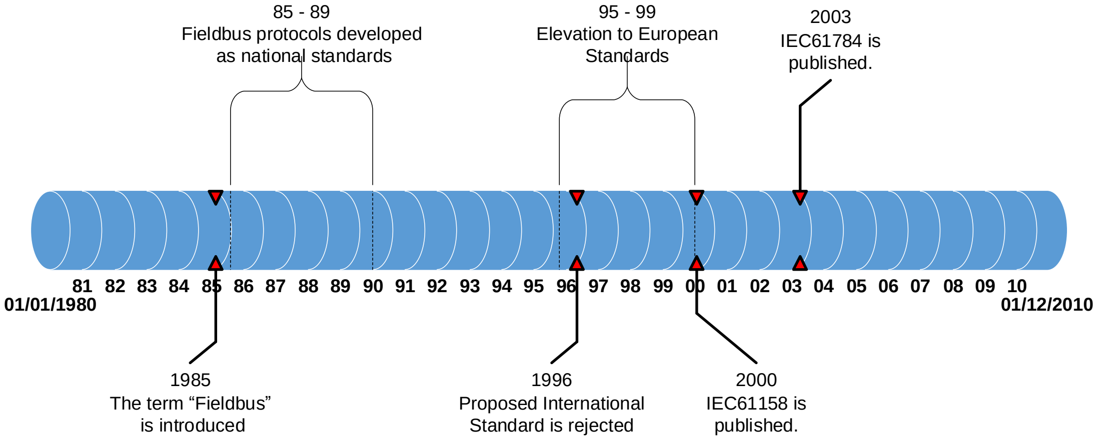


Figure 2.4 - Timeline of Fieldbus development

Source adapted from, (Galloway & Hancke, 2013).

The drive for a universal Fieldbus has not been hugely successful. *“Nowadays, the Fieldbus systems are standardised (though unfortunately not unified) and widely used within the industrial automation”* (Neumann, 2007, p. 1333). Proprietary Fieldbus such as Profibus DP, Profibus PA, DeviceNet, ControlNet, Foundation Bus and Modbus still exist. However these Fieldbuses *“have recently been developed or are under development, motivated by moving away from custom cable installations towards much cheaper Ethernet based equipment, which also has the advantage that one will be able to make use of the continuous improvements of the Ethernet technology”* (Theorin & Segovia, 2012, p. 16).

As with the example of the case study organisation, it is common to find a hybrid of Fieldbuses in use. The use a particular Fieldbus on machinery is influenced by the equipment vendor. For instance an equipment vendor who utilises Siemens PLCs would recommend the use of Profibus as the Fieldbus. If the customer prefers an alternative Fieldbus such as DeviceNet, the implementation costs will increase as additional hardware such as gateways will be required to facilitate connectivity between these disparate systems. There will also be an increase in software configuration costs.

The emergence of Ethernet in manufacturing cannot be understated. CISCO systems, a world leader in the design, manufacture and supply of networking equipment mentions that,

“IACS networks utilizing standard Ethernet and IP have a common core. This includes the physical transmission technology (Ethernet, Layer 1), the bus access method (Ethernet, Layer 2), the Internet Protocol (IP, Layer 3), the TCP and UDP protocols (Layer 4), and other standard protocols such as Hypertext Transfer Protocol (HTTP), File Transfer Protocol (FTP), and the Simple Network Management Protocol (SNMP). All these are established within IT and are being implemented to varying degrees, unchanged in IACS applications”. Source (Didier, et al., 2011, pp. 1-27).

This commonality in the fundamental building blocks makes Ethernet IP an attractive alternative for most OEMs as integration with the existing enterprise IT systems which utilise Ethernet protocols is simplified*. Table 2.2* shows some of the Fieldbus protocols which support standard Ethernet IP networking.

Table 2.2 - Fieldbus protocols supporting or partially supporting standard networking

Fieldbus Protocol	Ethernet Implementation	Leading Vendors	Standards body	Application
DeviceNet, ControlNet,	Ethernet/IP (EIP)	Rockwell Automation, Cisco, Schneider (EIP), Omron, Eaton	ODVA	Industrial automation (process, discrete, safety) control, motion control
PROFIBUS DP, PA, and so on	PROFINET CBA, I/O, IRT, and so on	Siemens	Profibus Foundation	Industrial Automation Process Control
Modbus	PROFINET CBA, I/O, and IRT	Schneider	Modbus.org	Industrial Automation Process Control
Foundation Fieldbus	Foundation Fieldbus High-Speed Ethernet	Emerson, Honeywell, ABB	Fieldbus Foundation	Process control
CAN/ CAN-Bus	ETHERNET Powerlink	Bernecker, + Rainer	ETHERNET Powerlink Standardization Group	Motion Control
Sercos Interface	Sercos III	Bosch Rexroth	SERCOS International	Motion Control
EtherCAT	EtherCAT		EtherCAT Technology Group	Motion control

Source adapted from, (Didier, et al., 2011).

2.5.4. When the PC arrived in manufacturing

A review of the convergence of IT and OT which ultimately enables the connected enterprise cannot be complete without discussing the impact that the arrival of the PC has had on manufacturing processes. Computers have been use in manufacturing for many years. *"Just as with IT, the technology has migrated from mainframes and mini-computers with dumb terminals to standalone, dedicated computing platforms"* (Didier, et al., 2011, p. 43).

Currently PCs play an integral role in the manufacturing processes, often hosting applications which facilitate connectivity with enterprise systems. The most commonly found is a special PC for manufacturing which is referred to as an Industrial PC (IPC). "*IPC processors are typically PC-based, multicore processors, and the communication options are open in nature and only limited by protocols requiring specialized hardware"* (Control Engineering, 2015, p. 28).

The use of the PC in automation owes a lot to the development of the semiconductor with the use of silicon electronics vis-à-vis the establishment of Silicon Valley. Some of the pioneers in silicon electronics were William Shockley and Arnold O. Beckman. "*Starting with their shared belief that 'automation' was key to the technological and industrial future, the discussion between Beckman and Shockley led to their creation of the Shockley Semiconductor Laboratory of Beckman Instruments, incorporated in late 1955*" (Brock, 2012, p. 376). It can thus be argued that the development of the semiconductor with silicon electronics which in turn revolutionised the development of PC was borne out of the desire to provide OT solutions to industry.

In addition to being able to run applications which can be programmed using the IEC 61131-3 programming language standard guidelines for programming PLCs, PCs can also be programmed using PC programming languages such as C++ and Visual Basic. For integrated camera vision, Human Machine Interface (HMI), or servo motion control, PCs also offer better solutions than PLCs or the slightly more advanced Programmable Automation Controller (PAC). This makes the versatility of the PC attractive to machine builders.

2.5.5. Comparison of IT and OT

IT and OT have similar characteristics. Although these two technologies have many similar characteristics, there are still some fundamental differences between the two technologies. It should be noted that for the context of this dissertation, the terms OT and ICS are used as synonyms since they fundamentally refer to the same thing. The table below shows the key differences between IT and OT/ICS.

Table 2.3 - Summary of IT System and ICS Differences

Category	Information Technology System	Industrial Control System
Performance Requirements	• Non-real-time • Response must be consistent • High throughput is demanded • High delay and jitter may be acceptable	• Real-time • Response is time-critical • Modest throughput is acceptable • High delay and/or jitter is not acceptable
Availability Requirements	• Responses such as rebooting are acceptable • Availability deficiencies can often be tolerated, depending on the system's operational requirements	• Responses such as rebooting may not be acceptable because of process availability requirements • Availability requirements may necessitate redundant systems • Outages must be planned and scheduled days/weeks in advance • High availability requires exhaustive pre deployment testing
Risk Management Requirements	• Data confidentiality and integrity is paramount • Fault tolerance is less important – momentary downtime is not a major risk • Major risk impact is delay of business operations	• Human safety is paramount, followed by protection of the process • Fault tolerance is essential; even momentary downtime may not be acceptable • Major risk impacts are regulatory noncompliance, • environmental impacts, loss of life, equipment, or production
Architecture Security Focus	• Primary focus is protecting the IT assets, and the information stored on or transmitted among these assets. • Central server may require more protection	• Primary goal is to protect edge clients (e.g., field devices such as process controllers) • Protection of central server is also important
Unintended Consequences	Security solutions are designed around typical IT systems	Security tools must be tested (e.g., off-line on a comparable ICS) to ensure that they do not compromise normal ICS operation

Source adapted from, (Stouffer, et al., 2011).

In pharmaceutical manufacturing other differences include the way change management is handled with more stringent requirements for changes on ICS components. This is because of their proximity to the pharmaceutical product.

2.5.6. Challenges and Opportunities presented by OT systems.

a) Legacy OT infrastructure

The Siemens Simatic S5 control system and Allen Bradley's highly adaptable PLC-5 controllers have been in use throughout industry for over 2 decades. "*Many SIMATIC S5 control systems are still in reliable service today, but rapid technological changes and increased market demands place stringent requirements on the automation system of today and tomorrow"* (Siemens, 2016, p. 1) . These two systems are examples of legacy control systems which although still in use today in the pharmaceutical manufacturing industry present several challenges and opportunities as summarised in *Table 2.4*.

Table 2.4 - Challenges and opportunities presented by legacy OT infrastructure

Challenges	Opportunities
Increase risk in unplanned downtime.	Modern control systems such as the use of SCADA systems can lead to higher productivity and higher compliance.
Raising maintenance costs and spare parts are becoming rare and expensive. Rockwell Automation announces that as of June 2017, the PLC-5® Control System will be discontinued and no longer available for sale (Rockwell Automation, 2016).	
Competitive disadvantage. PLCs are getting cheaper.	
Risks associated with compliance. Case in point: Rockwell Automation only recently added LDAP (Lightweight Directory Access Protocol) to the PanelView HMI terminals in 2014. The benefits of this are; • Windows-linked user and groups support centralized account management. • Support for 21 CFR Part 11 compliance (Rockwell Automation, 2016).	

b) The ever changing demographics

Support and maintenance for legacy systems such as for the Siemens S5 controllers is now hard to come by. The generation of engineers who would have been at the forefront of the deployment and maintenance of such systems when they were introduced in the mid 1980's is either in retirement or approaching retirement. The new generation of engineers has limited expertise or experience on legacy OT applications and systems mainly because the majority of such systems are being converted to the newer systems or being made obsolete. *"The migration of an old system to SIMATIC PCS 7 pays off many times over: It assures the continuity of process control system investments, makes the systems more efficient and productive, and extends the system service life in a cost-effective manner"* (Siemens, 2016, p. 1).

The challenges which are presented by the changing demographics also result from the emigration of highly qualified workers from Ireland. The pharmaceutical manufacturing companies are not spared from this skills drain. *"Highly qualified university graduates are dominating the flood of Irish people immigrating to Europe, the US, Canada and Australia for a better life"* (Riegel, 2013, p. 1).

These changing demographics however present some opportunities for pharmaceutical manufacturing companies. The increasing use of technology within pharmaceutical manufacturing processes should make it easier for pharmaceutical companies to recruit technically skilled personnel from outside the European Union (EU) as government policy framework supports this. *"In Ireland, the demand for specific skills has consistently exceeded available supply from the EEA labour market since the early 2000s. As a result, Ireland has aimed to attract key talent from non-EEA countries to fill skills shortages in specific sectors such as IT, engineering, finance and healthcare"* (Talbot, 2013, p. 4).

c) Constantly evolving technological changes

As new systems and applications are introduced to existing manufacturing facilities, the challenge is how to integrate these new resources without disrupting existing operations. *Table 2.5* shows the challenges and opportunities for Irish pharmaceutical companies which are brought about by these constantly evolving technologies.

Table 2.5 - Challenges and opportunities presented by technological changes

Challenges	**Opportunities**
Regulatory compliance issues as a result of the introduction of new applications and systems to a validated manufacturing process. The challenge for pharmaceutical manufacturing companies is to implement effective change management. Effective change management should be executed in parallel with configuration management. Key elements include: • Assessment of the impact of the change on the application, the underlying infrastructure, the people (users and engineering support staff) and the documentation. • Execution of the change from the financial, technical (IT or engineering), and compliance perspectives at the lowest technically competent level prior to management approval (ISPE, 2008).	The use of automated configuration and change management software applications within the pharmaceutical manufacturing industry to enforce regulatory compliance. An example of such software is Rockwell Automation's Factory Talk Asset Centre. FactoryTalk® AssetCentre provides you with a centralized tool for securing, managing, versioning, tracking and reporting automation related asset information across your entire facility. It can do this automatically, with limited additional management oversight or work from employees. FactoryTalk AssetCentre can impact uptime, productivity, quality, employee safety or regulatory compliance (Rockwell Automation, 2016).
Inadequate resources to host the new applications and systems. Considerations must be made on additional power, network and storage requirements. Technologies such as M2M (machine to machine), manufacturing 4.0, industrie 4.0 contribute significantly to these additional requirements. Gartner, Inc. forecasts that 6.4 billion connected things will be in use worldwide in 2016, up 30 percent from 2015, and will reach 20.8 billion by 2020. In 2016, 5.5 million new things will get connected every day (Gartner, 2015). Resource constraints may make it impossible to add new applications and systems.	The use of virtualisation, cloud computing, infrastructure as a service (IAAS), software as a service (SAAS) to meet the demand for IT services. The large scale emergence in the last decade of various cloud solutions, ranging from software-as-a-service (SaaS) based solutions for business process management and implementation to very sophisticated private cloud solutions capable of high performance computing (HPC) and efficient virtualization, constitute the building blocks for engineering the next generation of flexible enterprise systems that can respond with great agility to changes in their environment (Morariu, et al., 2015)

2.5.7. The role of the OPC in the connected enterprise

OPC is the interoperability standard for the secure and reliable exchange of data in the industrial automation space and in other industries.

"An OPC server can communicate data continuously among PLCs on the shop floor, RTUs in the field, HMI stations, and software applications on desktop PCs. Even when the hardware and software are from different vendors, OPC compliance makes continuous real-time communication possible" (Kepware Technologies, 2015, p. 1).

OPC is therefore key for data acquisition from the factory floor control systems such as facilitating the transfer of manufacturing batch information from the factory floor control systems to the enterprise systems. An example of how data flows from a PLC to a URL (universal resource locator) for eventual viewing by the various stakeholders throughout the organisation is illustrated in *Figure 2.5*.

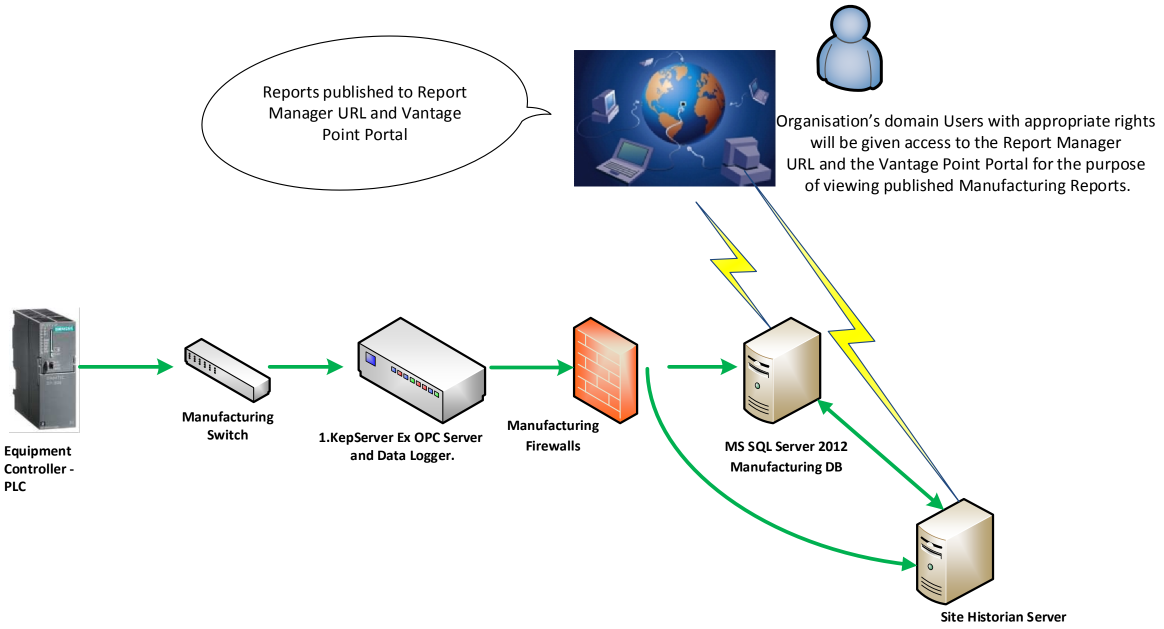


Figure 2.5 - Data flow from PLC to user's web browser within organisation.

2.5.8. Aligning manufacturing standards for the connected enterprise

ISA-95.01 provides the best solution for a manufacturing firm to align its standards thus enabling the establishment of the connected factory. "*ISA decided in the 1990s to develop a standard for integrating enterprise and control systems in order to reduce the risks, costs, and errors that go hand in hand with implementing interfaces between such systems* (Scholten, 2007, p. 27). ISA-95.01 is the standard and ISA 95 was the committee that was set up to develop the standard.

ISA-95.01 defines 5 levels for the hierarchical organisation of manufacturing enterprises. These are summarised in *Table 2.6*.

Table 2.6 - ISA-95.01 Levels

ISA-95 Level	**Description**
Levels 0, 1 and 2	Represent the process control levels and their objective is to control the physical shop floor equipment in order to execute the actual production operations that result in one or more finished products.
Level 3	This is the MES level and consists of several activities that have to be executed in order to prepare, monitor and complete the production process executed at level 0, 1 and 2. These activities are scheduling, quality management, maintenance, production tracking, and others depending on the specifics of each enterprise.
Level 4	Level 4 is the ERP level, where financial and logistic activities are executed. These activities are not integrated in real time to the production and include: long term planning, marketing and sales, procurement, and so on.

Source adapted from, (Morariu, et al., 2015).

2.6. OT and IT in the Irish pharmaceutical industry.

2.6.1. Overview of typical pharmaceutical manufacturing operations.

The manufacturing operations at the Dublin pharmaceutical company typify what is expected in terms of manufacturing processes for drug powder products such capsules or tablets. *"These processes are referred to as batch manufacturing processes and have distinct processing steps, conducted on a quantity of material" (Stouffer, et al., 2011, pp. 2-2)*. *Figure 2.6* shows typical drug manufacturing processes — processes which should be executed in a GMP Environment.

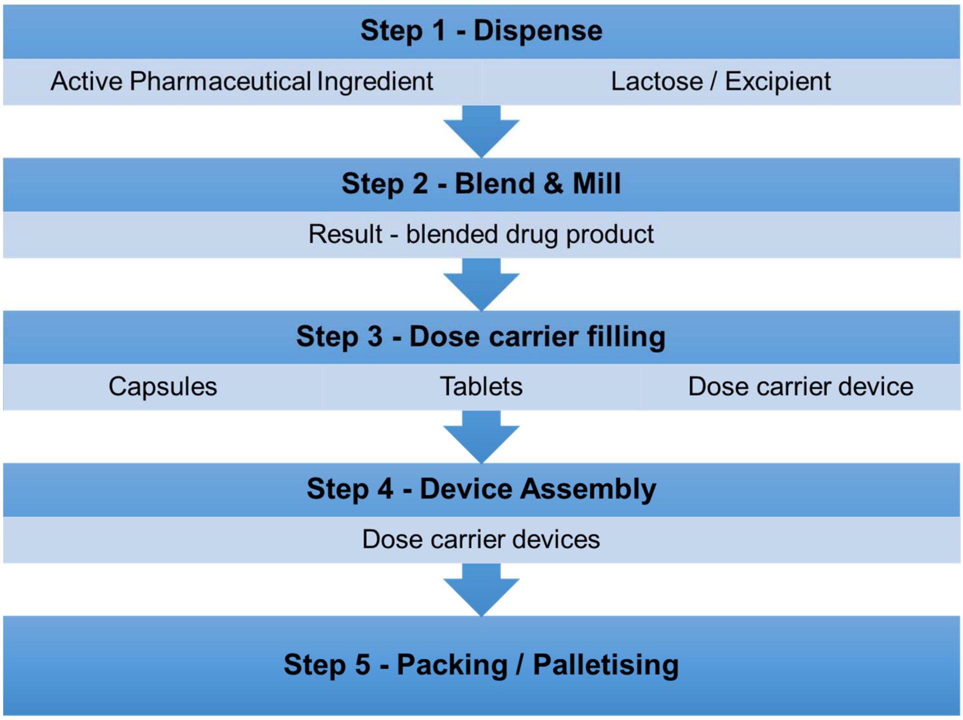


Figure 2.6 - Typical Pharmaceutical Manufacturing Processes

Batch processing for pharmaceutical manufacturing processes is mostly based on the ISA 88 standard which describes the philosophy for the design of equipment and processes. Some of the various components of ISA 88 are summarised in *Table 2.7*.

Table 2.7 - Summary description of various ANSI/ISA components

ANSI/ISA Component	Description
ANSI/ISA-88.01-2010 Batch Control Part 1	Models and terminology
ANSI/ISA-88.00.02-2001 Batch Control Part 2	Data structures and guidelines for languages
ANSI/ISA-88.00.03-2003 Batch Control Part 3	General and site recipe models and representation
ANSI/ISA-88.00.04-2006 Batch Control Part 4	Batch Production Records

Source (ISA, 2015).

"As pharmaceutical manufacturers implement automated electronic systems, such as a manufacturing execution system (MES) and electronic batch records (EBRs), there is an increasing need to simplify communication between process systems to improve manufacturing efficiency" (Markarian, 2015, p. 70). Communication between the various manufacturing equipment for the processes; dispensing, blend/mill, capsule/device fill/tableting, assembly and packaging is paramount to the establishment of the connected enterprise. *"ISA-88 can act as a common language to enable people and systems to work collaboratively to implement automated batch systems"* (Markarian, 2015, p. 71).

2.6.2. Existing IT/OT landscape: Case of the Dublin pharma company

The organisation went through several acquisitions and is now owned by a MNC. Some of the original manufacturing equipment from previous acquisitions utilises legacy control systems. Other batch manufacturing equipment operate as standalone entities. This equipment operates independent of other systems and is not connected to any other systems. To ensure that the benefits of the connected enterprise cascade throughout the organisation, there has to be connectivity between such equipment, other OT and the enterprise systems.

Implementation of new technologies for the Dublin pharmaceutical manufacturing company involves the use of the life cycle approach. *"A life cycle approach entails defining and performing activities in a systematic way from conception, understanding the requirements, through development, release, and operational use to system retirement"* (ISPE, 2008, p. 25). *Figure 2.7* shows a general specification, design and verification process which can be used to provide regulatory compliance guidelines during the implementation of new systems for pharmaceutical manufacturing companies.

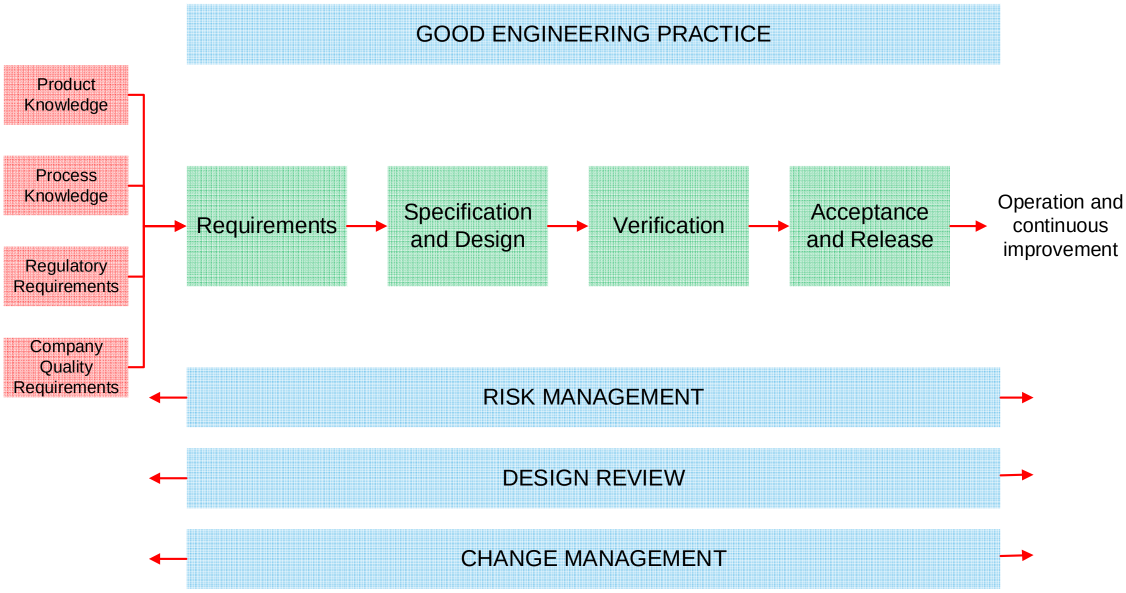


Figure 2.7 - The Specification, design and verification process

Source adapted from, (ISPE, 2008) .

Based on non- behavioural observational analysis of the existing physical processes within the case study organisation, the ISA-95.01 hierarchical model is the standard used for system integration.

It should also be noted that the ISA99 standard which focuses on security for industrial automation and control systems is also in use for the company. The ISA-95 and the ISA99 model are fundamentally the same with the exception that one focusses on integration while the other focuses on security. *Figure 2.8* shows a plant logical framework using the ISA99 model.

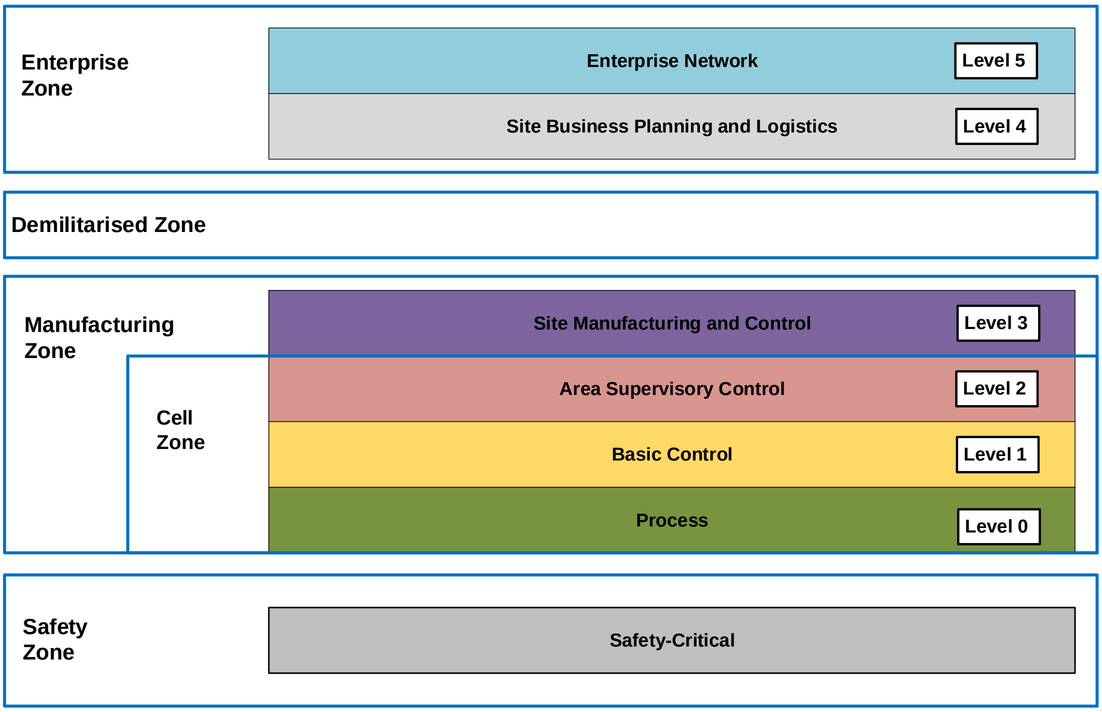


Figure 2.8 - ISA99 Plant logical framework

Source adapted from (ISA, 2016).

The issue of data integrity and security of the manufacturing and enterprise systems is of utmost importance. This is more so in a highly regulated environment such as the pharmaceutical industry. The ISA99 Committee addresses industrial automation and control systems whose compromise could result in any or all of the situations shown in Table 2.8.

Table 2.8 - Adverse consequences of information security breach

Endangerment of public or employee safety
Loss of public confidence
Violation of regulatory requirements
Loss of proprietary or confidential information
Economic loss impact on national security

Source adapted from (ISA, 2016).

To augment the security measures implemented as a result of the segregation of the manufacturing network and the enterprise network, the company has further introduced VLANs within the manufacturing network. What is implies is that each manufacturing cell has got its own VLAN which provides further insulation and segmentation. The availability of modern managed network switching infrastructure has facilitated this.

2.6.3.A review of the future outlook for IT/OT in healthcare manufacturing

"Manufacturing in 2050 will look very different from today, and will be virtually unrecognisable from that of 30 years ago" (The Government Office for Science, 2013, p. 6). (Vyatkin, et al., 2007, p. 17), posit that, *"manufacturing equipment is becoming more autonomous and intelligent".* This will help ensure that systems can handle agile production requirements.

Other subject matter experts and industry champions have also predicted that, "*the upcoming industrial revolution will be triggered by the Internet, which allows communication between humans as well as machines in Cyber-Physical-Systems (CPS) throughout large networks* " (Brettel, et al., 2014, p. 37). According to (Hu, 2015, p. 1), this CPS is, *"a system with a tight coupling of cyber and physical objects".*

The subsequent question is: what does this mean for OT?

The PLC has been shown to be one of the key devices for OT. This dissertation discussed the evolution of the PLC and it was noted that the PLC replaced the relay in industrial control. *Section 2.5.4* looked at the use of the PC in ICSs and noted how PC based applications are better for certain functions. This and the fact that the PC can also be programmed using traditional PLC programming languages makes the PC attractive to system integrators. Thus it is no wonder that some people are beginning to write obituaries for the PLC. However, the application usage for this technology shows that it will be around for a while longer. Industry analysts at ARC Advisory Group[1] and VDC Research[2]'s estimations on PLC usage are shown in *Table 2.9*.

[1] Founded in 1986, ARC Advisory Group is the leading technology research and advisory firm for industry and infrastructure (VDC Research, 2016).
[2] VDC Research is a leading M2M market intelligence and advisory firm for technology suppliers and engineering leaders (VDC Research, 2016).

Table 2.9 - Industry PLC usage

80% usage is for small applications (1 to 128 Input / Output points)
78% of PLC Input / Output handling is digital (no complex analogue signals to process)
80% of PLC application challenges are solved with a set of 20 ladder-logic instructions

Source adapted from (Weil, 2015).

According to (Weil, 2015, p. 1), the statistics in *Table 2.9, "support what some have called an 80/20 rule: if 80% of applications incorporate simple digital and analogue control, the boundaries of control applications are being pushed by a 20% minority"*. Implying that for the foreseeable future, the PLC will still play an important role in the connected enterprise.

Every piece of technology is bound to be superseded by newer technology and the PLC will be no exception to this. The use of PACs is an example of this. The fact that PACs can be programmed with open source software is one significant advantage they have over PLCs. Also, *"a PAC is geared more toward complex automation system architectures composed of a number of PC-based software applications, including HMI (human machine interface) functions, asset management, historian, advanced process control (APC), and others"* (Payne, 2013, p. 1). All of these software applications are now standard requirements for pharmaceutical manufacturing processes.

The replacement of the PLC with the PAC or the PC represents changes at factory floor operations level. In addition to this, there are other future key characteristics and technologies which are going to have a significant impact on manufacturing processes. Some of these drivers are:

a) Industrie 4.0

"The term Industrie 4.0 or Industrial Internet refers to, the fourth paradigm shift in production, in which intelligent manufacturing technology is interconnected. The first three were mechanization (steam engine), electrification (conveyor belt), and computerization (programmable logic controller / PLC)" (Bosch Software Innovations GmbH, 2015, p. 4).

At the IoT world conference held in Berlin in the autumn of 2015, Ernst Stöckl-Pukall of Germany's Federal Ministry for Economic Affairs and Energy (BMWi) presented the objectives of Industrie 4.0 shown in Table *2.10*:

Table 2.10 - Industry 4.0 Objectives

Innovative small and medium-sized companies as incitement of Germany's economic growth
Digitalization merges engineering sector with ICT-industry
Strong engineering and production industry sets excellent basis for the digitalization of the German economy

Source adapted from (Stöckl-Pukall, 2015, pp. 1-14).

From a German government's perspective, Industrie 4.0 is about preparing Germany for the digitalisation era. This public private initiative has an influence on manufacturing processes within the Irish pharmaceutical manufacturing industry because a considerable number of OEMs and software suppliers for this industry are based in Germany. At the Interpack Trade Fair of 2014, German companies such as Werum IT Solution AG were well represented. Werum IT Solution AG describes itself as, *"the world's leading supplier of manufacturing execution systems (MES) and manufacturing IT solutions for the pharmaceutical and biopharmaceutical industries"* (Werum IT Solutions AG, 2016, p. 1). Werum IT lists some of its clients as Allergan, Amgen, Bayer Healthcare, Teva and Johnston & Johnston. These healthcare manufacturing companies are major players in Irish healthcare manufacturing. The close relationship between Irish healthcare manufacturing and the German OEMs/ software suppliers implies that innovations related to Industry 4.0 will eventually cascade down to manufacturing operations of Irish healthcare companies.

b) Internet of Things (IoT)

A key feature of future manufacturing with healthcare manufacturing being no exception will be the Internet of Things (IoT). Industrial IoT will be of particular significance to future manufacturing practices and can be described as, *"An internet of things, machines, computers and people enabling intelligent industrial operations and using advanced data analytics for transformational business outcomes"* (Machina Research, 2015, p. 1). *"Currently, IoT technology and business models that utilize IoT are immature, with a minority of enterprises experimenting with the technology"* (Tully, 2015, p. 1). Gartner's hype cycle for emerging technologies for 2015 shows IoT reaching the plateau of productivity in 5 to 10 years' time as of July 2015 (Gartner, 2015, p. 1).

IoT and Industrie 4.0 are closely related phenomena. Industrie 4.0 focusses on digitalisation of industry which in itself is a key component of IoT. For healthcare manufacturing companies what this means is that establishing the connected enterprise by focussing on the adaptation of practices such as Industrie 4.0 in manufacturing processes is, in effect, a significant step in the implementation of IoT within the organisation.

c) Cloud based solutions

Industrie 4.0 and IoT result in the generation of Big Data. At the IoT World Conference, Berlin, 2015, Charles Cai of British Petroleum (BP) presented a use case for IoT. The case involved a Parkinson disease patient undergoing a new drug trial who was required to wear an IoT enable device to monitor patient behaviour during the drug trial. The use case showed that approximately 1GB of data is generated per patient per day. With the gradual adaption of Industrial IoT in manufacturing such as the use of smart sensors on manufacturing lines to aid predictive rather that preventative maintenance, the secure storage of such vast amounts of data has to be considered. As such, cloud based solutions - which offer more flexibility and agility - will become prevalent in future manufacturing applications. *"Industrial clouds will supply all kinds of manufacturing services and realise the open collaboration between manufacturing resources and services, as well as to enable a high degree of social resource sharing"* (Yue, et al., 2015, p. 2). For the case of the Dublin pharmaceutical manufacturing company, applications such as the LMS and the DMS are already hosted on cloud based platforms. *"The vast computation and storage resources available in the cloud that can scale out or up to the needs of the specific application, provide a motivating factor for the utilisation of cloud computing in industrial scenarios"* (Leita, et al., 2015, p. 6).

d) Data Analytics

With the vast amounts of transactional data available, it is becoming of strategic importance for manufacturing companies to assess their data analytical maturity and take appropriate steps to ensure that they can leverage success from these various data sources. In the case of the Dublin pharmaceutical manufacturing company, this involved recruiting IT Business Analysts for the MES and the ERP system. During the recruitment process, attention was paid to the candidate's IT and OT expertise. This process was carried out accordingly because it was considered that a business analyst who understands these technologies is better placed to utilise analytical methods to examine the manufacturing data available from IT and OT sources such as MES, PLCs and SCADA systems.

2.7. Conclusion.

The previous sections in this chapter have reviewed literature which was considered key to understanding how the evolution of OT has increasingly supported the implementation of the connected enterprise. The literature has demonstrated that this support offered by OT in the establishment of the connected enterprise is due to its increasing ability to converge with IT.

The literature review began with an examination of the historical background of automation. A brief review of some of the pioneers in automation was presented. Factors affecting the accelerated development of automation in the mid-19th century were discussed. Literature also revealed that this development of automation in the early to mid-20th century encountered some challenges such as the union labour problem.

An outline of some features of modern ICSs was provided. The literature revealed that PLCs and Fieldbus technology are still important facets of modern ICSs. The evolution of PLCs and Fieldbus technology was analysed from various literature sources. A review of the emergence of the PC in industrial manufacturing and its current usage in industry was carried out. In order to understand the terms IT and OT in the proper perspective, *Section 2.5.5* reviewed literature which compared the fundamental differences between these two technologies.

Challenges and opportunities presented by OT systems were examined. The literature introduced ISA-95.01 as a standard which can be used by a manufacturing organisation for guidance to align its own standards for the successful implementation of the connected enterprise.

The research literature has examined IT and OT as it relates to the pharmaceutical industry. ISA 88 standard which describes the philosophy for the design of equipment and processes was reviewed and its usage for the case study organisation was examined. The observation approach taken for this case study research which involved monitoring of non-behavioural conditions (outlined in *Section 3.10*), was used to analyse the existing IT/OT landscape. The case of the research organisation was considered. Research literature on the future outlook for IT and OT in health care manufacturing was analysed. Concepts such as Germany's Industrie 4.0 and IoT were introduced as key subjects for future healthcare manufacturing.

3. Research Methodology and Fieldwork

3.1. Introduction

The purpose of this chapter is to discuss the research methodology considered for this research. This includes justification as to why the approach taken to gather the data is considered ideal for addressing the research question. This chapter outlines the research philosophy adapted, the approach used for theory development, the methodological approach, the research strategies implemented and a review of the time dimension aspect of the research. Rationale for the selection of the research instrument is provided. This includes a review of the types of data used, the stability and reliability of the data. A review of the triangulation aspect of the research, the secondary sources of data, as well as the data analysis methods used is done. An outline of the ethical considerations, neutrality and engagement with the participants is also provided. A discussion on the limitations of the research methodology and fieldwork approach taken as well as lessons learnt is provided before the conclusion for this chapter.

3.2. Research objectives

The research objective is to identify the state of preparedness to the adaptation of the connected enterprise by a significant player in the Irish healthcare manufacturing industry. It is hoped that the data will help to answer the question as to how the connected enterprise which has been established as a result of the convergence of OT and IT can be successfully implemented within the Irish healthcare industry and how this successful implementation can be sustained to ensure that the organisation achieves its strategic business objectives.

3.3. Data collection technique and analysis procedure approach

The technique to collect the research data and the procedural approach used to analyse the data is adapted from what (Saunders, et al., 2016, p. 124) referred to as the research “onion”. *Figure 3.1* shows an adapted version of the research onion which shows the constituents of the various layers utilised during the course of this research.

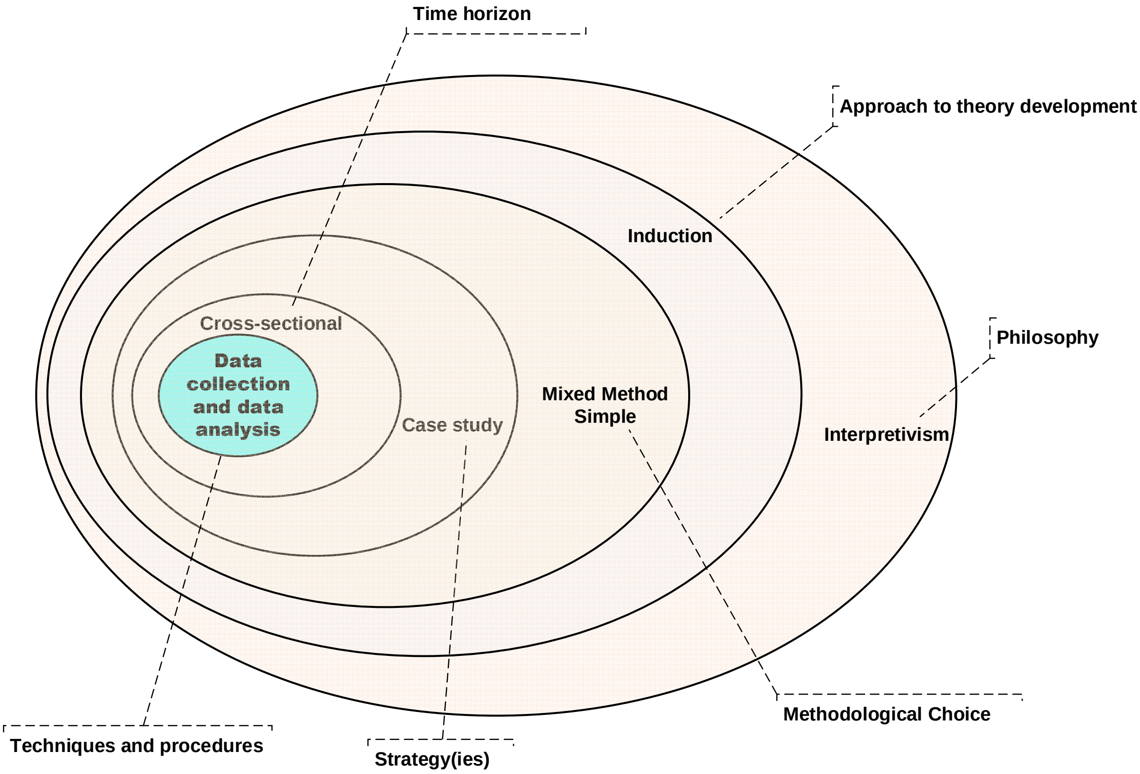


Figure 3.1 - Adaptation of the research onion for this research

Source adapted from, (Saunders, et al., 2016).

The choice of this research approach was found to be appropriate as it provides an unambiguous illustration of the various layers that need to be clearly understood and considered during the various stages of the research.

(Cooper & Schindler, 2003, p. 146), point out that, *"a number of different design approaches exist but, unfortunately, no simple classification system defines all the variations that must be considered"*. Considering this important observation, other research design classifications were reviewed. (Cooper & Schindler, 2003, p. 147)'s classification of research design using 8 different descriptors shown in *Table 3.1* also contributed to the research design.

Table 3.1 - Descriptors of research design

Category	Options
The degree to which the research question has crystallized	• Exploratory Study • Formal Study
The method of data collection	• Monitoring • Interrogation/communication
The power of the researcher to produce effects in the variables under study.	• Experimental • Ex post facto
The purpose of the study	• Descriptive • Causal
The time dimension	• Cross- sectional • Longitudinal
The topical scope-breadth and depth-of the study	• Case • Statistical study.
The research environment	• Field setting • Laboratory research • Simulation
The participants' perceptions of research activity	• Actual routine • Modified routine

Source adapted from, (Cooper & Schindler, 2003).

3.4. Research philosophy

The research philosophy is the outer layer of the research "onion" shown in *Figure 3.1*. To arrive at the research philosophy, (Saunders, et al., 2016, p. 127) posit that there are, *"three types of research assumptions to distinguish research philosophies: ontology, epistemology and axiology"*.

3.4.1. Research assumptions

a) Ontology

"Ontology refers to the assumptions about the nature of reality", (Saunders, et al., 2016, p. 127). This research design was influenced by (Saunders, et al., 2016, p. 127)'s position that, *"your ontological assumptions shape the way in which you see and study your research objects"*. The lack of known international research on the research topic and the fact that the connected enterprise represents the next generation of manufacturing created ontological assumptions used to arrive at the research question. Examples of questions with ontological connotations which were used to determine the research philosophy are;

- *Is the organisation prepared for the connected enterprise?*

- *How does the organisation approach the integration of the enterprise systems with the manufacturing systems in a safe and secure manner*?

b) *Epistemology*

Epistemology refers to, *"what constitutes acceptable knowledge"* (Saunders, et al., 2016, p. 136). In an effort to answer the research question, various sources of knowledge were used. This included empirical sources which were utilised to arrive at the research findings. Objective and subjective views as they relate to the epistemology assumption are shown in *Table 3.2*.

Table 3.2 - Objective and subjective views using the epistemology assumption

Epistemology		
Objectivism	↔	**Subjectivism**
Adopt the assumptions of the natural scientist	↔	**Adopt the assumptions of the arts and humanities**
Facts	↔	**Opinions**
Numbers	↔	**Narratives**
Observable phenomena	↔	**Attributed meanings**
Law-like generalisations	↔	**Individuals and contexts specifics**

Source adapted from, (Saunders, et al., 2016).

c) *Axiology*

Axiology refers to, *"the role of values and ethics within the ethics process"* (Saunders, et al., 2016, p. 128). Assumptions made about this important aspect shape the way in which the research is conducted. Further information related to the role of values and ethics is provided in *Section 3.12.*

3.4.2. Outline of the five major research philosophies

According to (Saunders, et al., 2016), there are five major paradigms of research thinking.

a) *Positivism.*

(Giddens, 1987, pp. 2-21), explains that, *"when a scientific approach is called positivist today, what is usually meant is that it attempts to understand minds, humans, or societies using methods from the natural sciences, purporting to maintain a strict value-neutrality"*. Emphasis should be on neutrality implying that the researcher should, *"undertake the research, as far as possible, in a value-free way"*, (Saunders, et al., 2016, p. 137). This philosophy was not adapted for this research because the researcher is an employee of the research study organisation. Furthermore, this approach requires a large sample size which was not going to be achievable due to time constraints.

b) Critical realism.

"The philosophy of critical realism focuses on explaining what we can see and experience, in terms of the underlying structures of reality that shape the observable events" (Saunders, et al., 2016, p. 138). This philosophical approach was considered not appropriate for this research as it was felt that in order to better understand how the convergence of IT and OT can successfully enable the implementation of the connected enterprise, the research also had to investigate the causal structures and mechanisms as opposed to looking at only the actual events or non-events within the organisation. This is despite the fact that the research study is descriptive in nature as it attempts to address the *'how'* question.

c) Pragmatism

Pragmatism was considered as a research philosophy because it, "*strives to reconcile both objectivism and subjectivism, facts and values, accurate and rigorous knowledge and different contextualised experiences"* (Saunders, et al., 2016, p. 143). Considering this definition, it can be argued that the pragmatic approach could work if it were adopted for this research as both objectivism and subjectivism feature in the research.

d) Postmodernism

"Postmodernism emphasises the role of language and power relations, seeking to question accepted ways of thinking" (Saunders, et al., 2016, p. 143). Although this philosophy was considered, it was felt that it offered a radical approach to addressing the research question. To ensure that there was acceptance from the business for the case study to take place, no controversial or confidential questions were asked to the participants. Postmodernism, requires thorough investigations of anomalies. Such thorough investigations would require review and approval from the organisation's legal department, a procedure which can take months to be completed successfully.

e) Interpretivism

Interpretivism was the research philosophy chosen for this research. .

3.4.3. Interpretivism as the research philosophy of choice

In coming up with the choice of the interpretivist philosophical approach, this research considered the research assumptions as outlined by (Saunders, et al., 2016). These assumptions and the typical research methods used are summarised in *Figure 3.2.*

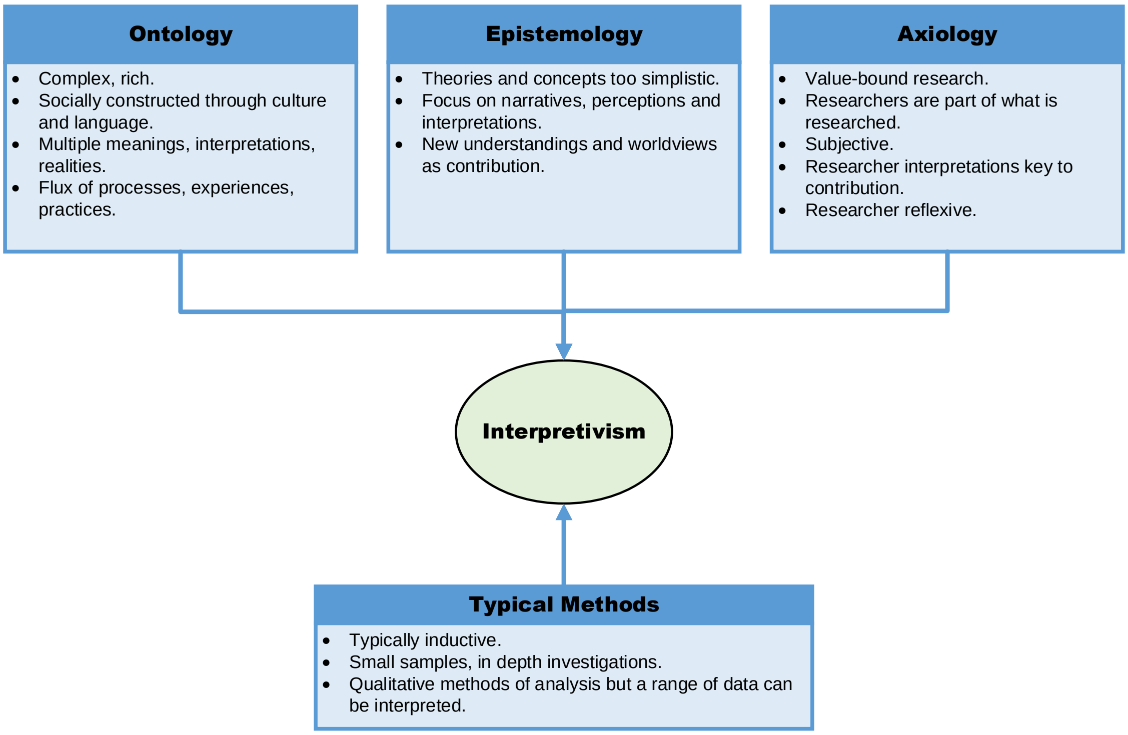


Figure 3.2 - Interpretivism research philosophy

Source adapted from, (Saunders, et al., 2016).

(Darke, et al., 1998, pp. 273-289), mentions that, "*The interpretivist attempts to gain a deep understanding of the phenomena being investigated, and acknowledges their own subjectivity as part of this process"*. In recognition of this fact, a potential conflict of interest was declared by the researcher prior to consent for participation being sought from the research study participants. Furthermore, the fact that the researcher works for the organisation being studied implies that the researcher is an active part of the research.

"The purpose of the interpretivist research is to create new, richer understandings and interpretations of social worlds and contexts" (Saunders, et al., 2016, p. 140). For this research, various views on the connected enterprise were sought from employees who work in different departments of the research organisation. One of the key objectives of the research is to add to the body of knowledge which currently exists on the implementation of the connected enterprise which is brought about by the convergence of IT and OT.

3.5. Theory development approach

Having peeled away the first layer of the research "onion" *and* in so doing determined that Interpretivism should be the research philosophy for this research, the next step was to determine the appropriate approach to developing the research theory. The inductive approach was considered as the most appropriate option as it involves collecting information on the organisation being studied though its employees and drawing conclusions from the observations. This approach is consistent with, (Holland, et al., 1989, p. 1)'s postulate that induction is taken to, *"encompass all inferential processes that expand knowledge in the face of uncertainty"*. The consideration to use the inductive approach was driven by the fact that the data derived from the case study can provide inferential statistical data when it is applied to other similar organisations in the Irish healthcare manufacturing industry.

On the other hand, *"with deduction, a theory and hypothesis (or hypotheses) are developed and a research strategy designed to test the hypothesis"* (Saunders, et al., 2016, p. 152). This research study did not commence with a theory or hypothesis which is the primary reason why the deductive approach was considered not appropriate for this research. (Johnson-Laird & Byrne, 1991, p. 3), suggest that deductions are made, "*in order to pursue arguments and negotiations; to weigh evidence and to decide between competing theories".*

3.6. Methodological choice

Both quantitative and qualitative methods were examined for the methodological choice. Ultimately a mixed method was considered the most ideal methodological choice. (Saunders, et al., 2016, p. 169), mention that mixed methods combine, "*the use of quantitative and qualitative data collections techniques and analytical procedures"*.

"Qualitative methods of data collection typically include in-depth interviews with key subjects, extended periods of observation by researchers, and various forms of the document analysis" (Buchanan & Bryman, 2011, p. 130). To facilitate the exploratory nature of qualitative investigations, respondents were provided with the option to enter "other" answers in their own words to questions posed. In addition to this, the last question in the instrument used for data collection was an open ended question in which the participants were asked to add their own views or opinions on the research subject.

While qualitative refers to meaning, quantitative is about numbers. (Saunders, et al., 2016, p. 166), state that, "*quantitative research is generally associated with positivism".* However, in addition to seeking attribute data on the organisation, the research also sought, "data based on opinions, sometimes referred to as 'qualitative numbers'. According to (Saunders, et al., 2016, p. 166), *"in this way, some survey research while conducted quantitatively, may be seen to fit in the interpretivist philosophy"*.

Other existing documents within the case study organisation such as network diagrams, electrical schematics, PLC code and SCADA configurations were analysed as part of the qualitative gathering of data.

3.7. Research strategies

The research strategies as posited by (Saunders, et al., 2016) were reviewed and most were considered not applicable for varying reasons:

- *Experiment* - The method of the experiment could not be easily determined.
- *Archival research* - There is no archival data nor was there a theory developed on the research topic.
- *Narrative* - There were no narrative sources of data such as stories, notes or recorded conversations to base the research on.
- *Ethnography* - The human behavioural or cultural preferences did not feature.
- *Action research* - The implementation of the connected enterprise which is brought about by the convergence of IT and OT can be a long drawn out process for any organisation. This research is not aiming to address any immediate problems related to the research topic as would be a key feature of action research.
- *Survey* - *"Survey studies involve researchers soliciting information from a relatively large number of individuals, either in a personal capacity or as representatives of an organisation or a subgroup within an organisation"* (Jones, 2014, p. 21). Due to time limitations for the research study, a large number of participants of the research would not have been achievable.

The case study research strategy was considered to be the most likely to provide both quantitative and qualitative data from the participants within a limited time frame.

3.7.1. Case Study

"A case study is useful when a researcher considers an existing phenomenon in its real life context where there is no clearly defined boundary between the subject of the study and its context" (Yin, 2014). *Figure 3.3* which is a brainstorming diagram shows some of the facets of the case study strategy design which underpins their suitability for organisational research using empirical methods.

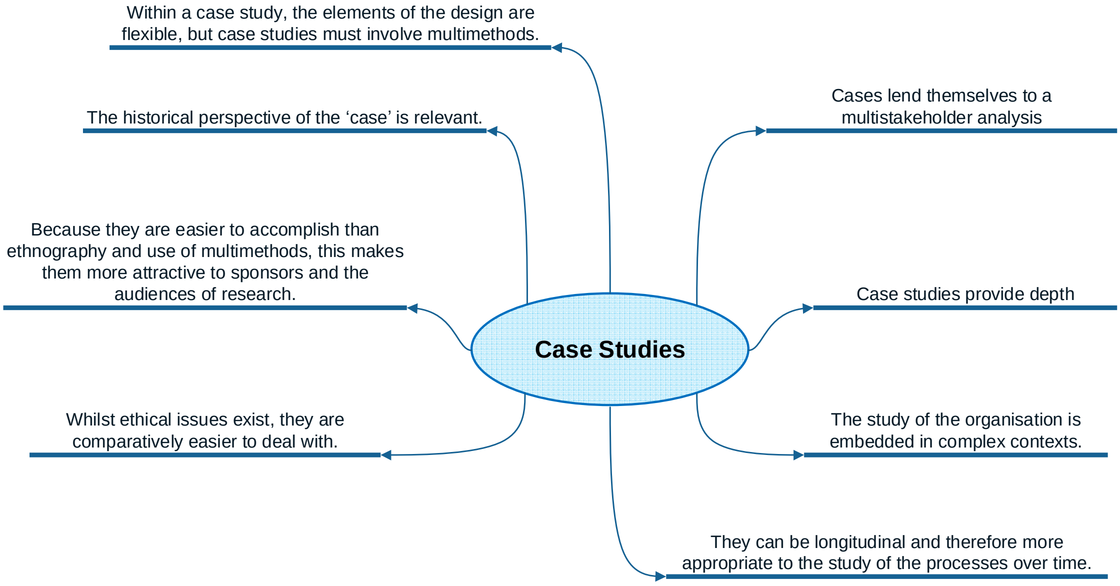


Figure 3.3 - Features of case study research strategy useful to organisational research

Source adapted from, (Buchanan & Bryman, 2011).

A multidimensional picture of the case being studied can be considered one of the key aims of a case study. As such, the connected enterprise within the case study organisation was looked at from an OT perspective as well as an IT perspective*.* *Chapter 0* provides an important source of secondary data. In addition to this, personal views were sought from employees who work in different departments within the organisation.

In addition to the considerations shown in *Figure 3.3*, time limitations for the research study also made a case study research the preferred research strategy. The fact that the researcher works for the case study organisation implies that a case study research could be done on a part-time basis with easier access to the primary data sources within the organisation.

One of the key objectives of this research is to add to the existing body of knowledge which exists on the implementation of the connected enterprise. From the onset of the research study, it was never expected that there would be ground breaking discoveries as a result of the research study. This is synonymous with a case study research.

3.8. Time horizon

The time horizon also referred to as the time dimension is made up of 2 types of research studies. Cross-sectional studies are carried out once and represent a snapshot of a point in time. "*Longitudinal studies are repeated over an extended period*" (Cooper & Schindler, 2003, p. 149). For this research study, the cross-sectional time dimension was considered primarily due to time constraints for the research study. A longitudinal study would be appropriate if the global business units within the organisation were being considered and the research study was carried out over a longer period of time.

3.9. Measurement instrument

This research utilised an online questionnaire administered through SurveyMonkey as a data collection method. SurveyMonkey is an online survey development company. This method of data collection was considered to meet the primary goal of organisational research which is to, *"obtain high-quality data that are reliable and valid and that accurately reflect the beliefs and attitudes of the target population*" (Buchanan & Bryman, 2011, p. 451).

3.9.1. Pilot study

A pilot test was conducted, *"to detect weaknesses in design and instrumentation"* (Cooper & Schindler, 2003, p. 86). The questionnaire was created on the 17th of September 2015. The questionnaire went through several revisions as various experts in IT, manufacturing and OT were asked to comment on the, *"representativeness and suitability"* (Saunders, et al., 2016) of the questions. In addition to this, valid comments on the questionnaire were received from the SCSS Research Ethics Committee of Trinity College Dublin prior to the parent survey being sent out to the participants.

As part of the pilot study, the questionnaire was sent to forty participants who work for various Irish healthcare manufacturing companies. The participants were chosen at random from social media platforms such as *LinkedIn*. The main reason for the choice of participants who do not work for the case organisation was to ascertain if a comparison of the data could be made. If there was compatibility, then the parent survey data could be used as inferential data. This implies that the data from the parent survey could be used to represent expected findings if respondents from a larger sample involving several similar organisations had been involved in the survey.

3.9.2. What was measured?

The objects studied as part of this research are employees of the Dublin pharmaceutical manufacturing company. Employees from; manufacturing; IT; quality and validation services; engineering (OT); supply chain and finance completed the online questionnaire. Properties which are the characteristics of these objects were then investigated using the online questionnaire.

3.9.3. Types of data gathered

"Measurement in research consists of assigning numbers to empirical events in compliance with a set of rules" (Cooper & Schindler, 2003, p. 220). The result of this measurement is several types of data which are summarised in *Table 3.3.*

Table 3.3 - Types of Data and their measurement characteristics

Types of Data	Characteristics of Data	Basic Empirical Operation	Example
Nominal	Classification but no order, distance or origin	Determination of equality	Gender (male, female)
Ordinal	Classification and order but no distance or unique origin	Determination of greater or lesser value	OT Expertise (novice, proficient, expert)
Interval	Classification, order, and distance but no unique origin	Determination of equality of intervals or differences	Strongly agree, disagree, undecided, strongly disagree
Ratio	Classification, order, distance, and unique origin	Determination of equality of ratios	Working experience in years

Source adapted from, *(Cooper & Schindler, 2003)*.

The majority of the data gathered as part of this research was ordinal data. To obtain this type of data, rating scales were used. The research also collected some nominal and ratio data although this was less than 5% of the total data collected.

3.9.4. Response Methods: The use of rating scales

"One uses rating scales to judge properties of objects without reference to other similar objects" (Cooper & Schindler, 2003, p. 252). Various scale types were used in the questionnaire:

a) Dichotomous scale

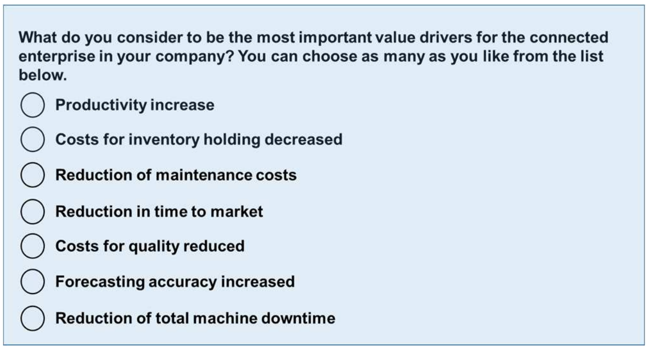
These scales offer two mutually exclusive response types.

b) Multiple choice, single response scale

Where one answer was sought from multiple options, the multiple choice single response scale as used.

c) Multiple choice, multiple response scale

In this case, the respondent was asked to select one or many alternatives from a list provided. An example of the use of this scale is shown in *Figure 3.4.*


What do you consider to be the most important value drivers for the connected enterprise in your company? You can choose as many as you like from the list below.

- Productivity increase
- Costs for inventory holding decreased
- Reduction of maintenance costs
- Reduction in time to market
- Costs for quality reduced
- Forecasting accuracy increased
- Reduction of total machine downtime

Figure 3.4 - Multiple choice, multiple response scale

d) Likert scale

A Likert-style rating question "*allows the respondent to indicate how strongly she or he agrees or disagrees with a statement"* (Saunders, et al., 2016, p. 720). *"Each response is given a numerical score to reflect its degree of attitudinal favourables, and the scores may be totalled to measure the respondent's attitude"* (Cooper & Schindler, 2003, p. 253). Likert scale summated rating was widely used in the questionnaire, particularly when it came to assessing the OT/IT expertise of the engineering and IT employees of the organisation.

3.9.5. Ensuring good measurement

According to (Cooper & Schindler, 2003, p. 231), *"there are three major criteria for evaluating a measurement tool: validity, reliability, and practicality"*. There criteria are summarised in *Table 3.4.*

Table 3.4 - Criteria for evaluating a measurement tool

Criteria	Description
Validity	Refers to the extent to which a test measures what we actually wish to measure.
Reliability	Has to do with the accuracy and precision of a measurement procedure.
Practicality	Concerned with a wide range of factors of economy, convenience and interpretability.

Source adapted from, (Cooper & Schindler, 2003).

One of the key objectives of the pilot study was to, *"seek other relevant evidence that confirms the answers found with a measurement device"* (Cooper & Schindler, 2003, p. 231). The pilot study was also used to gauge the reliability of the questionnaire. *"Reliability is the extent to which data collection technique or techniques yield similar results"* (Saunders, et al., 2016, p. 726). A reliable questionnaire implied that data from the pilot study would be consistent with the data from parent study.

3.9.6. Conduct of the measurement

"*A good questionnaire is dependent on the recipient being motivated to answer the questionnaire and to send it back"* (Saunders, et al., 2016, p. 476). The research was undertaken when the case study organisation was going through changes in the OT/IT landscape such as the implementation of the MES. These changes underpin the connected enterprise, therefore there was interest from the participants to complete the questionnaire as the questionnaire induced a sense of self-reflection with regards to how the participant views their own understanding of the connected enterprise. The questionnaire was delivered via a web link. A covering email was sent to the participants with a link to the questionnaire provided. The timeline for the research questionnaire is shown in *Figure 3.5.*

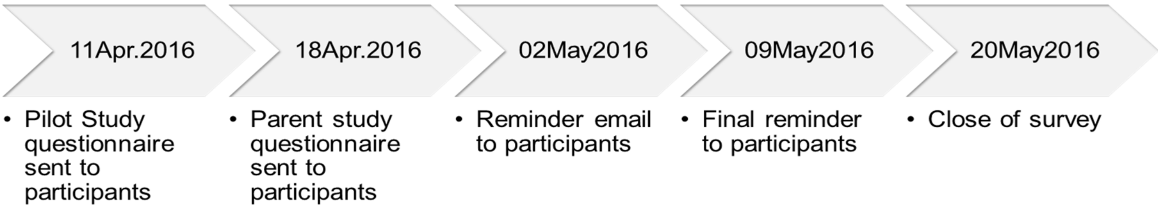


Figure 3.5 - Timeline for research questionnaire

The online questionnaire provided the most practical option considering the time constraints associated with the research study. Another factor which made the online questionnaire a practical option is the minimal cost associated with this data collection instrument.

3.10. Triangulation and secondary data sources

"Triangulation involves using more than one source of data and method of collection to confirm the validity/credibility/authenticity of research data, analysis and interpretation" (Saunders, et al., 2016, p. 207). (Buchanan & Bryman, 2011, p. 468), mention that, *"A case study consists of triangulation of data from several sources, thus, data collected from interviews might be partially validated by observations, archival data or survey data"*. The observation approach taken for this case study research involved the monitoring of non-behavioural conditions within the case study organisation. (Cooper & Schindler, 2003, p. 403), mention non- behavioural observation as involving, *"record analysis, physical condition analysis and physical process analysis"*. For this research study, non- behavioural observation involving physical condition analysis and physical process analysis it relates to the implementation of the connected enterprise was reviewed in *Section 2.6*

"Observation has the advantage of enabling the researcher to access the interactions of organisational members directly, rather than solely by report through an interview with individuals" (Buchanan & Bryman, 2011, p. 469). With this in mind, it was felt that there would be little value addition to the research if interviews were held in addition to using the online questionnaire as the primary data source. Additional unstructured data was obtained from meetings, workshops, seminars and training sessions related to the connected enterprise which were held by the case organisation during the research study period.

This additional source of independent data helped to ensure that the data received from the on-line questionnaire told what the researcher thought it was telling thus achieving triangulation. "*Observation qualifies as a scientific inquiry when it is conducted specifically to answer the research question, is systematically planned and executed, uses proper controls, and provides a reliable and valid account of what happened*" (Cooper & Schindler, 2003, p. 400).

3.11. Analysis of the data

In an effort to answer the research question and by so doing offer an informed opinion on the implementation of the connected enterprise which is brought about by the convergence of IT and OT, the questionnaire was organised into several themes:

Table 3.5 – Research questionnaire themes

Theme	Description
1	The participant's views on the connected enterprise.
2	If the participant works for IT, business intelligence or engineering, their Industrial Automation/OT skills.
3	If the participant works for IT, business intelligence or engineering, their IT skills.
4	If the participant works for IT, business intelligence or engineering, their data management skills.
5	The participant's MES / MOM experience.
6	The participant's ERP skills.
7	Demography questions.

Using the interpretivist research approach, the data from the questionnaire were interpreted and the validity of the data confirmed using secondary data.

3.12. Role of values and ethics

"*Process research often requires researchers to collect rich data in situ. This raises pragmatic and ethical questions that are not always addressed in published articles*" (Buchanan & Bryman, 2011, p. 421). To assure that this was not the case, prior to the research study, formal research ethics committee approval was sought from the SCSS Research Ethics Committee of Trinity College Dublin. (Cooper & Schindler, 2003, p. 400), mentions that, "*whether data are gathered in an experiment, interview, observation, or survey, the respondent has many rights to be safe-guarded. In general, research must be designed so a respondent does not suffer physical harm, discomfort, pain, embarrassment, or loss of privacy*". Included in the submission to the SCSS Research Ethics committee were the following documents:

- The information sheet for the participant explaining the background of the research, an explanation of the respondent's rights and the benefits of the study.
- The participant's informed consent form.

3.13. Limitations of the research methodology and learning outcomes

According to (Saunders, et al., 2016, p. 136), with Interpretivism, *"researchers are part of what is researched", implying that the research study can be, "subjective"*. To mitigate against subjectivity in the research study, ethical considerations were enforced. In addition to this, the data from the parent study were confirmed for validity using the pilot study data and the case study findings. Although the research findings are meant to provide inferential data which may be used for other similar organisations, the use of a single case study strategy did not afford the research study the opportunity to include actual data from other organisations.

An important lesson learnt was not to underestimate the time it takes to complete the research study. As previously mentioned, this research study was undertaken on a part-time basis. To assure that the research study was kept on schedule, a lot of late night and weekend work on the research study had to be done.

Another vital lesson learnt was that if a researcher works for the case study organisation it does not guarantee that participants will respond to the questionnaire in a timely manner. Early approval of the research study by the SCSS Research Ethics committee was instrumental in assuring that there was adequate time for the participants to respond thus mitigating against this potential problem.

3.14. Conclusion

This chapter discussed the research methodology considered for this research study. A justification was provided as to why the approach taken to gather the data is considered ideal for addressing the research question. This chapter outlined the research philosophy adapted, the approach used for theory development, the methodological approach, the research strategies implemented, and a review of the time dimension aspect of the research. Rationale for the selection for the research instrument was provided. This included a review of the types of data used, the stability and reliability of the data. A review of the triangulation aspect of the research, the secondary sources of data, as well as the data analysis methods used was undertaken. An outline of the ethical considerations was also provided in this chapter. A discussion on the limitations of the research methodology and fieldwork approach taken as well as learning outcomes has also been completed. The various elements of the research onion considered for this research are summarised in *Figure 3.1.*

4. Research Findings and analysis

4.1. Introduction

This chapter discusses findings and analysis of the research study. The focus of this chapter is on the provision of an explanation as to how the research data was analysed as well as reporting on what the research study revealed. As detailed in *Chapter 0*, the primary source of the data was an online questionnaire carried out within the case study organisation. Data from the pilot study provides a secondary source of data and is used to validate the data from the primary survey. Additional secondary data is from the open ended questions in the online questionnaire and observational data from the case study organisation. The road map for this chapter is shown *Table 4.1.*

Table 4.1 - Chapter 4 road map

Section	Section Summary
4.2	Provides a demographic profile of the participants.
4.2	The participants' views on the connected enterprise.
4.4	Participants' MES/MOM experience.
4.5	Participants' ERP expertise.
4.6	The findings and analysis of the Automation/OT skills data for the Technical participants is presented.
4.7	The findings and analysis of the Automation/OT skills data for the Technical participants is presented.

4.2. Respondents demographics

4.2.1. Summary of invitations and responses

For the pilot study, 40 email invitations were sent. 20 respondents successfully completed the questionnaire. This represents a 50% response rate for the pilot study. A total of 177 participants were invited for the parent survey within the case study organisation and 74 responses were received which is a 42% response rate. 10 of the 74 responses were disqualified after the respondents selected the option not to submit the response. This implies that the successful completion rate for the parent survey was 86%.

The positive response for both surveys can be attributed to the fact that ample time was allocated towards the pilot and parent surveys. Furthermore, the participants of the parent survey were already conscious of the connected enterprise initiatives due to related ongoing work within the organisation. As such, the connected enterprise was a hot topic within the organisation and any subject on the connected enterprise attracted interest from the organisations' employees.

4.2.2. Responses by department

The responses to the surveys by department are shown in *Table 4.2.*

Table 4.2 - Online questionnaire responses

	Pilot Survey		Parent Survey	
Answer Options	**Response Percent**	**Response Count**	**Response Percent**	**Response Count**
Accounting	0.0%	0	1.6%	1
Administrative	0.0%	0	1.6%	1
Customer Service	0.0%	0	1.6%	1
Marketing	0.0%	0	0.0%	0
Operations	0.0%	0	0.0%	0
Human Resources	0.0%	0	1.6%	1
Sales	10.0%	2	0.0%	0
Finance	0.0%	0	0.0%	0
Legal	0.0%	0	0.0%	0
IT	10.0%	2	7.8%	5
Engineering	70.0%	14	35.9%	23
Validation	10.0%	2	7.8%	5
Research &Development (Tech Services)	0.0%	0	6.3%	4
Quality	0.0%	0	7.8%	5
Business Intelligence	0.0%	0	0.0%	0
Manufacturing	0.0%	0	17.2%	11
Public Relations	0.0%	0	0.0%	0
Other	0.0%	0	10.9%	7
	answered question	**20**		**64**
	skipped question	**0**		**10**

In analysing the results in *Table 4.2,* the majority of the respondents of both surveys are from a technical background. The technical departments represented by IT, Engineering and Technical services are fairly important to the success of the connected enterprise. The views of respondents from these technical departments are key to determining the state of preparedness by the organisation to the adaptation of connected enterprise initiatives.

4.2.3. Working experience of participants

In an effort to determine the maturity of the respondents, the respondents were asked about their working experience. *Table* 4.3 shows the aggregated results.

Table 4.3 - Participants' working experience

	Pilot Survey		Parent Survey	
Working Experience (Years)	Response Percent	Response Count	Response Percent	Response Count
1-5	5.3%	1	4.8%	3
6-10	21.1%	4	17.5%	11
11-15	15.8%	3	25.4%	16
16-20	21.1%	4	23.8%	15
+20	36.8%	7	28.6%	18
answered question		**19**		**63**
skipped question		**1**		**11**

When the results are amalgamated further, the findings show that more than 90% of the respondents of both surveys have more than 5 years working experience. Based on these findings, the respondents can be classified as mature respondents.

4.2.4. Respondents' educational qualifications.

Table 4.4 shows the respondents' educational qualifications.

Table 4.4 - Respondents educational qualifications

	Pilot Survey		Parent Survey	
Working Experience (Years)	Response Percent	Response Count	Response Percent	Response Count
Did not attend school	0.0%	0	0.0%	0
Junior Certificate	0.0%	0	3.3%	2
Leaving Certificate	0.0%	0	6.6%	4
Graduated from college	77.8%	14	65.6%	40
Some graduate school	5.6%	1	4.9%	3
Completed graduate school	16.7%	3	19.7%	12
answered question		**18**		**61**
skipped question		**2**		**13**

The data in *Table 4.4* shows that all the respondents of the pilot study and 97% of the parent survey respondents have attained a minimum of leaving certificate education. Respondents are computer literate which is accentuated by the fact that both surveys were online questionnaires.

4.3. Respondents' views on the connected enterprise

4.3.1. Connected enterprise as a topic for discussion.

Considering the ongoing MES implementation within the case study organisation, the respondents were asked if the connected enterprise topic is currently being discussed within the departments they work in. 70% of the parent survey respondents confirmed that connected enterprise initiatives were being discussed within their departments. For the pilot survey, this figure is 79%. In both cases, the data obtained showed that a large proportion of the respondents are aware of the ongoing efforts to implement or enhance the connected enterprise with initiatives such as the MES for case study organisation. The expectation was that the figure would be much higher than 70% for the case study organisation considering the ongoing MES project.

4.3.2. Organisation's strategic outlook for the connected enterprise.

Respondents were asked to rate how high on the next 5-year agenda and strategic outlook they thought things the connected enterprise initiatives should be in their company. A 5-point Likert rating scale was applied with weights ranging from 1-5; 1 being 'Least important' up to 5 which is 'Most Important'. A weighted average of 4.00 was recorded from both surveys. For both survey data shows that more than 80% of the respondents thought that the connected enterprise is fairly important or most important for the organisation's strategic outlook as summarised in *Table 4.5*.

Table 4.5 - Respondent's views on the strategic outlook for the connected enterprise

How high on the next 5 year agenda and strategic outlook do you think things like the MES and the connected enterprise should be in your company? 1 being the least important and 5 the most important.							
Pilot Survey							
Answer Options	**1. Least Important**	**2**	**3**	**4**	**5. Most Important**	**Rating Average**	**Response Count**
Connected Enterprise 5 year agenda and strategic outlook importance	1	0	2	12	5	4.00	20
						answered question	**20**
						skipped question	**0**
Parent Survey							
Answer Options	**1. Least Important**	**2**	**3**	**4**	**5. Most Important**	**Rating Average**	**Response Count**
Connected Enterprise 5 year agenda and strategic outlook importance	1	1	10	37	14	3.98	63
						answered question	**63**
						skipped question	**11**

4.3.3. Value drivers for the connected enterprise.

Respondents were provided with a multiple choice, multiple response scale type of question in which they were asked to select one or many alternatives from a list of important value drivers for any manufacturing organisation. The data from the surveys is illustrated in *Figure 4.1*.

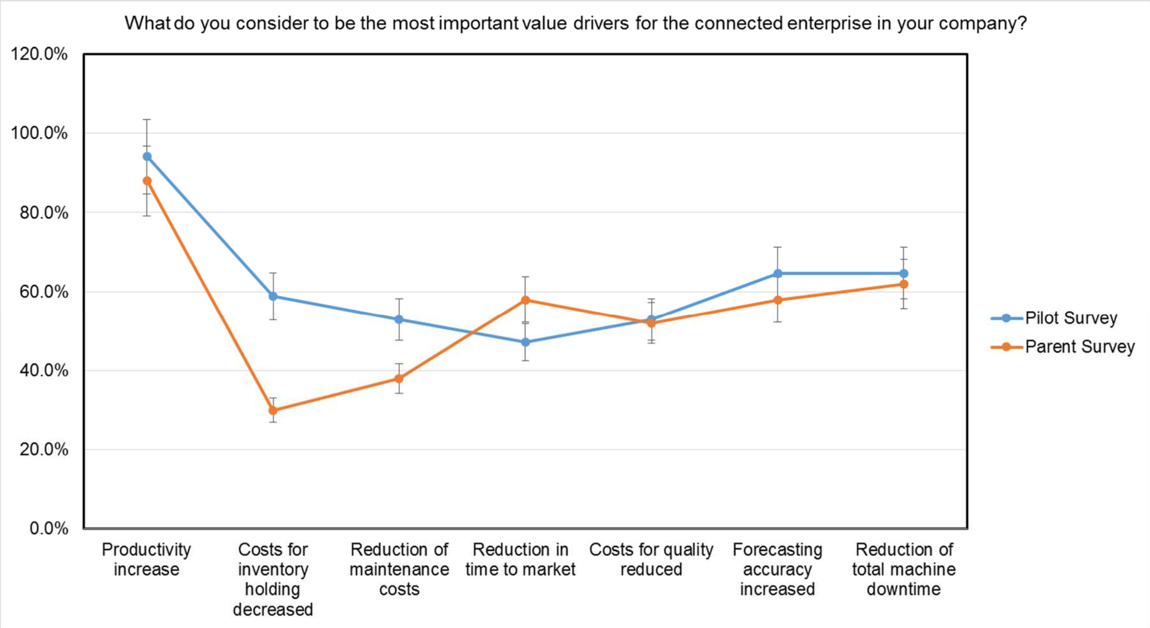


Figure 4.1 - Participants' views on the key value drivers for the connected enterprise

A 10% MOE has been applied to the statistical data in *Figure 4.1.* Taking this MOE into consideration, the results can be considered to be consistent for the two surveys. The only significant difference is on the percentage of the respondents who chose the cost of inventory as being an important driver however the general patterns of the graph can be considered to be similar. Inventory control for the case study organisation is limited to the ERP WMS. This function is not integrated with other systems such as a MES/MOM implying that aside from the supply chain personnel, other departments have not yet been exposed to this function. This may explain the discrepancy between the two sets of results when inventory control is considered.

4.3.4. Challenges presented by the connected enterprise.

The participants were provided with a list of challenges associated with the connected enterprise implementation and asked to choose which ones they considered to be the biggest challenges. Participants were also invited to provide open ended responses to the question. A lack of highly skilled personnel to support the connected enterprise initiatives was chosen by 77% of the pilot survey respondents and 61% of the parent survey respondents. This data is in-line with the literature review findings related to the lack of skilled personnel which was discussed in *Section 2.5.6.b).*

Using the data from the pilot survey for triangulation, the results of the parent survey can be said to be valid or authentic considering that when a 10% MOE is applied to the statistical data, the survey data is more or less the same as illustrated in *Figure 4.2*.

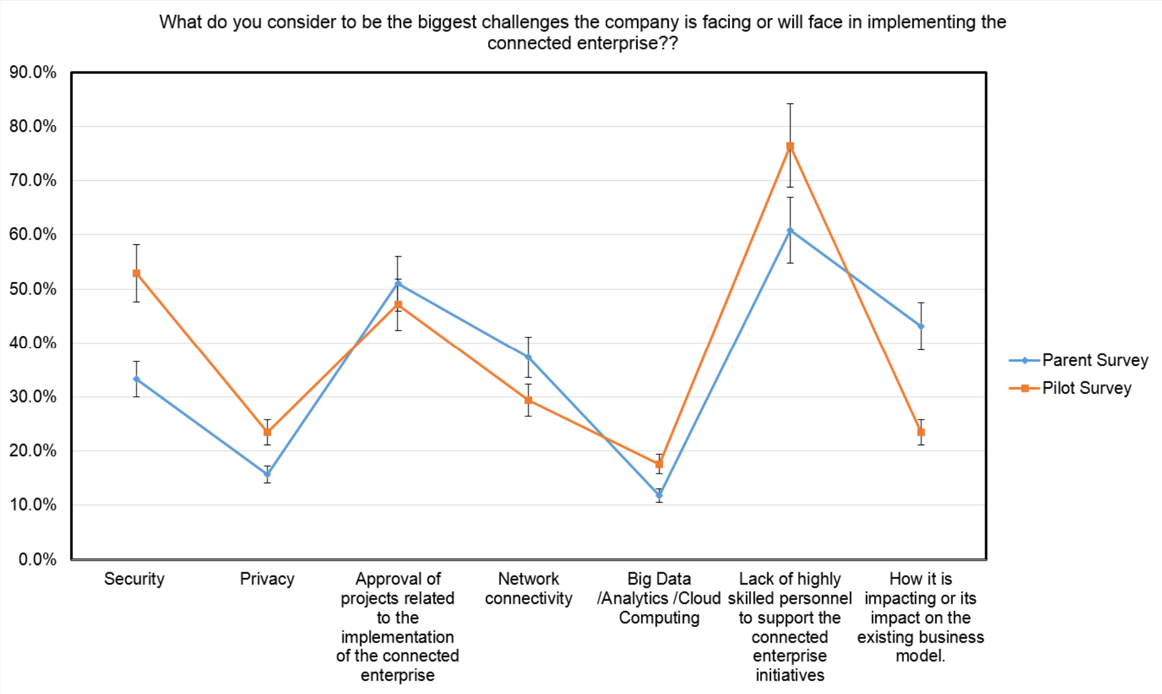


Figure 4.2 - Participants' views on the challenges related to the connected enterprise

The data shows that less than 20% of the participants thought that big data/analytics/cloud computing presents a challenge to the connected enterprise. This dissertation has reviewed a use case for IoT in healthcare which demonstrated that big data will become a challenge as the healthcare industry embraces the next generation of manufacturing.

It is also important to note that security as a challenge for the connected enterprise was selected by 33% of the parent survey respondents and 53% of the pilot survey respondents. When the data is filtered to include only respondents who work in Engineering, IT or Technical Services, the result becomes 28% for the parent survey and 43% for the parent survey. Further discussion on these findings is done in *Section 5.3.2.*

Some of the open ended responses to this question as per the associated category are as follows:

a) Lack of highly skilled personnel to support the connected enterprise initiatives

"The biggest challenge in my organisation is finding people with the right skill sets and experience to implement and maintain the connected enterprise. There is high employee mobility that even when you find the right personnel, it is difficult to keep them as their skills are in high demand".

"Cross engineering training in MES".

b) Approval of projects related to the implementation of the connected enterprise

"Willpower, budget limitations, inability of leaders to see the end-point (vision)".

“Priority Status - If it is not a priority it will not be done. Lack of true knowledge amongst senior people”.

“The arrival of the connected enterprise to users may offer challenges to them (how to fully understand and use the system)”.

4.3.5. Connected enterprise as an opportunity provider.

The respondents were asked if they thought that the connected enterprise will offer new opportunities to their organisation. Whilst 65% of the parent survey participants strongly agreed that there will be new opportunities offered by the connected enterprise, the figure for the pilot survey is 42%. This data which shows more participants from the parent survey strongly agreeing that there will be new opportunities offered by the connected enterprise than the pilot survey participants is to be expected. This can be explained by the fact that the case study organisation is currently going through several connected enterprise initiatives which may not be the case for some of the pilot survey participants. The data from the respondents who were undecided is somewhat consistent for the two surveys. The data for this research question is summarised in *Table 4.6.*

Table 4.6 - Respondents’ views on the connected enterprise as an opportunity provider

The connected enterprise with the use of applications such as the MES and other smart services will offer new opportunities for your company?				
	Pilot Survey		**Parent Survey**	
Working Experience (Years)	**Response Percent**	**Response Count**	**Response Percent**	**Response Count**
Strongly disagree	23.5%	4	5.9%	3
Disagree	0.0%	0	2.0%	1
Undecided	35.3%	6	27.5%	14
Strongly agree	41.2%	7	64.7%	33
Please elaborate if you wish		0		7
answered question		**17**		**51**
skipped question		**0**		**0**

Table 4.6 suggests that there is no outright agreement that the connected enterprise will offer new opportunities within the participants’ organisations. Notwithstanding this fact, more than 98% of the respondents of both surveys thought that this development towards the connected enterprise is more likely to strengthen or weaken the position of their company in the competitive pharmaceutical industry, thus acknowledging that the connected enterprise will have an impact on their organisation’s positioning in the industry.

After categorising the open ended responses to this question into the answer options shown in *Table 4.6*, some of the open ended responses are as follows:

a) Strongly Agree

"Allows greater flexibility in the various business processes and should lead to the streamlining of processes. Also with the accurate real time data provided from MES and various OPCs and smart services it gives the business valuable feedback as to where issues are occurring and where gains can be made. Smart services also allow more flexibility in the working day for end users meaning that communication and decisions can be made on the go leading to a better flow within the business".

b) Disagree

"It will improve how the business operates but may not offer new opportunities",

"The MES will not create opportunities but rather enable us to deliver opportunities we have already created".

4.3.6. Opportunities presented by the connected enterprise.

The participants were provided with a multiple choice, multiple response scale type of question in which they were asked to select one or many alternatives from a list of opportunities presented by the connected enterprise. These opportunities have previously been reviewed in *Section 2.5.6* . To assure data validity, a filter was applied to the research tool to exclude data from participants who disagreed or strongly disagreed with the notion that the connected enterprise will provide opportunities to their organisation. The results for this research question are illustrated in *Figure 4.3*.

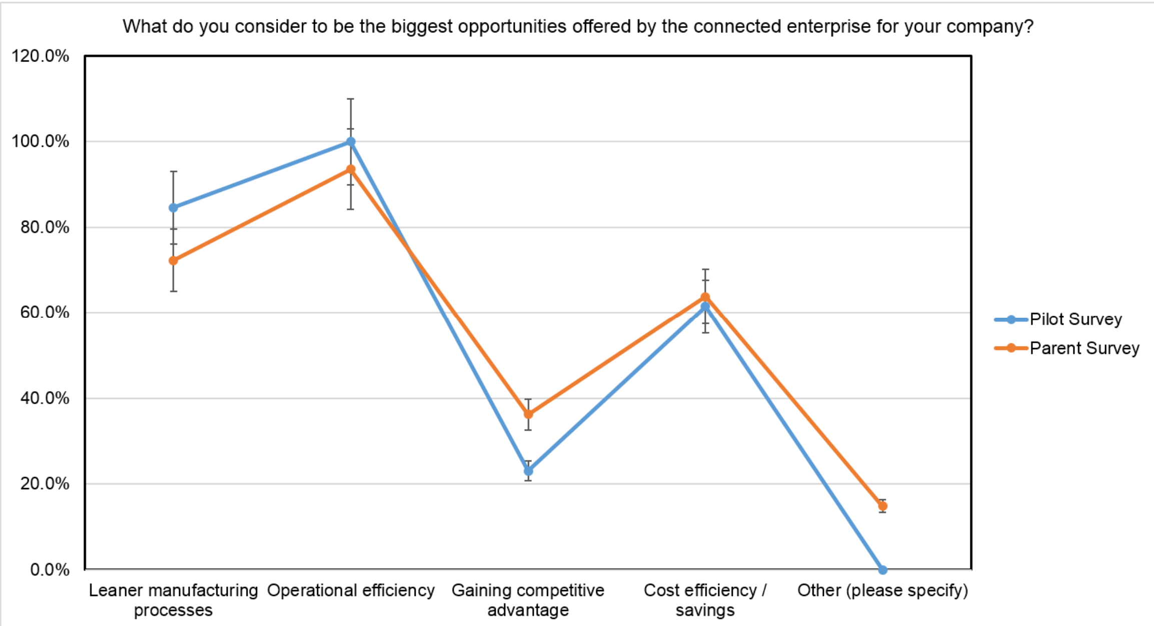


Figure 4.3 - Participants' views on opportunities presented by the connected enterprise

In analysing the results in *Figure 4.3*, more than 90% of participants of both surveys selected improvement in operational efficiency which is synonymous with the MES or MOM systems as the biggest opportunity offered by the connected enterprise. The results also show that the majority of the participants do not consider gaining competitive advantage as an opportunity presented by the connected enterprise.

4.4. MES or Manufacturing Operations Management (MOM) experience

4.4.1. End user MES/MOM experience

The participants were asked about their ISA-95.01 level 3 systems expertise. 60% of the participants from both surveys reported being very familiar or somewhat familiar with the use of a MES or MOM for the implementation of manufacturing operations such as workflow and recipe control during the manufacturing process. Of particular concern is the fact that 16% of the parent survey participants indicated that they were very unfamiliar with the use of a MES or MOM for the aforementioned manufacturing functions. Considering the fact that these systems cover the entire supply chain implying that essentially all departments are affected and also considering the ongoing connected enterprise initiatives within the case study organisation, this low figure - which shows a significant lack of familiarity with ISA-95.01 level 3 - is certainly a cause for concern. The data for this research question is summarised in *Table 4.7.*

Table 4.7 - Participants' MES/MOM End user experience

How familiar are you with the use of a Manufacturing Execution System (MES) or a Manufacturing Operations Management (MOM) system for workflow and recipe control during the manufacturing process?				
	Pilot Survey		**Parent Survey**	
Working Experience (Years)	**Response Percent**	**Response Count**	**Response Percent**	**Response Count**
Very familiar	29.4%	5	7.8%	4
Somewhat familiar	41.2%	7	52.9%	27
Neither familiar nor unfamiliar	5.9%	1	9.8%	5
Somewhat unfamiliar	23.5%	4	13.7%	7
Very unfamiliar	0.0%	0	15.7%	8
	answered question	**17**		**51**
	skipped question	**0**		**0**

4.4.2. Participants' expertise on the administration of MES/MOM systems

The participants were asked to rate their expertise on the use of MES/MOM systems for maintaining manufacturing data such as material master data or equipment master data as well as the use of the recipe or workflow designers in MES/MOM systems. The objective was to determine the participants' administrative expertise on the ISA-95.01 Level 3 systems. *Figure 4.4* shows a weighted average of 2.4 for the pilot study and 1.7 for the parent survey.

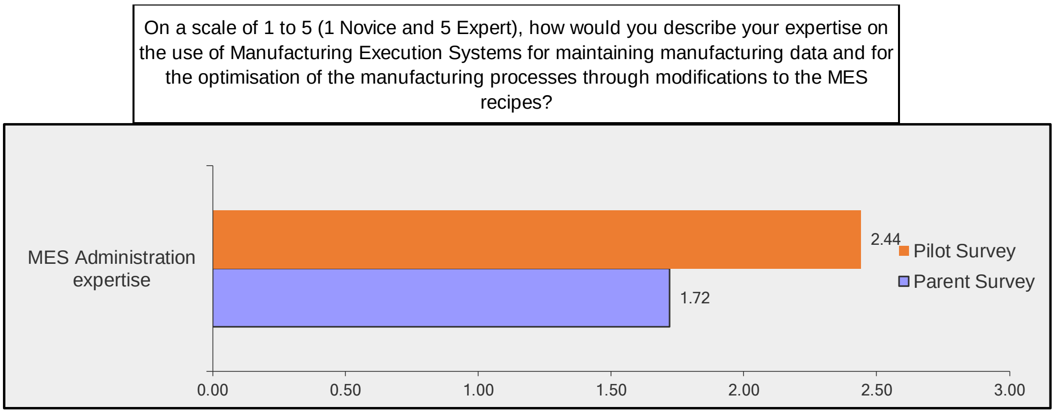


Figure 4.4 - Participants' MES/MOM administration experience

Analysis of the data reveals that the majority of the participants are not competent enough to be able to take ownership of ISA-95.01 level 3 systems for system administration. This question was posed to all participants since MES/MOM administration is not limited to the technical departments but rather transcends several departments within organisations.

4.4.3. Participants' previous experience in MES/MOM deployments

The participants were presented with a dichotomous scale type of question relating to their previous ISA-95.01 level 3 implementation participation. When the data from the pilot survey and the parent survey is analysed, a clear contrast of the datasets is evident. 71% of the pilot survey participants and 37% of the parent survey participants confirmed having participated in previous MES or MOM start-up activities. There is no significant change when the data is filtered to include only participants with more than 10 years working experience. The disparity between the two datasets is to be expected as the case study organisation is in the process of implementing a MES within one of its relatively new facilities at its Dublin location. As such, the organisation's employees who are themselves relatively new to the organisation are only now being exposed to MES or MOM systems. On the other hand, a high percentage rate from the pilot survey respondents is best summarised by one respondent's open ended response which is as follows;

"XXXX has had MES systems for past 10-12 years and will continue to develop and explore new MES functionality. The challenges that lay ahead will be skills to support the product/s and how to actually interface to products on many different and legacy platforms".

4.4.4. Participants' use of connected enterprise user experience features

The respondents were provided with a multiple choice, single response scale type of question in which they were asked to select a statement that best describes their usage of the existing web reports to view manufacturing web reports. The existing reports cover; GAMP, GMP, GEP and other GxP functions. Examples of the published reports include MBRs, IPC quality reports and other KPI reports. The goal was to determine the level of engagement by the respondents with the connected enterprise initiatives. The data from the parent survey is illustrated in *Figure 4.5*.

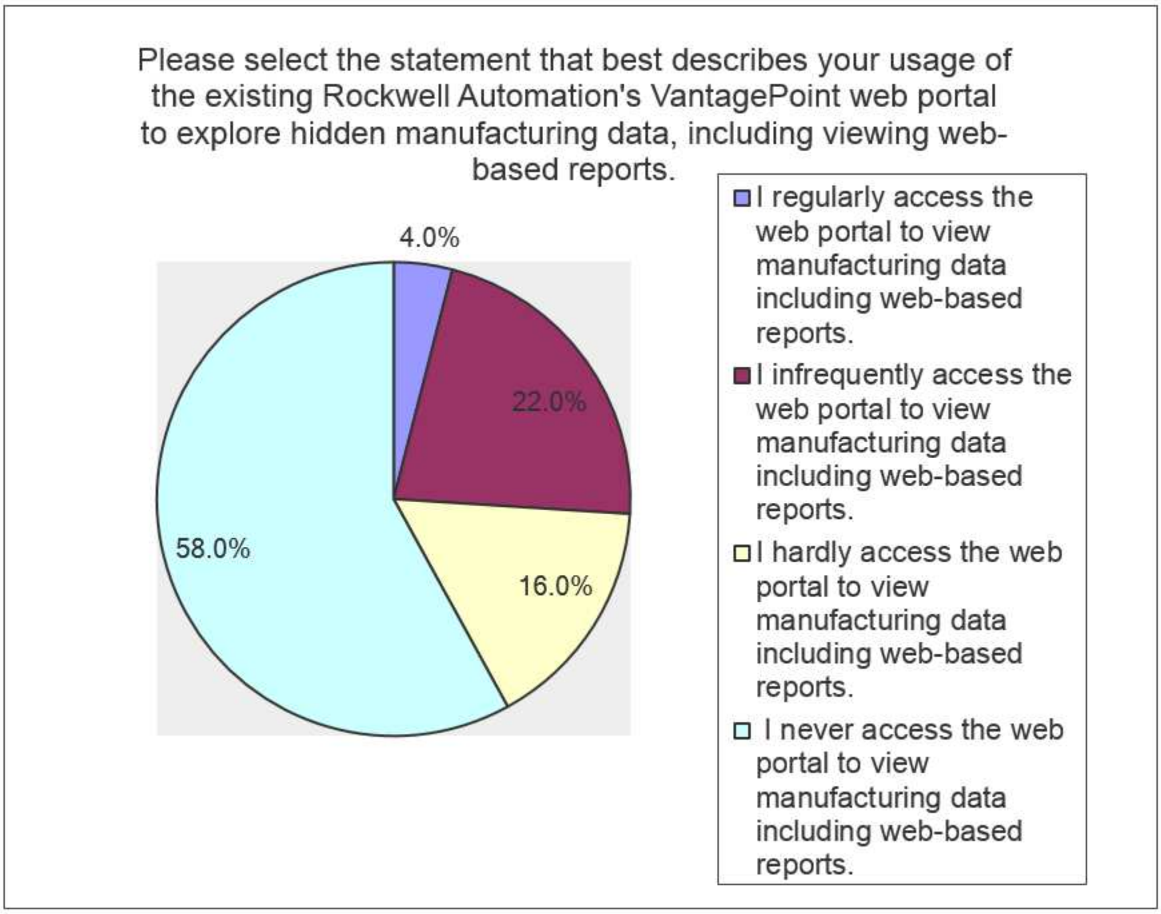


Figure 4.5 - Parent survey respondents' usage of manufacturing reporting URLs

58% of the participants surveyed stated that they had never accessed the web portal for viewing web reports. This is despite the fact that some of the reports have been in publication for more than a year and that the case organisation has actively encouraged its employees to make use of the web features to view manufacturing reports. The intention being to encourage active participation in the connected enterprise initiatives. Only 4% of the participants stated that they regularly access the web portal provided to view manufacturing data. The data suggests that either the participants have not fully understood the non-complexity involved with such exercises as such they shy away from any involvement or that they do not have the enthusiasm to be involved in such endeavours.

This does not augur well for any connected enterprise initiatives which are brought about by the convergence of IT and OT.

4.5. ISA 95 Level 4 (ERP) experience

The participants were asked to rate their skills on the usage of the ERP system within their organisation. ERP systems represent ISA-95.01 level 4 systems and are effectively the primary source and destination databases for all manufacturing related metadata. The data from this research question is illustrated in *Figure 4.6*.

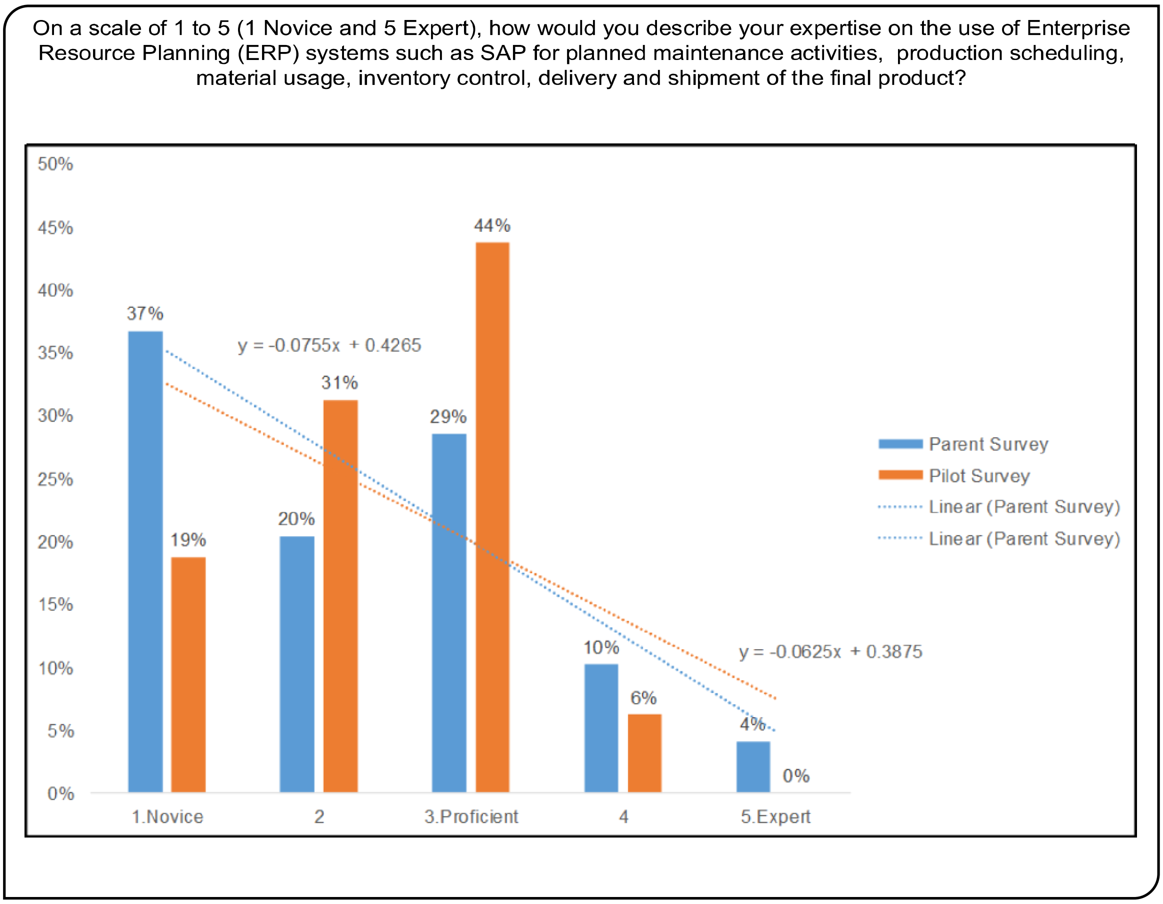


Figure 4.6 - Participants' expertise on the usage of ERP systems

Analysis of the data shows consistency between the parent and pilot survey data. The two linear trend lines have similar gradients (-0.076 for the parent survey and -0.063 for the pilot survey) and intercept at the proficiency skills level. Although the parent survey data shows 37% of the participants as being novices on the use of ERP systems, the overall ERP skills for both surveys shows an acceptable level of proficiency among the respondents with 4% of the parent survey respondents indicating that they are experts on the usage of ERP systems.

4.6. Participants' Operational Technology/Automation experience

The technical departments' respondents were asked to provide an opinion on their technical and conceptual skills as they relate to ISA-95 level 0 and level 1 systems. The participants are also asked to rate their industrial networking and telemetry expertise, bearing in mind that these two facets are the backbone of the connected enterprise The data from the parent survey is summarised in *Figure 4.7*.

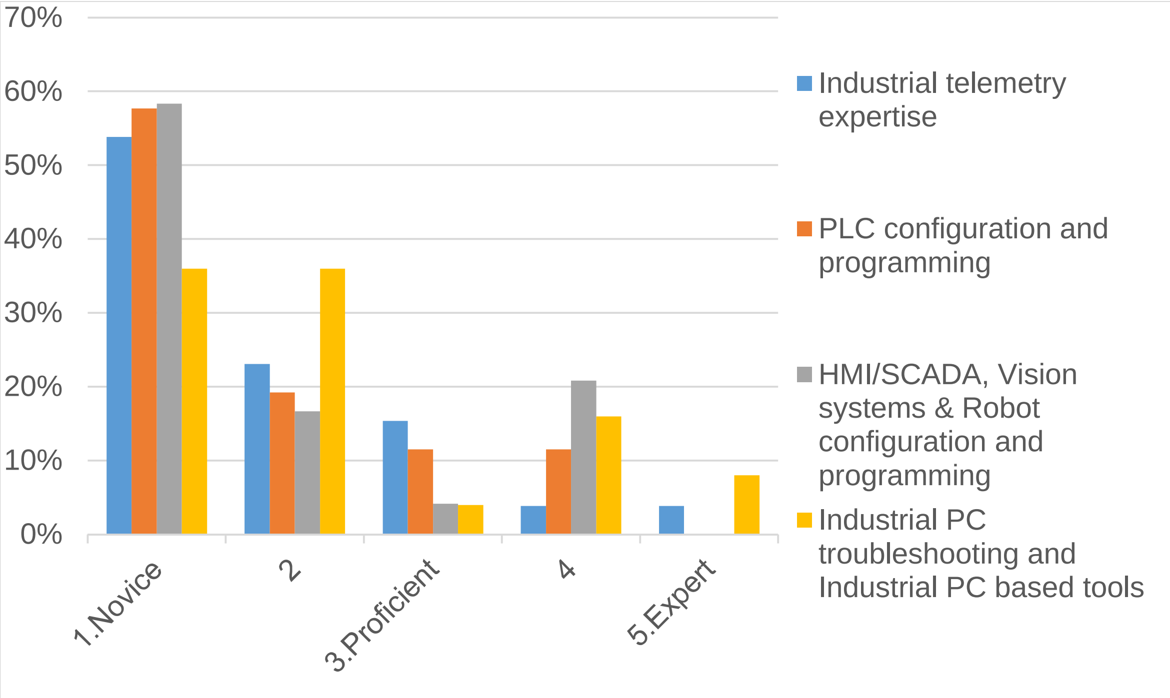


Figure 4.7 - Parent survey participants' expertise on OT

Analysis of the data shows that the technical departments' participants of the parent survey can be described as novices on the subject of industrial telemetry. A rating average of 1.8 was recorded for the parent survey and amounted to 3.3 for the pilot survey participants. The result of the parent survey data analysis shows an improvement to a rating average of 2.5 when a filter is applied to include only participants with more than 16 years of working experience. The same filter when applied to the pilot survey participants also shows an improvement in the rating average to 3.7. This implies that the participants of the parent survey with more than 16 years working experience can be described as being somewhat proficient in industrial telemetry whilst the corresponding group of the pilot survey participants can be described as being fairly proficient.

With regards to the configuration and programming of PLCs, a rating average of 1.8 was recorded for the parent survey participants and 3.6 was recorded for the pilot survey participants.

When the participants are asked to rate their skills on the configuration and programming of HMIs, SCADA systems, vision systems and industrial robots, an analysis of the data shows that there is close similarity with the data obtained from the PLC expertise question. A rating average of 1.9 was recorded with only 25% of the parent survey participants indicating proficiency or better than proficiency on the subject.

A slightly better picture emerges when the data from the question related to the participants' industrial PC troubleshooting expertise is reviewed. In this case, a weighted average of 2.2 is recorded. 32% of the parent survey participants indicated that they were proficient or better than proficient on industrial PC troubleshooting. There is no similarity between the data from the parent survey data and the pilot survey with 79% of the pilot survey participants indicating that they are proficient or better than proficient on industrial pc troubleshooting. An explanation of this disparity could be the fact that the majority of the participants from the case study organisation work within the new facility. This facility utilises new computer systems implying that the participants are not being challenged to test their PC troubleshooting skills since the requisite hardware infrastructure is still in a fairly new state.

4.7. Participants' Information Technology experience

In an attempt to determine the preparedness of the case study organisation towards the integration of IT systems in the connected enterprise, the technical departments' participants were asked to rate their IT expertise. Considering the fact that IT is an expansive field, the focus was to ensure that only those IT constituents which are key to enabling convergence with OT were considered. A 5-point Likert rating scale was applied with weights ranging from 1-5; 1 being 'Novice', 3 being 'Proficient' up to 5 which is 'Expert'. The data from the survey are summarised in the following subsections.

4.7.1. Participants' industrial networking expertise

Section 4.6 reviewed the participants' industrial telemetry expertise as it relates to industrial Fieldbuses. The data from this review as illustrated in *Figure 4.7* is a cause for concern as it is clear that the majority of the participants are not cognizant of the subject. *Section 2.5.3* also discussed how Ethernet is now a key feature within most ICNs existing alongside the Fieldbus. With this in mind, participants were asked to rate their networking experience/knowledge, including TCP/IP, LAN/WAN, DHCP, DNS, and firewalls. The data is summarised in *Figure 4.8*.

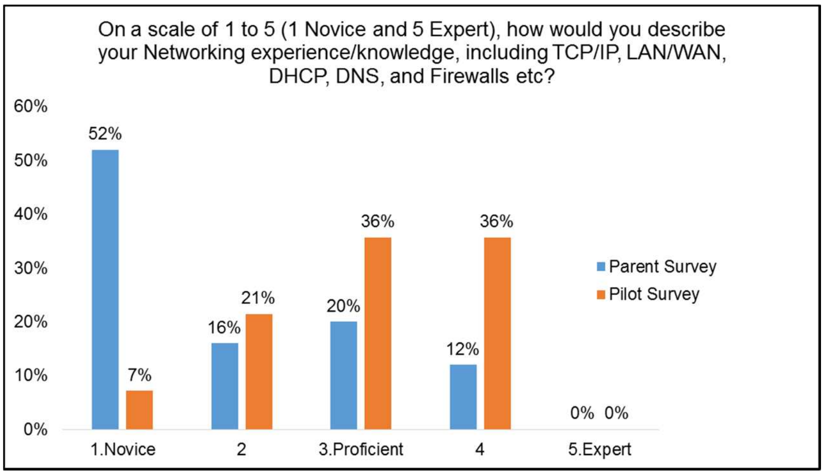


Figure 4.8 - Participants' industrial networking expertise

The data from the 2 surveys is not consistent. Data from the pilot survey participants shows a rating average of 3.0 whereas the rating average for the parent survey is 1.9. This disparity suggest that the pilot survey participants work in organisations which have more established industrial networks. With 68% percent of the parent survey participants rating their industrial networking expertise as being less than proficient, this indicates that the case study organisation is neither adequately resourced nor is it appropriately resourced to fully utilise the benefits of industrial networking.

4.7.2. Technical support for ISA-95.01 Level 3 and level 4 systems

The participants were asked to rate their expertise on the technical support for level 3 systems such as the MES and level 4 systems such as the SAP ERP system. This question was also limited to participants who work in technical departments. A weighted average of 1.8 was recorded for the parent survey with a corresponding figure of 2.2 being scored for the pilot survey. When the data is filtered to include only participants who work for IT, there is a significant increase in the weighted average with 3.5 being recorded for the case organisation and 3.0 being recorded for the pilot study. The data implies that the competency level in the technical support for level 3 and level 4 systems is generally acceptable. The IT department participants who are at the fore front of such endeavours are proficient on the subject. However, when considering the connected enterprise as whole, the data suggests that there is a need to upskill other technical but non IT departments' employees. The current data indicates that such employees can be classified as novices on the subject. *Figure 4.9* shows the amalgamated data for this research question. Trend-lines have been added for an illustrative presentation of the data trends.

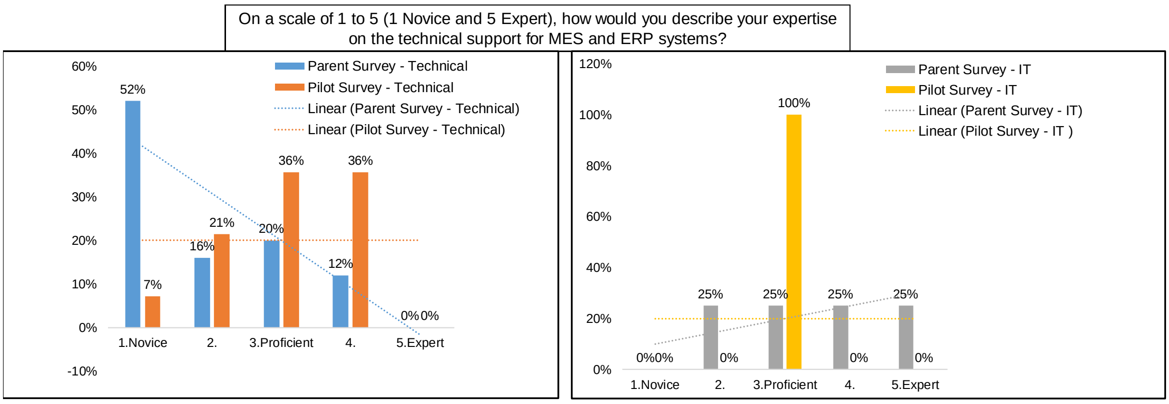


Figure 4.9 - Participants' ISA-95.01 Level 3 and level 4 technical support expertise

4.7.3. IT technical support for ISA-95.01 Level 2 systems

The participants were asked several questions to assist in determining the state of preparedness by their organisation towards the increasing demands for technical support of ISA-95.01 level 2 computer systems such as SCADA systems. Responses were sought from participants who work within the technical departments of their organisation and the results are analysed as follows:

a) Maintenance of manufacturing user permissions on the company domain.

When asked to describe their expertise on the maintenance of user permissions on the company domain for runtime authentication of manufacturing users such as operators, the majority response was that they were novices. 70% of the participants to both studies indicated that they were less than proficient on the subject. Analysis of this data implies that overall understanding of how the common login feature works is considerably low. In the example of the case study organisation such activity involves the configuring of windows active directory and ancillary OT applications such as the Simatic logon for the Siemens HMIs.

b) Antivirus protection and backup of ISA-95.01 level 2 computer systems.

With regards to the general maintenance of the ISA-95.01 computer systems such as the implementation of antivirus protection and the backup of systems for example the HMIs or SCADA PCs, the data shows that the majority of the respondents of both surveys are not proficient on the subject. The 1.9 weighted average scored, which improves to 3.4 when filtered to include only IT employees, suggests that other technical departments do not consider the general maintenance of the manufacturing computer systems to be a routine task capable of being executed by employees from other technical departments as the connected enterprise matures.

4.7.4. IoT and Industrie 4.0 expertise

Literature on IoT and Industrie 4.0 has been reviewed. With this in mind, the research sought the participants' views on their expertise on the subjects of IoT and Industrie 4.0. The data from this research question is summarised in *Figure 4.10*.

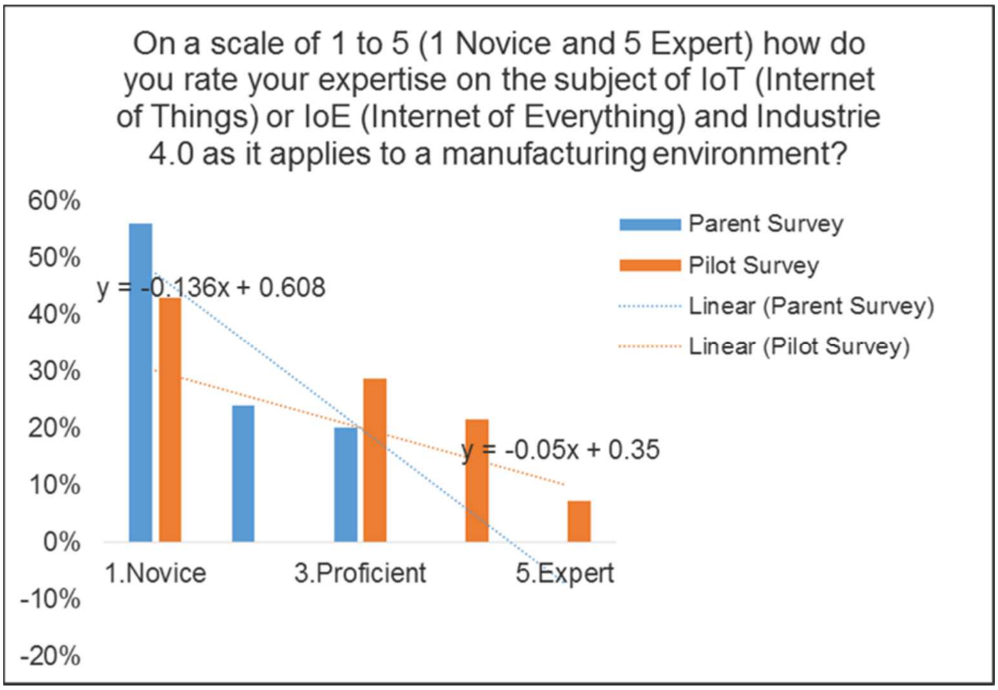


Figure 4.10 - IoT and Industrie 4.0 expertise

Analysis of the results shows that the linear trend patterns are consistent for the 2 surveys implying that the findings could be applied to other organisations within the healthcare manufacturing domain ion Ireland. The data shows a weighted average of 1.6 for the parent survey and a weighted average of 2.5 for the pilot survey. Both sets of data indicate that the IoT and Industrie 4.0 are still fresh subjects within healthcare manufacturing organisations. As such, the majority of the employees within these organisations are yet to attain adequate knowledge and expertise on IoT and Industrie 4.0.

5. Conclusions and future work

5.1. Introduction

The objective of this chapter is to discuss the conclusions of the findings from the case study in an effort to answer the research question. The research question was previously presented as follows;

"How has the evolution of Operational Technology supported the implementation of the connected enterprise for an Irish pharmaceutical manufacturing company?

This study's literature review, the results from the parent survey, pilot survey and the open ended responses from these surveys leads to the conclusion that in order to answer the research question, two fundamental factors have to be considered. These are technical factors and organisational factors. The interpretivist research philosophy was used in coming up with this determination. This chapter discusses these two factors and provides recommendations based on the research findings. Possible future approaches for related studies are also briefly discussed in this chapter.

5.2. Technical factors

Technology plays centre stage in the connected enterprise. The gradual influence which IT/OT has played and will continue to play in the implementation of the connected enterprise has been examined as part of the research literature review. This section provides further assessment of the technical considerations for the connected enterprise and concludes on the findings from the case study research on how technology has impacted the implementation of the connected enterprise in its various forms throughout history.

5.2.1. Early developments in automation as a technical consideration

The early developments in automation set the precedent in the evolution of OT to its present and future state whereby the convergence of IT and OT supports the implementation of the connected enterprise.

Chapter 2 pays homage to early developments in automation and the role that the Hellenistic engineers made in automation is noted. This is followed by a review of the developments in automation in the early 20th century. The role that the two world wars played in the drive for automation, the benefits which are brought about by automation and the availability of disposable income at the turn of the century as factors which accelerated developments in OT follows this discussion. The labour conundrum as a factor impacting the development of automation in the mid-20th century is also reviewed.

5.2.2. Footprint set by industrial control systems as contributing factor

Literature reviewed the evolution of the PLC and the development of the fieldbus. The implication of this literature review is that the onset of the connected enterprise initiatives can be traced back to the introduction of the PLC and Fieldbuses in manufacturing. Fieldbuses facilitate factory floor device connectivity in the connected enterprise and the PLC with all its simplicity relative to other technologies such as the PC still plays a key role in industrial manufacturing. PLCs and Fieldbuses are thus a considerable technical factor in the establishment of the connected enterprise.

When Dick Morley, who is widely regarded as the father of the PLC, was asked about the origins of the PLC, he responded by saying, "*We built them and we didn't know we built them*" (Design, 2015, p. 1). The role that this chance invention has played and continues to play in the connected enterprise as a whole has been examined in *Chapter 2*.

As reviewed in *Section 2.5.4,* the significance of the industrial PC in the successful implementation of the connected enterprise cannot be understated. The industrial PC has gradually grown to become a key feature for most ICSs therefore should be considered as a key technical factor in the implementation of the connected enterprise.

5.2.3. Present pharma IT/OT technical considerations

The present IT/OT landscape in Irish pharmaceutical manufacturing as it relates to the research organisation was reviewed in *Section 2.6.2.* The literature review in *Chapter* 2 suggests that Fieldbuses, PLC, IPCs and PACs are commonplace in present day pharmaceutical manufacturing. This assertion was found to be true when a non- behavioural observational analysis of the existing IT/OT physical conditions and physical processes within the case study organisation was carried out. This analysis was in the form of a review of the existing IT/OT documentation for the manufacturing lines within the case organisation.

Figure 5.1 illustrates the ISA-95.01 hierarchical model for the Dublin pharmaceutical manufacturing company. In conjunction with the use of non- behavioural observational analysis methods, the ISA-95.01 model described in *Table 2.6* was also used in configuring the model.

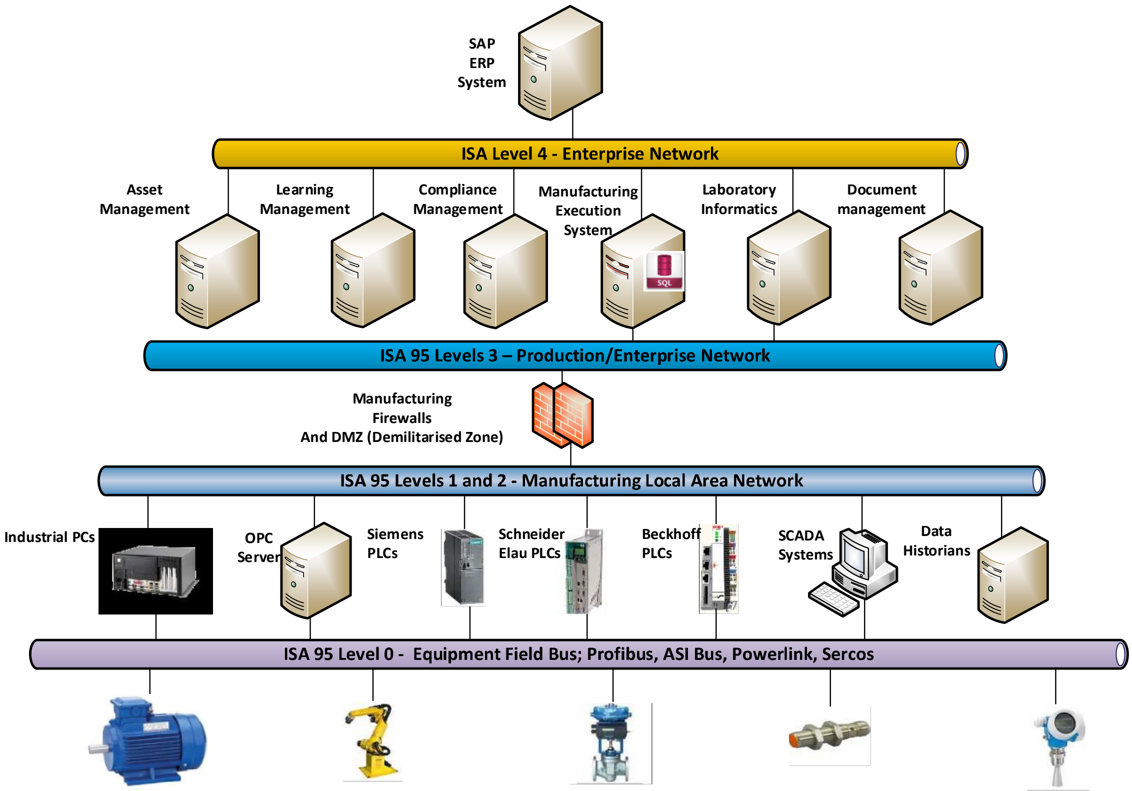


Figure 5.1 - ISA-95 hierarchical model for Dublin pharma manufacturing company

Connectivity has not been established between all the level 2 systems and some of the level 3 enterprise systems such as the LMS, DMS and the QMS. There are ongoing efforts to effect this connectivity. To enable full integration of the various systems, the Dublin pharmaceutical company is also in the process of implementing a MES. The implementation of a fully connected enterprise which utilises the ISA-95.01 model in *Figure 5.1* is a medium to long term project.

From a technical perspective, present IT/OT in manufacturing has supported the implementation of the connected enterprise through the increasing ability of these technologies to integrate with other systems for data exchange. The main technical challenge as it relates to this expansive IT/OT in pharmaceutical manufacturing is how to integrate these systems in the connected enterprise.

Other technical challenges which are presented by existing IT/OT in pharma manufacturing such as legacy OT infrastructure, changing demographics and constantly evolving technology were discussed in *Section 2.5.6.* Opportunities that these technologies present were also discussed in *Section 2.5.6*.

5.2.4. Future pharmaceutical manufacturing IT/OT technical considerations

Section 2.6.3 reviewed the future outlook for IT/OT in manufacturing. Phenomena such as Industrie 4.0, data analytics, IOT, and cloud based solutions were reviewed. *"The* *convergence of manufacturing and enterprise networks provides greater access to manufacturing data, which allows manufacturers to make more informed real-time business decisions"* (CISCO, Rockwell Automation, 2011, p. 1). The implication is that future IT/OT systems should be scalable and agile to cater for the ever increasing Big Data requirements of manufacturing.

5.2.5. Recommendations for the technical factor

To address the challenges that are inevitably brought about as a result of the convergence of IT and OT to establish the connected enterprise, models such as Rockwell Automation (RA)'s connected enterprise maturity model offer organisations the opportunity to manage the various stages in their connected enterprise journey. *"Rockwell Automation developed a five-stage maturity model that incorporates measures and best practices necessary to ensure effective change in both technologies and organisational cultures"* (Rockwell Automation, 2016, p. 1). The RA maturity model is illustrated in *Figure 5.2.*

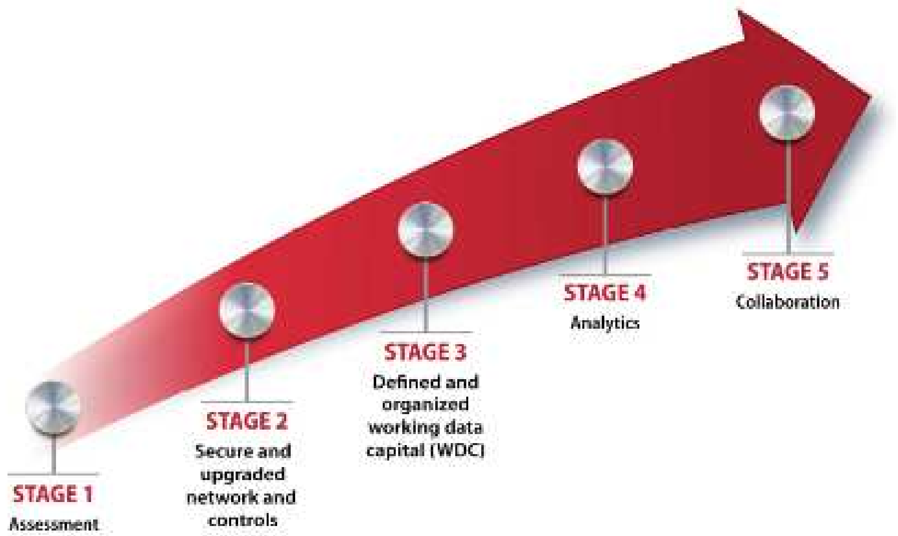


Figure 5.2 - Rockwell Automation's 5 stage connected enterprise maturity model
Source taken from (Rockwell Automation, 2016)

Stages 1 and 2 deal with addressing the technical challenges.

a) Stage 1

The specific objectives for Stage 1 should be to:

- Align on a common understanding and maturity model for the IT/OT.
- Assess as-is and the level of automation maturity of the organisation.
- Identify high risk areas / processes.
- Identify highest impact opportunities.
- Prioritise highest impact automation opportunities.

- Develop automation upgrade strategy, implementation roadmap, and indicative costings.

With reference to *Figure 2.6* which shows the typical pharmaceutical manufacturing processes, the common functions of the equipment involved in these manufacturing processes which need to be considered during the Stage one assessment are, cleaning/equipment preparation, material loading / charging, equipment operation – setup, equipment operation – processing, sampling / In process controls and data capture.

b) Stage 2

The objective of Stage 2 should be to ensure that the IACS network for the manufacturing facility is fit for purpose. Stage 2 deals with upgrades to the existing IACS networks. For the case study organisation, this includes extending the Ethernet/IP MLAN to the stand alone equipment. The challenge is to justify these costs to the business. (Meredith & Suresh, 1986, p. 5), propose a justification approach shown in *Figure 5.3*.

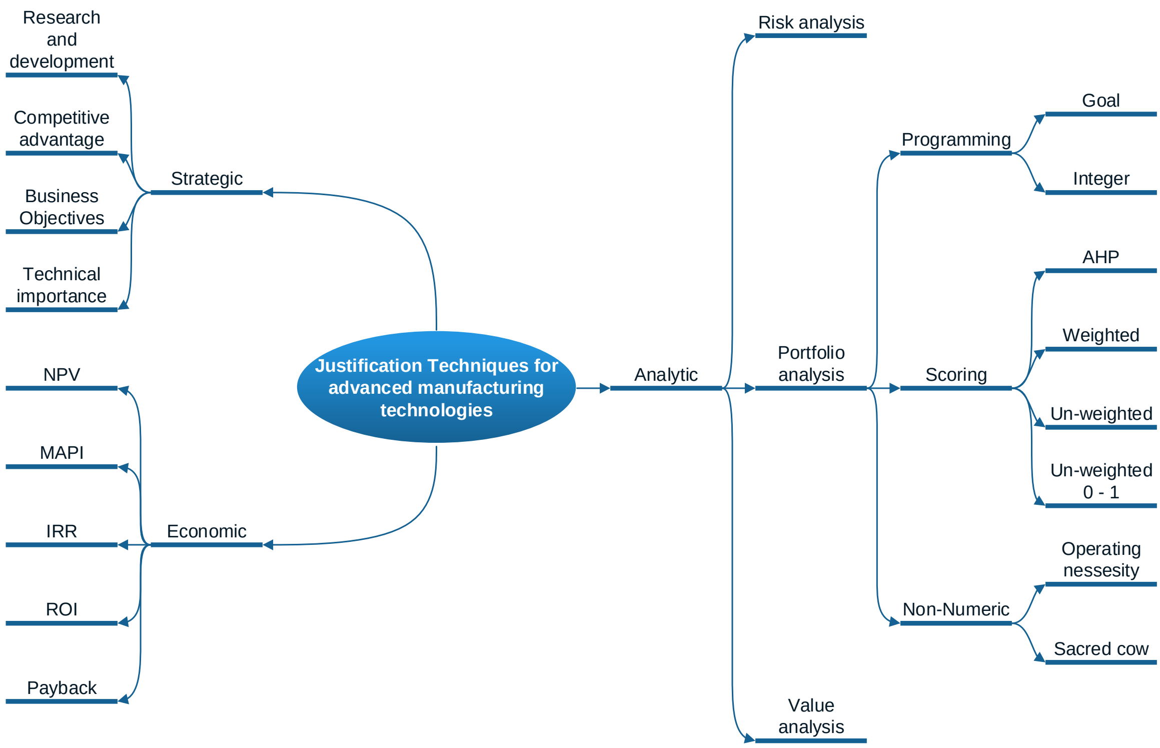


Figure 5.3 - Justification techniques for advanced manufacturing technologies.

Source adapted from (Meredith & Suresh, 1986)

Table 5.1 - Glossary of economic terms for justification of manufacturing technologies

Term	Description
IRR	Incremental Rate of Return
MAPI	Machinery and Allied Products Institute
NPV	Net Present Value
Payback	Also referred to as the pay-out method
ROI	Return on Investment

Solutions such as CISCO's CPwE can be used as a guideline towards ensuring that the IACS networks are geared towards the convergence of IT and OT in the connected enterprise. This new CISCO solution, "*represents further integration of the standard Ethernet and IP network infrastructure with the IACS applications as well as the convergence of IACS and enterprise networks"* (CISCO, Rockwell Automation, 2011, p. 5).

5.3. Organisational factors

To enable the successful implementation of the connected enterprise, the main considerations for the organisation should be on the people, the processes, the IT/OT and the structure of the organisation. *Section 5.2* considered the technical or IT/OT factor. This section will consider the people, the process and structure domains. As part of this research study, empirical data was gathered from the organisation's employees. This effort was to try to get a better understanding of the aforementioned domains. This data was used to determine the case organisation's preparedness for the connected enterprise. This research data can be used as inferential data as explained in *Section 3.9.1.* The following subsections provide further assessments and conclusions on the findings from the research case study.

5.3.1. Demographic landscape

By virtue of the fact that the Irish healthcare manufacturing company is a highly regulated industry, the demographic profile of the participants to the research study online questionnaire is consistent with what would be expected from such an industry. Participants were found to be mature with the majority having more than 5 years working experience. The majority of the participants were also found to have attained tertiary education. Suffice to say that any connected enterprise initiatives which are embodied in the convergence of IT and OT require this education level and computer literacy for successful adaptation. This is more so for the technical departments which support both OT and IT. When the data for the respondents' educational qualifications is filtered to include the technical departments only, the results show that 100% of the respondents either graduated from college or have some postgraduate qualification. This augurs well for any connected enterprise initiatives.

5.3.2. The human perception of the connected enterprise

The research study found that overall the connected enterprise initiatives underway within the case organisation were a topic for discussion within the various departments. The importance of the connected enterprise to the organisation's strategic outlook was also found to be appreciated within the organisation albeit not fully understood. Case in point:

- In analysing the results shown in *Figure 4.1* further, only 52% of the respondents of both surveys chose the costs for quality reduction as an important value driver. This is not in-line with one of the key features of MES/MOMs which is the elimination of the tedious and often error prone GMP paper records; in the process ensuring that manufacturing is executed on a 'right first time' basis. The expectation was that more respondents would have chosen this important value driver considering that the research study is centred on pharmaceutical manufacturing operations.

The research study also found that the majority of the case study survey respondents felt that the lack of adequate technical skills will hinder the implementation of the connected enterprise. This is consistent with previously reviewed literature which highlighted this factor as a challenge in the implementation of the connected enterprise.

Despite the fact that the research organisation utilises the ISA99 plant logical framework as reviewed in *Section 2.6.2, a* key human perception which was also found was that participants from the technical departments did not overwhelmingly consider the issue of security as a significant challenge. This is contra to ISA99's considerations on security as outlined in;

- ISA99.00.02 – Part 2: Establishing an Industrial Automation and Control System Security Program and
- ISA99.00.03 – Part 3: Operating an Industrial Automation and Control System Security Program'.

5.3.3. End user ISA-95.01 level 3 systems knowledge assessment

When the data from the research study is used as inferential data, a conclusion which can be made is that the majority of employees within Irish pharmaceutical companies have experienced the connected enterprise. However, despite this finding (as with the case of the research study organisation) and despite the fact that the majority of the case organisation's employees who participated in this research study are vastly experience, only a minority of employees have actually been involved in start-up projects for ISA-95.01 level 3 systems such as MES/MOM.

The general lack of the administrative skills required for such systems recorded from the research survey participants is also consistent with the skills shortage conundrum which was identified as a key challenge for the implementation of the connected enterprise.

Figure 2.5 illustrated the data flow from the factory floor to websites accessible by the case organisation's employees. Various GxP reports generated from this data are available at these websites. This being an example of the connected enterprise, one surprise finding from this research study was that more than half of the respondents had not utilised this feature. For those who did, only a small minority used the feature regularly.

5.3.4. OT and IT technical support knowledge assessment

As part of this research study, the competency levels as they relate to the support of IT/OT in manufacturing were investigated. The research study found that overall the technical respondents can at best be described as being less than proficient on the technical support for the IT/OT systems. Only 23% of the parent survey participants indicated that they were proficient or better than proficient when asked about their PLC configuration and programming expertise. Considering the fact that the case study organisation employs primarily manufacturing and automation engineers who should be fairly well versed on the subject, this low figure does not augur well for the connected enterprise initiatives. Although some IEC 61131 languages are very similar to IT programming languages such as C#, the data from this research question does not improve when a filter is applied to include only IT participants. In addition to this, a knowledge assessment of future IT/OT expertise shows that the respondents were less than proficient on the subjects of IoT and Industries 4.0.

5.3.5. Recommendations for the organisational factor

a) Understanding the business processes

To take advantage of the technical possibilities brought about by the convergence of IT and OT, it is important for all stakeholders to understand the business processes which will be affected by the implementation of the connected enterprise initiatives. Early involvement of stakeholders from the entire supply chain is key. There are various process models which can be used to ensure that there is adequate understanding of these business processes. One such model is the ISA-95 functional hierarchical model. Another useful model which can be used to map business processes is the SIPOC model. This model, *"helps define a complex project that may not be well scoped, and is typically employed at the Measure phase of the Six Sigma DMAIC (Define, Measure, Analyse, Improve, Control)"* (Simon, 2016, p. 1). *Figure 5.4* shows an example of a SIPOC diagram for a connected enterprise related project.

Suppliers	Input	Process	Output	Customers
IT Project Manager	Project description URS FRS SDS	**Project Description:** Developing manufacturing KPI reports and publishing on the Factory Talk Vantage Point web portal	>Infrastructure >Reporting software >Reports Data extracts for business analytics	>Management >Executive >Report Customers >IT/OT Staff
Vendors	Project Description			
IT staff	Project description URS FRS SDS			
Engineering staff	Project description OPC Configuration file URS FRS			
	Metrics Engineering Time IT Staff Time Milestones Costs Risks	Metrics Time to complete OPC configuration process Time to complete h/w and s/w configurations Time to complete the entire process	Metrics Cost of OT Cost of IT Cost of implementation Project cost Data integrity	

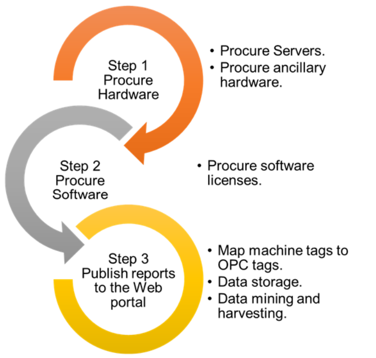


Figure 5.4 - Example of SIPOC diagram

Other business process models which can be used to cover integration activities particularly at ISA-95 level 3 and 4 are;

- Supply Chain Operations Reference model (SCOR).
- Design Chain Operations Reference model (DCOR).
- Customer Chain Operations Reference model (CCOR).

b) Taking care of the organisational structure

Successful implementation of the connected enterprise established as a result of the convergence of IT and OT is based on a well-defined organisational structure. This results in a clear definition of the authority, responsibility and roles of the core team members. There are various models which can be used for the implementation of IT/OT governance within any organisation. Although the main focus to date has been on IT or ICT governance, a review of such models shows that they are also applicable to IT/OT governance.

The IT Capability Maturity Framework (IT-CMF) model illustrated in *Figure 5.5* is one example of an ICT governance model.

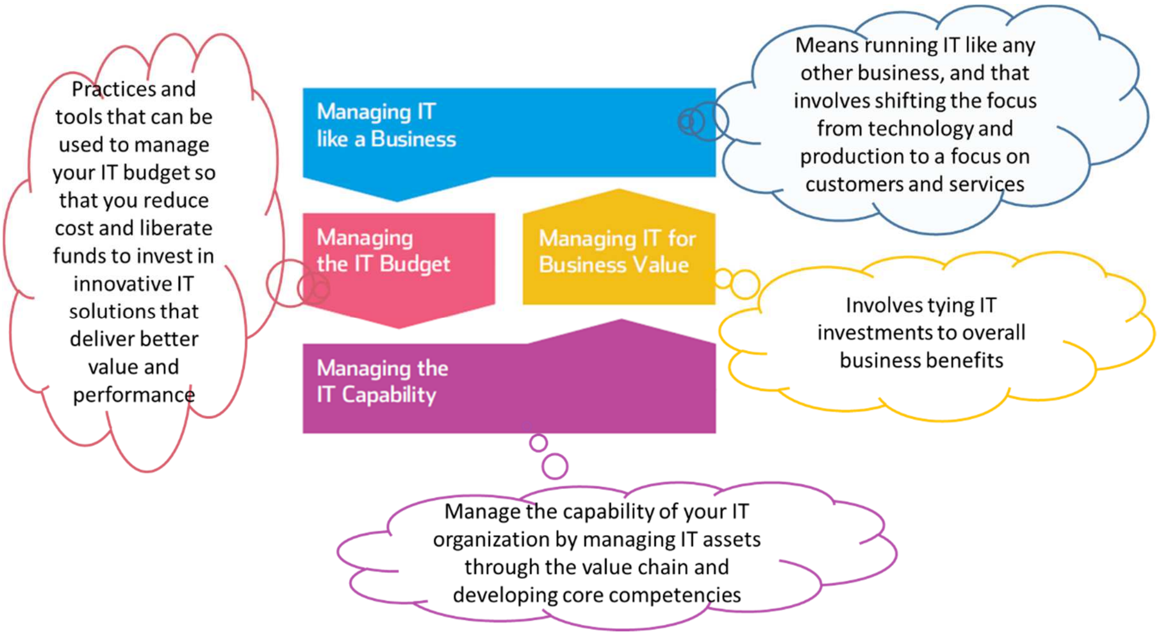


Figure 5.5 - IVI's IT-CMF Model

Source taken from (IVI, 2015).

Of particular importance to the establishment of a governance strategy for the connected enterprise initiatives should be the creation of a steering group or committee whose role is to, *"establish the strategic direction, aligned to the business strategy"* (Ward & Peppard, 2002, p. 373). *Figure 5.6* shows an example of a steering committee and *Table 5.2* provides a brief summary of some of the functions which these groups should perform to ensure the success of the connected enterprise initiatives.

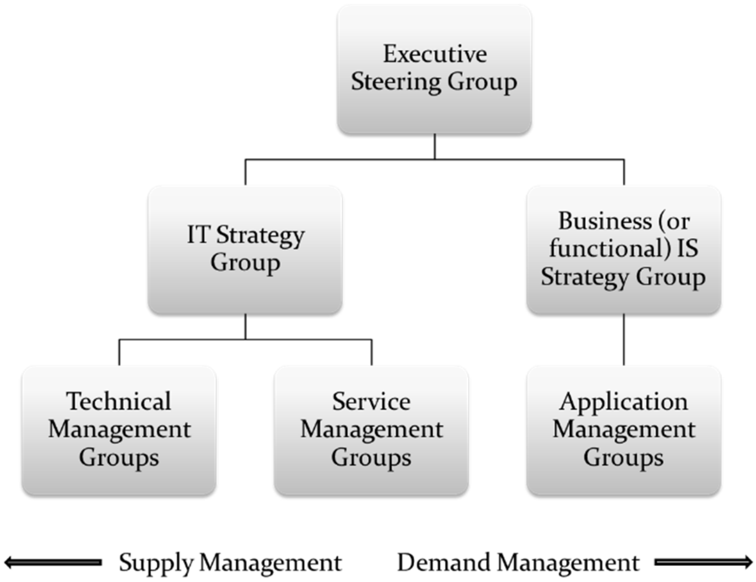


Figure 5.6 - Example of Steering organisation for IS/IT strategic management

Source adapted from (Ward & Peppard, 2002).

Table 5.2 - Summary of Steering committee group functions

Executive steering group ➢ Alignment of business and IT/OT strategy. ➢ Investment in portfolio management, selection, prioritization, funding and final authorization of any connected enterprise projects. ➢ Review and final approval of project implementation plans. ➢ Final escalation of any issues related to projects within the organisation.	*Business (or functional) IS strategy groups* ➢ Determining what the business wants from IT/OT as well as identifying opportunities which IT/OT can offer to the business. ➢ This group may consist of the major functions within an organisation such as supply chain, marketing & sales, customer service and finance. ➢ Ensuring appropriate resources are allocated to projects and appoint application managers (Ward & Peppard, 2002).
IT (OT) strategy groups ➢ Architecture, infrastructure, security, risk and continuity. ➢ Timely deployment of the "right" technology to the business.	*Application management groups* ➢ Managing the operation, maintenance, any upgrades and version control of the organisation's applications throughout the applications' life cycles. ➢ Implementing best practices on deployed applications for performance and efficiency throughout the organisation.
Service management groups ➢ Aligning an organisation's IT/OT services with the rest of the business to ensure the best service to the customer. ➢ Use of tools and literature such as ITIL (Information Technology Infrastructure Library). The ITIL is "comprehensive suite of best practices, procedures, standards and an authoritative framework for ITSM which helps organization and individuals to govern IT services in a structured format and ensure meeting service standards both within the organization or across third party service providers" (Cory, 2015).	*Technical management groups* ➢ Providing leadership and technical guidance on technology developments for the applications portfolio. ➢ Resolving technical issues/problems with the suppliers and ensuring service groups are effectively supported (Ward & Peppard, 2002). ➢ Providing guidance on change control, system back up, disaster recovery, data integrity and security set-up. ➢ Development and implementation of appropriate strategic plans for skills development for IT/OT staff

Source adapted from (Ward & Peppard, 2002)

c) The people domain

The effect that the people domain plays in the successful implementation of the connected enterprise cannot be understated. This is to do with the behaviour, cultural backgrounds, skills, experience and the benefits of the individuals who will be involved the connected enterprise initiatives. This research study has investigated these various contributing factors to the people domain.

It is important, therefore, for organisations to get a better understanding of the people domain. There are several models which can be used to get a better understanding of the organisation's workforce capabilities prior to embarking on any connected enterprise initiatives. One such model is the People Capability Maturity Model (People CMM®) which provides guidance for improving the capability of an organisation's workforce. "*The People Capability Maturity Model® (People CMM®) is a roadmap for implementing workforce practices that continuously improve the capability of an organisation's workforce"* (Curtis, et al., 2001, p. 25). The People CMM® introduces these workforce practices in stages enabling organisations to clearly understand the maturity model for their workforce. *Figure 5.7* is an illustration of the People Capability Maturity Model (People CMM®).

Figure 5.7 - People Capability Maturity Model (People CMM®)

Source taken from (Curtis, et al., 2001).

5.4. Other recommendations

- The implementation of the connected enterprise should be regarded as a constantly evolving activity. As the connected enterprise matures, the organisation will inevitably gain increased insight through the availability of business metrics. This will result in further business demands. The implication is that when the particular project is completed, it does not mean that the journey has ended. The connected enterprise is a continuous improvement project.
- It is important to work with early adapters who will be key to the success of any continuous improvement activities.
- Establish a CoE group for the roll out of the connected enterprise initiatives throughout the global organisation. The CoE can drive the leveraging of concepts and the standardisation of technology.
- Organisations should be more accommodating with regards to experience requirements when it comes to recruiting graduates for connected enterprise related projects. This case study research has shown that skills in IT/OT and ISA 95.01 level 3 systems were not directly related to the working experience of the case study participants. After all, universities in Ireland offer courses which can adequately

prepare students for graduate positions in IT or OT. For instance, *"The DCU School of Mechanical and Manufacturing Engineering and the School of Electronic Engineering were the first in Ireland to offer a degree course in Mechatronic Engineering"* (Dublin City University, 2016, p. 1) . The various modules taught for the mechatronics course in DCU are ideal for preparing graduates for technical roles in pharmaceutical manufacturing companies. With a structured graduate learner-ship program in place, the graduate learner will soon be able to seamlessly traverse from IT to OT and vice versa.

5.5. Strengths of the research

The research was conducted during the period when the case study organisation was in the process of implementing a MES with a technical go-live for the project of 23rd December 2016.The MES/MOM has been shown to be one of the key systems for the integration of the factory floor and enterprise systems. The implications of this project schedule to the research study are as follows:

- Workshops to discuss project governance, the project charter and user requirements at the onset of the project provided unstructured data. This data was used to gauge the suitability of the survey questionnaire during the questionnaire design.
- Workshops to draft the MES solution concept which were attended by the system vendor provided insight into how to understand and model business processes.
- Workshops to define technical specifications of the MES and the integration of this system with the ERP and the OT provided additional technical data on the successful integration of IT and OT.

5.6. Future research opportunities

The future scope of this research could be expanded to include the case organisations' other global business units thus adapting a multiple-case study research strategy using the longitudinal time horizon.

Another related future research opportunity would be on investigating the adaptation of smart technology such as smart sensors in Irish healthcare manufacturing processes. Such a study would provide useful data on the level of usage of the Industrial Internet of Things within Irish healthcare manufacturing companies.

Expanding the study to include the entire supply chain (including vendors and customers) as part of the connected enterprise could also form the basis for future related studies.

Bibliography

ARC Advisory Group, 2016. *ARC Advisory Group Vision, Experience, Answers For Industry.* [Online]
Available at: http://www.arcweb.com/about-arc
[Accessed 6 February 2016].

Bosch Software Innovations GmbH, 2015. *Industrial Internet: Putting the vision into practice ,* Berlin: Bosch Software Innovations GmbH.

Schneider Electric Telemetry & Remote SCADA Solutions, 2012. *SCADA Systems.* [Online]
Available at: http://www.schneider-electric.com/solutions/ww/en/med/20340568/application/pdf/1485_se-whitepaper-letter-scadaoverview-v005.pdf
[Accessed 22 September 2015].

Assante, M. & Conway, T., 2014. An Abbreviated History of Automation & Industrial Controls Systems and Cybersecurity. *A SANS Analyst Whitepaper*, August, pp. 1-31.

Brettel, M., Friederichsen, N., Keller, M. & Rosenberg, M., 2014. How Virtualization, Decentralization and Network Building Change the Manufacturing Landscape: An Industry 4.0 Perspective. *World Academy of Science, Engineering and Technology International Journal of Mechanical, Aerospace, Industrial, Mechatronic and Manufacturing Engineering,* 14(No.1), pp. 37-44.

Brock, D. C., 2012. From automation to Silicon Valley: the automation movement of the 1950s, Arnold Beckman, and William Shockley. *History and Technology,* XXVIII(4), pp. 375-401.

Buchanan, D. A. & Bryman, A., 2011. *The SAGE Handbook of Organizational Research Methods.* 1st ed. London: SAGE Publications Inc..

Cai, C., 2015. *The Essenes of IoT – Open Source Hardware + Open Source Next-gen Big Data Analytics Platform + Crowdsourcing Data Science Model.* Berlin, IoT World Europe.

CISCO, Rockwell Automation, 2011. *Converged Plantwide Ethernet (CPwE) Design and Implementation Guide.* [Online]
Available at: http://literature.rockwellautomation.com/idc/groups/literature/documents/td/enet-td001_-en-p.pdf
[Accessed 3 July 2016].

Control Engineering, 2015. *Convergence of PLCs, PACs, IPCs.* [Online]
Available at: http://www.controleng.com/single-article/convergence-of-pacs-plcs-ipcs/807160da9168bf5a35b34b4ca74a4ad5.html
[Accessed 30 December 2015].

Cooper, D. R. & Schindler, P. S., 2003. *Business Research Methods.* 8th ed. New York: McGraw-Hill/Irwin.

Curtis, B., Hefley, W. E. & Miller, S. A., 2001. *People Capability Maturity Model,* Pittsburgh: Software Engineering Institute.

Darke, P., Shanks, G. & Broadbent, M., 1998. Successfully completing case study research: combining rigour, relevance and pragmatism. *Information Systems Journal,* Issue 8, pp. 273-289.

Design, C., 2015. *The Ever-Expanding Mind of Morley.* [Sound Recording] (Control Design).

Didier, P. et al., 2011. *Converged Plantwide Ethernet (CPwE) Design and Implementation Guide.* 1st ed. s.l.:CISCO.

Dublin City University, 2016. *Prospective Students.* [Online]
Available at: https://www.dcu.ie/prospective/deginfo.php?classname=ME
[Accessed 10 January 2016].

Elau GmbH, 2009. *PacDrive C600 Controller,* Marktheindenfeld: Elau GmbH.

Enterprise Ireland, 2010. *Enterprise Ireland.* [Online]
Available at: https://www.enterprise-ireland.com/en/Source-a-Product-or-Service-from-Ireland/Sector-and-Company-Directories/Pharmaceutical-Sector-Profile.pdf
[Accessed 01 December 2015].

European Commission Health Consumers Directorate General, 2014. *EudraLex Volume 4 EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use,* Brussels: European Commission.

Felser, M., 2002. *The Fieldbus Standards: History and Structures. Technology Leadership Day.* [Online]
Available at:
https://scholar.google.com/scholar?hl=en&q=The+Fieldbus+Standards%3A+History+and+Structures&btnG=&as_sdt=1%2C5&as_sdtp=
[Accessed 30 December 2015].

Felser, M. & Sauter, T., 2002. *The Fieldbus War: History or Short Break Between Battles?.* Vasteras, IEEE.

Fitzgerald, B., Lenihan, H., Gomez, L. C. & Eoin, O., 2014. *Irish Software Landscape Study, Interim Report,* Limerick: LERO.

Galloway, B. & Hancke, G. P., 2013. Introduction to Industrial Control Networks. *IEEE COMMUNICATIONS SURVEYS & TUTORIALS,* 15(2), pp. 860-879.

Gartner, 2013. *Gartner IT Glossary.* [Online]
Available at: http://www.gartner.com/it-glossary/operational-technology-ot
[Accessed 22 September 2015].

Gartner, 2015. *Gartner.* [Online]
Available at: http://www.gartner.com/newsroom/id/3165317
[Accessed 17 January 2016].

Gartner, 2015. *What Is Industrie 4.0 and What Should CIOs Do About It?.* [Online]
Available at: http://www.gartner.com/newsroom/id/3054921
[Accessed 6 February 2016].

Giddens, A., 1987. *Positivism and sociology.* 1st ed. Hampshire: Gower Publishing Company Limited.

goodreads.com, 2015. *goodreads.com.* [Online]
Available at: https://www.goodreads.com/author/quotes/203714.Henry_Ford
[Accessed 16 December 2015].

Guarnieri, M., 2010. The Roots of Automation Before Mechatronics. *IEEE INDUSTRIAL ELECTRONICS MAGAZINE,* pp. 42-43.

Holland, J. H., Holyoak, K. J., Nisbett, R. E. & Thagard, P. R., 1989. *Induction: Process of inference, learning and discovery.* 1st ed. Massachusetts: The MIT Press.

Hu, F., 2015. *Robust Cyber–Physical Systems: Concept, models, and implementation, Future Generation Computer Systems.* [Online]
Available at: http://www.sciencedirect.com/science/article/pii/S0167739X15002071
[Accessed 22 November 2015].

ISA, 2015. *ISA The Standard for Automation.* [Online]
Available at: https://www.isa.org/
[Accessed 1 January 2016].

ISA, 2016. *ISA99, Industrial Automation and Control Systems Security.* [Online]
Available at: https://www.isa.org/isa99/
[Accessed 31 January 2016].

ISPE, 2008. *GAMP 5 A Risk-Based Approach to Compliant GxP Computerized Systems.* 1st ed. s.l.:International Society for Pharmaceutical Engineering.

IVI, 2015. *IVI Innovation Value Institute.* [Online]
Available at: http://ivi.nuim.ie/it-cmf
[Accessed 10 March 2015].

Johnson-Laird, P. N. & Byrne, R. M. J., 1991. *Deduction.* 1st ed. Hove, East Sussex: Lawrence Erlbaum Associates Ltd.,Publishers.

Jones, M., 2014. *Researching organisations: The Practice of Organisational Fieldwork.* 1st ed. London: Sage publications Inc..

Kepware Technologies, 2015. *Understanding OPC.* [Online]
Available at: https://www.kepware.com/products/kepserverex/opc-interoperability/
[Accessed 23 January 2016].

Lean Validation, 2014. *Lean Validation.* [Online]
Available at: http://www.leanvalidation.eu/index.php/isa-standards/isa-95
[Accessed 22 September 2015].

Leita, P., Colombo, W. A. & Karnouskos, S., 2015. Industrial automation based on cyber-physical systems technologies: Prototype implementations and challenges. *Computers in Industry,* Issue 2719, pp. 1-15.

Machina Research, 2015. *Machina Research.* [Online]
Available at: https://machinaresearch.com/
[Accessed 12 Oct 2015].

Machina Research, 2015. *Machine Research.* [Online]
Available at: https://machinaresearch.com/
[Accessed 12 October 2015].

Markarian, J., 2015. Connecting MES to Process Control. *Pharmaceutical Technology,* pp. 70-71.

Mayer, G., 2004. *Union Membership Trends in the United States.* [Online]
Available at:
http://digitalcommons.ilr.cornell.edu/cgi/viewcontent.cgi?article=1176&context=key_workplace
[Accessed 21 January 2016].

Mehta, Y., 2015. *What is Industrial Internet of Things? Industrial IoT.* [Online]
Available at: http://www.theinternetofthings.eu/yash-mehta-what-industrial-internet-things-industrial-iot
[Accessed 21 September 2015].

Meredith, J. R. & Suresh, N. C., 1986. Justification techniques for advanced manufacturing technologies.. *INT. J. PROD. RES,* XXIV(5), pp. 1043-1057.

Morariu, O., Borangiu, T. & Raileanu, S., 2015. vMES: Virtualization aware manufacturing execution system. *Computers in Industry,* Issue 67, pp. 27-37.

Nathan, S., 2015. Getting to grips with Industry 4.0.. *Engineer (00137758),* CCXCVI(7867), pp. 30-34.

Neumann, P., 2007. Communication in industrial automation—What is going on?. *Control Engineering Practice,* 11 December, Volume XV, p. 1332–1347.

Norman, J., 2015. *Automata Invented by Heron of Alexandria.* [Online]
Available at: http://www.historyofinformation.com/expanded.php?id=16
[Accessed 14 December 2015].

OPC Foundation, 2015. *OPC Foundation: The Interoperability Standard for Industrial Automation.* [Online]
Available at: https://opcfoundation.org/about/what-is-opc/
[Accessed 22 Septembder 2015].

Payne, J., 2013. *Control Engineering PLC vc. PAC.* [Online]
Available at: http://www.controleng.com/single-article/plc-vs-pac/44448cf771be09bff7115c621633bd94.html
[Accessed 6 February 2016].

Riegel, R., 2013. *independent.ie.* [Online]
Available at: http://www.independent.ie/life/family/learning/highly-qualified-graduates-now-make-up-majority-of-emigrants-29614325.html
[Accessed 10 01 2016].

Rockwell Automation, 2015. *The Connected Enterprise.* [Online]
Available at: http://www.rockwellautomation.com/global/innovation/connected-enterprise/overview.page?
[Accessed 28 December 2015].

Rockwell Automation, 2016. *FactoryTalk AssetCentre.* [Online]
Available at: http://www.rockwellautomation.com/rockwellsoftware/products/factorytalk-assetcentre.page
[Accessed 18 January 2016].

Rockwell Automation, 2016. *Rockwell Automation.* [Online]
Available at: http://ab.rockwellautomation.com/programmable-controllers/plc-5-controllers
[Accessed 10 January 2016].

Rockwell Automation, 2016. *Rockwell Automation.* [Online]
Available at:
https://www.rockwellautomation.com/resources/downloads/rockwellautomation/pdf/events/raotm/sessions/tech/T31WhatsNewinVizualization.pdf
[Accessed 10 January 2016].

Rockwell Automation, 2016. *Rockwell Automation The Connected Enterprise.* [Online]
Available at: http://www.rockwellautomation.com/global/innovation/connected-enterprise/maturity-model.page?
[Accessed 26 June 2016].

Saunders, M., Lewis, P. & Thornhill, A., 2016. *Research methods for business students.* 7th ed. Essex: Pitman Publishing.

Scholten, B., 2007. *The Road to Integration: A guide to applying the ISA-95 Standard in manufacturing.* 1st ed. North Carolina: ISA-Instrumentation, Systems and Automation Society.

Siemens, 2016. *Siemens.* [Online]
Available at: http://w3.siemens.com/mcms/process-control-systems/en/simatic-pcs7-migration/simatic-s5/pages/simatic-s5.aspx
[Accessed 10 January 2016].

Simon, K., 2016. *iSixSigma SIPOC Diagram.* [Online]
Available at: https://www.isixsigma.com/tools-templates/sipoc-copis/sipoc-diagram/
[Accessed 16 July 2016].

Steigerwald, D., 2010. Walter Reuther, the UAW, and the dilemmas of automation. *Labor History,* 51(3), pp. 429-453.

Stöckl-Pukall, E., 2015. *"Platform Industrie 4.0", Industry Innovation meets Politics.* Berlin, Federal Ministry for Economic Affairs and Energy (BMWi)..

Stouffer, K., Falco, J. & Kent, K., 2006. *Guide to Supervisory Control and Data Acquisition (SCADA) and Industrial Control Systems Security.* [Online]
Available at: https://www.dhs.gov/sites/default/files/publications/csd-nist-guidetosupervisoryanddataccquisition-scadaandindustrialcontrolsystemssecurity-2007.pdf
[Accessed 13 August 2016].

Stouffer, K., Falco, J. & Scarfone, K., 2011. GUIDE TO INDUSTRIAL CONTROL SYSTEMS (ICS) SECURITY. *National Institute of Standards and Technology,* 800(82), pp. 1-155.

Talbot, C., 2013. *CARIM INDIA – DEVELOPING A KNOWLEDGE BASE FOR POLICYMAKING ON INDIA-EU MIGRATION: Highly Skilled Indian migrants in Ireland,* San Domenico di Fiesole: European University Institute.

The Design Observer Group, 2016. *Design Observer.* [Online]
Available at: http://designobserver.com/slideshow.php?entry=10617&view=17&slide=3
[Accessed 22 January 2016].

The Government Office for Science, 2013. *Foresight (2013) The future of manufacturing: A new era of opportunity and challenge for the UK Project Report,* London: The Government Office for Science.

Theorin, A. & Segovia, V. R., 2012. *History of Control; History of PLC and DCS.* [Online]
Available at:
http://www.control.lth.se/media/Education/DoctorateProgram/2012/HistoryOfControl/Vanessa_Alfred_report.pdf
[Accessed 21 December 2015].

Theorin, A. & V.R., S., 2012. *History of Control; History of PLC and DCS,* s.l.: s.n.

Thomesse, J.-P., 2005. Fieldbus Technology in Industrial Automation. *Proceedings of the IEEE,* XCIII(6), pp. 1073-1101.

Tully, J., 2015. *Mass Adoption of the Internet of Things Will Create New Opportunities and Challenges for Enterprises.* [Online]
Available at: https://www.gartner.com/doc/2994817?ref=SiteSearch&refval=&pcp=mpe
[Accessed 7 February 2016].

VDC Research, 2016. *VDC Research Insights into the connected world.* [Online]
Available at: http://www.vdcresearch.com/
[Accessed 6 February 2106].

Vyatkin, V., Salcic, Z., Roop, P. & Fitzgerald, J., 2007. Now That's Smart!. *Industrial Electronics Magazine, IEEE,* 1(4), pp. 17-29.

Ward, J. & Peppard, J., 2002. *Strategic Planning for Information Systems.* 3rd ed. Chichester: John Wiles & Sons Ltd.

Weichhart, G. et al., 2015. Challenges and current developments for Sensing, Smart and Susstainable Enterprise Systems. *Computers in Industry*, 2 July, pp. 1-13.

Weil, M., 2015. *Control design for Machine Builders.* [Online]
Available at: http://www.controldesign.com/articles/2015/is-the-plcs-obituary-premature/?show=all
[Accessed 6 February 2016].

Werum IT Solutions AG, 2016. *Werum IT Solutions.* [Online]
Available at: http://www.werum.com/en/company/about-werum-it-solutions/
[Accessed 6 February 2016].

whatis.techtarget.com, 2015. *whatis.techtarget.com.* [Online]
Available at: http://whatis.techtarget.com/definition/machine-to-machine-M2M
[Accessed 24 September 2015].

Yin, R. K., 2014. *Case Study Research: Design and Methods.* 5th ed. London: Sage.

Yue, X. et al., 2015. Cloud-assisted industrial cyber-physical systems: An insight. *Microprocessors and Microsystems*, 17 August, pp. 1-9.

Appendices

Appendix A – SCSS research ethics committee application form

School of Computer Science and Statistics
Research Ethical Application Form

Part A

Project Title: IT and OT convergence: The case of implementing the connected enterprise

Name of Lead Researcher (student in case of project work): Simbarashe Pagious Wekare

Name of Supervisor: ~~Anthony Niland~~ ANTHONY NILAND

TCD E-mail: swekare@tcd.ie Contact Tel No.: +353-86-7945313

Course Name and Code (if applicable): MSc. in Management of Information Systems

Estimated start date of survey/research: 04 April 2016

I confirm that I will (where relevant):

- Familiarize myself with the Data Protection Act and the College Good Research Practice guidelines http://www.tcd.ie/info_compliance/dp/legislation.php;
- Tell participants that any recordings, e.g. audio/video/photographs, will not be identifiable unless prior written permission has been given. I will obtain permission for specific reuse (in papers, talks, etc.)
- Provide participants with an information sheet (or web-page for web-based experiments) that describes the main procedures (a copy of the information sheet must be included with this application)
- Obtain informed consent for participation (a copy of the informed consent form must be included with this application)
- Should the research be observational, ask participants for their consent to be observed
- Tell participants that their participation is voluntary
- Tell participants that they may withdraw at any time and for any reason without penalty
- Give participants the option of omitting questions they do not wish to answer if a questionnaire is used
- Tell participants that their data will be treated with full confidentiality and that, if published, it will not be identified as theirs
- On request, debrief participants at the end of their participation (i.e. give them a brief explanation of the study)
- Verify that participants are 18 years or older and competent to supply consent.
- If the study involves participants viewing video displays then I will verify that they understand that if they or anyone in their family has a history of epilepsy then the participant is proceeding at their own risk
- Declare any potential conflict of interest to participants.
- Inform participants that in the extremely unlikely event that illicit activity is reported to me during the study I will be obliged to report it to appropriate authorities.
- Act in accordance with the information provided (i.e. if I tell participants I will not do something, then I will not do it).

Signed: .... Date: 10 March 2016
Lead Researcher/student in case of project work

Part B

Please answer the following questions.		*Yes/No*
Has this research application or any application of a similar nature connected to this research project been refused ethical approval by another review committee of the College (or at the institutions of any collaborators)?		No
Will your project involve photographing participants or electronic audio or video recordings?		NO
Will your project deliberately involve misleading participants in any way?		NO
Is there a risk of participants experiencing either physical or psychological distress or discomfort? If yes, give details on a separate sheet and state what you will tell them to do if they should experience any such problems (e.g. who they can contact for help).		NO
Does your study involve any of the following?	Children (under 18 years of age)	NO
	People with intellectual or communication difficulties	NO
	Patients	NO

SCSS Research Ethics Application Form September 2011

School of Computer Science and Statistics
Research Ethical Application Form

Details of the Research Project Proposal must be submitted as a separate document to include the following information:

1. Title of project
2. Purpose of project including academic rationale
3. Brief description of methods and measurements to be used
4. Participants - recruitment methods, number, age, gender, exclusion/inclusion criteria, including statistical justification for numbers of participants
5. Debriefing arrangements
6. A clear concise statement of the ethical considerations raised by the project and how you intend to deal with them
7. Cite any relevant legislation relevant to the project with the method of compliance e.g. Data Protection Act etc.

Part C

I confirm that the materials I have submitted provided a complete and accurate account of the research I propose to conduct in this context, including my assessment of the ethical ramifications.

Signed: .... Date: 10 March 2016
Lead Researcher/student in case of project work

There is an obligation on the lead researcher to bring to the attention of the SCSS Research Ethics Committee any issues with ethical implications not clearly covered above.

Part D

If external ethical approval has been received, please complete below.

External ethical approval has been received and no further ethical approval is required from the School's Research Ethical Committee. I have attached a copy of the external ethical approval for the School's Research Unit.

Signed: .... Date: ....
Lead Researcher/student in case of project work

Part E

If the research is proposed by an undergraduate or postgraduate student, please have the below section completed.

I confirm, as an academic supervisor of this proposed research that the documents at hand are complete (i.e. each item on the submission checklist is accounted for) and are in a form that is adequate for review by the SCSS Research Ethics Committee

Signed: .... Date: 10/3/2016
Supervisor

Completed application forms together with supporting documentation should be submitted electronically to research-ethics@scss.tcd.ie Please use TCD e-mail addresses only. When your application has been reviewed and approved by the Ethics committee hardcopies with original signatures should be submitted to the School of Computer Science & Statistics, Room F37, O'Reilly Institute, Trinity College, Dublin 2.

Appendix B – Informed Consent Form

LEAD RESEARCHER: SIMBARASHE WEKARE

BACKGROUND OF RESEARCH

Operational Technology (OT) and Information Technology (IT) have traditionally existed as different entities within the same organisation. The evolution of operational technology/automation and the resultant convergence of this technology with information technology has been proved to be key to the establishment of the connected enterprise.

This research project proposal aims to add to the body of knowledge which currently exists in relation to the convergence of IT and OT resulting in the establishment of the connected enterprise. Notwithstanding the fact that there are several literature sources which theorize the concept of the connected enterprise, there has been little international research on how the evolution in OT and its subsequent convergence with IT has supported the implementation of the connected enterprise in the healthcare manufacturing industry.

Although the research is limited to one significant player in the healthcare manufacturing industry in Ireland, it is hoped that the research findings will be consistent with any future related research studies which utilise a multiple-case study research strategy approach. The aim of this research which is being carried out in partial fulfillment of the requirements for the award of a Master's Degree in Management of Information Systems by the School of Computer Science and Statistics, Trinity College Dublin, Ireland, is to identity the state of preparedness to the adaptation of connected enterprise practices by your organisation.

Please note that you are requested to express your own views when answering any of the questions in this survey questionnaire. This research is not requesting you to express views of your organisation.

PROCEDURES OF THIS STUDY

As part of the research, you are asked to devote 15-20 minutes to complete an anonymous online survey that will focus on your views on the connected enterprise. If you work in Information Technology (IT) or Engineering you will be asked to answer additional questions. The survey will include the following:

- Your views on the connected enterprise.
- Current department you work in.

- If you work for IT, Business Intelligence or Engineering, your Industrial Automation/Operational Technology (OT) skills.
- If you work for IT, Business Intelligence or Engineering, your Information Technology (IT) skills.
- If you work for IT, Business Intelligence or Engineering, your Data Management skills.
- Your Manufacturing Execution Systems (MES) / Manufacturing Operations Management Experience.
- Your Enterprise Resource Planning (ERP) skills.
- Demography questions.

RELEVANCE

Your participation in this research will enable better understanding of what needs to be done to ensure that healthcare manufacturing companies can best prepare themselves for the next generation of manufacturing of which the connected enterprise plays a key part. The information gathered from responses to this questionnaire will be used to add to the body of knowledge on related subjects and will also provide additional knowledge. This research is critically important. Hence your co-operation is sought.

DECLARATION OF POTENTIAL CONFLICT OF INTEREST

This survey is being undertaken by Simbarashe Wekare who works for the same company as you. As such, it is acknowledged that this represents a possible conflict of interest. In respect of this acknowledgement, you are asked to act with integrity and I (Simbarashe Wekare), will undertake to do the same.

EXITING SURVEY

Please be reminded that you may choose not to submit your response to the questionnaire with no penalty. This option is provided on the last page of this questionnaire. Also please note that prior to being asked to respond to the questionnaire, your consent is sought as explained on page 3. However, I will appreciate it if all the questions are completed and the survey is submitted using the "Done" button on the last page.

PUBLICATION

Individual results will be aggregated anonymously and research reported on aggregate results. The survey results will form part of the lead researcher's dissertation submission for a MSC in Management of Information Systems degree. The dissertation will be available for distribution throughout Trinity College. Only grouped data will be used, no individual will be identifiable in any report (or journal article). In keeping with standard professional practice, your data may be retained for 10 years, during which time only the investigators on this project will have access to them. The identity of you and all participants will be totally confidential.

DECLARATION

- I am 18 years or older and am competent to provide consent.
- I have read, or had read to me, a document providing information about this research and this consent form. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction and understand the description of the research that is being provided to me.
- I agree that my data is used for scientific purposes and I have no objection that my data is published in scientific publications in a way that does not reveal my identity.
- I understand that if I make illicit activities known, these will be reported to appropriate authorities.
- I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights.
- I understand that I may refuse to answer any question and that I may withdraw at any time without penalty.
- I understand that my participation is fully anonymous and that no personal details about me will be recorded.
- I understand that if I or anyone in my family has a history of epilepsy then I am proceeding at my own risk.
- I have received a copy of this agreement

CONSENT STATEMENT

I have read the description of the procedure. I am 18 years or older and am competent to supply consent. I wish to proceed and I consent to participate in the study that has been described above.

1. Would you like to proceed with the survey?

☐ Yes, I would like to proceed with the survey

☐ No, I would not like to proceed with the survey

2. Please enter the date when survey was completed

DD / MM / YYYY

STATEMENT OF INVESTIGATOR'S RESPONSIBILITY AND RESEARCHER'S CONTACT DETAILS

Statement of investigator's responsibility: I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.

RESEARCHERS CONTACT DETAILS:

Simbarashe Wekare,

Mobile: +353-86-7945313

Tel: +353-1-896 3415

Email: swekare@tcd.ie

Appendix C – Survey questions

5. YOUR VIEWS ON THE CONNECTED ENTERPRISE

Please be reminded that answering all questions is optional.

In 2015, Rockwell stated that, *"The Connected Enterprise helps operations managers profitably manage and improve manufacturing and industrial processes. It helps IT executives reduce network complexities and exposure to information security risks. It shares productivity-improving information to workers across the organization in a context that is meaningful for each role"*.

3. With the above in mind and also considering the ongoing implementation of the Manufacturing Execution System (MES), are things like the MES and the connected enterprise being discussed in your department?

☐ Yes

☐ No

4. How high on the next 5 year agenda and strategic outlook do you think things like the MES and the connected enterprise should be in your company?

1 being the least important and 5 the most important.

	1. Least Important	2.	3.	4.	5. Most Important
Connected Enterprise 5 year agenda and strategic outlook importance	○	○	○	○	○

5. Do you think this development towards the connected enterprise is more likely to strengthen or weaken the position of your company in the competitive pharmaceutical industry?

☐ More likely to weaken

☐ More likely to strengthen

☐ I do not know

6. The connected enterprise with the use of applications such as the MES and other smart services will offer new opportunities for your company

☐ Strongly disagree

☐ Disagree

☐ Undecided

☐ Strongly agree

Please elaborate if you wish

7. Do you think there should be more investment in technology; pc tablets, smart phones and other smart technologies?

☐ Yes

☐ No

☐ I do not know

8. What do you consider to be the most important value drivers for the connected enterprise in your company? You can choose as many as you like from the list below.

☐ Productivity increase

☐ Costs for inventory holding decreased

☐ Reduction of maintenance costs

☐ Reduction in time to market

☐ Costs for quality reduced

☐ Forecasting accuracy increased

☐ Reduction of total machine downtime

9. What do you consider to be the biggest challenges the company is facing or will face in implementing the connected enterprise? You can choose as many as you like from list below.

☐ Security

☐ Privacy

☐ Approval of projects related to the implementation of the connected enterprise

☐ Network connectivity

☐ Big Data / Analytics / Cloud Computing

☐ Lack of highly skilled personnel to support the connected enterprise initiatives

☐ How it is impacting or its impact on the existing business model.

☐ Other (please specify)

10. What do you consider to be the biggest opportunities offered by the connected enterprise for your company? You can choose as many as you like from the list below.

☐ Leaner manufacturing processes

☐ Operational efficiency

☐ Gaining competitive advantage

☐ Cost efficiency / savings

☐ Other (please specify)

6. ABOUT YOUR CURRENT DEPARTMENT IN THE ORGANISATION

Please be reminded that answering all questions is optional.

11. Which department do you work in?

☐ Accounting

☐ Administrative

☐ Customer service

☐ Marketing

☐ Operations

☐ Human Resources

☐ Sales

☐ Finance

☐ Legal

☐ IT

☐ Engineering

☐ Validation

☐ Research & Development (Tech Services)

☐ Quality

☐ Business Intelligence

☐ Manufacturing

☐ Public Relations

☐ Other

7. YOUR SKILLS ON AUTOMATION / OPERATIONAL TECHNOLOGY

Please be reminded that answering all questions is optional.

12. On a scale of 1 to 5 (1 Novice and 5 Expert), how do you rate your expertise on Industrial fieldbuses at ISA 95.01 Levels 0 and 1? Examples of such fieldbuses are; RS 232, RS485, DeviceNet, ControlNet, Profibus and ASI?

	1.Novice	2.	3.Proficient	4.	5.Expert
Industrial Telemetry Expertise	○	○	○	○	○

13. On a scale of 1 to 5 (1 Novice and 5 Expert), how do you rate your expertise on; IEC 61131 programming for PLCs?

	1.Novice	2.	3.Proficient	4.	5.Expert
PLC&SCADA configuration and programming	○	○	○	○	○

14. On a scale of 1 to 5 (1 Novice and 5 Expert), how do you rate your expertise on; HMI/SCADA systems configuration; Vision systems configuration and programming; robot configuration and programming?

	1.Novice	2.	3.Proficient	4.	5.Expert
PLC&SCADA configuration and programming	○	○	○	○	○

15. On a scale of 1 to 5 (1 Novice and 5 Expert), how do you rate your expertise on trouble shooting Industrial PCs and the use of Industrial PC based tools?

	1.Novice	2.	3.Proficient	4.	5.Expert
PC Troubleshooting and Industrial PC based tools	○	○	○	○	○

8. YOUR SKILLS - INFORMATION TECHNOLOGY

Please be reminded that answering all questions is optional.

16. On a scale of 1 to 5 (1 Novice and 5 Expert), how would you describe your Networking experience/knowledge, including TCP/IP, LAN/WAN, DHCP, DNS, and Firewalls etc?

	1.Novice	2.	3.Proficient	4.	5.Expert
Networking experience/knowledge	○	○	○	○	○

17. On a scale of 1 to 5 (1 Novice and 5 Expert), how would you describe your expertise on the technical support for MES and ERP systems?

	1.Novice	2.	3.Proficient	4.	5.Expert
MES and ERP Technical Expertise	○	○	○	○	○

18. On a scale of 1 to 5 (1 Novice and 5 Expert), how would you describe your expertise on the maintenance of user permissions on your company domain for runtime authentication of manufacturing users such as operators, supervisors etc? (Managing and configuring Windows Active Directory and Group Policy Structure).

	1.Novice	2.	3.Proficient	4.	5.Expert
Windows Active Directory and Group Policy structure management	○	○	○	○	○

19. On a scale of 1 to 5 (1 Novice and 5 Expert), how would you describe your expertise on the administration and maintenance of antivirus systems e.g. Symantec AV for manufacturing industrial PCs and the operation of software back-ups applications e.g. Arcserve?

	1.Novice	2.	3.Proficient	4.	5.Expert
AntiVirus Maintenance System Backup and Restoration	○	○	○	○	○

20. On a scale of 1 to 5 (1 Novice and 5 Expert), how would you describe your expertise on Virtual and Cloud computing?

	1.Novice	2.	3.Proficient	4.	5.Expert
Virtual and Cloud computing expertise	○	○	○	○	○

21. On a scale of 1 to 5 (1 Novice and 5 Expert) how do you rate your expertise on the subject of IoT (Internet of Things) or IoE (Internet of Everything) and Industrie 4.0 as it applies to a manufacturing environment?

	1.Novice	2.	3.Proficient	4.	5.Expert
IoT & Industrie 4.0 Expertise	○	○	○	○	○

9. YOUR SKILLS - DATA MANAGEMENT

Please be reminded that answering all questions is optional.

22. Which of the following best describes your experience with OPC Servers?

☐ I regularly configure an OPC Server to enable connection between manufacturing and enterprise systems for data exchange.

☐ I infrequently configure an OPC Server to enable connection between manufacturing and enterprise systems for data exchange.

☐ I hardly configure an OPC Server to enable connection between manufacturing and enterprise systems for data exchange.

☐ I never configure an OPC Server to enable connection between manufacturing and enterprise systems for data exchange.

23. On a scale of 1 to 5 (1 Novice and 5 Expert), how would you describe your expertise on the implementation, maintenance of databases such as MS SQL and Data Historians such as Rockwell's Factory Talk Historian?

	1.Novice	2.	3.Proficient	4.	5.Expert
Database and Historian expertise	○	○	○	○	○

24. On a scale of 1 to 5 (1 Novice and 5 Expert), how would you describe your expertise on the implementation and maintenance of reporting services such as Crystal Reports, MS SQL Reporting Services?

	1.Novice	2.	3.Proficient	4.	5.Expert
Reporting Services Expertise	○	○	○	○	○

10. MANUFACTURING EXECUTION SYSTEM (MES) / MANUFACTURING OPERATIONS MANAGEMENT (MOM) EXPERIENCE

Please be reminded that answering all questions is optional.

25. How familiar are you with the use of a Manufacturing Execution System (MES) or a Manufacturing Operations Management (MOM) system for workflow and recipe control during the manufacturing process?

☐ Very familiar

☐ Somewhat familiar

☐ Neither familiar nor unfamiliar

☐ Somewhat unfamiliar

☐ Very unfamiliar

26. Please select the statement that best describes your usage of the existing Rockwell Automation's VantagePoint web portal to explore hidden manufacturing data, including viewing web-based reports.

☐ I regularly access the web portal to view manufacturing data including web-based reports.

☐ I infrequently access the web portal to view manufacturing data including web-based reports.

☐ I hardly access the web portal to view manufacturing data including web-based reports.

☐ I never access the web portal to view manufacturing data including web-based reports.

27. On a scale of 1 to 5 (1 Novice and 5 Expert), how would you describe your expertise on the use of Manufacturing Execution Systems for maintaining manufacturing data and for the optimisation of the manufacturing processes through modifications to the MES recipes?

	1.Novice	2.	3.Proficient	4.	5.Expert
MES Administration	○	○	○	○	○

28. Have you ever actively participated in the roll out of a Manufacturing Execution System (MES) or Manufacturing Operations Management (MOM) for an organisation?

☐ Yes

☐ No

11. YOUR SKILLS – ENTERPRISE RESOURCE PLANNING (ERP) SYSTEMS

Please be reminded that answering all questions is optional.

29. On a scale of 1 to 5 (1 Novice and 5 Expert), how would you describe your expertise on the use of Enterprise Resource Planning (ERP) systems such as SAP for planned maintenance activities, production scheduling, material usage, inventory control, delivery and shipment of the final product?

	1.Novice	2.	3.Proficient	4.	5.Expert
ERP system expertise	○	○	○	○	○

12. DEMOGRAPHY

Please be reminded that answering all questions is optional.

30. What is the highest level of education you have completed?

31. How many years of working experience do you have?

☐ 1-5

☐ 6-10

☐ 11-15

☐ 16-20

☐ +20

13. DEMOGRAPHY

Please be reminded that answering all questions is optional.

32. Please feel free to add any further comments regarding your views on the implementation of the connected enterprise within your organisation which were not covered in the survey questions presented to you.