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Implementing S88 in Discrete Manufacturing Equipment

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BEng Engineering (University of Ulster)

A Research Dissertation submitted
in partial fulfilment for the degree of
Masters of Science in Technology Management

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College of Business, Public Policy and Law - School of Business & Economics

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Certification of Authorship:
I hereby certify that I am the author of this document and that any assistance I received in its preparation is fully acknowledged and disclosed in the document. I have also cited all sources from which I obtained data, ideas or words that are copied directly or paraphrased in the document. Sources are properly credited according to accepted standards for professional publications. I also certify that this paper was prepared by me for the purpose of partial fulfilment of requirements for the Degree Programme.

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Abstract

In the medical device industry, software has become a more integral component of the manufacturing process, which in the main, consists of discrete manufacturing equipment. As these software systems control the equipment that manufactures the medical devices, they are required to be validated to comply with the regulatory bodies requirements. As software systems become more complex coupled with more enforcement from the regulatory bodies, medical device manufacturers are investing additional resources to maintain compliance. This research project examines a case study of how a medical device manufacturer implemented a new software standard to reduce the software development and validation costs of new discrete manufacturing equipment.

The ISA-88 standard was evaluated as the basis for the software standard. This standard, which has it roots in the batch process industry, has had a major impact on the way batch process automation is engineered. S88 has been a focal point for defining and automating batch processes for over a decade; its acceptance within the batch processing community is widespread. While ISA-88 has achieved general acceptance in the batch process industry, it has not yet enjoyed widespread use in discrete manufacturing equipment applications.

This research examines how the S88 design standard was applied to discrete manufacturing equipment and the benefits of applying the software standard at a medical device manufacturing organisation. This was complemented with a survey of similar organisations that had recently implemented the ISA-88 design philosophy.

The final deliverable of this research was to develop a useful decision tree that should provide practical guidance to engineering professional investigating the option of implementing S88 at their organisation.
1 Introduction

1.1 Chapter introduction

The opening chapter of this dissertation looks at the background to the research and the rationale for undertaking it. This will initially outline the various standards and regulatory bodies that greatly impact the software development lifecycle for equipment in regulated industries. This will be followed by a review of discrete\(^1\) manufacturing and automation equipment, making particular reference to the similarities and differences with the batch\(^2\) process industries. An overview of the typical hardware and software systems that are used to control equipment is also discussed.

The final deliverable of this research is to develop a useful decision tree for end users who may be planning to introduce, replace or enhance their design philosophy for control systems for their manufacturing equipment. This will aim to provide guidance as to when it is appropriate and beneficial to apply the S88 design philosophy. The development of this decision tree was generated from the research data of the case study at the researcher’s workplace and additional supporting data from other organisations. This chapter concludes with a summary of the dissertation structure and an overview of the subsequent chapters.

1.2 Rationale for the study

The Application of S88 has been used to much success for Batch Processes, particularly in the pharmaceutical industry. Automation software to control processes in the pharmaceutical industry is typically modular. Modules are integrated in a given system to control the plant. Modules have varying degrees of complexity depending on what they’re controlling.

Traditionally, PLC software development and equipment design for custom discrete manufacturing equipment has not utilised the object oriented principles or the S88 standard. However, recent developments from some of the main automation OEM suppliers, such as Rockwell Automation, have promoted the use of the S88 standard in applications other than the traditional batch process manufacturing where it was typically used. Similar to most manufacturing processes across a range of industries, software systems are getting utilised more extensively within manufacturing plants in regulated environments. In addition to this, end users in an effort to comply with the regulatory bodies

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\(^1\) Discrete manufacturing equipment usually consists of custom discrete manufacturing stations performing at least one process on the product. It is widely used across a range of industries from medical device to automotive manufacturing.

\(^2\) Batch process manufacturing create finished products by heating, mixing, or separating single or multiple inputs to create multiple outputs.
(such as the FDA) have been applying more focus to ensure that these software systems are designed, tested and maintained correctly. The General Principles of Software Validation (2002) states:

‘The FDA’s analysis of 3140 medical device recalls conducted between 1992 and 1998 reveals that 242 of them (7.7%) are attributable to software failures. Software validation and other related good software engineering practices discussed in this guidance are a principal means of avoiding such defects and resultant recalls.’

In practice, this has resulted in organisations utilising a lot of resources to ensure that they are compliant with the FDA’s guidelines. Regulated industries who do not have specific standards for software development are finding it more difficult and expensive to demonstrate compliance for custom designed equipment.

This dissertation will examine where the S88 standard has been implemented on custom discrete manufacturing equipment in a regulated environment. This research will then be used to develop a decision tree to enable end users determine the benefits of applying the S88 design philosophy to custom discrete manufacturing equipment.

Organisations such as WBF and OMAC (WBF: S88 for Researchers and Scientists) and automation OEM suppliers (Rockwell Automation, ‘Integrated Architecture - Foundations of Modular Programming’) have made claims about the applicability of S88 to the discrete manufacturing domain. As of yet, it has not yet enjoyed widespread use throughout non-batch industries. This paper will enable engineers to better assess the benefits of applying S88 in their organisation prior to its implementation.

1.3 Standards and Regulatory Bodies

This dissertation is focussed on the S88 standard - shorthand for ANSI/ISA-88. This standard was initially introduced by ISA in 1995 and was subsequently accredited by ANSI. It was adopted by the IEC in 1997 as IEC 61512-1.

The ISA (International Society of Automation) develops standards; certifies industry professionals; provides education and training; publishes books and technical articles (www.isa.org). Accreditation by ANSI (American National Standards Institute) signifies that the procedures used by the standards body in connection with the development of American National Standards meet the Institute’s essential requirements for openness, balance, consensus and due process (www.ansi.org). The IEC (International Electrotechnical Commission) is the world's leading organization that prepares and publishes International Standards for all electrical, electronic and related technologies. The IEC also

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3 Non-batch industries in this context refer to all manufacturing or process industries that are considered not to be batch process. This includes, but is not limited to, discrete manufacturing as used in medical device manufacturing and continuous process industries such as primary petrochemicals where the output of the product is uninterrupted.
manages conformity assessment systems that certify that equipment, systems or components conform to its International Standards (www.iec.ch). The IEC also has a standard that is used extensively in the programming of programmable controllers (see next section) and defines both graphical and textual programming language standards.

The S88 standard has been used throughout the world, particularly in the pharmaceutical batch process industries. Pharmaceutical industries are tightly regulated industries and for the context of this dissertation, the focus will be on complying with the FDA - the American Food and Drug Administration. The FDA is a federal science-based law enforcement agency mandated to protect public health and safety (www.fda.org).

One of the key requirements when designing equipment for use in the manufacturing process in the regulated industry is that the equipment must be validated. Typically, this will require that the equipments’ intended use is well documented, and that throughout the design, build and test phases, evidence of thorough design, configuration and test activities are documented.

1.4 Discrete manufacturing equipment

There are significant differences between batch process industries, where S88 has been used extensively and discrete manufacturing equipment. Process industries are typically characterized by very high fixed capital, concentrated in a small number of workstations. A batch process plant consists of individual plant items linked by a pipe network through which product is routed. The production equipment is often physically large and relatively fixed in nature. Process manufacturing create finished products by heating, mixing, or separating single or multiple inputs to create multiple outputs (Kalakota & Whinston, 1997).

In most discrete manufacturing operations, the capital investment is smaller and is spread across many workstations. Discrete manufacturing equipment is used to manufacture products from automobiles to medical devices by gathering multiple raw materials and components inputs to create a single finished product.

1.5 Controls Hardware and Software

A programmable logic controller is used for automation of mechatronic processes, such as control of machinery on factory assembly lines. A PLC is an example of a real time system since output results must be produced in response to input conditions within a bounded time, otherwise unintended operation will result.

Under the IEC 61131-3 standard, PLCs can be programmed using standards-based programming languages. IEC 61131-3 currently defines five programming languages for programmable control systems: FBD (Function block diagram), LD (Ladder diagram), ST (Structured text, similar to the
Pascal programming language), IL (Instruction list, similar to assembly language) and SFC (Sequential function chart).

Except in simple applications, most control systems include a HMI (human machine interface) for operator instructions and machine diagnostics. More recently, control systems interface to higher level business systems that control process recipes, schedule production orders, log process data and alarm information.

Application software for programmable controllers and human machine interfaces are typically developed through dedicated software development languages. Some of the most common hardware controllers used in Ireland are Allen Bradley, Siemens and Mitsubishi. Software tools from Rockwell such as RSLogix and Factory View and from Siemens such as Simatic Step 7 and WinCC are used to develop PLC application and HMI software. Alternatively, HMI’s can be developed using common Microsoft tools such as Microsoft Visual Basic.

1.6 Research Objectives

Initially, at a purely technical level, the research will determine what changes, if any, need to be applied to the S88 models to enable them to be used successfully for discrete manufacturing equipment. Next, from more of a business perspective, the research will determine the conditions necessary to support the introduction of a new controls standard into an organisation. This will then lead to the final two questions to be answered by this research. The first of these questions is to determine the success factors associated with the implementation of the S88 standard. The second of these questions is to quantify the benefits of applying the S88 standard to discrete manufacturing equipment.

As a deliverable from the findings above, it will be possible to develop a decision tree to enable end users determine the benefits of applying the S88 design philosophy to custom discrete manufacturing equipment within an organisation.

1.7 Summary of Chapters

Chapter 2, the literature review, provides a definition of the controls systems standards and regulatory guidelines that have been followed in this case study. From a controls systems perspective, the IEC-61131-3 and S88 standard will be reviewed and the application of S88 in the batch process industry will be discussed. A review of both academic and industry publications on the benefits of applying the S88 standard in the batch industry will be discussed and trends highlighted as to the main themes that are emerging. The S88 standard shares many of its principles with Object Oriented software development techniques and a review of applying Object Oriented principles to PLC programming will be discussed.

Chapter 3, the research methodology, commences with an outline of the organisation in which the case study was conducted and the objectives of the research. This is followed by a discussion on some of the appropriate research
paradigms and associated methods. Each method is discussed with respect to its suitability in conducting and evaluating the research, to ultimately achieve the research objectives. This chapter will conclude by summarising the three sets of questions that will be used to gather the necessary data to conduct the research analysis.

Chapter 4, the findings and analysis, presents the results and findings of the primary research questions. This chapter discusses the S88 software design standard that was applied to discrete manufacturing equipment in the case study, and presents the models developed to support its introduction at Medical Technology Ltd\(^4\). For each set of the research questions, the results and findings from both the case study and survey respondents are discussed. The decision tree framework to determine if applying S88 is suitable for individual organisations is presented and discussed.

Chapter 5, the concluding chapter, discusses the main findings of the research project, the recommendations arising from this research and suggests future research work.

\(^4\) Pseudonym for the medical device company in which research was conducted
2 Literature Review

2.1 Chapter Introduction

This chapter provides a definition of the controls systems standards and regulatory guidelines that are applicable in this research. Initially, the relevant sections of the FDA Guidelines on software validation will be presented and a review of the literature on the impact that complying with FDA guidelines has for equipment development life-cycles in the life sciences industry. From a controls systems perspective, the IEC-61131-3 and S88 standard will be reviewed and summarised. A review of both academic and industry publications on the benefits of applying the S88 standard in the batch industry will be discussed and trends highlighted as to the main themes that are emerging. As the S88 standard has been applied mainly in the batch process industry, the differences between discrete manufacturing equipment and batch processing equipment will be highlighted. Finally, as the S88 standard shares many of its principles with Object Oriented software development techniques, a review of applying Object Oriented principles to PLC programming will be discussed.

2.2 FDA / Regulatory Compliance

2.2.1 Background

Regulatory bodies worldwide are tasked with the job of ensuring that only safe medical devices are placed on the market. A safe device is one that cannot cause serious harm or injury to a patient or end-user of the device. Some of the main regulatory bodies are listed below. In the European Union, devices cleared by a notified body, receive an EC certificate and a CE mark, which is placed on the device. The Japanese ministry of health and welfare issue a Shonin as an approval to market. In the United States of America manufacturers must first receive a 510K premarket notification or a pre-market approval (PMA) from the FDA. These regulatory bodies also publish guidelines on the requirements on manufacturers to demonstrate that their production systems are suitably qualified to manufacture products. The research in this case study is closely linked to the guidelines that are prescribed in the FDA’s recommendations. The FDA’s inspection of software validation of automated processes has increased significantly over the last decade, since the FDA officially introduced the quality system regulation, 21 CFR 820, in 1996. Prior to that, software validation activities were required to comply with the original good manufacturing practices regulations (Hooten, 1996).

2.2.2 FDA Regulations and Guidance

‘For a variety of reasons, software verification and validation has proven to be one of the more challenging and nebulous areas of compliance for companies
regulated by FDA’ (Chojnowski 2008). In the General Principles of Software Validation (2002), the FDA provides clear definition of verification and validation, which are described below:

Software verification provides objective evidence that the design outputs of a particular phase of the software development life cycle meet all of the specified requirements for that phase. Software verification looks for consistency, completeness, and correctness of the software and its supporting documentation, as it is being developed, and provides support for a subsequent conclusion that software is validated. Software testing is one of many verification activities intended to confirm that software development output meets its input.

Software validation is defined as “Confirmation by examination and provision of objective evidence that software specifications conform to user needs and intended uses, and that the particular requirements implemented through software can be consistently fulfilled.”

The challenge for many organisations is being able to interpret the guidelines and develop systems and procedures to effectively demonstrate their compliance. Most companies in the medical device industry understand and accept the need to validate software that is critical to the functioning of a medical device. Perhaps not as widely understood or accepted is the regulatory requirement to validate software that is used to automate any process that is part of a medical device manufacturer’s quality system. This broad requirement encompasses manufacturing, engineering, quality, and regulatory functions within the firm. (Vogel 2006) Since 1996, the FDA began to enforce section 820.70(i), as evidenced by the increasing number of observations and warning letters from the agency, which cited the industry’s lack of compliance with software validation requirements (Rubenacker 2005).

2.3 Validation of Manufacturing Equipment Systems

The software validation requirements for automated processes are stated in 21 CFR 820.70(i). This regulation indicates that validation should focus on the software’s intended use in the automated system. FDA guidance in the general principles of software validation emphasizes the need to assess the risks related to validating automated process equipment and quality system software. The level of effort for validation activities should be commensurate with risk.

As noted earlier, 21 CFR 820.70(i) requires validation of software that automates all or part of any process that is part of the quality system. That software includes the following:

- Software used as part of the manufacturing process (including software embedded in machine tools, statistical process control software, programmable logic controllers, and software in automated inspection or test systems).
• Software used to create, transmit, modify, or store electronic records or signatures that must comply with FDA guidance on electronic records and signatures, 21CFR Part 11.

2.4 Validation Activities

For all automated systems, manufacturers should follow internal software validation procedures that are consistent with FDA expectations for such validation. This typically utilizes a software development lifecycle. A software development lifecycle is a description of the phases that software goes through from the initial concept that software might be used to automate a process through the acquisition, installation, maintenance, and eventual retirement of the software. The level of effort and detail for software validation (e.g., testing and documentation) should be commensurate with safety risk.

Many activities can contribute to the conclusion that software has been validated. Requirements management, design reviews, and defect tracking, as well as unit, integration, and system-level testing are all techniques available to software professionals during development. Many of these techniques help prevent defects from getting into the software during development. Risk management, change control, life cycle planning, system-level testing, and output verification are well within the grasp of non-software professionals. These techniques are focused on identifying any defects that are in the software, preventing defects from appearing later in the life cycle, and planning for the inevitability that defects will be discovered once the software is used.

Testing may be one of the means that is used to provide the objective evidence that the requirements implemented in software can be fulfilled, however, it is not the only means, nor is it sufficient alone. This should be achieved by compiling a suite of verification or test procedures for confirming that the identified software usage requirements for the software’s intended use in the automated system are implemented. Change controls should address the identification of software versions so that changes can be tracked and revalidated as appropriate.

2.5 IEC-61131

Programmable logic controllers (PLCs) have been controlling industrial automation since the late 1960s when they were introduced for machine control systems for major U.S. car manufacturers. Before the PLC, control, sequencing, and safety interlock logic for manufacturing automobiles was accomplished using hundreds or thousands of relays, cam timers, and drum sequencers and dedicated closed-loop controllers. The process for updating such facilities for product or process changes was very time consuming and expensive, as the relay systems needed to be rewired by skilled electricians.

The IEC (International Electrotechnical Commission) is a worldwide organisation for standardisation comprising all national electrotechnical committees (IEC National Committees). The objective of the IEC is to promote international co-operation on all questions concerning standardization in the
electrical and electronic fields. In order to achieve this and in addition to other activities, the IEC publishes International Standards. The IEC collaborates closely with the ISO (International Organization for Standardisation).

IEC 61131 provides general information on programmable controllers and introduces the different parts of the standard, under the general title of Programmable Controllers. Part 1 establishes the definitions and identifies the principal characteristics relevant to the selection and application of programmable controllers and their associated peripherals. Part 2 specifies equipment requirements and related tests for programmable controllers (PLC) and their associated peripherals. Part 3 defines, for each of the most commonly used programming languages, major fields of application, syntactic and semantic rules, simple but complete basic sets of programming elements, applicable tests and means by which manufacturers may expand or adapt those basic sets to their own programmable controller implementations. Part 4 gives a general overview of information and application guidelines of the standard for the PLC end-user. Part 5 defines the communication between programmable controllers and other electronic systems. Part 6 is reserved. Part 7 defines the programming language for fuzzy control. Part 8 gives guidelines for the application and implementation of the programming languages defined in Part 3.

This research is concerned primarily with the impact of a new software development methodology for programming Programmable Controllers. Therefore, Part 3 of the IEC 61131 standard will be presented in more detail.

IEC 61131-3 is the third part of the open international standard IEC 61131, and was first published in December 1993 by the IEC. The current (second) edition was published in 2003. Part 3 of IEC 61131, shown in Figure 2-1, deals with programming languages and defines three graphical and two textual PLC programming language standards:

- Ladder diagram (LD), graphical
- Function block diagram (FBD), graphical
- Structured text (ST), textual
- Instruction list (IL), textual
- Sequential function chart (SFC), has elements to organize programs for sequential and parallel control processing.
Also, configuration elements are defined which support the installation of programmable controller programs into programmable controller systems. In addition, features are defined which facilitate communication among programmable controllers and other components of automated systems. The programming language elements defined in this part may be used in an interactive programming environment.

### 2.6 Batch Processing & Discrete Manufacturing

This case study is analysing the use of an automation design standard that is typically used in the batch process industry in the design of discrete manufacturing equipment.

Batch processing differs from discrete manufacturing in a number of fundamental ways. Batch process industries are typically characterized by very high fixed capital, concentrated in a small number of workstations. A batch process plant consists of individual plant items linked by a pipe network through which product is routed. The production equipment is often physically large and relatively fixed in nature. Batch process manufacturing create finished products by heating, mixing, or separating single or multiple inputs to create multiple outputs (Kalakota & Whinston, 1997). Automation software to control processes in the batch process industry is typically modular and are integrated in a given system to control the plant. Modules have varying degrees of complexity.
Batch processes are used in the chemical and pharmaceutical industries as well as food, beverages and paper industries. One characteristic of batch processing is that it is hard to preserve the batch identity if a batch is stored together with another batch. Another characteristic is that it is possible to make different end products with the same equipment. That is why a high amount of flexibility is required. The S88 standard provides a way to bring flexibility into batch control. A typical batch process is shown in Figure 2-2 and this can be contrasted with the typical discrete manufacturing equipment that is shown in Figure 2-3.

![Typical Batch Process Equipment (PDC Machines)](image)

The first most obvious difference with discrete manufacturing equipment is in the manufacturing methods. Other differences include the packaging requirements, asset allocation and product consistency. In most discrete manufacturing operations, the capital investment is smaller and is spread across many workstations. Typically, Medical Device manufacturing equipment consists of many stand-alone custom discrete manufacturing stations performing at least one process on the product.

From a controls perspective, traditionally, DCS (Distributed Control Systems) were used to control batch systems and programmable controllers were used to control discrete manufacturing equipment. However, in recent times, this norm is being challenged as the functionality offered by a DCS and a PLC are converging and the practical and technological boundaries between a DCS,
PLC, and personal computer control are merging. Units traditionally associated with process control are being used in discrete applications. Likewise, traditionally discrete solutions are used increasingly in both batch and continuous process control.

Figure 2-3  Typical Discrete Manufacturing Equipment (Medical Technology Limited)

2.7 ISA-88

This standard was initially introduced by ISA in 1995 and was subsequently accredited by ANSI. It was adopted by the IEC in 1997 as IEC 61512-1. Although the official name of the standard is ISA-88, it is often referred to as just S88 in industry and the terms are interchangeable. Both ISA-88 and S88 are used interchangeably throughout this document. The ISA (International Society of Automation) develops standards, certifies industry professionals, provides education and training and publishes books and technical articles. Accreditation by ANSI (American National Standards Institute) signifies that the procedures used by the standards body in connection with the development of American National Standards meet the Institute’s essential requirements for openness, balance, consensus and due process. The IEC (International Electrotechnical Commission) is the world's leading organization that prepares and publishes International Standards for all electrical, electronic and related technologies. The IEC also manages conformity assessment systems that certify that equipment, systems or components conform to its International Standards.
This batch control standard has had a major impact on the way batch process automation is engineered. S88 has been a focal point for defining and automating batch processes for over a decade; its acceptance within the batch processing community is widespread; and its adoption has had a positive impact on the development of modular programming, integration practices, diagnostics and debugging practices. The purpose of the standard was to emphasize good practices for the design and operation of batch manufacturing plants and to improve control of batch manufacturing plants. (Scholten, 2004) In addition, it has influenced everything from the way control systems are built to the way project requirements are written and has simplified and reduced the cost of batch control automation.

However, it is stressed that the standard "is not intended to suggest that there is only one way to implement or apply batch control". The models described by the standard are independent of underlying control algorithms as well as control systems such as PLC or DCS. In principle, the standard is applicable in any production situation where flexibility is an important issue (Lukszo, 2004).

2.8 Principles of ISA-88

2.8.1 Overview

The S88 standard is split up into three standard documents:
- ISA 88.01 describes the standard models and terminology,
- ISA 88.02 describes the data structures for the standard,
- ISA 88.03 describes the recipe model.

Part 1 of the standard describes modular design of the machine using a modular approach of implementing code based on standard modules.
Part 2 describes a state model for all machines that allow a user/system to handle transitions and interrupts all in the same way and control them from a central MES environment.
Part 3 describes a layered implementation of the recipe model, where the basic control of the machine at the phase level is split from the recipe execution of the machine. The layered implementation enables systems whereby the phase logic may reside in a PLC and the recipe engine may reside on a PLC, MES or Batch Server (Pingle, 2004)

S88 is a highly modular method of developing control systems for machines, starting with modularizing the design and using that design to build control code (routines) and by piecing together code modules matching the design modules. Using the standard for developing equipment allows for greater flexibility in how a machine is designed and later implemented at a production facility (Pingle, 2004).

2.8.2 S88.01: Models and Terminology

S88 consists of models and terminology for structuring the production process. The main idea of S88 is to separate equipment control from the procedure that describes how to make the end product. This is how it becomes possible to
execute different procedures for different end products, using the same equipment.

2.8.2.1 Physical model

S88.01 provides a hierarchical model for structuring the physical equipment, which is called the Physical model. Based on this model the control system engineer programs all the possible functions of the equipment. The full physical model is shown below for completeness; however, the S88 standard does not address the batch control boundaries above the Process Cell.

![Physical Model Diagram](image)

Figure 2-4   Physical Model (Parshall & Lamb, 1999)

The highest level in this model is the Enterprise, which can have one or more Sites. A Site can have one or more Area’s that consist of one or more Process cells. A process cell contains all of the equipment required to make batches. From a software development and equipment design perspective, the focus is on the lower level of the Physical model.

Process Cell / Production Line:   Logical grouping of equipment required for production of one or more batches.
Unit: Collection of related control modules and equipment modules that can carry out processing activities.

Equipment Module: A functional group of equipment and/or control modules that can carry out a finite number of processing activities.

Control Module: A regulating device, state-oriented device, or a combination of both that is operated as a single device without regard to the underlying logic.

A process cell may contain a number of units, which can be modularized into smaller physical entities called Control Modules and Equipment Modules. A unit is a fundamental equipment entity that manufactures batches or parts of batches.

2.8.2.2 Recipes

The product knowledge is described in recipes. S88.01 defines 4 different kinds of recipes: General, Site, Master and Control Recipes. Every recipe consists of different levels. The highest level defines the process described in the recipe. The lowest level shows what has to be done, step by step, to make the end product.

![Recipe Model](Figure 2-5 Recipe Model (Parshall & Lamb, 1999))

2.8.2.3 Procedural Model

The Procedural Model describes a hierarchical representation of the functions that can be performed, i.e. the recipes. It has four levels referred to as; procedure, unit procedure, operations and phases. The Procedure consists of one or more Unit procedure, which consists of one or more Operations, which consists of one or more Phases.
2.8.3 How S88 works

When a batch is produced, equipment and recipes are required. But there are also a lot of activities such as scheduling, recipe management, process control that are important in the control of batch processes. S88 provides a model for these activities: the Control Activity Model. By using this model, a flexible control system can be developed in order to realize a flexible production process.

When all the possibilities of the equipment have been programmed, the process engineer can choose phases (basic equipment functions like mixing, heating, adding raw materials). The process engineer develops a recipe by putting these phases in the right sequence. The recipe will tell the equipment what function to execute, and in which sequence.
2.8.4 Machine States

A Machine State completely defines the current condition of a machine. The S88 State model is shown in Figure 2-8. A State can consist of one or more commands to control objects, or consist of the status of a control objects, or both. In performing the function specified by the state, the state will issue a set of commands to the machine control object(s) which in turn can report status. The state will perform conditional logic which will either lead to further execution within the current machine state or cause an enabling transition to another state. States are arranged in an ordered fashion that is consistent with the specified operation of the machine. The number of these states required for a particular mode is dependent on the machine and the function of the mode.
2.8.5 S88 – Benefits

The benefits of S88 have been promoted by institutions such as ISA, WBF (World Batch Forum) and OMAC (Organisation for Machine Automation and Control), all of whom are promoting the use and further development of the S88 standard to maximise its use in the batch industry and also to help it gain momentum and acceptance in packaging and discrete manufacturing equipment.

Throughout the ISA’s publications, trade journals and the marketing material of various hardware and software suppliers, there is a common theme on the range of benefits available from implementing S88. These improvements that are realised throughout all stages of the equipment design process include ensuring a consistent design, re-use of pre-verified software modules, reduced testing, following a system recognised by FDA inspectors and ultimately reducing costs and schedule, whilst also improving quality.

McDonald (2003) was in general agreement with many of the benefits claimed above and noted that:

'The S88 standard has delivered significant cost savings benefits to the batch industry worldwide. This has been achieved through standard
terminology and models as well as inherent reusability of recipes and equipment phases’

In addition to this, McDonald applauded the work of OMAC’s PackML sub-team whose objective is to significantly simplify the design and integration of packing machinery. PackML is aiming to achieve this by enhancing and developing the S88 model transfer models, terminology and principles used in batch manufacturing into the discrete world of packaging. Pingle (2004) acknowledged the effort involved in implementing S88 and considered both the short term and long term benefits to be worthwhile. Pingle (2004) made particular reference to introducing a structured process for developing code and design documentation.

2.9 **PLC Programming Techniques and Developments**

PLC’s are used to control equipment and processes ranging from low cost small simple systems, with a few Inputs and Outputs (I/O) up to multi million euro high speed automated manufacturing lines with thousands of I/O points. IEC 61131 provides general information on programmable controllers with part 3 defining the commonly used programming languages. There is a wide range of techniques used for programming PLC’s, depending on the resources available and requirements of the end-user. For this reason, many machine builders and system integrators have their own internal PLC software standard. This enables machine builders and system integrators to reuse portions of code and ensures that all code has the same look and feel, independent of the programmer. From a machine builder’s perspective, this allows flexibility to have multiple programmers working on one machine and ensures the equipment is easier to support. In addition, some end-users may insist that a particular standard is used on their equipment, to ease testing and maintenance and provide a similar interface on all equipment for the operator.

Over the last decade, there has been a general movement towards a more modularised, object oriented method of programming programmable controllers. Ferrarini (2001) described an advanced methodology for the control system design, which proposed a structured framework based on object-orientation, hierarchy and formal models for specification and design. Ferrarini’s aims were to reduce the overall design time, enhancing reusability and forcing the designer to stay within a predefined framework rather than allowing free reign to deliver the application code. In the same period, Bohn (2001) also demonstrated the application of object oriented methodology to the development of Programmable Logic Controller (PLC) programs.

There are some inherent problems that have been identified with the traditional techniques of programming programmable controllers. Ekberg et al (2006) recognised that traditional methods for discrete control software development are not rigorous and lack a solid theoretical foundation. Consequently, current practices often create rigid solutions that inhibit future changes and have poor recovery sequences from abnormal events. This is further compounded in regulated industries, when, if such software deficiencies are found after the
equipment has initially been validated and in production, it can be expensive and slow to remediate.

McDonald (2003) noted that there are no published standards specifically relating to packaging machinery control and little work has been done to define packaging recipes and systems which have the capability to deliver the flexibility demanded by the market. McDonald also proposed that there is therefore an opportunity to leverage the ideas, models and terminology defined within S88 and apply them in packaging and discrete manufacturing equipment. As of early 2009, this work has developed into the draft version of ISA88 Part 5.

Chappel (2009) noted that:

‘For any programmer who has worked control code the traditional way, doing things according to ISA88 Part 5 methods is a life-changing revelation. Once automation programmers internalise these concepts, I am certain they will never program code the traditional way again. The computer industry has embraced many of these concepts, now the control environment needs to reach a higher level of efficiency. Using automation objects (chunks or modules of reusable code) that can intercommunicate in a common and standardized way saves time and effort.’

2.10 Reuse of code

It is important to note, while introducing this section of the literature review, that although the literature being reviewed in this section has been published for almost 20 years, it is still very relevant today when these principles, which were originally published in relation to mainstream programming, are applied within an Equipment Controls and Automation environment.

Many researchers have worked to make software code reuse faster, easier, more systematic, and an integral part of the normal process of programming. These are some of the main goals behind the invention of object-oriented programming, which has become one of the most common forms of formalized reuse.

Object-oriented programming (OOP) is a programming paradigm that uses "objects" and their interactions to design applications and computer programs. Programming techniques may include features such as encapsulation, modularity, polymorphism, and inheritance. It was not commonly used in mainstream software application development until the early 1990s. Most modern programming languages now support OOP. However, from a controls and automation perspective, it is only within the last ten years that the major PLC suppliers have been offering development tools that provide the ability to utilise object-oriented programming. As the S88 standard is based on an object-oriented approach, it is worth reviewing the literature concerned with code reuse being introduced to mainstream software application development.
It has been well proven in mainstream programming that code reuse is beneficial and that it is good practice to incorporate reuse of software in the development process where possible. As far back as 1987, Tracz (1987) had argued that general consent had been reached concerning the basic motives: using prefabricated parts will lead to higher productivity, and to better and more reliable code. Tracz (1990) helped define the concepts of reuse and reusable software that is equally applicable to the programming of PLC code. These concepts are:

- Reuse: All activity that has using previously written software (in the form of specification, design, code, or related texts) as its goal.

- Reusability: That quality of a piece of software, that enables it to be used again, be it partial, modified or complete.

- Reusable Software: Software (specification, design, code, etc.) that has been made with reuse in mind.

In the case of the S88 standard, the last definition of reusable software is important, and should also include reference to the fact that reusable software is tested and verified to meet specification as this has huge benefits to reducing the over-all validation costs.

2.10.1 Measuring the benefits of code reuse

As with all business process improvement activities, there needs to be a business reason for adopting S88 and hence a set of metrics to help define and measure whether its introduction to an organisation is beneficial.

There are a number of different metrics that may be used for this. One of the most common approaches is to quote the number of lines of code written versus the number of lines reused, but considering issues as program layout and code-comments, drawing conclusions from this looks questionable. A more sensible approach would be to look at the time spent on the development, and in the long run on maintenance. In many controls applications, it is of upmost importance that the end-user has the ability to ‘understand’ the code to keep their plant running (i.e. troubleshoot equipment). Poulin (1993) proposed a metrics system which uses measurements of code written, code reused, code reused by others and estimates of development costs, error rates and error repair costs. Using these values, new values for reuse percentage, cost avoidance through reuse and reuse value added are determined. This leads to an estimate of the return on investment.

2.10.2 Why software re-use?

Again, although some of this literature was published over 20 years ago in relation to mainstream computer programming, it is only recently that the tools
have become available for Automation Controls professionals to enable them to re-use code modules between applications. Bonfh & Fantuzzi (2001) noted in 2001, that it was now possible for controls engineers to develop well structured, object oriented control software. Prior to this, object oriented equipment control software was hardly possible, due to the former vendor-specific low-level languages which were the only tools available to controls engineers.

Tracz (1987) provided an overview of reasons for and against reuse, as seen by the different parties involved. Many of these reasons are still quite applicable to the attitudes of controls engineers today – especially, when the main goal of many controls engineers is to get the current equipment project commissioned on schedule.

Tracz (1987) proposed the following reasons for not ‘doing’ reuse:

- Why should I trust code I don’t know?
- Why should I trust code I don’t have the sources of?
- Why spoil the fun of writing code?
- Libraries are too expensive to buy.
- Libraries take too much time to build.
- Libraries take too much time to search through.
- Libraries usually aren’t very well designed.
- The language we use isn’t particularly fit for reuse.

The question why one should spend some extra effort and investments on software reuse can not always be answered effectively. Tracz (1987) offered two main reasons why software reuse should be pursued.

**Productivity:** Why spend time to build something you can reuse? If the emphasis is on production speed and effort, what can be more productive than being able to use a collection of ready-made parts to plug in where needed?

**Quality:** Why risk making old mistakes? If the emphasis is on quality, what can be more dependable than a piece of code that has been carefully designed and implemented for inclusion in a reuse library and has a proven and tested behaviour.

When the same argument is applied to S88 projects which are regulated by agencies such as the FDA and objective evidence of software validation is required, the software reuse case becomes much stronger.

### 2.11 Research Questions

The research will examine how applicable the classical S88 models are when applied to discrete manufacturing equipment and the resources required to
implement the S88 design methodology within an organisation. New models that are more applicable to discrete manufacturing equipment will be developed and presented.

This research will also answer the following questions:

- What resources are required to implement the S88 design methodology within an organisation?
- What are the success factors associated with the implementation of the S88 standard?
- What are the benefits of applying the S88 standard to discrete manufacturing equipment?

As a deliverable from the findings above, it will be possible to develop a decision tree to enable end users determine the benefits of applying the S88 design philosophy to custom discrete manufacturing equipment within their organisation.
3 Research Methodology

3.1 Introduction

This chapter commences with an outline of the organisation in which the research was conducted and the objectives of the research. This is followed by a discussion on some of the appropriate research paradigms and associated methods. Finally, the specific aspects of the research that will be examined in detail will be presented. This consists of three sets of questions, which are used to collect data from the case study and also issued in survey format to obtain feedback from other organisations.

3.2 Case Study Company Profile

For more than 25 years, Medical Technology Ltd, a major player in the medical device industry, has advanced the practice of less-invasive medicine by providing a broad and deep portfolio of innovative products, technologies and services across a wide range of medical specialties. These less-invasive medical technologies provide alternatives to major surgery and other medical procedures that are typically traumatic to the body. In less-invasive procedures, devices are usually inserted into the body through natural openings or small incisions and can be guided to most areas of the anatomy to diagnose and treat a wide range of medical problems.

Medical Technology Ltd has invested nearly $6 billion in new technologies over the past five years. A key area to support the research and development and manufacturing capabilities within Medical Technology Ltd is the design and development of innovative manufacturing equipment to manufacture new and existing products. In recent years, this manufacturing equipment is becoming increasingly software dependent. Therefore, given the domain within which Medical Technology Ltd operates, it is also important that the software controlling the manufacturing equipment is developed and maintained such as to comply with regulatory requirements. Medical Technology Ltd are continually implementing systems to improve the software development and equipment validation activities associated with qualifying new manufacturing equipment in a regulated environment.

3.3 Equipment Engineering Department

At its facility in Ireland, Medical Technology Ltd, has approximately 3000 employees and is engaged in the design and manufacture of medical devices. The Equipment Engineering department operates as a service group to the other Business Units in the facility. The main focus of the department is in the design and build of custom manufacturing and test equipment for
manufacturing plants in Ireland and the US. The Equipment Engineering department develops highly technical equipment that may require manufacturing, mechanical, software, control and machine vision expertise, depending on the application.

The requirement to comply with the regulations, as prescribed by the agencies that regulate the Medical Device Industry, significantly impact how the Equipment Engineering department design, document and test equipment. As part of each equipment design project, it is a key deliverable to produce the full documentation suite that includes all design, testing and validation documents. Typically, the largest proportion of the costs for new equipment is for NRE (non-recurring engineering) labour time. Therefore, efforts to reduce costs and improve quality in this area are of huge strategic importance to the Equipment Engineering department.

3.4 Access to the Key Personnel

3.4.1 Medical Technology Personnel

The researcher is employed in a full-time capacity as a Principal Controls Engineer within the Equipment Engineering organisation of Medical Technology Ltd. There are approximately fifteen software and controls engineers in this organisation, with one principal engineer, four senior engineers and ten engineers. In that role, I am responsible for the controls and software design of new equipment design projects. I also give direction on the approach taken to document, test and validate new equipment. Within this remit, I am responsible for developing and approving systems and procedures to ensure that all regulatory compliance requirements are met. Therefore access was available to all required resources for the term of the research project including:

- Medical device regulatory guidance papers and standards
- Internal procedural, design and audit documents
- Project metrics for current and historical projects
- Training logs and production logs
- Management and engineering personnel within all other departments as required.

3.4.2 Access to external organisations

The researcher presented on ‘The application of S88 to Machine Control’ at the annual ‘Winning Strategies and Best Practices for Global Manufacturers’, hosted by ARC Advisory Group in Florida in February 4th 2008. ARC Advisory Group is the thought leader in manufacturing, logistics, and supply chain solutions and their analysts help clients find the best practices and strategies to achieve operational excellence and superior results. Appendix D contains a copy of this presentation which includes a request for other organisations to assist in this research. Consequently, the researcher met with influential members of the World Batch Forum (WBF) and the Organisation for Machine
Automation and Control (OMAC) group, and with engineers who were performing similar activities in their respective organisations. As a result of this initiative, a much larger and varied pool of data that spans different industries and organisations is available to this study. Hence, it offered more options on the research design available.

During this conference, the researcher had the opportunity to discuss the challenges encountered with the initial prototypes developed at Medical Technology Limited with engineers from other organisations. Engineers from systems integrators, OEM suppliers and other end-users were actively involved in these discussions. As other organisations had encountered and overcome similar issues, Medical Technology Limited were able to learn from other organisations’ experiences, and adjust their software development standard to better meet the requirements of discrete manufacturing equipment at Medical Technology Limited’s facility.

### 3.5 Impetus for Change

The performance metrics of a project team is generally reported in terms of information on scope, schedule, cost and quality (ANSI / PMI 99-001-2004). These key metrics are measured and reviewed for all equipment design projects at Medical Technology Ltd. Recently, the Equipment Engineering department initiated process improvement projects to improve these key metrics. The Equipment Engineering department had already standardised on their controller platform and on other key hardware components and the next stage was to investigate the challenges of standardising on a software development methodology and to successfully implement that change.

#### 3.5.1 Pre-Requisites

Prior to implementing a new software development standard, there are a number of issues that have to be investigated to determine if there is a business case to justify the effort and investment. The following pre-requisites were deemed necessary, within the Equipment Engineering organisation, to support a new software development standard:

- A team (minimum of 6) of experienced Controls Engineers to implement a software standard.
- A business case to demonstrate the long term benefits of investing in a software standard.
- A management team who will support the long term benefits of implementing a software standard and accept that benefits will only start to accrue after the first project is complete.
- A company culture that has a strong commitment to quality.
- Internal stakeholders who recognise the benefits of standardising on equipment components.
The decision to adopt the S88 standard was reached after careful consideration of the options available. This decision process that was followed is described in Figure 3.1.

Figure 3-1 Decision Process to adopt S88 standard

To determine the benefits that were to be gained from applying the S88 standard to discrete manufacturing equipment, various options were available to conduct this research. These options and the justification for the chosen methods are described in the next sections.
3.6 Research Design

There are a number of deliverables from this research project. The first deliverable will be to determine what changes, if any, need to be applied to the S88 models to enable the models to be used successfully for discrete manufacturing equipment. The second deliverable will be to determine the pre-requisites necessary to apply the S88 design philosophy to custom discrete manufacturing equipment within an organisation. Finally, from these findings, it will be possible to develop a decision tree to enable end users determine whether it will be beneficial for them to apply S88 models within their own organisation.

The research design is ‘a structure that guides the execution of a research method and the analysis of the subsequent data’ (Brynam & Bell, 2003). Saunders et al (2007) outline a number of research designs available and these include:

- Experiment
- Survey
- Case Study
- Action Research
- Comparative Research Study

In this instance, a combination of the case study and the survey are used. An in-depth case study at the researcher’s workplace is used to develop the main analysis. To complement this case study, a questionnaire survey of external organisations involved in similar work is used to develop further analysis and to validate the findings of the case study.

3.7 Case Study

A case study is concerned with gaining an in-depth understanding through examination and observation within a real-life context. Braa & Vidgen (1999) point out ‘with case study methods, the researcher aim to collect a rich set of data to provide insight into some situation’. The key concepts of a case study include observation, reconstruction, and analysis (Zonabend, 1992) and these are employed by the researcher to provide a thorough investigation. The case study method was chosen for this research because its focus is on observation and understanding of the business process improvement of introducing a new software standard and measuring the benefits of these changes. Tellis (1997) proposed that single-case studies are ideal for revelatory cases where an observer may have access to a phenomenon that was previously inaccessible. This study would fall under this criterion, as the application of S88 to discrete machine control is an emerging phenomenon and during the literature review, the researcher was unable to discover published articles on the implementation and benefits of applying S88 to discrete manufacturing equipment.

A constant criticism of the single case study method is that its findings are based on a single case only. It has been argued that a single case is insufficient
in terms of providing reliable conclusions and also in terms of being able to
generalise the research in a broader sense (Yin 1993). As in all research,
consideration must be given to construct validity and Yin (1994) suggested
using multiple sources of evidence as the way to construct validity.
Kitchenham (1996) had discussed the use of the case study to evaluate a
method after it has been used on a “real” software project. Kitchenham (1996)
argued that case studies are easier for software development organisations to
perform because they do not require replication and also noted the following
advantages and disadvantages of case studies, which are outlined in Table 3-1.

<table>
<thead>
<tr>
<th>Advantages of case studies</th>
<th>Disadvantages of case studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>They can be incorporated into normal software development activities.</td>
<td>With little or no replication, they may give inaccurate results.</td>
</tr>
<tr>
<td>If they are performed on real projects, they are already “scaled-up”.</td>
<td>There is no guarantee that similar results will be found on other projects.</td>
</tr>
<tr>
<td>They allow you to determine whether (or not) expected effects apply in your own organisational and cultural circumstances.</td>
<td>There are few agreed standards or procedures for undertaking case studies. Different disciplines often use the term to mean different things.</td>
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Table 3-1 Advantages & Disadvantages of Case Studies (Kitchenham, 1996)

3.8 Surveys

In this research study, the use of a survey to obtain feedback from other organisations to validate the case study data will also be used. Denzin (1984) defined data source triangulation as when the researcher looks for the data to remain the same in different contexts. Kitchenham (1996) highlighted the advantages of using surveys in software development methods research studies, which are outlined in Table 3-2.

<table>
<thead>
<tr>
<th>Advantages of surveys</th>
<th>Disadvantages of surveys</th>
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<tbody>
<tr>
<td>They make use of existing experience (i.e. existing data).</td>
<td>They rely on different organisations keeping comparable data.</td>
</tr>
<tr>
<td>They can confirm that an effect generalises to many organisations.</td>
<td>They only confirm association not causality.</td>
</tr>
<tr>
<td>They make use of standard statistical analysis techniques.</td>
<td>They can be biased due to differences between those who respond and those who do not respond.</td>
</tr>
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Table 3-2 Advantages & Disadvantages of Survey (Kitchenham, 1996)
The choice to also utilise a survey in this research project was to achieve the first two advantages as outlined by Kitchenham in Table 3-2. It was important to utilise the experiences of other organisations who were involved in similar work and to determine if results were consistent across a number of organisations. Also, as the author is involved with OMAC, other OMAC members were keen to contribute to this research and ultimately to share with the research analysis and findings.

3.9 Research Methods

Yin (1994) listed six sources of evidence for data collection in the case study protocol: documentation, archival records, interviews, direct observation, participant observation, and physical artefacts. No single source has a complete advantage over the others; rather, they might be complementary and could be used in tandem. Thus a case study should use as many sources as are relevant to the study. Not all sources are essential in every case study, but the importance of multiple sources of data to the reliability of the study is well established (Yin, 1994).

The case study was used to examine how to apply the S88 standard to discrete manufacturing equipment. This was achieved by interviews with project engineers and reviews of project documentation and software. Additionally, a suite of questions in the form of a survey were initially piloted and subsequently refined based on feedback from project engineers involved in the case study project. The case study documentation that was reviewed included details on equipment complexity, project management data (schedule and budget), software development plan, software design standards, functional specification and the software design specification. A review of the validation plan and the software testing strategy was reviewed, particularly in relation to how the testing strategy changed due to the introduction of modular and re-useable S88 based software. A source code review was conducted to establish how the S88 standard was applied, and in particular to determine what changes, if any, were required to the S88 models to allow them to be applied to discrete manufacturing equipment.

The survey results provide the basis for most of the analysis and findings of this research. In order to add credence to the research and to minimise Kitchenham’s (1996) second disadvantage that with case studies there is no guarantee that similar results will be found on other projects, the survey questions were sent to other organisation involved in applying S88 to discrete manufacturing equipment. The survey questions, which are included in Appendix B, were e-mailed to engineers in organisations that are involved in applying an S88 based standard. There were two distinct groups of organisations to whom this survey was issued. The first group comprised of engineers that are familiar with OMAC and the WBF, and the researcher collaborated with these OMAC and WBF members at the ARC Forum in Florida in February 2008 (see section 3.4 and Appendix D). In addition to this, the survey was also e-mailed to several organisations in the US, Ireland and the UK who have experience of applying S88 and modular programming techniques, but are not directly involved with OMAC or WBF. Surveys were issued directly to twenty one organisations and also to the Technical Director of OMAC, who encouraged OMAC members to contribute to this research.
The twenty one organisations that were survey operated in the following industry sectors:

- Life Sciences Industry
- Food & Beverage Industry
- Brewing Industry
- Cosmetics & Beauty Product Manufacturing
- System Integrators
- Machine / Equipment Builders
- OEM Suppliers

A total of seven surveys were completed and returned, and these seven surveys in conjunction with the case study, provided the data for analysis.

The rationale for using multiple sources of data is the triangulation of evidence. Triangulation increases the reliability of the data and the process of gathering it. In the context of data collection, triangulation serves to corroborate the data gathered from other sources. In this research project, the multiple sources of data came from the in-depth case study review, discussed above, substantiated with survey results from other organisations.

### 3.10 Research Aids

The survey is structured into three main sets of questions. In order to develop and apply a controls software standard based on S88, an organisation will need a certain minimum level of resources to support this work. The first set of questions was used to collect data to identify the criteria necessary to support a new software development standard based on the S88 standard. The next set of questions is to establish the success factors associated with the implementation of a standard based on the S88 Standard. The third and final set of questions was to quantify the benefits of applying the S88 standard to discrete manufacturing equipment.

The benefits gained from applying the S88 standard was assessed throughout each phase of the traditional software development life cycle. As results were gathered across a number of organisations, slightly different metrics to measure project performance would have been used, hence, results have been normalised in terms of percentage improvements. A negative percentage indicates that the process change was detrimental to that particular metric in that organisation.

From the literature review, it has been shown that there are a range of benefits from applying S88 in the batch industry. In this study, each of these benefits will be analysed to determine if they have been realised in the application of S88 in the discrete manufacturing domain. In addition to these benefits, the opportunity to declare any other benefit or detriment that was realised is facilitated. A simple matrix was generated to assist with the collection and analysis of research data, which comprises the third and final set of questions.
3.11 Summary

The research design provides the structure to the research project and brings together the people, technologies, research methods used and data collected to answer the research questions. In order to answer the research questions, it was necessary to employ a number of different research methods to gain an in-depth insight into the application of S88 in discrete manufacturing equipment and to compare the experiences of several organisations when doing so. The research methods chosen will enable the research to examine the key S88 models as identified in the literature review. These methods of data collection were described, and their advantages and disadvantages in the context of this research discussed.

In developing the research methods, the researcher took cognisance of the material presented in the literature review and sought to use tools and methods that would collect accurate and meaningful information. The researcher enrolled the assistance of the Technical Director within OMAC to raise awareness of this research and encourage OMAC colleagues to support this research area. This, in conjunction with the researcher’s own network of industry colleagues in the US, UK & Ireland ensured that a broad spectrum of very well qualified engineers contributed to this research. The design of the questionnaire was extremely important and this questionnaire was first piloted with the researchers own organisation and then refined prior to circulation to the wider survey group.
4 Findings & Analysis

4.1 Introduction

This chapter presents the results and findings of the primary research questions. In the literature review, the type of organisation that could implement S88 and the benefits that can be achieved by its implementation, particularly in the batch industry was discussed. The case study and questionnaire respondents revealed the results of probing questions to determine the suitability of S88 in the discrete manufacturing domain. For each set of the research questions, the results and findings from both the case study and survey respondents are discussed. The results from the questionnaires are included in Appendix C. This chapter will begin with a review of the S88 software design standard that was applied to discrete manufacturing equipment in the case study, and present the models developed to support its introduction to Medical Technology Ltd. Next, there will be a discussion on the results of the three main research question results and findings. Finally, the three research questions were posed to enable the researcher to develop a decision tree to assist engineering professional determine if applying S88 is suitable for their organisation. This framework and guidance on how to apply it is presented at the end of this chapter.

4.2 S88 Software Design standard as applied at Medical Technology Ltd

In the literature review in Chapter 2, the physical, procedural and state models of S88 were discussed in section 2.8. During the course of the case study, machine control software was developed based on this model; however, it became increasingly difficult to develop all the required machine functionality within the constraints of this S88 state model.

As outlined in section 2.6, the pharmaceutical industry, where S88 is used extensively, is based in batch production with a linear equipment control model. In this industry, the procedures (e.g. fill tank) usually take a relatively long time to complete, and the procedures start and complete per each part of the batch. In the pharmaceutical industry there are high documentation requirements so the use of software layers when defining the code is an advantage that S88 provides. Medical Technology Limited utilises discrete manufacturing equipment that requires parallel and high speed equipment control, and more flexibility is needed. This equipment performs short tasks (e.g. servo motion control) with a high level of complexity and where extra modes are required in order to allow maintenance and operator intervention.

A key element in the implementation of the S88 standard at Medical Technology was adapting the S88 models to precisely meet the requirements of discrete manufacturing equipment. Medical Technology Limited had
previously standardised on the Rockwell Automation range of hardware controllers, and initially enlisted the assistance of Rockwell Automation to consult on the new software standard that was being developed. In order to create a modular control program that complies with S88, the manufacturing processes were broken down into logical groupings and specific control modules were identified. Next, the control modules were grouped into phases that would perform logical functionality so that these phases could be supervised and coordinated by unit procedural controls.

During the early stages of implementing the software standard, many challenges were encountered and these included:

- Requirement for extra modes for maintenance, calibration, setting up equipment and operator intervention
- Relatively large PLC program resulting in a slow PLC scan rate
- Unacceptably long control system response time caused through a combination of commanding actions through several software layers and a long PLC scan rate
- Defining entities such as conveyors and robotics which are not directly part of the process and cannot be defined as units. (These components are just used to transfer product between units.)
- Defining complex entities (i.e. with Servo movements) which are in conflict with S88 definitions

In an effort to address these issues, several software designs were developed and tested. During this period, the development team also consulted with fellow members of OMAC, who provided useful suggestions, such as the PackML Mode & States Definition document, and examples of similar issues OMAC members encountered. This resulted in subtle changes to how S88 was implemented in the case study. The S88 models were adapted further to provide additional flexibility to the software developer and these models are shown in Figure 4.1 and Figure 4.2.
The models shown in Figure 4-1 and Figure 4-2 were developed and tested on a relatively complex machine that was used as the initial test bed for the new software standard. The new modified S88 software models offered the software developers more flexibility to program the full functionality required for this equipment. More significantly, it still maintained the modularity required to minimise the software validation effort.
The next phase of the project was to roll out this standard to other equipment and prove that the code modules could be re-used without any updates between projects. As the first machine was relatively complex in nature, it was decided to implement the standard next on a relatively simple machine with just one unit. It was discovered that all the lower level layers, that consisted of control modules and recipe phases could be re-used very efficiently. However, although the machine state model, as shown in Figure 4-2 could be applied, it was creating unnecessary complexity. Therefore, a new simpler machine state model, specifically for smaller simpler machines was developed and is shown in Figure 4-3. The model is just a leaner version of the original machine state model and enables the software developer to develop a smaller, more efficient program.
It is important to note that the new development standard, developed by Medical Technology Limited, is not intended to be an industry standard (i.e., a standard that can be used for all types of industries, with different controllers and equipment requirements). This standard should be considered a software implementation standard to be used exclusively on the manufacturing equipment within Medical Technology Limited. This standard establishes the framework for coding applications, so a high level of software re-use, quality performance, and consistency can be achieved. This implementation standard shares most of the concepts contained within S88 allowing the broader engineering community to understand it and use it. This provides advantages for system integrators and machine builders, already familiar with S88, who are supplying equipment and software services to Medical Technology Limited.
4.3 Research Objective 1

Identify the criteria necessary to support a new software development standard based on S88

4.3.1 Engineering Expertise

There are pre-requisites that are required to support the implementation of an S88 based software standard in an organisation. Initially, the research set out to identify the criteria necessary to support a new software development standard based on the S88 standard. With reference to the case-study, these observations were established based on, in the first instance, knowledge of the case study, supported where necessary by interviews of key personnel throughout the organisation.

There was unanimous consensus from the research that an engineering team of at least five engineers were required to develop and support a software standard based on S88. The typical profile and expertise of each of these team members, with roles and responsibilities are shown in table 4.1.

<table>
<thead>
<tr>
<th>Roles</th>
<th>Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lead Engineer</strong></td>
<td>Set Goals for Team and Individuals</td>
</tr>
<tr>
<td></td>
<td>Approved Software design</td>
</tr>
<tr>
<td><strong>PLC Software Dev.</strong></td>
<td>Interpreted S88 standard and applied to suit organisation</td>
</tr>
<tr>
<td></td>
<td>Applied Standard to multiple machines to prove its value</td>
</tr>
<tr>
<td><strong>HMI / Database Dev.</strong></td>
<td>Design, develop, document and test HMI Software</td>
</tr>
<tr>
<td></td>
<td>Investigate options and design standard for interfacing with MES systems</td>
</tr>
</tbody>
</table>
Table 4-1  Roles and Responsibilities of Development Team

<table>
<thead>
<tr>
<th>Role</th>
<th>Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Engineer</td>
<td>Developed Over-all Software Test Plan and Test Strategy</td>
</tr>
<tr>
<td></td>
<td>Developed system to control software library</td>
</tr>
<tr>
<td></td>
<td>Developed standard templates for all design and test documents</td>
</tr>
<tr>
<td>Quality Engineer</td>
<td>Reviewed and Approved all design and test documents</td>
</tr>
</tbody>
</table>

The engineering expertise within an organisation is of critical importance. There is a certain level of complexity introduced to equipment design, when a design has to comply with a software standard. Each organisation needs to ensure that it has the required number of skilled resources to develop, maintain and implement a software standard, before embarking on the journey of developing the software standard.

### 4.3.2 Business Case and Benefits

The development and implementation of a software standard required some up-front investment of resources, and the benefit was considered to be more significant in the long term, rather than the short term. At Medical Technology Limited, an initial business case was developed to promote the long term benefits of implementing an S88 based software standard, and also to secure funding to enable its development. The main justification was based on projected cost and schedule savings, particularly during the development and testing phases. The ratio of engineering costs to total machine costs vary, depending on complexity and technologies used. However, by applying the S88 standard, it was possible to reduce engineering, program development and test costs as shown in Figure 4.3.

![Figure 4-4 Savings achieved by applying S88 Standard (Rockwell Automation Marketing Material, 2008)]
The chart on the left – Total OEM Machine Cost, is representative of the costs to design and build a new piece of equipment. The split between product costs, build labour, engineering, program and test will vary greatly between projects and it is important to note that the charts above are just representative of the costs involved and are not actual costs for any particular machine. There will always be product costs – for the components in the machine. This would include items such as tooling, mechanical, electrical and controls components such as custom tooling, pneumatics, power distribution components, controllers, input/output modules and instrumentation. The build labour is the costs to assemble all the components mentioned above, to build the machine. The design engineering, programming and testing are also significant costs in the total OEM machine costs. It is assumed that the S88 standard does not impact on the product and build activities, and therefore will not affect the costs of these sections. However, by applying the S88 standard, saving can be accrued during the engineering design, programming and testing phases. The chart on the right is representative of how the total cost of the machine can be reduced by applying the S88 standard. The product and build labour costs are constant, with savings achieved during the engineering, test and program phases. These savings are accrued through standardisation and the re-use of software code modules, engineering designs and the subsequent reduced testing.

At Medical Technology Limited, it was determined that a saving on software design, development and test labour of 31% was realised by applying the S88 standard. It is also important to note that other less tangible benefits were accrued, and these are presented in terms of the stakeholder map and associated benefit of applying the S88 standard for that function.

Figure 4-5 Stakeholder Map and Benefits of applying S88 at Medical Technology Ltd.
Interestingly, in 62.5% of the respondents, a business case had been developed prior to implementation and the group had received support from senior management. In the other 37.5% of respondents, engineering groups had taken on the responsibility of applying S88 based on ‘they knew it was the right thing to do’ and had incorporated the development of the standard as part of their continuous improvement programs.

### 4.3.3 Organisation Profile

A key element that the research indicated was that all the organisations that were involved in implementing this software standard has a strong commitment to quality and was compelled to produce documented evidence of testing of their equipment. The level of testing required varied, as the range of industries who participated in the research ranged from Class III medical device manufacturers to food and beverage manufacturers. There were a total of eight survey respondents and these respondents were representative of the following industries as shown in table 4.2.

<table>
<thead>
<tr>
<th>Industry Sector</th>
<th>Responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Life Sciences</td>
<td>3</td>
</tr>
<tr>
<td>Food &amp; Beverages</td>
<td>2</td>
</tr>
<tr>
<td>Original Equipment Manufacturer</td>
<td>1</td>
</tr>
<tr>
<td>System Integrator</td>
<td>1</td>
</tr>
<tr>
<td>Cosmetic &amp; Beauty Product Manufacturing</td>
<td>1</td>
</tr>
</tbody>
</table>

Table 4-2 Industry Sector of Survey Respondents

As outlined in Chapter 3, Medical Technology Ltd is a major player in the medical device industry, and over the last five years, has invested heavily to expand its portfolio of products within the medical device industry. The annual turnover of the organisation in 2007 was $8.5 Billion, and the company invested almost $6 Billion in Research and Development over the last five years. Medical Technology Limited has a strong commitment to quality and invests millions every year to ensure it complies with regulatory requirements. Almost every aspect of the business is impacted by this commitment to quality, and the general company culture, is that above everything else, quality come first. As such, Medical Technology Limited validates all equipment and software that falls under the scope of validation as defined in their Quality Systems.

All the groups who implemented an S88 standard were from large multinational organisations with a significant number of engineering staff. Note that this conclusion could be biased, as 62.5% of the respondents were either involved with OMAC or participated at the ARC Forum, at which the
researcher presented his research. This was a necessity of the research, as currently, the S88 standard is not in widespread use in the discrete manufacturing domain, and these were the majority of organisations currently involved in these activities that could be discovered. The bias lies in the fact that smaller, less affluent manufacturing organisations will typically not invest in their resource to participate in groups such as OMAC or attend international conferences such as the ARC Forum.

An interesting trend was that all the multi-national organisations had aspirations that the S88 software standard that had been developed would eventually get rolled out throughout the organisation, however, as of yet, only one of the organisation had successfully implemented the standard in a second facility and none of the organisations had adopted the standard throughout their entire organisation.

### 4.4 Research Objective 2

**Establish success factors associated with the implementation of a standard based on the S88 Standard**

The next set of questions focussed on the success factors associated with the introduction of a software standard based on S88. It was confirmed by the research that all the organisations that were implementing standards for their controls software had already previously standardised on one programmable controller. This is not surprising as standardising on one programmable controller offers other proven benefits such as reducing spares inventory, training for engineering and maintenance and easier integration between equipment and business systems.

The results from each of the seven respondents were combined to produce an average result for each question in this section of the survey. In some instances, no answer was received for a given question, for either not being applicable to that organisation or that the respondent was unable to obtain the information within their organisation to answer the specific question. In these instances the results from the other six respondents was used to calculate the average result. These average results are shown in Table 4.3.
Establish success factors associated with the implementation of a standard based on the S88 Standard?

<table>
<thead>
<tr>
<th>Survey Response Average</th>
</tr>
</thead>
</table>

**Technical:**

Have you standardised on one programmable controller, where possible?

Yes - 100%

Was the software standard developed and tested independently of a specific equipment design project or was the development of the software standard incorporated into a new machine design?

85% - Independent of design project

Is the software standard developed to interface with an MES system?

Yes - 85%

How long did it take to develop, test and document these standards? Estimate to completion date, if not yet completed.

1.3 Years

Do you have 1 software standard that covers your complete range of equipment – from small stand-alone machines to large multi-station equipment?

85% - 1 Standard applies to all equipment

Have you applied only standard Machine States and PackTags (PackML) or all elements of S88 (Units, EM, CM, Phases etc ) into your software standard?

50% of companies implemented only Machine States and Pack Tags

**Equipment Build:**

What percentage of your equipment is Off the Shelf (OTS)?

15%

How many external machine builder partners / vendors do you use?

5

Do all your external vendors apply these standards or reserved for 1 or 2 strategic partners?

75% of respondents required all vendors to apply the standards

Do you apply this standard to all manufacturing equipment?

All new Custom Equipment.

Do you apply this standard to proto-type equipment?

28% of respondents did not apply standards on prototypes

How would you rate the support you received from your controls supplier? (Excellent, Average, None)

25% - Excellent

75% - Average
Establish success factors associated with the implementation of a standard based on the S88 Standard?

<table>
<thead>
<tr>
<th>Quality:</th>
<th>Survey Response Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you need to validate your equipment?</td>
<td>Yes - 85%,</td>
</tr>
<tr>
<td>What % of your overall engineering costs for new equipment is related to verification and validation activities?</td>
<td>18%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Standards in your Organisation:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you have Standard Operating Procedures (SOP) that govern all equipment design activities?</td>
</tr>
<tr>
<td>Is this the company’s first effort to introduce a controls standard?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>In-House or Contract Resources:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did you develop your PLC software standard in-house or through external consultants?</td>
</tr>
<tr>
<td>50% External Consultants</td>
</tr>
<tr>
<td>Do you have the in-house expertise to develop the standard further?</td>
</tr>
</tbody>
</table>

Table 4-3 Average Results from Survey Respondents on success factors to required to implement S88

In all instances, except for the case study, the project to develop a new software standard was completed independently of any equipment design projects. This is considered a more successful approach, because, the design and development of a new machine design typically needs to be delivered by a specific date. In the case study, a calculated risk was taken to develop the new software standard and pilot it on a new equipment design. This risk was taken because in order to develop and approve the design documents and testing strategy, other stakeholders, such as manufacturing and quality functions were required, and a ‘real’ project was required to drive the documentation suite through the quality system. However, the safer more conservative approach would be to develop and test the software standard independently of any equipment design project. It was also found that the organisations that had a high degree of automated equipment and highly skilled equipment engineering resources were typically able to easily justify and obtain funding to work on projects to put correct systems in place such as equipment design standards.

In all but one respondent, the software standard was developed to interface with an MES (Manufacturing Execution Systems) or data collection system. In some instances, the main driver to developing the new software standard was to ease integration of the equipment with other equipment and MES systems. In these instances, the organisation did not apply all elements of S88 and just
applied the PackML and machine states standards. The average time to develop the software standard was just over a year – which demonstrates that strong commitment and a business case that is built on the long term benefits of applying S88 is required. In the case study and with most of the survey respondents, the same software standard was scalable to use with both simple and complex machine systems. One organisation had made the decision that the software standard would not always be used on simple systems as their costs and schedules for smaller simpler systems did not necessitate the need for implementing the software standard and the flexibility offered by not using a software standard was deemed more appropriate.

A common lesson learnt from the implementation of the S88 standard across a number of organisations was not to underestimate the schedule involved to get the standard accepted and approved. Some other lessons that were learnt was the need to review designs early, test code on real systems, address issues and re-iterate this process until a finely tuned standard was developed. Also, there is a learning curve involved in training new employees, external machine builders and system integrators on the new software standard. This involves the generation of detailed software design documents to document the standard and hands-on training of external vendors.

At Medical Technology Limited, one of the biggest challenges was to explain to other stake-holders how the standard works, how it will improve quality and how it will drive costs down. This challenge was made more difficult as many of the stake-holders (Manufacturing, Quality, and Production) do not have a strong software background and have difficulty understanding concepts such as object oriented programming.

4.5 Research Objective 3

Quantifying the Benefits of S88

The final set of questions was to quantify the benefits from applying the S88 standard to discrete manufacturing equipment. It was interesting to find that the benefits that organisations obtained were determined to a large extent on whether they applied all aspects of S88, such as re-usable control modules, or only applied PackML Tags and standard machine states (as prescribed by PackML) with traditionally designed PLC code controlling the machine. In instances where all aspects of S88 were applied, the main benefits were achieved in the areas of re-useable code/documentation and pre-verified software modules. There were also benefits achieved in application development and equipment commissioning phases. There is an obvious correlation between the re-use of code and reduced development and commissioning. If modules of code have been pre-verified, commissioning is more focussed on just integrating software and hardware elements. Invariably, this also led to benefits in the test and validation areas.

In instances where the standardisation was only focussed on PackML Tags and standard machine states, the main benefits achieved were interfacing to other
systems and providing a consistent HMI (Human Machine Interface) for operators. The broad mission of PackML is to develop common machine operational guidelines, visualization, and naming conventions for communications between production machinery, and these benefits were confirmed by the research results.

In the case study, a number of projects that implemented the S88 standard were compared to other similar projects that were completed prior to the introduction of the S88 standard. It is important to note that the benefits quoted here do not include any of the development costs or time to initially develop the standard and are based on the subsequent roll-out of the standard. The historical projects were used to set the benchmark, and the percentage improvement achieved by applying the S88 standard is shown in Table 4.4.

<table>
<thead>
<tr>
<th>Project Activity Vs. Project Metrics</th>
<th>Schedule</th>
<th>Cost</th>
<th>Quality</th>
<th>Overall project risk</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Standardised approach</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Established methods and work flows</td>
<td>15%</td>
<td>15%</td>
<td>20%</td>
<td>5%</td>
</tr>
<tr>
<td>Consistent design and documentation</td>
<td>20%</td>
<td>20%</td>
<td>20%</td>
<td>5%</td>
</tr>
<tr>
<td>Simplify definition and design</td>
<td>20%</td>
<td>15%</td>
<td>20%</td>
<td>5%</td>
</tr>
<tr>
<td><strong>Modularized Solutions</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Re-usable code modules</td>
<td>25%</td>
<td>40%</td>
<td>30%</td>
<td>10%</td>
</tr>
<tr>
<td>Re-usable documentation</td>
<td>25%</td>
<td>40%</td>
<td>30%</td>
<td>10%</td>
</tr>
<tr>
<td>Pre-verified software modules</td>
<td>25%</td>
<td>45%</td>
<td>30%</td>
<td>14%</td>
</tr>
<tr>
<td><strong>Application Development</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Code Development</td>
<td>25%</td>
<td>25%</td>
<td>5%</td>
<td>12%</td>
</tr>
<tr>
<td>Equipment Commissioning</td>
<td>12%</td>
<td>25%</td>
<td>5%</td>
<td>5%</td>
</tr>
<tr>
<td>Interface to other Systems (eg. MES)</td>
<td>10%</td>
<td>10%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td><strong>Test &amp; Validation Methods</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reduce / eliminate duplicate testing</td>
<td>40%</td>
<td>40%</td>
<td>25%</td>
<td>15%</td>
</tr>
<tr>
<td>Higher level of confidence in Application</td>
<td>0%</td>
<td>0%</td>
<td>25%</td>
<td>10%</td>
</tr>
<tr>
<td>Combine testing activities</td>
<td>20%</td>
<td>10%</td>
<td>10%</td>
<td>7%</td>
</tr>
<tr>
<td>Standard Test Plan</td>
<td>5%</td>
<td>15%</td>
<td>25%</td>
<td>3%</td>
</tr>
<tr>
<td><strong>Maintenance / Upgrades</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Consistent HMI for Operators</td>
<td>0%</td>
<td>0%</td>
<td>10%</td>
<td>4%</td>
</tr>
<tr>
<td>Less Training for Maintenance</td>
<td>5%</td>
<td>10%</td>
<td>5%</td>
<td>2%</td>
</tr>
<tr>
<td>Learning curve for new engineers</td>
<td>5%</td>
<td>5%</td>
<td>5%</td>
<td>4%</td>
</tr>
</tbody>
</table>

Table 4-4  Case Study Results-Benefits of Applying S88

As in the previous set of answers, the results from each of the seven respondents were combined to produce an average result for each question in this section of the survey. Also, if a specific question was not answered, the results from the other six respondents were used to calculate the average result. These average results are shown in Table 4.5. Although the results from all the
respondents were used to calculate an average result, it was beyond the scope of this research project to investigate how each respondent calculated their individual answers. In fact, some respondents commented on their survey returns that their results were based on their individual assessment, based on their knowledge of the organisation, and not based on any particular project metrics that they use to manage their business.

<table>
<thead>
<tr>
<th>Project Activity Vs. Project Metrics</th>
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<td>Established methods and work flows</td>
<td>10%</td>
<td>12%</td>
<td>15%</td>
<td>3%</td>
</tr>
<tr>
<td>Consistent design and documentation</td>
<td>18%</td>
<td>16%</td>
<td>19%</td>
<td>7%</td>
</tr>
<tr>
<td>Simplify definition and design</td>
<td>13%</td>
<td>7%</td>
<td>11%</td>
<td>3%</td>
</tr>
<tr>
<td><strong>Modularized Solutions</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Re-usable code modules</td>
<td>15%</td>
<td>15%</td>
<td>8%</td>
<td>4%</td>
</tr>
<tr>
<td>Re-usable documentation</td>
<td>12%</td>
<td>12%</td>
<td>6%</td>
<td>4%</td>
</tr>
<tr>
<td>Pre-verified software modules</td>
<td>15%</td>
<td>19%</td>
<td>12%</td>
<td>5%</td>
</tr>
<tr>
<td><strong>Application Development</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Code Development</td>
<td>15%</td>
<td>15%</td>
<td>5%</td>
<td>12%</td>
</tr>
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<td>12%</td>
<td>10%</td>
<td>6%</td>
</tr>
<tr>
<td>Higher level of confidence in Application</td>
<td>4%</td>
<td>0%</td>
<td>10%</td>
<td>3%</td>
</tr>
<tr>
<td>Combine testing activities</td>
<td>8%</td>
<td>6%</td>
<td>5%</td>
<td>2%</td>
</tr>
<tr>
<td>Standard Test Plan</td>
<td>3%</td>
<td>5%</td>
<td>6%</td>
<td>2%</td>
</tr>
<tr>
<td><strong>Maintenance / Upgrades</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Consistent HMI for Operators</td>
<td>0%</td>
<td>6%</td>
<td>10%</td>
<td>2%</td>
</tr>
<tr>
<td>Less Training for Maintenance</td>
<td>3%</td>
<td>7%</td>
<td>7%</td>
<td>4%</td>
</tr>
<tr>
<td>Learning curve for new engineers</td>
<td>5%</td>
<td>5%</td>
<td>5%</td>
<td>6%</td>
</tr>
</tbody>
</table>

Table 4-5 Survey Respondents Results - Benefits of applying S88

It is important to reiterate that the benefits accrued and reported in this section are concerned with the subsequent roll-out of S88, after it has been initially developed at an organisation.

In the literature review in chapter 2, we noted that Chappel (2009) stated that:

‘For any programmer who has worked control code the traditional way, doing things according to ISA88 Part 5 methods is a life-changing revelation……. Using automation objects (chunks or modules of reusable code) that can intercommunicate in a common and standardized way will save time and effort.’
In all organisations who participated in this research, their strong intention is to continue to use the S88 standard on all new equipment designs. With particular reference to the case study at Medical Technology Limited, some less tangible benefits were also observed and reported back through interviews with the engineering and management team. In addition to the quantifiable benefits reported in Appendix A, the overall engineering discipline, documentation and quality of work produced in all controls area improved significantly. This is attributed to the fact that the engineering team are aware that they are producing designs, documents, code and test scripts that may be re-used often by their peers. With such an obvious and open peer review system inevitably put in place through the deliverable of re-useable code, the outcome was that the overall quality of work increased.
4.6 S88 Decision Tree to apply S88

A key deliverable from this research project was to develop a decision tree to enable end users determine the benefits of applying the S88 design philosophy to custom discrete manufacturing equipment within an organisation. Based on the research gathered, it was noted in section 4.5 that the benefits accrued were dependent on whether all aspects of the S88 model were adopted. From the analysis of the results, it was evident, that the business case and perceived benefits that different organisations applied to justify the implementation of an S88 software standard could be classified into two broad criteria.

The first criteria consisted of organisations that had significant costs associated with documenting, testing and validating equipment design and controls software. These organisations tended to be in the life sciences industries – and considered validation of manufacturing equipment to be a key area where costs could be reduced, while still maintaining compliance. The benefits of applying S88 in the batch process industry were well understood and the aim here was to replicate these benefits in the discrete manufacturing equipment domain. Importantly, the regulators in the life sciences industries such as the FDA, are already familiar with the methods, techniques and terminology used to validate equipment and software, when an S88 software standard is used. This was considered a significant benefit to organisations in the life sciences industry.

The second criteria consisted of organisations that procured equipment from a number of vendors and had to integrate these together into a production line. These organisations were keen to establish a standard method for machine states and communication tags that are used to interface with equipment. This was considered the main driver for the introduction of a software standard. The decision to base the standard on S88 was based on the fact that the S88 standard was already popular in the batch process industries and machine vendors and system integrators were familiar with the S88 terms and concepts.

A key deliverable from this research was to produce a decision tree that would aid engineers in their decision on whether developing and applying a software standard based on the S88 model would be beneficial to their organisation. This decision tree is shown in Figure 4.5, followed by a brief description of its main assumptions and features.
4.6.1 Decision Tree Guidance

It is assumed that the engineers and management team using this decision tree are controls engineers with some knowledge of the main concepts of S88. The purpose of this decision tree is to assist them in making an informed decision on whether developing a software standard based on S88 would be appropriate for their organisation. Given that each organisation will present a unique set of circumstances, this decision tree does not attempt to estimate on potential savings or benefits – as this would be outside the scope of this research project. However, it does provide a quick and useful guide to enable the decision maker to either proceed to their next stage of investigation for their organisation or to eliminate S88 as being a standard that they could utilise.

The decision tree asks seven basic questions in order to categorise the organisation that is considering developing a software standard based on the S88 model. The decision tree first establishes whether there are sufficient resources and schedule to proceed. If not, it recommends eliminating S88. If sufficient resources and schedule are available, it then considers the annual budget for custom equipment and standardization of controllers and hardware. If these are not necessary, it proceeds to consider software validation and the high opportunity for software reuse. If software validation is required or there is a high opportunity for software reuse, it recommends implementing all aspects of S88 standard. Otherwise, it considers the interface to MES or other equipment, suggesting either implementing PackML tags & standard machine states or insufficiency of justification or payback.
resources and time-scale to implement a software standard. Next, in order to build a business case for the development of a software standard, it is necessary to establish that there is a sufficient amount of custom equipment design and software development within an organisation to justify the initial investment.

4.6.2 Costs
The figure of €2m is calculated using the simple criteria described in this section. It was identified that a core team of 5 engineers was required to develop the software standard over a period of approximately one year. This assumes that the efforts to develop the software standard will not require all the resource to be full time. For example, it is assumed that the Quality and Testing Engineer will be required for less time than the main PLC developer and that due to design review and the different phases of review and testing, no resource will be working full time on the project for the full year. Therefore, a budgetary figure of €100k to document, develop and test the software standard is used.

4.6.3 Savings
The controls engineering tasks of design documentation, software development, commissioning, testing and validation, typically accounts for 25% of new equipment designs budgets. The projected benefit of applying an S88 standard will realise savings of approximately 20% for the tasks listed above. Therefore, the projected savings on new equipment designs will be approximately 5% of the total cost for new custom equipment budgets. 5% of the €2m per annum capital equipment budget yields €100k savings per year. These calculations are shown in Table 4.6

The simple business case used in this model is that in order to justify an initial investment of €100k, a projected saving of €100k per annum is required. Obviously, each organisation will have their own criteria to justify business cases based on investment, return and risk.

<table>
<thead>
<tr>
<th>Description</th>
<th>Cost</th>
<th>Saving</th>
</tr>
</thead>
<tbody>
<tr>
<td>Development Costs to introduce S88</td>
<td>€100k</td>
<td></td>
</tr>
<tr>
<td>Controls Costs as % of new designs</td>
<td>25%</td>
<td></td>
</tr>
<tr>
<td>Savings as % from applying S88 std</td>
<td></td>
<td>20%</td>
</tr>
<tr>
<td>Saving as % of new design (20% of 25%)</td>
<td></td>
<td>5%</td>
</tr>
<tr>
<td>5% saving on €2m new equipment</td>
<td></td>
<td>€100k</td>
</tr>
</tbody>
</table>

Table 4-6 Costs & Savings of Introducing S88

4.6.4 Technical Considerations
The next set of questions establishes whether hardware standards are already in place. This is necessary to determine as it will only be possible to create software libraries of re-usable PLC code, if the underlying hardware controller is consistent. The potential to re-use software modules and the requirements to interface with MES or validate the equipment will determine whether it is beneficial or not to develop a software standard. There are two broad suggestions as to what extent the software standard should be developed. The first suggestion available is to standardise on common communication tags and machine states to report the status of the machine. This will also present a standard HMI and mode of operation to the machine operator. The second suggestion is to apply all elements of S88 including the re-use of control modules, equipment modules as well as defining standard machine states.

### 4.6.5 Summary

This chapter presented the results and findings of the primary research questions. Through the case study, a discussion on how the team developed and refined their software and design models to achieve the dual goals of a software implementation standard that can efficiently be re-used on new equipment design, yet also complies with the industry standard S88 models. The survey responses are presented and the limitations and scope of this data is discussed. The survey responses are then analysed to identify trends, with particular reference to different industry sectors, which is used to ultimately build the decision tree that should provide practical guidance to engineering professional investigating the option of implementing S88 at their organisation.
5 Conclusions & Recommendations

5.1 Introduction

This concluding chapter discusses the main findings of the research project, the recommendations arising from this research and suggests future research work. The application of S88 has been used to much success for batch processes, particularly in the pharmaceutical industry. S88 has been a focal point for defining and automating batch processes for over a decade. Its acceptance within the batch processing community is widespread; and its adoption has had a positive impact on the development of modular programming, integration practices, and diagnostics and debugging practices. In addition, it has influenced everything from the way control systems are built to the way project requirements are written and has simplified and reduced the cost of batch control automation. Traditionally, PLC software development and equipment design for custom discrete manufacturing equipment has not utilised the object oriented principles or the S88 standard. However, recent developments from some of the main automation OEM suppliers, such as Rockwell Automation, have promoted the use of the S88 standard in non-batch applications. Organisations such as WBF and OMAC have made claims about the applicability of S88 to the discrete manufacturing domain. As of yet, it has not yet enjoyed widespread use throughout non-batch industries. In regulated industries, such as healthcare, organisations are utilising a lot of resources to ensure that they are compliant with the FDA’s guidelines on equipment and software validation. Regulated industries who do not have specific standards for software development are finding it more difficult and expensive to demonstrate compliance for custom designed equipment.

This dissertation examined in detail a case study, at Medical Technology Limited, a medical device company, where the S88 standard has been implemented on custom discrete manufacturing equipment. In addition to the case study data, a questionnaire survey was used to collect data from a number of other end-user organisations, so that the over-all findings were more generalised than is possible with the results of a single case study.

This research enabled the development of a decision tree to enable end users to quickly assess if applying the S88 design philosophy to custom discrete manufacturing equipment is suitable for their organisation. This decision tree provides guidance as to when it is appropriate and beneficial to apply the S88 design philosophy for engineers who may be planning to introduce, replace or enhance their design philosophy for control systems for their manufacturing equipment. This chapter will review the main research objectives and comment on their findings.
5.2 S88 Models at Medical Technology Limited

Initially, at a purely technical level, the research has presented what changes had to be applied to the S88 models to enable them to be used successfully for discrete manufacturing equipment within Medical Technology Limited. In the literature review in Chapter 2, the classical S88 physical, procedural and state models were discussed in section 2.8. At Medical Technology Limited, the main driver behind choosing the S88 standard was to introduce a software standard that could reduce the overall software validation costs.

During the course of the case study, machine control software was developed based on this model; however, it became increasingly difficult to develop all the required machine functionality within the constraints of this S88 models. The breakthrough occurred when the team decided that slight modifications to the S88 models created the flexibility to program the full functionality required for discrete manufacturing equipment. These new models are still based on the original S88 models, and have still maintained the modularity required to minimise the software validation effort. These models have subsequently been used to develop software for a number of new equipment designs, and as the research results from the other organisations surveyed would support, the implementation and savings accrued become easier to achieve with each re-use. It is important to state that the models developed by Medical Technology Limited and shown in Figures 4.1, Figure 4.2 and Figure 4.3 have been customised to precisely meet the unique requirements of Medical Technology Limited. Designers of discrete manufacturing equipment for off-the-shelf equipment or in another organisation may need to customise these slightly to suit their own requirements.

5.3 Questionnaire Results

The first set of questions on the questionnaire, which were from more of a business perspective, was to discover the conditions necessary to support the introduction of a new software controls standard into an organisation. There are a number of pre-requisites that the research identified as being necessary to support the implementation of a software controls standard in an organisation. These included a minimum number of controls engineers and also a business case to justify its introduction. In order to build the business case, it was identified that the organisation needs to have a minimum level of equipment design work and / or have a requirement to validate that equipment or interface it to other equipment or an MES system. The main justification was based on projected cost and schedule savings, particularly during the software development and testing phases.

The second set of these questions on the questionnaire was to determine the success factors associated with the implementation of the S88 standard. It was confirmed by the research that all the organisations that were implementing standards for their controls software had already previously standardised on one programmable controller. This is not surprising as standardising on one programmable controller offers other proven benefits such as reducing spares
inventory, training for engineering and maintenance and easier integration between equipment and business systems. It was also found that the organisations that had a high degree of automated equipment and highly skilled equipment engineering resources were typically able to easily justify and obtain funding to work on projects to put correct systems in place such as equipment design standards.

In all cases, the software standard was developed to interface with an MES system or data collection system. In some instances, the main driver to developing the new software standard was to ease integration of the equipment with other equipment and MES systems. In these instances, the organisation did not apply all elements of S88 and just applied the PackML and Machine states standards. This was key to the development of the decision tree, in that it gave different options to organisations that were investigating standardising their software development tasks, or alternatively, organisations who worked with a large number of equipment / machine build vendors.

The third set of the research questions on the questionnaire was to quantify the benefits of applying the S88 standard to discrete manufacturing equipment. In instances were all aspects of S88 were applied, the main benefits were achieved in the areas of re-useable code/documentation and pre-verified software modules. There were also benefits achieved in application development and equipment commissioning phases. There is an obvious correlation between the re-use of code and reduced development and commissioning. If modules of code have been pre-verified, commissioning is more focussed on just integrating software and hardware elements. Invariably, this also led to benefits in the test and validation areas.

In instances where the standardisation was only focussed on PackML Tags and standard machine states, the main benefits achieved were interfacing to other systems and providing a consistent HMI (Human Machine Interface) for operators. The broad mission of PackML is to develop common machine operational guidelines, visualization, and naming conventions for communications between production machinery, and these benefits were confirmed by the research results.

5.4 Deliverable - Decision Tree

As a deliverable from all of the research findings and analysis, a decision tree to enable end users determine the benefits of applying the S88 design philosophy to custom discrete manufacturing equipment within an organisation was developed. Although, the decision tree was generated as a direct result of this research project, it is planned that this will be used within Medical Technology Limited globally. The next phase of the software standardisation project within Medical Technology Limited is to roll out this software standard, corporate wide. This decision tree will be used as a tool to enable other facilities within the Medical Technology Limited organisation to quickly
assess if they should adopt the software standard that was created and presented in this case study.

5.5 Recommendations

The decision to embark on a journey to introduce a software controls standard within an organisation is one that demands a significant amount of investigation, experience and a long term vision. As outlined in this research study, there are a number of controls standards that have evolved out of the automotive and electronics industries. In addition to this, of course, is the S88 standard that emerged from the batch process industry. Also, a lot of end-user organisations and machine builders have developed their own custom controls standard and implemented them very successfully. Although the S88 standard is approved by the ISA and recognised globally, this does not infer that this standard is suitable for all applications. The decision tree that was developed from this research is a useful first step to make a quick assessment on whether the S88 standard should be investigated further for a specific organisation. However, it is important to note that the decision on the choice of software standard should not be rushed. It will form the basis for new equipment designs for the next 3 to 5 years or more – until the software standard may be re-assessed to ensure that it still meets the requirements of the business. Finally, although most of this research work has been aimed at the end-user of equipment, it could also be very beneficial to system integrators and machine builders. From a marketing perspective, if they can market their products and services as being S88 compliant, it will help to attract new customers and lock in existing customers.

5.6 Future Research

There is one area of future research, which could be completed to complement the work presented in this research project. Although outside the scope of the literature review of this project, the software development lifecycle of S88 based projects typically follow a sequential software development process such as the Waterfall model. The Waterfall development lifecycle in which ‘a software product is viewed as progressing linearly from conception through requirements, design, code and test’ (Laplante and Neill, 2004) was the original approach to software development. In many cases, the development of traditional S88 applications for pharmaceutical batch processes involved the commissioning of large capital projects with long lead times and often several vendors involved including end-users, project managers, plant designers, system integrators and system testers. The typical software development lifecycle documentation such as User Requirements, Functional Specification, System Design Specifications and Test specifications are often used to tie in vendors contractually to their deliverables. This results in ensuring that a very rigid sequential software development process is followed.

However, as has been shown through this research, it is possible to apply S88 to discrete manufacturing equipment. Typically, the capital costs and lead times associated with discrete manufacturing equipment will be less than that
associated with a pharmaceutical plant and fewer vendors will be involved. In addition to this, with custom discrete manufacturing equipment, it is very difficult, nigh impossible, to capture all the machines functionality in a functional specification before the first prototype of that machine is commissioned. In practice, this usually requires that an initial functional specification is drafted and then when the equipment is commissioned and new functionality is discovered as being required, the initial functional specification is updated to reflect this. Depending on the complexity of the equipment, this loop may be repeated several times. An alternative to this rigid sequential approach to software development for equipment would be to utilise the agile software development lifecycle process. Larman (2004) describes the focus of agile development as:

- Close collaboration between the development teams and stakeholder
- Less documentation
- Frequent delivery of code (less features, more often)
- Ways to craft the code and team such that inevitable changes to requirements are not an issue

There could be a lot of advantages to applying the agile software development lifecycle to equipment design. For example, the quicker delivery of code would enable machine builders to test the mechatronic elements of their machines earlier in the projects and correct issues, if required. Often, mechatronic issues with new equipment are not identified until the machine is commissioned.

The application of S88 to discrete manufacturing equipment could be integrated with software process improvement research in regulated industries. The software process research aims to deliver software that will be developed in an efficient, traceable, repeatable manner that will satisfy the regulatory requirements of the FDA and other associated standards. This future research will discover if it is possible to combine plan-driven and agile practices, when developing S88 based equipment software, in a manner that complement each other so that the equipment may be delivered in a timely manner, whilst also improving the quality.
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7 Appendices

7.1 Appendix A – Abbreviations

ANSI - American National Standards Institute
DCS - Distributed Control Systems
FBD - Function block diagram
FDA - Food and Drug Administration
HMI - Human machine interface
IEC - International Electrotechnical Commission
IL - Instruction list
I/O - Inputs and Outputs
ISO - International Organization for Standardisation
LD - Ladder diagram
MES - Manufacturing Execution Systems
NRE - Non-recurring engineering
OMAC - Organisation for Machine Automation & Control
PLC - Programmable Logic Controller
PMA - Pre-market approval
SFC - Sequential function chart.
ST - Structured text
S88 - ANSI/ISA-88
WBF - World Batch Forum
7.2 Appendix B – Survey Questions
Dear Sir, Madam,

I am employed as a principal controls engineer by Medical Technology Ltd (Real company name was shared with survey respondents), Ireland. We have recently implemented a new controls standard for our discrete manufacturing equipment, which is based on the S88 standard.

Also, I am currently completing a Masters Degree in Technology Management at University of Limerick, and am basing my thesis research on the application of S88 to discrete manufacturing equipment. The thesis research is based on a case study at Medical Technology Ltd and a survey of similar projects (this is where you come in!!).

I have discussed this topic with David Bauman (Technical Director of OMAC) and have received his support in completing this study.

As such, I would be grateful, if you could complete the attached survey at your earliest convenience. I hope to have all the data analysed by the summer of 2009 and will share my findings with all participants and OMAC. Please be assured that all information disclosed will remain strictly confidential, and individual responses or the names of participating companies will not be published or distributed.

The survey (which is also attached in excel format, to ease completion) is quite short, mainly consists of 1 word / number answers and should take less than 20 minutes to complete. Finally, if a particular question is not applicable to your organisation or you do not want to disclose that information, please skip this and continue with the rest of the survey.

Thanks in advance,

Kevin Donaghey
Principal Engineer

Kevin.Donaghey@bsci.com

Phone: +353 91 517298
7.2.1 Identify criteria to support S88

Identify the criteria necessary to support a new software development standard based on the S88 standard?

<table>
<thead>
<tr>
<th>Identifying the criteria necessary to support a new software development standard based on S88</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Organisation Profile</strong></td>
</tr>
<tr>
<td>Which industry sector(s) is your organisation in?</td>
</tr>
<tr>
<td>What is the annual turnover of your organisation?</td>
</tr>
<tr>
<td>How many employees in your organisation?</td>
</tr>
<tr>
<td><strong>Engineering Expertise</strong></td>
</tr>
<tr>
<td>What is the minimum number of experienced controls engineers that will be required to develop and benefit from a software standard?</td>
</tr>
<tr>
<td>How many controls engineers (Staff or Contract) are typically active at your organisation for equipment design projects?</td>
</tr>
<tr>
<td><strong>Business Case</strong></td>
</tr>
<tr>
<td>Did you develop a business case to demonstrate the long term benefits of investing in a software standard?</td>
</tr>
<tr>
<td>What was the main justification for the investment?</td>
</tr>
<tr>
<td>Did you have a senior management team who will support the long term benefits of implementing a software standard?</td>
</tr>
<tr>
<td><strong>Realising Benefits</strong></td>
</tr>
<tr>
<td>In terms of number of projects or length of time, when did you start realising the benefits (cost, schedule, quality) of applying a software standard?</td>
</tr>
<tr>
<td>Is the software standard rolled out throughout the organisation or just local to a few facilities?</td>
</tr>
<tr>
<td><strong>Regulatory Compliance</strong></td>
</tr>
<tr>
<td>Do you have a company culture that has a strong commitment to quality?</td>
</tr>
<tr>
<td>Do you need to validate your equipment / software to comply with regulatory bodies such as the FDA?</td>
</tr>
</tbody>
</table>
7.2.2 Establish success factors

Establish success factors associated with the implementation of a standard based on the S88 Standard?

<table>
<thead>
<tr>
<th>Technical:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Have you standardised on one programmable controller, where possible?</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Was the software standard developed and tested independently of a</td>
</tr>
<tr>
<td>specific equipment design project or was the development of the</td>
</tr>
<tr>
<td>software standard incorporated into a new machine design?</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Is the software standard developed to interface with an MES system?</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>How long did it take to develop, test and document these standards?</td>
</tr>
<tr>
<td>Estimate to completion date, if not yet completed.</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Do you have 1 software standard that covers your complete range of</td>
</tr>
<tr>
<td>equipment – from small stand-alone machines to large multi-station</td>
</tr>
<tr>
<td>equipment?</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Have you applied only standard Machine States and PackTags (PackML) or</td>
</tr>
<tr>
<td>all elements of S88 (Units, EM, CM, Phases etc ) into your software</td>
</tr>
<tr>
<td>standard?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Equipment Build:</th>
</tr>
</thead>
<tbody>
<tr>
<td>What percentage of your equipment is Off the Shelf (OTS)?</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>How many external machine builder partners / vendors do you use?</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Do all your external vendors apply these standards or reserved for 1</td>
</tr>
<tr>
<td>or 2 strategic partners?</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Do you apply this standard to all manufacturing equipment?</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Do you apply this standard to proto-type equipment?</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>How would you rate the support you received from your controls supplier?</td>
</tr>
<tr>
<td>(Excellent, Average, None)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Quality:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you need to validate your equipment?</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>What % of your overall engineering costs for new equipment is related to</td>
</tr>
<tr>
<td>verification and validation activities?</td>
</tr>
</tbody>
</table>
### Standards in your Organisation:
Do you have Standard Operating Procedures (SOP) that govern all equipment design activities?

Is this the company’s first effort to introduce a controls standard?

### In-House or Contract Resources:
Did you develop your PLC software standard in-house or through external consultants?

Do you have the in-house expertise to develop the standard further?

### Other:
What lessons were learnt from developing and implementing the S88 Standard? Expand below:

What was the biggest challenge encountered during the development of the standard? Expand below:
### 7.2.3 Quantify benefits of S88

In terms of % improvement, enter the approximate benefits realised from applying the S88 standard to discrete manufacturing equipment?

<table>
<thead>
<tr>
<th>Project Activity Vs. Project Metrics</th>
<th>Schedule</th>
<th>Cost</th>
<th>Quality</th>
<th>Overall project risk</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Standardised approach</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Established methods and work flows</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Consistent design and documentation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Simplify definition and design</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Modularized Solutions</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Re-usable code modules</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Re-usable documentation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-verified software modules</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Application Development</strong></td>
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</tr>
<tr>
<td>Code Development</td>
<td></td>
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</tr>
<tr>
<td>Equipment Commission</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Interface to other Systems (eg. MES)</td>
<td></td>
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</tr>
<tr>
<td><strong>Test &amp; Validation Methods</strong></td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>Reduce / eliminate duplicate testing</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Higher level of confidence</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Combine testing activities</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Standard Test Plan</td>
<td></td>
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</tr>
<tr>
<td><strong>Maintenance / Upgrades</strong></td>
<td></td>
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<tr>
<td>Consistent HMI for Operators</td>
<td></td>
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</tr>
<tr>
<td>Less Training for Maintenance</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Learning curve for new engineers</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Other Pros or Cons : List each</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pro 1:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pro 2:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Con 1:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Con 2:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
7.3 Appendix C – Survey Results

7.3.1 Case Study Results

Research Objective 1 – Identify the criteria necessary to support a new software development standard based on S88

<table>
<thead>
<tr>
<th>Organisation Profile</th>
</tr>
</thead>
<tbody>
<tr>
<td>Which industry sector(s) is your organisation in?</td>
</tr>
<tr>
<td>What is the annual turnover of your organisation?</td>
</tr>
<tr>
<td>How many employees in your organisation?</td>
</tr>
</tbody>
</table>

Medical Technology Ltd is a major player in the medical device industry, and over the last five years, has invested heavily to expand its portfolio of products within the medical device industry. The company makes medical supplies used in minimally invasive surgical procedures. Its devices are used to diagnose and treat conditions in a variety of medical fields, including cardiology, gynaecology, urology, endoscopy, and neuromodulation. Products include defibrillators, catheters, coronary and urethral stents, pacemakers, biopsy forceps and needles, and urethral slings. The annual turnover of the organisation in 2007 was $8.5 Billion, and the company invested almost $6 Billion in Research and Development over the last five years. It has approximately 27,000 employees worldwide, with approximately 4500 employed in Ireland.

<table>
<thead>
<tr>
<th>Engineering Expertise</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is the minimum number of experienced controls engineers that will be required to develop and benefit from a software standard?</td>
</tr>
<tr>
<td>How many controls engineers (Staff or Contract) are typically active at your organisation for equipment design projects?</td>
</tr>
</tbody>
</table>

There are a core team of 6 engineers who developed the software standard. The profile and influence of each of these team members are all from slightly different backgrounds and the team composition, with roles and responsibilities is shown below:
### Roles and Responsibilities

<table>
<thead>
<tr>
<th>Roles</th>
<th>Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead Engineer</td>
<td>Set Goals for Team and Individuals</td>
</tr>
<tr>
<td></td>
<td>Controlled Budget &amp; Schedule</td>
</tr>
<tr>
<td></td>
<td>Approved Software design</td>
</tr>
<tr>
<td></td>
<td>Reported / Promoted Std throughout Organisation</td>
</tr>
<tr>
<td>PLC Software</td>
<td>Interpreted S88 and applied to suit organisation</td>
</tr>
<tr>
<td></td>
<td>Design, develop, document and test PLC Software</td>
</tr>
<tr>
<td></td>
<td>Applied Std to multiple machine to prove its value</td>
</tr>
<tr>
<td>HMI / Database</td>
<td>Design, develop, document and test HMI Software</td>
</tr>
<tr>
<td></td>
<td>Design, develop, document and test Database</td>
</tr>
<tr>
<td></td>
<td>Investigate options for interfacing with MES systems</td>
</tr>
<tr>
<td>Test Engineer</td>
<td>Developed Over-all Software Test Plan and Test Strategy</td>
</tr>
<tr>
<td></td>
<td>Developed system to control software library</td>
</tr>
<tr>
<td></td>
<td>Developed standard templates for all design and test documents</td>
</tr>
<tr>
<td>Quality Engineer</td>
<td>Reviewed and Approved all design and test documents</td>
</tr>
<tr>
<td>Electrical Controls</td>
<td>Update electrical drawings conventions to reflect new standard</td>
</tr>
</tbody>
</table>

| Table 7-1 Medical Technology Development Team Profile |

This activity was completed in a facility located in Ireland; however, the development team in Ireland worked very closely with their direct counterparts in a sister plant of the organisation in the US. Currently, activities are underway to adopt this standard in the US facility, and long term, the expectation is that the standard may be rolled out to other facilities, which have a requirement for such a standard and the in-house resources to support the standard. At the Irish facility, there are typically between 15 - 20 controls engineers working on equipment design projects, all of whom will reap the benefits of this software development standard. There would be a similar number of controls engineers working on equipment design projects in the sister plant in the US. Globally, Medical Technology Ltd would have in excess of 60 controls engineers working on equipment design projects.

### Business Case

- Did you develop a business case to demonstrate the long term benefits of investing in a software standard?
- What was the main justification for the investment?
- Did you have a senior management team who will support the long term benefits of implementing a software standard?
Senior management support, namely the engineering directors in both facilities in Ireland and the US strongly supported the implementation of a software standard. It was determined that a saving on software design, development and test labour of 31% could be realised by applying the S88 standard. As the organisation was also in the process of implementing a new ‘Lean Business’ initiative, senior management were particularly supportive of the fact that by standardising on the software development standard, it was possible to introduce an element of ‘standard work’ into the testing phases.

<table>
<thead>
<tr>
<th>Realising Benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>In terms of number of projects or length of time, when did you start realising the benefits (cost, schedule, quality) of applying a software standard?</td>
</tr>
<tr>
<td>Is the software standard rolled out throughout the organisation or just local to a few facilities?</td>
</tr>
</tbody>
</table>

The benefits from using the software standard and re-using pre-verified code modules accrued after the first implementation was completed. As the standard was developed in conjunction with a new equipment design project, there were the additional costs of developing re-usable modules of code. Also, the first project had to absorb the costs of designing, documenting and verifying the initial software framework and code modules. However, even in the first implementation, as there was multiple control modules that all were just an instance of their respective class, the powerful benefits of this standard was realised.

The decision to implement the new S88 software standard was timed to be completed during the introduction of a new set of procedures and templates which are governed by the Quality System for software development and validation. Although, this added to the complexity and unknowns involved with the project, the net result was the development of a new software standard that had been validated to comply with all the latest quality systems guidelines.

<table>
<thead>
<tr>
<th>Regulatory Compliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do you have a company culture that has a strong commitment to quality?</td>
</tr>
<tr>
<td>Do you need to validate your equipment / software to comply with regulatory bodies such as the FDA?</td>
</tr>
</tbody>
</table>

Medical Technology Limited has a strong commitment to Quality and invests millions every year to ensure it complies with regulatory requirements. Almost every aspect of the business is impacted by this commitment to quality, and the general company culture, is that above everything else, quality come first. As such, Medical Technology Limited validates all equipment and software that falls under the scope of validation as defined in their Quality Systems.
Research Objective 2

<table>
<thead>
<tr>
<th>Establish success factors associated with the implementation of a standard based on the S88 Standard</th>
<th>Medical Technology Ltd Response</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Technical:</strong> Have you standardised on one programmable controller, where possible?</td>
<td>Yes, Allen Bradley</td>
</tr>
<tr>
<td>Was the software standard developed and tested independently of a specific equipment design project or was the development of the software standard incorporated into a new machine design?</td>
<td>Software standard development incorporated into a new machine.</td>
</tr>
<tr>
<td>Is the software standard developed to interface with an MES system?</td>
<td>Yes, CAMSTAR</td>
</tr>
<tr>
<td>How long did it take to develop, test and document these standards? Estimate to completion date, if not yet completed.</td>
<td>1 year</td>
</tr>
<tr>
<td>Do you have 1 software standard that covers your complete range of equipment – from small stand-alone machines to large multi-station equipment?</td>
<td>Yes</td>
</tr>
<tr>
<td>Have you applied only standard Machine States and PackTags (PackML) or all elements of S88 (Units, EM, CM, Phases etc) into your software standard?</td>
<td>All aspects of S88 have been implemented</td>
</tr>
<tr>
<td><strong>Equipment Build:</strong> What percentage of your equipment is Off the Shelf (OTS)?</td>
<td>30%</td>
</tr>
<tr>
<td>How many external machine builder partners / vendors do you use?</td>
<td>7</td>
</tr>
<tr>
<td>Do all your external vendors apply these standards or reserved for 1 or 2 strategic partners?</td>
<td>No, currently just 2 of them</td>
</tr>
<tr>
<td>Do you apply this standard to all manufacturing equipment?</td>
<td>Yes, where possible</td>
</tr>
<tr>
<td>Do you apply this standard to proto-type equipment?</td>
<td>Yes, where possible</td>
</tr>
<tr>
<td>How would you rate the support you received from your controls supplier? (Excellent, Average, None)</td>
<td>Average</td>
</tr>
</tbody>
</table>

Table 7-2 Case Study Results (1) from Medical Technology Ltd.
Table 7-3  Case Study Results (2) from Medical Technology Ltd.

The final two questions in this section deserve a more expanded descriptive response, rather than what can be offered by the tabular format above.

**What lessons were learnt from developing and implementing the S88 Standard?**

The main lesson learnt from the implementation at Medical Technology Ltd was not to underestimate the schedule involved to get the standard accepted and approved. Some other lessons that were learnt was the need to review designs early, test code on real systems, address issues and re-iterate this process until a finely tuned standard was developed. Initially, there was not enough thorough performance testing completed. The decision was made early in the project to base the software standard on the industry standard – S88. However, during the course of the project, it was realised that by trying to remain completely loyal to the S88 standard, (which originally was developed for Batch Processes), it was difficult to implement. Following discussions with members of OMAC (and some of the survey respondents) , the lesson was learnt that a better, more flexible standard that was more loosely based on S88 was more appropriate for discrete manufacturing equipment within Medical Technology Ltd. However, it is important to stress that although a more flexible approach was taken on how to apply S88; all elements of S88 are used within the new standard.

**What was the biggest challenge encountered during the development of the standard?**

One of biggest challenges was to explain to other stake-holders how the standard works, how it will improve quality and how it will drive costs down. This challenge is made more difficult as many of the stake-holders
Manufacturing, Quality, Production, and Management) do not have a strong software background and have difficulty understanding concepts such as object oriented programming.

One of the main findings here was that if the development of the software standard was to delay the delivery of a new equipment design, senior management would perceive the use of software standards to be driving extended schedules and costs.
Research Objective 3 - Quantifying the Benefits of S88

<table>
<thead>
<tr>
<th>Project Activity Vs. Project Metrics</th>
<th>Schedule</th>
<th>Cost</th>
<th>Quality</th>
<th>Overall project risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Standardised approach</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Established methods and work flows</td>
<td>15%</td>
<td>15%</td>
<td>20%</td>
<td>5%</td>
</tr>
<tr>
<td>Consistent design and documentation</td>
<td>20%</td>
<td>20%</td>
<td>20%</td>
<td>5%</td>
</tr>
<tr>
<td>Simplify definition and design</td>
<td>20%</td>
<td>15%</td>
<td>20%</td>
<td>5%</td>
</tr>
<tr>
<td>Modularized Solutions</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Re-usable code modules</td>
<td>25%</td>
<td>40%</td>
<td>30%</td>
<td>10%</td>
</tr>
<tr>
<td>Re-usable documentation</td>
<td>25%</td>
<td>40%</td>
<td>30%</td>
<td>10%</td>
</tr>
<tr>
<td>Pre-verified software modules</td>
<td>25%</td>
<td>45%</td>
<td>30%</td>
<td>14%</td>
</tr>
<tr>
<td>Application Development</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Code Development</td>
<td>25%</td>
<td>25%</td>
<td>5%</td>
<td>12%</td>
</tr>
<tr>
<td>Equipment Commissioning</td>
<td>12%</td>
<td>25%</td>
<td>5%</td>
<td>5%</td>
</tr>
<tr>
<td>Interface to other Systems (eg. MES)</td>
<td>10%</td>
<td>10%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Test &amp; Validation Methods</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reduce / eliminate duplicate testing</td>
<td>40%</td>
<td>40%</td>
<td>25%</td>
<td>15%</td>
</tr>
<tr>
<td>Higher level of confidence in Application</td>
<td>0%</td>
<td>0%</td>
<td>25%</td>
<td>10%</td>
</tr>
<tr>
<td>Combine testing activities</td>
<td>20%</td>
<td>10%</td>
<td>10%</td>
<td>7%</td>
</tr>
<tr>
<td>Standard Test Plan</td>
<td>5%</td>
<td>15%</td>
<td>25%</td>
<td>3%</td>
</tr>
<tr>
<td>Maintenance / Upgrades</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Consistent HMI for Operators</td>
<td>0%</td>
<td>0%</td>
<td>10%</td>
<td>4%</td>
</tr>
<tr>
<td>Less Training for Maintenance</td>
<td>5%</td>
<td>10%</td>
<td>5%</td>
<td>2%</td>
</tr>
<tr>
<td>Learning curve for new engineers</td>
<td>5%</td>
<td>5%</td>
<td>5%</td>
<td>4%</td>
</tr>
</tbody>
</table>

Table 7-4 Case Study Results (3) from Medical Technology Ltd.
### 7.3.2 Survey Respondents Results

<table>
<thead>
<tr>
<th>Establish success factors associated with the implementation of a standard based on the S88 Standard?</th>
<th>Survey Response Average</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Technical:</strong></td>
<td></td>
</tr>
<tr>
<td>Have you standardised on one programmable controller, where possible?</td>
<td>Yes - 100%</td>
</tr>
<tr>
<td>Was the software standard developed and tested independently of a specific equipment design project or was the development of the software standard incorporated into a new machine design?</td>
<td>85% - Independent of design project</td>
</tr>
<tr>
<td>Is the software standard developed to interface with an MES system?</td>
<td>Yes - 85%</td>
</tr>
<tr>
<td>How long did it take to develop, test and document these standards? Estimate to completion date, if not yet completed.</td>
<td>1.3 Years</td>
</tr>
<tr>
<td>Do you have 1 software standard that covers your complete range of equipment – from small stand-alone machines to large multi-station equipment?</td>
<td>85% - 1 Standard applies to all equipment</td>
</tr>
<tr>
<td>Have you applied only standard Machine States and PackTags (PackML) or all elements of S88 (Units, EM, CM, Phases etc) into your software standard?</td>
<td>50% of companies implemented only Machine States and Pack Tags</td>
</tr>
<tr>
<td><strong>Equipment Build:</strong></td>
<td></td>
</tr>
<tr>
<td>What percentage of your equipment is Off the Shelf (OTS)?</td>
<td>15%</td>
</tr>
<tr>
<td>How many external machine builder partners/vendors do you use?</td>
<td>5</td>
</tr>
<tr>
<td>Do all your external vendors apply these standards or reserved for 1 or 2 strategic partners?</td>
<td>75% of respondents required all vendors to apply the standards</td>
</tr>
<tr>
<td>Do you apply this standard to all manufacturing equipment?</td>
<td>All new Custom Equipment.</td>
</tr>
<tr>
<td>Do you apply this standard to proto-type equipment?</td>
<td>28% of respondents did not apply standards on prototypes</td>
</tr>
<tr>
<td>How would you rate the support you received from your controls supplier? (Excellent, Average, None)</td>
<td>25% - Excellent 75% - Average</td>
</tr>
<tr>
<td>Quality:</td>
<td></td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td></td>
</tr>
</tbody>
</table>
| Do you need to validate your equipment?                                 | Yes - 85%,  
| What % of your overall engineering costs for new equipment is related to verification and validation activities? | 18% |
| Standards in your Organisation:                                        |  
| Do you have Standard Operating Procedures (SOP) that govern all equipment design activities? | Yes |
| Is this the company’s first effort to introduce a controls standard?   | Yes - 50% |
| In-House or Contract Resources:                                        |  
| Did you develop your PLC software standard in-house or through external consultants? | 50% In House  
50% Ext. Consultants |
| Do you have the in-house expertise to develop the standard further?    | 50% - Yes |

Table 7-5 Case Study Results (1) from Survey Respondents
<table>
<thead>
<tr>
<th>Project Activity Vs. Project Metrics</th>
<th>Schedule</th>
<th>Cost</th>
<th>Quality</th>
<th>Overall project risk</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Standardised approach</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Established methods and work flows</td>
<td>10%</td>
<td>12%</td>
<td>15%</td>
<td>3%</td>
</tr>
<tr>
<td>Consistent design and documentation</td>
<td>18%</td>
<td>16%</td>
<td>19%</td>
<td>7%</td>
</tr>
<tr>
<td>Simplify definition and design</td>
<td>13%</td>
<td>7%</td>
<td>11%</td>
<td>3%</td>
</tr>
<tr>
<td><strong>Modularized Solutions</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Re-usable code modules</td>
<td>15%</td>
<td>15%</td>
<td>8%</td>
<td>4%</td>
</tr>
<tr>
<td>Re-usable documentation</td>
<td>12%</td>
<td>12%</td>
<td>6%</td>
<td>4%</td>
</tr>
<tr>
<td>Pre-verified software modules</td>
<td>15%</td>
<td>19%</td>
<td>12%</td>
<td>5%</td>
</tr>
<tr>
<td><strong>Application Development</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Code Development</td>
<td>15%</td>
<td>15%</td>
<td>5%</td>
<td>12%</td>
</tr>
<tr>
<td>Equipment Commissioning</td>
<td>12%</td>
<td>25%</td>
<td>5%</td>
<td>5%</td>
</tr>
<tr>
<td>Interface to other Systems (eg. MES)</td>
<td>30%</td>
<td>30%</td>
<td>25%</td>
<td>4%</td>
</tr>
<tr>
<td><strong>Test &amp; Validation Methods</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reduce / eliminate duplicate testing</td>
<td>18%</td>
<td>12%</td>
<td>10%</td>
<td>6%</td>
</tr>
<tr>
<td>Higher level of confidence in Application</td>
<td>4%</td>
<td>0%</td>
<td>10%</td>
<td>3%</td>
</tr>
<tr>
<td>Combine testing activities</td>
<td>8%</td>
<td>6%</td>
<td>5%</td>
<td>2%</td>
</tr>
<tr>
<td>Standard Test Plan</td>
<td>3%</td>
<td>5%</td>
<td>6%</td>
<td>2%</td>
</tr>
<tr>
<td><strong>Maintenance / Upgrades</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Consistent HMI for Operators</td>
<td>0%</td>
<td>6%</td>
<td>10%</td>
<td>2%</td>
</tr>
<tr>
<td>Less Training for Maintenance</td>
<td>3%</td>
<td>7%</td>
<td>7%</td>
<td>4%</td>
</tr>
<tr>
<td>Learning curve for new engineers</td>
<td>5%</td>
<td>5%</td>
<td>5%</td>
<td>6%</td>
</tr>
</tbody>
</table>

Table 7-6  Case Study Results (1) from Survey Respondents
7.4 Appendix D - ARC Forum Material

(Referenced in section 3.4)

ARC’s Twelfth Annual Orlando Forum
Winning Strategies and Best Practices for Global Manufacturers
February 4-7, 2008 - Orlando, Florida

Manufacturers from All Disciplines Discuss Key Challenges at ARC Forum
The 2008 ARC Forum in Orlando highlighted some of the key challenges faced by end users across all manufacturing disciplines. If you ever wanted to know the common challenges faced by the chemical, aerospace, life sciences, and automotive industries, all you had to do was be present at the keynote segment of the forum. End users from Dow, Boeing, Bristol-Meyers Squibb, and General Motors talked about some of the recent key projects they implemented, lessons learned, and obstacles overcome. Many of these revolved around common themes of getting the best possible performance out of your employees and your partners, leveraging standardization while making room for site-specific requirements, and leveraging technology to create a real business value proposition.

Agenda
Following is the schedule for the Forum:

<table>
<thead>
<tr>
<th>Monday, February 4</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pre-Forum Sessions</strong></td>
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<tr>
<td>Track 1</td>
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<tr>
<td><strong>1:00 PM</strong></td>
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<tr>
<td>SOA for Manufacturing Workshop (Manufacturing Companies Only)</td>
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<tr>
<td><strong>3:00 PM</strong></td>
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<tr>
<td>Automation and Control Benchmarking for Continuous Improvement Workshop (Manufacturing Companies Only)</td>
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<tr>
<td><strong>4:30 PM</strong></td>
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<tr>
<td>Plant Performance Benchmarking (Manufacturing Companies Only)</td>
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<td><strong>6-10 PM</strong></td>
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<tr>
<td>Registration and Welcome Reception with Hors d’Oeuvres</td>
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The text below is from the ARC Forum website and was included in the ARC Forum Agenda to promote the discussion that the researcher hosted at the ARC Forum in February 2008.

(http://www.arcweb.com/Events/Orlando08/Pages/default.aspx#overview)

**The Application of S88 to Machine Control**

Boston Scientific will be discussing the benefits and lessons learned from the implementation of the S88 standard at the control level of a single machine on one of their manufacturing lines. This will be an interactive presentation followed by a discussion workshop on implementation methodologies and the benefits of applying the S88 standard (including S88.05) to machine control. Boston Scientific is currently reviewing the benefits to be gained by implementing a full batch execution engine at the server level and is seeking input from the experiences of other manufacturers.

This session is recommended for user manufacturers, machine builders, and automation technology providers involved in converting and packaging machine selection or machine and machine control design.
The Application of S88 to Machine Control

Kevin Donaghey
Principal Controls Engineer, Galway, Ireland

Contents

Topics:
- Company Background
- Business Case for using S88
- Implementation
- Discussion Points
- Master of Science Thesis Research Subject
Boston Scientific Corporation Profile

**General Facts:**
- Founded in 1979 with 38 employees and $2 million in sales
- Now a global leader in cardiovascular medicine and one of the world’s largest medical device companies
- Portfolio of approx. 12,000 products, many with market leading positions
- The TAXUS® drug-eluting coronary stent was the most successfully launched product in the history of the industry
- Added Cardiac Rhythm Management Group through acquisition of Guidant Corporation in April 2006
- Corporate HQ: Natick, MA
- Regional HQs: Paris, Tokyo, Singapore
- Website: www.bostonscientific.com

**Product Innovation:**
- 12,995 Patents issued worldwide
- More than $1 Billion invested in R&D ('06)
- $22.1 Billion in 27 alliances/acquisitions ('06)

**Financials:**
- $7.8 Billion Revenue ('06)
- 28% CAGR1 ('02-'06)
- $1.4 Billion Net Income2 ('06)
- NYSE: BSX

**Demographics:**
- 29,000 Employees
- Dedicated marketing and sales force in more than 45 countries
- 37 manufacturing, distribution and technology centers worldwide

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**Ireland Locations and Employees**
- Ireland Locations:
  - Galway
  - Tullamore
  - Cork
  - Letterkenny

- Employees:
  - 5,225 employees in Ireland
  - 1,200 employees in Cork
  - 1,000 employees in Galway
  - 275 employees in Tullamore
  - 150 employees in Letterkenny
  - 600 employees in Clonmel

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1. Compound Annual Growth Rate
2. Excluding purchased R&D, litigation-related and other charges
Boston Scientific products help treat a broad range of medical conditions throughout the body.

VASCULAR SURGERY
PERIPHERAL VASCULAR
CARDIAC SURGERY
VASCULAR SURGERY
ENDOSCOPY
ONCOLOGY

Business Case for the need to change...

BSC estimates a 30% savings potential from code and document reuse during the SDLC.
Equipment Types with BSC

- Wide range of Equipment Types.

From small discrete stand-alone fixtures to full automated assembly and electro-polishing lines.

Standardisation

Identified the need to develop a Corporate Software Standard

Multiple Sites Developing Software to different Standards:

Inefficiency when transferring equipment – due to install, qualification and support.
How to create a standard that works?

1. S88 Design Reviews with RA
2. Develop Standard
3. Develop & Test on Real Equipment
4. Develop Lean Design Documents
5. Repeat Step 1 – 4!!!

Equipment Type

Hardware
- Custom Mechanical Design
- GuardLogix PLC
- 10 Axis Servo control motion
- 200+ Digital I/O
- 40+ Analog I/O

Software
- RSLogix 5000
- RSView SE
- RSSQL
- SQL Server Database

High Level Requirements
- Several Integrated Process Steps
- 21CFR 11 - Records & Signatures
- Routing, Transfer and RFID Tracking of Product
- Produce 1 part / min.
S88 Model at Boston Scientific

- Flexible to collapse layers in Equipment and Procedural Models.
- Some simple Machines will be single units, but the model also supports multi-units machines.
- Follows many of the guidelines from RA’s ‘Foundations of Modular Programming’

Accomplishments to date

- Software standard created
- Machine Commissioned on schedule
- Design Documentation & Guidelines in progress.
Discussion Points

Use of S88 Standard on discrete manufacturing systems.
- Issues encountered – Lesson Learnt
- Successful implementation on High speed automated equipment
- Software Validation approach for discrete machines
- Implementation of Batch on configurable discrete machines?

Masters of Science – Thesis topic

Formal Quantitative Research
- Financial Data
- Technical Data
- Performance Data

- S88 introduced for Traditional Batch Processes Vs. discrete systems.
- Compare improvements in Development, Commissioning & Validation.

Review of Literature
- Industry Reports
- Published Academic Papers

Identify Success Factors / Best Practices.
Collaborate with ARC to collate data and publish results report.