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Project Submission Sheet

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Dissertation

A critical analysis of project management methodologies used in the Pharmaceutical Industry

Your Name/Student Number	Course	Date
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National College of Ireland
Research Students Declaration Form
(Thesis/Author Declaration Form)

Name: Leon Burns

Student Number:23156031

Degree for which thesis is submitted: Master's in Business Administration

Title of Thesis: A critical analysis of project management methodologies used in the Pharmaceutical Industry – '*Do project management methodologies impact project cost control performance?*'

Date: 15 Aug 2025

Material submitted for award

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Contents

Abstract

Purpose: To understand if there is a relationship between various types of project management execution methodologies commonly used within the pharmaceutical industry for engineering and construction capital projects and project cost-overruns.

Approach: Literature review on project failings, project management tools and techniques used in the pharmaceutical industry in combination with semi-structured interviews with pharmaceutical industry professionals with significant capital project execution experience.

Findings: Research indicates that PMBOK or waterfall type project management methodology is the most preferred and reliable project management system for pharma construction projects. PMBOK in conjunction with PMO and specific elements of agile & lean methods, would make for a more fit for purpose methodology for the pharmaceutical industry.

Research Limitations: Semi-Structured interview approach & lack of published information regarding pharmaceutical project failures

Originality/Value: No historical data or literature to suggest this subject matter has been previously researched or documented. The value of this paper is in the data that has been collated on the perceived most appropriate types of PM methodologies for higher levels of cost control on pharmaceutical capital engineering projects.

Keywords: Pharmaceutical Industry, Project Management, DMAIC (Define Measure Analyse Improve Control), Cost Control, Methodologies, PMBOK (Project Management Body of Knowledge), Agile.

Paper Type: Masters Research Dissertation

1.0 Introduction

The pharmaceutical industry is major contributor to the landscape of Irelands economy both from an employment and economic tax revenue generation perspective. The industry itself in Ireland provides high end labour for approximately 70,000 people working in the sector and generates €9.5BN of Irish manufacturing corporation tax revenues. (Fitzgerald , 2025).

Capital project management in the context of the pharmaceutical industry relates to the capital funding, planning, design/development and construction of assets used for the manufacturing, distribution and administration management of medicines and drugs. (The Investopedia Team, 2024)

As the world increasingly requires larger quantities of critical medicines which are becoming more complex to manufacture and demanded faster on the market, there is a fundamental requirement for the use of best-in-class project management methodologies and principles to manage these new drug introductions while operating within the triple constraint of projects. That being quality, cost and schedule (Pandya, 2017).

There are many operational business units that are key to successful pharmaceutical operations both in Ireland and Worldwide. This includes departments such has quality control, quality assurance, maintenance, engineering and in recent years the scope has increased to include operational excellence. Operational excellence has a cross functional responsibility to work with the various interdepartmental teams to focus on efficiencies and continuous improvement initiatives. (Friedli, 2010).

All of these departments must adhere to the market regulatory bodies for which the products are being manufactured for and are manufactured under a general controlled set of policies and procedures commonly referred to as GMP. (Laugen, et al., 2005). These regulations apply to anything that is being manufactured for human medicinal treatments ranging from topical (skin) to advanced medical therapy products such as biologics. (ABOU-EL-ENEIN, et al., 2013)

As part of the engineering function of these pharmaceutical operations, both capital project engineering teams and their externally contracted consultants must adhere to GDP (good design practices) and cGMP (Current good manufacturing practices). (Jacobs

& A. Signore, 2017). As a result of these strictly imposed regulations, and the procedures and policies that must be adhered to, the pharma capital project world which is responsible for building the facilities and utilities where final drug products and ingredients are made, is a highly complex and expensive environment to operate within.

To add further complication and cost, it is now well recognised that we reside in a volatile, uncertain, complex and ambiguous (VUCA) (Abidi & Joshi, 2018) world. The world of capital project delivery within the pharmaceutical industry also suffers from the ongoing existential threats and risks that are associated with the new VUCA world.

The environment is constantly evolving and becoming exceedingly more expensive to operate within and more complex. Breaking down VUCA into its constituent parts and using it as a risk analysis prompt in the context of the industry provides us with some startling points:

V - Although the industry up to the last decade remained relatively consistent in terms of growth and output, the new world in which we live in with significant trade tariffs being touted by America in the hope to reduce drug costs by up to 80% is sending the industry into the unknown where budgetary shrewdness will be become key. (Peel, 2025)

U – Supply chain uncertainty for raw materials used in drug manufacturing and supply routes of products has come into focus recent years, as we face a world that is more prone to natural disasters and to political fallout which prohibits the safe delivery of drugs to those who need it in the world. (Challener, Ph.D., 2025)

C – The Pharma industry has become a more complex environment in recent years, which has seen investors choose less frivolously than previous generations as the industry is being considered more difficult to judge in terms of revenue returns. With pharma companies spending more on marketing in recent times then research and development. (Taylor, 2015)

A – Unfortunately one of the defining factors of the global pharmaceutical industry is the ambiguity overserved in relation to how the public perceive the industry in terms of ethics and how pharma companies operate from a financial and compliance regulatory standpoint. One would assume that an industry that's focus is to manufacture and supply products to improve people's lives should behave in an appropriate and ethical manner, but in fact there are multiple publications and literature suggesting that pharma

companies have acted in an unethical manner and have even in some severe cases actually increased harm to patients. (Arnold, et al., 2022)

Large scale capital projects are an important aspect of the pharmaceutical environment in Ireland with significant FDI (Foreign direct investment) being implanted in the country over the last 5+years. Examples of this include Eli-Lilly's investment in Limerick with a Capex (Capital expenditure) cost of over $1BN, likewise Pfizer's investment in Grange castle Dublin estimated at €1.2BN and Astellas Killorglin's fill finish plant at €330MM. (Hargreaves, 2023)

Completing these type projects is becoming more difficult, in a time when cost escalations on capital and infrastructural projects are becoming both corporately and politically a highly contentious issue. A prime example of this that has been in the public eye for some time in Ireland is our nations national maternity hospital campus, a large super-project that is currently being built at St. James Dublin. (O'Connor, 2025). This specific project has seen an increase in base cost from €296MM in 2017 to a recent final forecast in excess of €2.24BB in 2025, equating to approximate 757% increase from base estimate to final finished forecast within the space of 8 years. (Wall, 2025)

As project leaders and business owners, we must learn to understand project cost escalations better and develop systems and processes that seek to gain better fiscal control of projects in order to prevent both internal and external stakeholder and corporate organisational upset as these attributes can lead to financial discomfort.

After all the global pharmaceutical industry is wholly responsible for the research, development, production, and distribution of life saving critical medical treatments throughout the world, which has seen continual exponential growth and development since its inception in the 40's which has been estimated to be worth $1.42 Trillion US Dollars worldwide in 2022. (Fitzgerald & Wilson, 2023)

In this chapter the introductory context and outline importance has been discussed with a viewing to setting the scene for the literature review that will contain the main element of the document that relates to relevant publications and literature that has been researched for this paper. Continuing from the literature review section will be the research question, methodology, findings and concluding sections of the paper.

2.0 Literature Review

This section of the paper will discuss literature and publications that have been examined for this dissertation that have relevance to the research topic relating to pharmaceutical project management, project management methodologies and project failures.

Overview

The oxford dictionary defines a project as *'a piece of planned work or an activity that is finished over a period of time and intended to achieve a particular purpose*'. (Oxford Dictionary, 2025). For contextual purposes, in this dissertation when a capital project is referred to, it refers to any engineering or construction effort that is required for any business reason within the confines of the pharmaceutical industry.

One of the areas that consistently appear as a reoccurring theme during project lessons learned workshops, which are typically carried out at the back-end of a project, is the consideration of the project management methodology used. And more specifically if it was the correct methodology, and whether another system or set of business processes would have improved the overall outcome (Astellas Pharma, 2024). More specifically the expanse that the researcher would like to explore, is the area of project failures as a result of PM methodologies and systems, and moreover whether or not they can negatively or positively impact project schedules, cost and overall delivery performance of projects.

The literature review submitted as part of this dissertation paper provides selected theories and foundation on the specific research themes. Investigating initially research on project management methodologies and techniques commonly used within the pharmaceutical industry and project management concepts, following on to examine project cost overruns and how they may link to project methodologies.

In this section of the dissertation the hypothesis that will be explored will determine if there is a relationship between selected project management methodologies and project cost overruns within projects, this will be completed by researching relevant literature related to the subject.

2.1 Project Management Methodologies

The pharmaceutical industry has historically been well versed in using project management as a general philosophy for completing non routine business tasks for some time now. Within the industry PM systems, philosophies and tools have been refined from long established traditional waterfall PM methodologies such as PRINCE 2 (PRojects IN Controlled Environments) (Bentley, 2012) and PMBOK (Project Management Book of Knowledge) (Heldman, 2018). Notwithstanding this, in recent years there has been a shift in the industry to make a break away from these systems due to their complex and sometimes bureaucratic approaches towards something leaner, faster and more flexible. This grew largely from the successes that agile and scrum practices have had in the software development and engineering sectors. (Shah, 2017). Hence the rise in popularity of Agile and Lean approaches in the industry.

PMBOK

The Project Management Body of Knowledge (PMBOK) is the chosen methodology that has been most widely adopted by the pharmaceutical and consultant engineering industry for the last 20+ years. Individual companies may slightly tailor the system to specifically suit a particular chosen project application however the overall processes and stage and gated project management approaches and systems are largely the same and follow the PMBOK guidelines as published by PMI. Many of the core documents and business process have a degree of similarity and feel within the industry from one organisation to another. When executing projects using PMBOK processes project and task management is controlled and monitored with the application and integration of the 47 logically grouped project management processes, which are categorized into 5 Process Groups and 10 subject groups (Project Management Institute, 2021).

To illustrate these groups and processes a table has been provided as figure 5.0 in appendix 1 for further explanation.

PMBOK can be considered a form of waterfall project management methodology. The original waterfall methodology was developed and documented by Royce in the 1970's

for the computer design and software engineering industries. In essence Royce identified a series of logical phased progressions whereby when one logical phase (and its associated tasks) was completed the project moved onto the next, this helps to form and co-ordinate a series of tasks grouped together so that the software design project can come to a logical conclusion. (Aroral, 2021). The term 'waterfall' refers to the tiered logical approach whereby one phase is completed and is subsequently followed by another phase in sequential logical order as can be seen in figure 1.0 below.

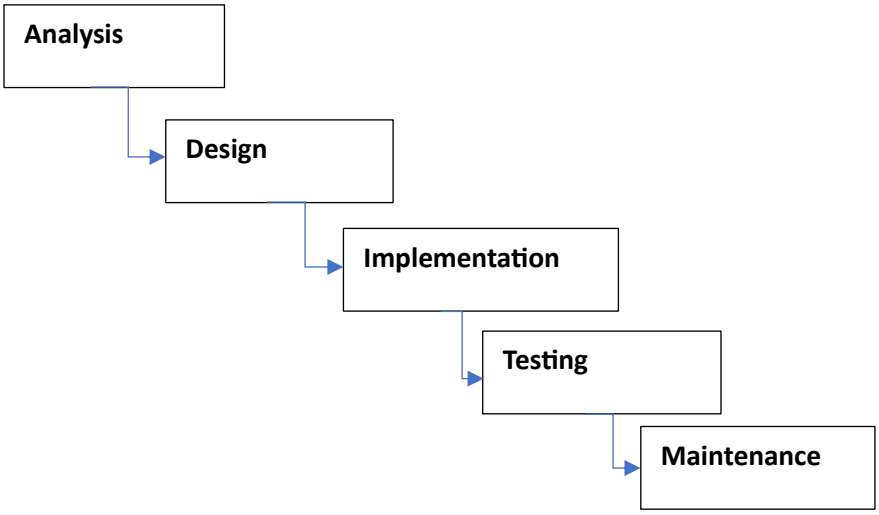

Figure 1.0 Original 1970's Waterfall methodology diagram explanation (Morgan, 2018)

Although PMBOK and waterfall appear on the surface to both be methodologies that could indeed be well suited to the pharmaceutical environment due to their process driven logical approach, the lack of flexibility during design, coupled with the fact that phases must be completed with defined outcomes, can lead to stakeholder frustration and can often take more time to complete than initially anticipated. This, for obvious reasons, can lead to significant cost and schedule implications during project execution.

Prince 2

PRINCE 2 was developed in 1989 by the CCTA (the central computer and telecommunications agency) and is an abbreviation for a methodology known as (projects in controlled environments). PRINCE 2 is a follow-on system that was developed as a successor to a methodology known as PROMPT which was created in 1975 by an organisation trading as Simpact Systems. (Seymour & Hussein, 2014). Prince 2 was a collaborative effort and was developed originally utilising various project management academics, consultants and project end-users.

The methodology is based heavily on business case and the initial requirement for the project from a business perspective. All process tasks and objectives are centred around this point.

During project execution phases the business case is constantly reviewed to justify the project in terms of the business case and the final end product. At the heart of Prince 2 lies 7 themes and guiding principles. The 7 themes being; business case, organisation, plans, quality, risk, progress and change. The 7 principles which reside under the themes are defined as: continued business justification, learn from experience, management by stages, defined roles and responsibilities, manage by expectation, focus on products & tailor to suit the project environment. (Caha, 2017). The 7 principles are captured in figure 2.0 overleaf.

Matos & Lopes 2013 outline the direct comparisons between PRINCE 2 and PMBOK methodologies from a PM process perspective and the differences between both systems are highlighted and evaluated to some extent. The paper is largely written from an IT project perspective, but as many IT PM systems and engineering project systems have cross over, it can be considered to be relevant in the context of this paper.

The paper concludes to inform us that the fundamental difference between PMBOK and PRINCE 2 is that PMBOK is more document, systems and process based. Versus PRINCE 2, which appears to have a more product output based. What is also clear is the cross over in terms of output deliverables within the various project stage gates, e.g. in PMBOK the overall breakdown of the project is broken into work packages knows as WBS (work breakdown structures), within the PRINCE 2 method, this same work breakdown is known as the PBS (product breakdown structure). To complete, the paper is finalised by

stating that either systems are more than adequate for the management of critical or complex projects, however neither are mentioned in a positive or negative fashion to indicate which may be better for managing projects from a cost control perspective.

7 Principles	**7 Themes**	**7 Processes**
Continually justifying the business case	Business Case	Project Start-up
Experiential learning	Organisation	Project Direction
Defined roles and responsibilities	Product or Project Quality	Project Initiation
Stage gate management	Planning	Project Controls
Exception Management	Risk Management	Project delivery management
Remain product focussed	Management of change	Stage gate boundary management
Amend to be fit for purpose and suit the product or project	Progress reporting	Project Closeout

(ILX Marketing Team, 2016)

Figure 2.0 PRINCE2 comprises of 7 Themes, 7 Principles and 7 Processes.

PMO (Project Management Office)

Pharma projects can be complex to manage from a cost perspective, with often times several costing structures and financial streams having to be monitored from several data sources. This can lead to difficulties in identifying basic control facts such as how the project is performing from a financial perspective; how much budget is left, identifying the earned value of the project & identifying if any cost risks exist – where they are stemming from and how they might be mitigated.

For these reasons many pharma organizations have transitioned away from org structures that have project managers interdepartmentally managing projects to *'single point of contact structures'* that have introduced what's known as PMO's (project management office).

The theory being, that consistent project management tools and techniques can be applied to all projects being executed within the organization, this in principle should lead to greater project controls and hence a reduction in project overruns. Martin 2017 tells us that initially the use and popularity of embedding PMO's within organisations has increased dramatically since 2000 with a then 47% establishment rate in large pharmaceutical orgs, compared to 14 years later in 2014 when 88-90% of organisations had an established, dedicated PMO. (Martins, 2017)

Martins also illustrates the point that having dedicated PMO's can create an accountable, auditable ready environment that can robustly uphold proceduralized project management techniques and strategies in combination with more sophisticated levels of risk management structures, which can assist with portfolio and program tracking. Cost control has a major part to play in the latter, so it can be safely assumed that cost adherence and control may improve with the introduction of these types of dedicated structures into the pharmaceutical environment. (Martins, 2017)

An example of what can be introduced as part of PMO implementation is a more structured approach to risk and schedule risk/outcome modeling. As cost in capital projects (time x money) is explicitly linked to schedule control it can be advised to apply

specific risk methodology when approaching schedule overrun potential situations such as the following:

1. Identify the problem area with the schedule
2. Quantify the time and cost risk
3. Model the overrun scenario using Monte Carlo or Latin Hypercube to assess various outcomes.

   (Nalewaik, 2005)

Ralf 2013 suggests a 3-tier approach can be adopted and applied for analysing communication flow and effectiveness throughout the PMO and the wider organisation. He also suggests that this approach can significantly improve project performance though slicker and more efficient information flow throughout the project team. (Ralf, et al., 2013).

However, looking at the literature from a critical thinking perspective, it does not implicitly suggest that these improvements in process and knowledge flow will bring a net positive overall impact to the cost performance of a project or indeed promote schedule adherence improvements in any manner. The article does touch on the fact that pharma projects can run into significant cost issues due to size and complexity, but critically no mitigations have been cited to improve this potential inevitability. (Ralf, et al., 2013).

This leads us to the theme of whether or not PMO structures within organisations can effectively manage project cost overruns on their own merit without additional project and cost control mechanisms.

Scrum Methodology

As project management within the pharma industry has developed so have the varieties of project management tools and techniques that are applied to certain projects and business endeavours. Some project management methodologies have been developed from the software industry such as Scrum and Agile project management. Although scrum in particular has been historically documented as being strong from a design development *right-first-time* perspective, it doesn't lend itself to improving the cost

control element of projects in any way. Scrum primarily focuses on development 'sprints' which involves 'sprinting' quickly though a design phase, even if the output is not 100% or fully functional with the end goal of having developed 'something' rather than just completing PM documentation for the sake of it. Azanha 2017, tells us that when using the scrum methodology development time (or design time in the case of the pharma industry) is generally 75% quicker than when more traditional waterfall type PM methodologies are used. (Azanha, 2017). Here it is important to note that in theory a quicker design phase should keep a project in better position financially as forecasted soft costs should stay within budgetary allocation.

This style of methodology has also been known to encourage more experimental and learning type practices, which doesn't necessarily lend itself naturally to the process driven and regulatory driven nature of pharmaceutical projects or pharma-engineering as a whole. Azanha 2017, again tells us that agile project management and scrum methodologies are more suited to projects that have a large degree of elemental change required to actually get to the end goal. These are the type of projects that don't necessarily work if traditional waterfall methodologies are used. From a critical thinking perspective, the question must be asked in this case, surely cost overruns are inevitable if the project is constantly evolving and the scope continues to creep and develop.

Perhaps in this case there is a theme that should be explored that being the concept that agile and scrum methodologies are less concerned with project cost control, and more suited to continuous developing design scenarios, rather than projects that require stringent cost control.

Six-Sigma

The Six-Sigma methodology (6σ) was developed by Motorola in the 1970s primarily in direct response to issues that the organization was suffering from with respect to poor product quality in combination with a strong customer complaint backlog. These issues in combination were resulting in considerable margin and productivity losses. Pyzdek 2003 advises in his publication that has a result of implementing six-Sigma culture and the customer focused, efficiency driven, continuous improvements that six-sigma endorses, that Motorola saved $15B over an 11-year period (Pyzdek, 2003). Six-Sigma as a methodological approach can be defined as a systematic improvement method for

existing and new product introductions that focuses on using scientific and metric based analysis to improve rates in customer defects. (Linderman, et al., 2002).

This drive for overall efficiency and quality improvement culture in combination with a customer defect philosophy created the main critical attribute for the Six-Sigma quality management standard that being *'3.4 million problems for every 1 million opportunities'*.

Although strictly speaking Six-Sigma wasn't intended to be a project management system per se, there are elements of the methodology that lends itself ideally to the co-ordination, and problem solving/business case focus that is strongly desired within robust project management practices. 6σ also provides a training framework so that personnel within the organisation can be trained to various levels from basic instruction to achieve the standard qualification requirements, to advanced practitioners, these grades are known as White Belt, Yellow Belt, Green Belt Black Belt and Master Black Belt. With the overall philosophy and culture six-sigma utilise planning tools such as DMAIC. (Define, measure, analyse, improve & control). This approach can be seen as a further development to the early PDCA (Plan-Do-Check-Act) as defined by Deming in the 1930's (Monday, 2022)

Taking a high-level glance at the DMAIC approach, which has been simplified in the figure 3.0 below, poses us to ask the question, if implemented could this system improve cost control and project overruns due to the nature of its simplicity. Surely pairing down project management methodologies and using a system such as this that actively puts emphasis on the 'control' aspect of the change or problem could bring positive dividends. This will theme should be explored within the research interviews that will be completed as part of this research study.

D	Define goals of the improvement activity.
M	Measure the existing system.
A	Analyze the system to identify ways to eliminate the gap between the current performance of the system or process and the desired goal.
I	Improve the system.
C	Control the new system.

Figure 3.0 DMAIC system Explained (Jami, et al., 2020)

Lean

Lean manufacturing principles were originally developed at the dawn of the industrial era after the turn of the century around 1913 and subsequently have been heavily adopted in the pharma industry for the last 2 decades. More so in the production and manufacturing environment, but as of late has started to move into the project execution realm. Although not strictly a project management methodology, many aspects of lean can be successfully used in project execution and of late many construction companies and engineering consultants have adopted lean construction initiatives. The elimination of 'waste' is at the core philosophy of lean principles. The 7 waste elimination principles can be identified by referencing the abbreviation TIMWOOD (Eaton, 2013). The table listed as figure 6.0 in appendix 2 provides an explanation for the various abbreviations and potential applications of the idealisms within the project environment.

Using AI as a PM Tool or Methodology

The concept has been touted that AI has the potential to be used for lower-level project management tasks that currently require human interaction to complete. The academic in this case introduces us to a scenario where AI could be employed, for arguments sake, to develop the outline project budget, schedule and work breakdown structure (WBS) for the construction of a domestic house roof. Although presented in an entirely basic manner, the concept proves to demonstrate that AI could potentially be used for resource loading, and cost estimation modelling analysis and even define critical paths within project schedules (Abdomerovic, 2024). Critically within this literature the author does not discuss the potential downsides and compliance regulation required when using AI for critical business decision making, which is certainly an additional consideration that would have to be explored extensively for use within the pharma industry.

2.2 Project Failures

Reasons for project failure

Rao & Jigeesh 2015 completed a pronounced deep dive into pharmaceutical project failures by employing statistical analysis in order to provide tabulated data across each of the project phases and specific reasoning for why that aspect of the project or phase failed. Critically they also provide a list of mitigations that could potentially be used to prevent future project failures. However within the literature no attention has been given to recommending systems, methodologies or processes that could be employed to prevent project failings from the outset. (SAI NANDESWARA RAO & JIGEESH, 2015).

It can be assumed from this piece of literature that little is known on the link between project cost overruns and specific project management methodologies. As the authors were quite clear for the reasons for project failures, but didn't complete an in-depth analysis providing the reader with information as to how this might be future mitigated or prevented.

Hwang 2008, looks at the potential use of metrics, standardisation and benchmarking within pharmaceutical capital project delivery to ascertain the connection between high performing projects and continuous improvement practices and established benchmarking arrangements. The literature brings attention to the complexity and level of regulatory compliance required for pharmaceutical projects and suggests that robust project management should significantly improve project performance and overall compliances outcomes. Critically within the article there is no concern to project management methodologies or to the link between PM systems and the potential for project cost escalation which can lead to economical investment decisions. (HWANG, et al., 2008)

To date there has been attempts at project costs analysis research, but the exercise has been focused on R&D (Research and Development) costs and more specifically trying to define a suitable cost appraisal model for R&D pharmaceutical projects and future pharmaceutical treatment opportunities (Thu Trang, et al., 2002) ,with the overall outcome of the literature suggesting that net present value is the most appropriate appraisal technique generally speaking for this type of investment opportunity. The

literature does not suggest any project recovery methodologies or techniques that should be employed if this type of project finds itself in financial difficulty, or indeed systems to prevent these issues from happening at the front end of the project. (Thu Trang, et al., 2002)

Communications & Stakeholder Engagement

While considering project success and failures within the pharma industry the theme and the importance of communication within the project organisation is widely documented and discussed. The trick of navigating through the complex regulatory and business processes that are inherently built into the pharma industry as a requirement of the high quality and right-first-time approach of making drugs for human consumption, cannot be underestimated. The International Society for Pharmaceutical Engineering (ISPE) offers a suite of training documentation known as the *'project management for the pharmaceutical industry'* which provides an adapted methodology containing tools and techniques that specifically support project delivery for the pharmaceutical industry. These tools and processes have been developed to ensure that (sometimes forced) collaboration exists been stakeholders that might not necessarily work together on an ongoing basis. The methodologies are developed in such fashion that they become *the 'bricks and mortar'* of how the project will be ran and the interdependencies between project outputs and how they will be managed. Curiously there is no mention in any serious way of cost control as part of the ISPE methodology, other than light touch approach references to project cost estimation and budgetary control. However, within the methodology collaboration and communications feature heavily as a common theme throughout. (ISPE, 2011)

Melton 2012, takes an in-depth look at the development of the ISPE project management handbook with a particular view as to how projects operate within the pharmaceutical industry and the nuances that occur during project execution. Dr. Melton's approach places a strong emphasis on stakeholder engagement throughout the lifecycle of the project and also provides some additional key frameworks for project delivery such ask risk matrix mitigation and standard stage gated project management approach which appears to be a take on the PMBOK stage and gated (waterfall) framework. (Melton, 2012)

The ISPE framework also provides some basic fundamental key guidance concepts for project delivery, these being Business context, stage and gated project approach, context of regulatory impact, integrated risk management, integrated validation lifecycle approach, best use of latest technology, collaboration and finally value management. The later may contain tools for cost management, but it seems overall the methodology isn't focused directly on cost management as a 'theme'. (ISPE, 2011)

However, notwithstanding the aforementioned, Melton does place emphasis on *'engaged stakeholder scope development'* which in theory if relatively well defined as a concept, this should prevent additional scope creep and hence additional cost burden overall to the project. In summary it appears ISPE's project management methodology doesn't particularly address the prevention of cost overruns as an overall methodology aim, it does appear to lightly address it as a minor theme. This literature has provided room for thought regarding the dissertation interviews, as there is a theme appearing which could be explored on stakeholder scope development and cost control during project execution.

In this chapter project methodologies, the introduction of project management organization, project failures and the use if AI within projects has been researched and discussed with a view to setting the relevance of the research question and also to discuss and understand in a deeper context what has been previously researched in this subject matter.

3.0 Research Problem & Aims of Research

Following on from the literature review which was carried out on methodologies, project failures and other systems that can help improve project performance, this chapter of the dissertation will aim to set out the aims of the research which will develop into the main research question of the dissertation.

Overview

This element of the research project has been academically referenced as being one of the harder tasks for the researcher to complete as there is no formal set process or methodology for identifying research gaps within research articles, journals and academic books. (Farooq, 2017).

Moreover, it is critical to point out at this stage during this research phase of the dissertation that when defining the research question and the subsequent hypothesis that will inevitability be tested, that the wheel is not being re-invented. It is also critical that the gap that has been identified within the researched literature is genuine and has not already been answered or addressed in another slightly different manner. (White, 2017)

As discussed in the previous chapter, project management methodologies have been previously researched and documented with outline themes and applicability completed for appropriate specific project intent. A specific focus has been applicability to the pharmaceutical environment, as this dissertation is based around that. Project failures have also been researched to ascertain if specific PM methodologies are to blame for individual project failure cases, and more specifically cost overruns.

Considering current world economics and business pressure points, it is of upmost importance that the pharmaceutical industry continually restructures and refines its business operating models in order to drive cost reductions and maximise value for product users (patients) and also internal/external organisational stakeholders. (Capo, et al., 2014).

With a view to this, the research methodology section of this research paper will seek to understand if project professionals within the Irish Pharma industry can shed a light on project cost overruns from previous experience, and whether they feel there is an appropriate PM methodology that is any better than another.

It has been noted that 84% of project leaders within the international pharma environment have experienced significant cost overruns during capital project execution (35 North, 2023), this also correlates with data published by Segelod. Therefore, it could be recommended from a business optimisation strategy perspective that should be considered industry-wide, to improve capital project financial controls, with a view to improving capital estimation techniques and providing more accurate control of project costs during the execution phase. (Segelod, 2018).

It is clear within the research that has been completed on methodologies and the value that good project management practices can bring to the pharmaceutical environment, if executed correctly throughout the organisation. The documented net benefits non-exhaustively include better business process techniques, better control of risk and risk evaluation, higher chances of achieving RFT (Right First Time), better cost and schedule control. (Gibbs, 2012)

However, throughout the literature review research that has been completed as part of this paper, no documented evidence has been located or referenced which indicates that any research has been completed to link project & cost overruns in pharmaceutical capital construction or engineering projects with the various types of project management methodologies that are primarily used and applied worldwide within the industry. For the purpose of this research dissertation this is the gap that has been identified and which hasn't been addressed correctly. This ultimately drives the research and the proposed research hypothesis.

Research Question

To address the identified gap within the research a hypothesis has been suggested that project management methodologies may impact cost control on projects (either negatively or positively), therefore some PM systems may be more suitable for maintaining a higher degree of cost control on capital projects than others.

Therefore, the research question that this paper proposes to ask and conclude through research findings is, '*Do project management methodologies impact project cost control performance?*'

Project cost control 'monitoring' systems have been explored and systems developed to some degree with terminology such as, leading parameter technique, the variances method and activity-based ratios techniques (Al-Jibouri, 2003) however no research has been completed linking PM systems to cost performance.

4.0 Research Methodology

This chapter explains the methodology used in the research and will follow on from the themes and discussion points that have been discussed in the literature review and define the most appropriate research method for the paper. The research methodology section also discusses the approach that has been taken to answer the research question that has been posed in the previous chapter of the paper. Finally, the chapter explains how the data was analysed, so that meaningful conclusions can be brought to the hypothesis.

Quantitative Vs. Qualitative Analysis

To correctly define that the most appropriate type of research that will yield the greatest benefit for this project, firstly we must specifically differentiate between quantitative and qualitative analysis. Quantitative analysis focuses on data as result of research, and its measurement in terms of statistical data. The analysis helps researchers to understand hypotheses, identify examples, and potentially make projections and predications, based on the observed data. There are several ways in which data can be gathered for example through surveys and questionnaires and further analysed into data models and processed using SPSS or other software variants to conduct experiments on the dataset. The outcomes of the proposed hypotheses are either proven to be correct via the statistical data, or it highlights areas that need to be investigated further or improved. It is a good analytical tool for discovering trends or identify patterns in the data which in turn could prove or disprove research in existence or new research that is coming to fruition. It is vital that the data designed is not leading or biased in any way. This can impact on the results of the research. Quantitative analysis can have outliers which if not identified can impact and distort the result of the research. This can have a huge impact on the result and lead to incorrect trends being identified, which may not exist or in some cases suggest there are trends or truths which are inaccurate, potentially leading to serious consequences for the integrity and validity of the research. (Lakshman,, et al., 2000).

Qualitative analysis focusses on data which is not numerical. The data focusses on motivation, experiences and values. The data is conducted and produced by conducting interviews, focus groups, open ended surveys and observations based on research. The

analysis can be subjective, therefore at times if the researcher is not strictly focused on how the data is presented, the data can be biased. If this occurs it can limit the outcomes of the research and not present true findings. It is therefore paramount that analysis is conducted without bias by the researchers and the questions presented and posed to the research subjects are done in a way that that can be easily understood without any misrepresentation.

Both tools are very effective ways of establishing research and understanding it its entirety. However, it is vitally important that when conducting and considering research, both models are examined and assessed for suitability prior to executing any research efforts. (Galway Business School, 2023)

Looking at the research subject matter that has been examined as part of this research paper, with a view to choosing from one of two analysis models. It was felt that the most appropriate method to investigate the research for this project was the Qualitative analysis model. The research question that has been proposed was best conducted through interview style questions. Another reason for adopting this approach over quantitative, is the limited amount of numerical data available in this field which was realised during the literature review phase of the dissertation.

Semi-structured interviews were used for the purposes of data gathering, as this type of interview style allows the interview to be highly focussed while still giving the interviewer the freedom to explore other ideas, themes and ancillary information that may be pertinent to the data that is being presented from the interviewee. (Adeoye-Olatunde, 2021)

Using qualitative analysis and semi-structured interview techniques helped to position the research and link it back to the research literature. This was completed by engaging with individuals from the pharmaceutical industry and exploring the topic further to understand if the models proposed are working in the real-world applications. Caution was required to be maintained by the researcher during the interview sessions to ensure that the research was bias free and to also ensure that research interview questions were being properly answered and discussed, which in-turn ultimately lead to more meaningful and reliable findings.

As referenced above, this dissertation research analysis was carried out in a qualitative manner and adopted the semi-structured method of interviewing, this was used in the hope that additional insights and perceptions from the interviewee's perspective (Smith, 1998) could be captured and shall further test the hypothesis that is being explored within the research question, that being, '*can project costs be negatively impacted by certain project management execution methodologies*'.

The primary target group that has been interviewed are comprised of personnel who currently fulfil roles that have vast experience with capital projects within the pharmaceutical industry in Ireland, both from within the authors organization, but also from other organizations that the author had access to. Participants were from primarily an engineering background, but some had pharma operations and scientific backgrounds also. See tabulated data presented in figure 4.0 overleaf for additional information on the participant group chosen. Other candidates were explored for suitability for interview but were not used for data collection, as it was felt that this sample group had the most applicable experience to apply to the hypothesis testing.

The sample group unfortunately contains significantly more males than females which provided a skewed male-female ratio. During the selection process attempts were made to balance this however due to the male dominated nature of the industry it was not feasible.

Interview Participants Biography Table

Participant Number	Gender	Age	Current Position	Current Position	Previous Experiences	Qualifications	Interview Length (mins)
#1	M	40-60	30+	Director of Engineering	Head of Manufacturing, Engineering Supervisor, Project Engineer	B.Sc.	45
#2	F	45-65	25	Director of strategic services & Operational Excellence	Senior Manager Technical Services, Quality Control Manager & Various Quality Roles	B.Sc., MSc, MSc, Lean Six-Sigma Blackbelt	40
#3	M	40-60	30+	Director of Operations	Project Director, Senior Project Manager, Project Manager & Project engineer	B.Eng., P.GD, MBA. P.GD, PMP	60
#4	M	45-55	30	Capital Projects Site Lead	Engineering Manager, Senior Project Manager, Project Manager & Project engineer	B.Eng.	60
#5	M	40-50	20	Capital Projects Manager	Portfolio Lead, Project Manager & Project Engineer	B.Eng.	45
#6	M	40-50	25	Capital Projects Manager	Project Manager & Project Engineer	B.Eng. P.GD	40
#7	M	40-50	20	Technical Transfer Portfolio Lead	OEP Lead, Project Manager, Project Engineer & E&I Engineer	B.Sc.	40

Figure 4.0 Interview Participants Biography Table

Interview qualitative research is now common for this type of project or business process analysis (Qu & Dumay, 2011) , as interviews are quite straightforward to develop and easy to implement, although the obvious downside being that there is the risk of bias on behalf of the interviewer. The interviews that have been undertaken as part of this research methodology were completed with selective participants that act as capital project leads or have had significant pharma project experience. This was carried out with the intent that this would provide reliable & comparable information and data that will form the basis of the qualitative analysis aspect of the research topic. The aim of the research interviews and proposed questions was to ascertain 2 key pieces of information from participants that have experience in lead pharma capital projects, that being, A. *What is the most appropriate project management execution model for projects within the pharmaceutical environment* and B. *Does a lack of formal project execution model negatively impact project performance therefore causing overall project costs to rise?*

It was also necessary that a synchronized approach be adopted for the execution of the interviews which were carried out on the Microsoft teams in some circumstances and face to face in others. All candidates for interview were asked to complete an appropriate privacy form which aligns with NCI's Ethical Guidelines and Procedures for Research Involving Human Participants. Examples of these forms used have been referenced in appendix 4.

The personnel approached have been appropriately defined as the sample group, as they are the most appropriate group to address the research question. The sample size has been additionally narrowed down in agreement with the dissertation supervisor to a group of 6-7 participants. This sample size has been validated as being adequate and appropriate to ensure that sample saturation occurs, i.e it is iterative. (Vasileiou, et al., 2018).

The interview questions were developed using an interview matrix. The interview matrix questions have been derived from the literature review and have been further developed specifically for the participant group based on the researched literature and the gap identified. Each question relates to an element of the literature review. The full matrix has been listed as figure 7.0 in appendix 3.

The interviews were completed and recorded using the Microsoft teams recording function. All participants were asked the same questions, which expanded in different areas based on the answers that were being provided. The data extrapolated from the interviews has been safely stored on an external hard drive and will be kept for the required amount of time as per NCI data protection policy. (Scannell , 2022)

The interview questions were primarily based on a series of questions related to project management methodologies, project issues that arose during project execution, AI, project cost control and other issues that may have arisen during project execution.

During the listening back and findings analysis step, the 12 tips for conducting qualitative research interviews, as discussed by McGrath et al 2019 was used. The main aim here was to focus more the listening aspect of the interview and to build rapport with the interviewees, which McGrath argues provides a more comfortable environment in which valuable information can be extracted and in turn become worthy research data. (McGrath, et al., 2019)

Post interview of the chosen candidates, the following methodology steps were used to analyse the data and further test the research project hypothesis (Rev Press, 2025):

1. All participants interview transcripts were read through and understood in detail.

2. All transcripts were interpreted

3. All data gathered from transcripts was theorize

4. Data was divided into themes

5. Themes were analysed

6. Analysis was written up

(Archibald, et al., 2019)

When analysing and interpreting the interview results, it was important to logically breakout the ‘themes’ that appear in the transcripts. From this the themes were quantitatively analysed to understand if the research question did indeed stand up, i.e If

there was a relationship between lack of or poor project management methodologies and general project cost escalation or not. (Burns, 2025)

To complete the theme analysis a seven-step template analysis approach was adopted as defined by Tabari et al. 2020. To use this theme analysis technique the following was completed:

1. Preliminary coding – coding data within the transcripts that sparked interest and was applicable and relevant
2. Clustering – Collating clusters of themes and sub-themes
3. Developing the initial template – Organising themes in template
4. Modifying the template – Change the template to better suit the theme and clean-up any outliers
5. Developing the final template
6. Using the template to interpret the data

(Tabari, et al., 2020)

The primary themes that were extrapolated from the interview data was as follows:

1. Predominant PM Methodology – Process Driven Stage and Gating
2. Other PM Systems
3. Use of DMAIC
4. Front End Loading (Scheduling + Integrated Cost Estimation)
5. PMO Successfulness
6. Metrics

Research Ethics Approach

All research interviews and the subsequent handling of research data was carried out in line with NCI's ethical guidelines. (National College of Ireland, 2018). During the interview and data collection phase of the project key areas of focus that were employed were: prevention of harm to participants, ensuring informed consent was present for all recording and interview methods, ensuring confidentiality of participants and data collated and ensuring that no deception was carried out during the process. (MacDonald, 2025). The forms that were used to gather ethical consent for recording of data and interview participation can be found in appendix 5.

For full transparency a copy of the ethical assessment which was drafted as part of the research proposal for this dissertation, has been uploaded via a separate Turnitin upload point on the research methods dissertation Moodle page.

5.0 Findings

This section of the report will present the findings from the data that was collated from the semi-structured interviews that were completed. The findings have been based on the interview participants answers to the questions that were drafted as part of the previous section of this paper.

The interviewees are all seasoned professionals that have previous significant experience of or are currently working within the Irish pharmaceutical industry.

Research Objective Theme 1 – PM Methodologies/Approach

Project Management Methodologies and Approach – What methodology is the best for pharmaceutical capital projects and yields the most success from a cost control perspective.

Q1. Of all your experience in project management within the pharma industry can you remember using a methodology that really worked, and did it yield a good result in terms of cost control?

Whether a project management methodology is a good system or not is clearly a subjective question and can clearly mean different things depending on whom is being interviewed. Experiences of a good project management methodology maybe interpreted by the interviewee as a system that yielded a successful project, a system that was easy to use or that had relevant process driven documentation that assisted with monitoring and controlling the project.

The general themes across the board were that the preferred style of project management methodology was a PMBOK (style) methodology with appropriate process driven stage and gating. The general consensus was that this methodology wasn't necessarily the most agile but served good purpose. Interviewees had mixed thoughts on using agile as methodology with 1 participant sighting from their experience that the

process was not particularly suitable, although in the case of this research this is most certainly the outlier:

“It's a very structured approach. It is big on documentation, big on structure, big on following a process, not necessarily very agile, but it does put a structure on a project that force teams to ensure it is followed”

“I found that very, very useful for getting the cost under control in terms of getting our initial budget estimate together. So if you can get experience & contractors have experience of the site and get a very early involved in the design, the budgeting exercise and putting the estimate together, it means that you have an estimate that's reflecting what the job is going to cost. The hybrid PMBOK structure focusses the project within the stage gates to aid this process”

“.. a hybrid approach like Agile doesn't work in pharma, in my experience in pharma it gets very resource heavy across the board and I don't see it as being value add from concept through to handover. I do see it in in certain types of troubleshooting or change of scope or whatever you might have during a project, for example You might look at it on a focused area, but definitely agile from my experience doesn't work in the general type of pharma projects we have, which would be equipment construction & facilities, type of type of stuff”

The response from the interviewee that had experience of both the drinks (whiskey distilling) and pharma industry had a slightly different take on the traditional process driven PMBOK or waterfall methodology, as a positive light was set on the potential use for scrum within the industry.

“One (project) was for food and beverage and the other was for pharmaceutical. They were both doing boilers replacements of a similar size with the same company and the first company was using scrum and the other was using more of a PMBOK EPCMV managed services style model, this business model left the client feeling kind of left out. They were involved in the initial scoping of the project and then it was kind of taken out of their hands and they didn't have a clear visibility from a cost management perspective. It was more than managed services company was aligning with their Cost delivery plan, which ended up with the significant overruns and change management because there was a lot of unforeseen interaction between the suppliers, and I suppose the customer in the end also. This is where the customer

wasn't involved, but the suppliers were very much involved. And then you'd end up having to go back to the design, so that didn't really work from a cost perspective at all"

"so I suppose like the main methodologies that I'd be familiar with will be obviously stage gates (PMBOK) , so you know you're doing your front end loading and all that sort of stuff just to kind of get a good solid design and then make sure it's thoroughly thought out. So you're reducing the risks there upfront on the project before anything hits the ground and you get a much better control of costs right from the off"

Q2. What other project management systems or methodologies have you used or come in contact with, and can you discuss how useful were they and if they resulted in success?

General themes that arose here from the interview participants on this question were based around additional systems that they had experienced during project execution such as agile, lean scrum and a scheduling system known as last planner.

"Yeah, I'm beginning to see more agile methods in pharmaceutical projects I suppose the overall agile approach works well as you can pivot quickly when issues arise, sometimes that doesn't always happen using traditional waterfall methods"

Interviewees commented on how lean methods lead to quicker decision making, which is faster and more effective and overall has a positive effect on reducing soft cost burn time on projects, which in-turn reduces project cost burden.

"I think it's more fluid, but it's also lean. You know you're not burning hours, waiting on major project decisions. I suppose it feeds into or collaborates into that kind of getting things resolved quicker way of working"

Participants also commented on how using lean and the DMAIC method that resides within lean, leads to early project focus on the business case which has a very much financially motivated focus in setting out cost expectations and benefits.

"And what I liked about that system was at the start you have to have your business case in the define stage, so you have to have a business case to move forward with your

project. So within that, then I suppose you have to show that there is a financial benefit statement to do and sell to the business, if this wasn't there then you wouldn't bother with the project"

The last planner system was referenced by 2 participants who had positive experiences with this system:

"I've not used the last planner on pharmaceutical projects, but I can see how I can see how it would work, I have used it the last couple of years in the semiconductor arena, so that's where I've used it and it has been extremely successful"

"Last planner was super-useful for tracking works in the field, which helped schedule, which of course keeps costs under control"

Again the upfront nature of the DMAIC project charter was discussed in a positive light by another participant, in the same vein another participant discussed the use of scrum, lean, agile and other methods in a hybrid system that yielded a positive outcome.

"And that's kind of called out very early on in the defining part of the project charter. So some of the systems that we've used here before that don't, although it's not a requirement and I suppose we didn't tightly manage those from a cost perspective, so within this system there was a nice financial win at the end of the project"

"it was a tiered approach to escalation and project management, so your mix of scrum, Kanban and some other agile methodologies in there and using the other one which is again part of the agile approach is lean. And also last planner. So I would have used that as well and again you would have also had Kanban approach feeding into that system, in terms of batching, maybe of types of work. But overall that system maintained a pretty tight control on the project"

Q3. Do you think There is any particular methodology better then another for pharmaceutical capital project delivery

Participants discussed that in certain circumstances using tiered costs escalation techniques through the agile route had positive outcomes when it came to faster decision-making during project execution.

"But the speed of decision making there was what was really good. So if there was something that had a cost impact to it, you weren't going to the ends of the earth to detail out the costs and to make a business case which usually for us is a long drawn out procedure. You're able to give a quick assessment of the cost"

The use of scrum as a methodology also came back into the mix with a participant noting that the sprint element of the scrum methodology was useful during one particular project that the participant worked on.

"but having a sprint down at the area definitely with a daily whiteboard Monday to Friday, detailing out what you're doing for the day. Asking the questions Did you get it done on Monday? Did you? It really does help focus the mind on task execution.
10 minutes and it's a hard stop at 10 minutes and gives the opportunity for escalation as well on an as needed basis. You get the people that you need to escalate up and down on the floor to discuss the problem. We found this useful to cost control also, as schedule adherence was much better"

In another case a participant noted that a variant of PMBOK waterfall system was used for large projects within a pharma company that yielded success.

"Yeah. So the other one I've seen and used is Wave which is a system that our consultants McKenzie brought to Astellas. So, the wave platform was introduced a couple of years ago…. So it's a stage and gated process, for example L1 would be ident idea generation and then you move through different stages and then L5 would be your final approval. So it has different kind of stages which is useful for tracking the project through to completion"

Exploring whether there are perceived benefits to introduce and use a PMO as a project management philosophy within the modern pharmaceutical context.

Q4. Do you think introducing a PMO into an organisation would improve project management consistency and improve cost control? And if so, how?

The overwhelming response to this section of the interview was positive. All participants reacted positively to the introduction of a PMO structure into the organisation, with very little ambiguity between them as to whether the change could help project cost overruns or not. Most response themes were based around procedural control, expertise and the likely improvement across the board of standardisation.

"I suppose a quick and maybe smart answer would be that yes, anytime you bring in a level of understanding or A level of specific standardisation and knowledge in a particular area, that's always going to help, and capital projects is no different"

"typically, in my experience, what you find is that they may be working on ongoing smaller projects on the site for existing facilities and equipment that may be there. Lets refer to them I suppose, as smaller OpEx maintenance projects, then suddenly a new larger CapEx project arrives and its launched into the existing small projects team there. They're not used to the structure"

"there's a lot more cost control. There's, I suppose, a lot more transparency and a less amount of working in the grey areas as you have standards and procedures, So I do think when you introduce a PMO to something like a pharmaceutical Maintenance based projects it does kind of give you that specific delivery model"

"It also provides a platform for getting the projects delivered within a certain budget, but we're also planning for the future. You can see a 5 or 10 year plan down the line, whereas. When it came to the maintenance engineering side of things, it was purely reactive"

"Projects were reactive, based on what you could refer to as say end of life or legacy issues that were within the plant. Whereas when you get a PMO onsite, you've got a defined project delivery model"

"So I suppose anytime you go into a pharmaceutical semiconductor, a data centre, the client there is in the business of doing something other than projects. Making drugs, making wafers, making. I don't know, storing data, whatever they do, its generally not in the business of running projects, their experience is not in the business of running projects. They may have some people in a capital projects team. But this is where PMO shines and can certainly standardise how projects are executed and how costs are controlled"

"I suppose you could call it project controls that to me is the most important benefit that a PMO brings, as it brings a certain level of cost forecasting and estimation to an organisation that generally doesn't have that capability, to me that's the ultimate piece that improves cost control on projects"

Research Objective Theme 3 – Project Execution Improvements

Exploring how project execution may be improved using other methodologies, tools or technique's not currently being widely used.

Q5. Do you think there is a benefit of using standardised metrics and benchmarking to improve cost control?

Participants overall agreed that cost validation and benchmarking was invaluable at the start of a project for estimation purposes. They also indicated the value post project and during the project execution phase, that benchmarking can provide such as early indicators of costs arising on projects, which can positively benefit cost problem solving.

"Yes. So, I'd be hugely in favour of it and generally it works well if the industry isn't absolutely saturated, or where prices are out of control. But most disciplines that we would deal with would be say, mechanical, electrical or civil, right. So obviously in terms of mechanical, if your pricing jobs, and you need to put a front-end price together fairly quickly and you have to run x metres of lets say 1 inch stainless pipe. It's very handy to have the norms that you can benchmark against, if you're getting a quantity surveyor to put together a cost"

"putting prices together at the early stage of the project is very, very important. It's also important to be able to validate the quotations you're getting from contractors and

consultants, because some of the contractors and design houses have very inexperienced QS's, some of them maybe better than others. So from a project perspective, it's good to have an idea of those norms and benchmarks. I think it's very important to put an estimate together upfront so that the estimate is going to be reflective of what the job is going to cost in the long run"

"Look, it's down to your required level of accuracy., and what you're communicating out to the to the customer or the client. Generally, the customer decides that the project should be broken down into five different stage gates and will want a different level of accuracy all the way through"

"you have to start off with a level of benchmarking to get your order of magnitude costs correct upfront and you know you are in a good position. You also need a QS that can review the project engineers or project managers work and use benchmarking to compare to market rates and costs"

Participants also discussed the positives around using benchmarking and norms in the lessons learned process and during stage gate reviews.

"So I do think there's another level of benchmarking and standardisation use that can be useful across projects., you can actually, you know, retrospectively look at the lessons learned or as the project is ongoing to understand trends for example a CSA element may be trending under, or over here on scaffolding, you know? Or what the difference in preliminaries are from one contractor versus another?"

Participants also indicated the potential use of benchmarking and KPI's for pitching projects and verifying global project trend data.

"If the costs are there when you're going looking for funding from, you know, head office or when you're looking to pitch an idea to government or whatever, you know it helps to have all that benchmarking and it's relevant recent data so that you can make informed cost decisions"

"And also for a lot of these companies, they're global as well. So, they can start seeing trends globally which may affect investment decisions in terms of countries that they may want to invest in or not. They also have a keen interest in projects that have performed well in terms of cost control, so this is one way of doing it"

Q6. Do you think AI could help improve the cost control outcomes of a project?

Participants agreed that the use of AI overall can bring positive benefits to project execution and to cost control. They noted that predictive analysis may be something that will be useful in the future and noted an example below.

"Yeah, I think it is going to be exponential. The benefits that we're going to see from AI and yeah, you're to give an example if your trying to do standardisation across the board and you have just say you have a historic folder of projects and costs,
and you want to collate it on your on your network, you can use AI to essentially group all of that, trend them, you know, which will give you trends for future projects to make better decisions with. So, it'll be more like localised real time versus national or global kind of project cost predictions"

"Obviously you know it's going to help with, predictive analytics and all that stuff for forecasting material and labour prices and all of that. So yeah, I suppose the sky is the limit when it comes to AI and how it may improve cost control for projects"

"So I would think that, say, since we're talking about cost control and estimates, so say as a project manager, if I wanted to get a front end estimate get together fairly quickly like I do know that the engineering firms have these kind of say coded tools that they can put in, you know the lengths of pipe and they put in the productivity and difficulty factor what we may have with a job and be able to get an estimate. These tools are good but slow as there is a level of human intervention required to enter the data, I think if you could develop that further that if you had an AI tool that could complete that labour piece it would be massively beneficial"

Participants also again viewed AI as a tool that could simply aid labour intensive business processes.

"And that's why I say I think there is a place for it, but it's not start to finish. It's the manipulation of that data or the generation of data into a more manageable form"

"I think AI could provide cost analysis in the form of earned value for forecasting the difference between your forecast, your previous quarters forecast etc"

“It could be used to facilitate additional and meaningful project cost KPIs as well. Sometimes KPIs are actually just too complex and expensive in soft costs to actually generate by humans, but if you have an AI engine that would be made much easier”

Q7. Have you any experience (positive or negative) of using lean or six sigma in projects, and if so, how did it impact the performance of the project

“I suppose from my experience we were referring to DMAIC. So obviously, you'd have to define the project. Then the problem, and ensure the measure is right, we then implemented a solution, it kind of analyses itself and then you control it. So I suppose we've used that system for some of the more complex projects in terms of process driven projects, we've probably used to make to a substantial continuous improvement change”

“From a portfolio lead perspective, we're always looking at continuous improvement in terms of how we can get better cost estimates, how we can do better on cost overruns and variations and how we can do better in terms of scheduling projects. And then combining the last planner system with the Six Sigma system, there's a lot of stuff in there that is it works really, really well and helps to improve control. I think SIPOC which is, suppliers, input, process, outputs and customers, also works really-well, but you need a very, very defined and tightly scoped project”

Other participants had mixed feelings on using sig-sigma as a methodology as their experiences were mixed comparatively speaking to some of the other systems that they had experiences within project execution.

“The Six Sigma process? So it didn't really work. You need to kind of have everybody aligned and even just trained in what the Six Sigma process is. I do agree with the black belt, green belt training philosophy for all project managers as it's good to have a basic knowledge of those type of project delivery models, but I don’t think its really suitable for large scale capital projects”

“Yeah. So I suppose the only one that I've run myself is to make projects. So that's following the Lean 6 Sigma methodology. So I guess we ran those at Greenbelt and Black belt level and we did pick a few meaty initiatives over the years, following the DMAIC process, overall they worked quite well, but it was agreed at a senior

management level that the system wouldn't be suitable for larger Capex style engineering projects"

Q8. Is there anything else you would like to mention that could help cost overruns on projects from a PM perspective?

General responses picked up in this section include choosing the right trade partner that is aligned with the modern collaborative approach to projects and in general more up front planning in the front end of the scheduling phase leads to more successful projects overall.

"picking partners as well that are like minded on projects, and fully support collaboration. A lot of the contracts, historical contracts will be adversarial, between contractor, client and engineering house"

Other themes to responses for this section were mainly based around the suggestion that more up front planning and due-diligence in the early stages of the projects, generally yielded a more positive outcome in the end.

"I suppose trying to think of upcoming issues ahead of time rather than trying to react to issues that could come up later, obviously risk workshops, you know, monthly sessions, cross functional teams, that sort of stuff so"

"Taking all that into account at the start of the scheduling process and trying to plan for the implementation date, knowing where you're starting from and reviewing even at the early stages, and asking the questions is it realistic to expect that you're going to be able to fully implement this change in that window assuming you have a full understanding of the complexity of the project"

"I think upfront planning is probably something that could be improved and more due diligence in that up-front area. Just looking at the business case, looking at the potential risks involved and the actual end game output and financial impact"

Project risk management throughout the project was also discussed as being potentially useful by one of the participants.

“And not just project risks, but the wider cross functional teams or the stakeholder risks, you know it's taking all of that on board at an early stage and then obviously making sure that that its continuously reviewed, kind of like a life cycle kind of exercise you do throughout the project”

“Understand exactly what exactly the ask is from an end-user or client, all the way through the lifecycle even to the point of when is it to be implemented, continuously challenging that in terms of understanding”

Again, having a specific project management methodology also arose as being crucial in running a successful project from a financial control perspective.

“So there’s a lot of factors outside of our control when you're running projects from a project management point of view. That you don't necessarily have the ability to control, but having systems there that allow you to control whatever comes down the line is important. Otherwise, you know you start digging a hole and just keep digging a hole and there's no stop to it. So, I think it's just very important, going back to one of your earlier questions that there is a methodology there, there is a structure, there's somebody overseeing that, and the governance is there, that's certainly very important”

6.0 Discussion

The final chapter of this research dissertation will endeavour to explain some of the findings from the qualitative interview sessions that were carried out and referred to in the previous section of this paper.

The purpose of the research study was to understand the relationship between cost overruns in pharmaceutical capital projects and understand and test the hypothesis 'Do project management methodologies impact project cost control performance?'. To understand this research an analysis of literature related to project management, project failures and other relevant publications have been analysed from an understanding and relevance perspective. This piece of work in combination with semi-structured interviews with people that have experience with pharmaceutical project management have brought us to this chapter of the dissertation which will seek to discuss the findings. This chapter will contain the following headings; key findings, relevance of study, findings related to comparable studies, limitations and further research opportunities.

Key Findings

One of the major findings of the study Is that the interviewee group felt that the traditional PMBOK or waterfall type project management methodology, was on a whole, the most reliable project management system for pharma construction projects and more widely used then some of the other tools and systems that have been previously discussed in earlier sections of this paper. It was noted that when this was used as part of a PMO offering this was the strongest use of methodology. This finding is substantiated by how the interviewees answered questions with key theme words included in their answers such as 'stage gates' 'processes' 'front-end loading' & 'control'. These are all key words considered to be associated with traditional PM approach. Interestingly the other waterfall methodology that has been researched, PRINCE2, didn't appear as a methodology that any of the participants had experience of in the interviews that were carried out, leading us to the conclusion that the former is not a prominent PM tool that is currently being used within the industry or by the pool of data subjects that were used in this study.

However, notwithstanding the above, other approaches have been discussed and have also being identified as being useful in other PM contexts both in pharma and other industries closely related. These being scrum methodology, agile approaches and lean/six-sigma. The interviewees all linked the usefulness of these methods back to upfront loading and decision making on projects. This is a common theme across any of the referenced methodologies. Language like '..in the define stage you have to have a business case to move forward with your project. So within that, then I suppose you have to show that there is a financial benefit'. This excerpt is in the context of using lean-six sigma as a PM tool, but the theme of planning and business case/financial control is present across all of the tools that have been researched in one form or another, it is difficult to ascertain from research data if 1 PM tool is better or worse than another when it comes to keeping tight reins on project finances and governance. Although in saying this, 5 of the interviewees discussed the stage and gated approach to project management and suggested that was the most suitable for project execution within pharma.

There was an overall positive reaction to potential use of AI and lean six-sigma to provide better cost control on projects with themes arising around using AI to remove time consuming interactions on budgeting & estimating and providing faster market analysis and trend reporting on costs items which is currently an expensive and labour-intensive exercise to pull together.

Likewise there was a positive response to the introduction of benchmarking and metrics within projects, with participants, although one participant critically noted that too much data gathering and metrics can lead to over load.

"yeah, an individual project basis definitely, definitely a must. But then to your point, widening it out to a portfolio view, if you're able to do that on all your projects, you're now suddenly accumulating a huge amount of data and the question must be asked how to we manage this?"

Standardization of how projects are delivered was also a key topic and was mentioned in various contexts from the interviewees, both in relation to systems but also in relation to how projects are managed and delivered.

'If you can standardize the way you deliver projects, you're now standardizing the way you're getting that data back as well with, you know, with the advent of Power BI, you

can now very quickly have dashboards that will give you the visual status on an individual project or you can have another dashboard that will give you a compare and contrast with loads of other projects and you can benchmark and contrast against multiples, this is hugely advantageous'

'the DMAIC standard is the standard toolkit that we used for PM and again would defiantly recommend for future projects and it provides a standard way of managing projects. I suppose it pushes you to not rush the solution, so it makes you stand back understand the current state and pose the question what are we trying to achieve here?'

The response to PMO introduction seems to be positive across the board with most of the interviewees providing positive experiences of same with some suggesting that the standardisation of procedures and ways of delivery is always a positive thing within the engineering environment.

'I suppose a quick and maybe smart answer would be, that yes, anytime you bring in a level of higher understanding or level of standardisation and knowledge in a particular area, that's always going to help the process'

Relevance of Findings

In today's highly competitive environment it is essential that good project management practices are implemented for faster more cost-effective drug and healthcare delivery. Both internal corporate margin pressures and the continuing cost of doing business in the modern world requires that companies complete research, manufacturing and engineering projects faster than ever before. (Kikerkov, et al., 2023). This paper and its findings have suggested that although there is one prominent PM methodology within the industry there is still mass indecisiveness in terms of which is the de-facto system that should be used industry wide by all, i.e. there is no perfect solution. Although the relevance of the stage and gated approach that was popular in the participant response has been theorised by others as being a worthwhile approach for pharma project management, as discussed by (Brown & Grundy, 2011). Brown et al. suggests that appropriate stage and gating should be applied for successful projects management, and furthermore define the gating as the following: 1. Project definition; 2. Strategy creation, 3. Detailed planning, 4. Implementation and control, 5. Revision and learning.

This broadly follows the stage gating philosophy that traditional waterfall PM methodologies follow along with Six-Sigma & DMAIC also. (Brown & Grundy, 2011)

Limitations of Study

The semi structured interview approach does provide some limitations in terms of bias when the interviewer is required to interpret the interviewee and may display signs of positive or negative reaction towards certain questions being asked. This drove the interviewer to be aware of this and to try to ensure bias was not present when interpreting answers. Another limitation to the study is the limited amount of information available on project management failures within the pharmaceutical industry. Although from the authors experience that projects do and quite frequently fail for various reasons, it doesn't seem to be well documented within academic and professional publications.

Further Research

This paper contributes to the overall academic area of project management systems and methodologies, specifically associated with the pharmaceutical industry. Although from a data gathering perspective, it seems that the traditional waterfall approach (or a hybrid of) is the most consistently used methodology across the industry which yields a positive result in terms of project cost control. However further research could be carried out on the specific areas with the PMBOK system that contribute to effective cost control with a view to taking things even further and developing a project management system specifically for the pharma industry that focusses on cost performance management.

Further quantitative research work could also be suggested to statistically analyse various capital projects to develop a further understanding of when specifically in a project that cost overruns occur and link this back to a refined newly developed methodology.

7.0 Conclusion & Recommendations

Conclusions

In the conclusion section of this dissertation, the overall aim will be to conclude the research paper taking into account the findings that have been observed and recommending future research exercises that could be completed within the subject matter area in future.

From the outset the intent of this research project was to understand if there was a link between certain types of project management methodologies commonly used within the pharmaceutical industry and project cost overruns in engineering and construction capital projects.

From the qualitative data that was collected from participants, some of which has been displayed in the earlier chapters of this dissertation would suggest that the majority of the projects that the interviewees have been involved with that were classified during the interview discussions as the subjective term 'successful', were indeed managed using traditional waterfall techniques.

However, the answer isn't as clear cut, as success in terms of financial cost control has also been achieved using other PM methods such as scrum and lean six-sigma also. There was no mention from any of the interviewees that PRINCE2 was a methodology that is now commonly used within the industry, so perhaps this can be discounted from any further studies in the area.

The literature review that has been completed also hasn't specially shed any additional light on the subjective in terms of suggesting a fit for purpose PM methodology that will specifically focus on tighter cost control within the Pharma industry, although academic studies have suggested that PMO has become more widely used within pharma giving us the indication that standardized methods and training will deliver higher degrees of success when it comes to projects execution. This suggestion of introducing PMO's into the organization was also corroborated with the interviewees who agreed it was the way forward for the most part.

As per the literature review, the reasons for project failure are the typical loss of control points that all good projects mangers should abide by during project execution, good stakeholder engagement, good scoping, good upfront planning. (link to pm system stage gating and further research).

Due to the lack of numerical data available at time of research a quantitative analysis was not the chosen research analysis for this project, however in future if this type of data becomes available, there is value in quantitative analysis and statistically projects failures and the potential link to certain PM methods to same.

The overall recommendation for further research based on the data collated for this dissertation could a be a suggested project on developing a specific PM methodology for pharma projects that focuses heavily on processes that provide tighter decision making on scope and schedule impact, thus controlling cost performance to a greater level which in theory should reduce cost overruns.

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9.0 Appendices

Appendix 1 – PMBOK PM Process Groups

Knowledge Areas	PMBOK Project Management Process Groups					
		Initiating	**Planning**	**Executing**	**Monitoring & controlling**	**Closing**
	Project Integration Management	Develop project Charter	Develop Project Management Plan	1. Direct and manage project work 2. Manage project knowledge	1. Monitor and control project work 2. Perform integrated change control	Close Project or phase
	Project Scope Management		1. Plan Scope Management 2. Collect Project Requirements 3. Define Scope 4. Create WBS (Work Breakdown Structure)		1. Validate Scope 2. Control Scope	
	Project Schedule		1. Plan schedule Management 2. Define Activities 3. Sequence Activities 4. Estimate Activity durations 5. Develop Schedule		Control Schedule	
	Project Cost Management		1. Plan Cost Management 2. Estimate Costs 3. Determine Budget		Control Costs	
	Project Quality Management		Plan Quality Management	Manage Quality	Control Quality	
	Project Resource Management		1. Plan Resource Management 2. Estimate activity resources	1. Acquire Resources 2. Develop Team 3. Manage Team	Control Resources	
	Project Communications Management		Plan communications management	Manage Communications	Monitor Communications	
	Project Risk Management		4. Plan Risk Management 5. Identify Risks 6. Perform Qualitative risk analysis 7. Perform quantitative risk analysis 8. Plan Risk Responses	Implement Risk Reponses	Monitor Risks	
	Project Procurement Management		Plan Procurement management	Conduct Procurements	Control Procurements	
	Project Stakeholder Management	Identify Stakeholders	Plan Stakeholder Engagement	Manage Stakeholder Engagement	Monitor Stakeholder Engagement	

(Simonette, et al., 2016)

Figure 5.0 Breakdown of PMBOK Project Management Stage Gate Processes

Appendix 2 – TIMWOODS Lean Abbreviation Breakout

Transport	Where the inefficiencies of transport exist within a process. I.e. movement of documentation of personnel throughout a workspace or office area.
Inventory	The waste of maintaining an inventory of documentation or project designs surplus to requirement during the execution of a project.
Motion	Where personnel or project materials are required to be moved unnecessarily.
Waiting	Waiting for a process to begin or to be completed. E.g. the time it may take for a design to be approved or a form to be signed.
Over Processing	The waste of spending longer than expected or scheduled for a specific process. E.g. additional reviewing on a project document or specification.
Over Production	Creating more than the minimum requirement for a project or process. E.g. creation of specifications too early in concept phase for a project that are not required in the final design.
Defects	Anywhere within a project whereby remediable work needs to be completed. E.g. and incorrect design or physical installation.

(Roble & Arante , 2025)

Figure 6.0 LEAN TIMWOOD Abbreviation Explanation Table

Appendix 3 – Research Interview Questions- Matrix

Ref	Question	Relates back to which Research Question?	Source of Question e.g. refer to a specific item of academic literature etc.	Additional Comments
	Theme 1: Project Management Methodologies and Approach			
Q1	Of all of your experience in project management within the pharma industry can you remember using a methodology that really worked and did it yield a good result in terms of cost control	Do project management methodologies impact project cost control performance?	Gibbs, K. D., 2012. *Between Love and Madness Lies Obsession: Project Management in the Pharmaceutical Industry.* Boston, International Society for Pharmaceutical Engineering	N/A
Q2	What other project management systems or methodologies have you used or come in contact with and can you discuss how useful were they and if they resulted in success	*Do project management methodologies impact project cost control performance?*	Shah, V., 2017. *The Implication of Agile & Traditional Method as a Practice in Pharmaceutical Industry,* Harrisburg: Harrisburg University of Science and Technology.	N/A
Q3	Do you think There is any particular methodology better then another for pharmaceutical capital project delivery	*Do project management methodologies impact project cost control performance?*	Gibbs, K. D., 2012. *Between Love and Madness Lies Obsession: Project Management in the Pharmaceutical Industry.* Boston, International Society for Pharmaceutical Engineering	N/A
	Theme 2: PMO in the organisation			
Q4	Do you think introducing a PMO into an organisation would improve project management consistency and improve cost control? And if so how?	*Do project management methodologies impact project cost control performance?*	Martins, P., 2017. Speeding Time to Market With Better Pharmaceutical Project Management. *Pharmaceutical Technology: OUTSOURCING*	N/A

			RESOURCES, 1 08, pp. 40-45.	
Q5	Do you think there is a benefit of using standardised metrics and benchmarking to improve cost control?	*Do project management methodologies impact project cost control performance?*	HWANG, B.-G., Thomas, S. R., DEGEZELLE, D. & H. CALDAS, C., 2008. Development of a benchmarking framework for pharmaceutical capital projects. *Construction Management and Economics,* Volume 26, p. 77–195.	N/A
	Theme 3: Project Execution Improvements			
Q6	Do you think AI could help improve the cost control outcomes of a project?	*Do project management methodologies impact project cost control performance?*	Abdomerovic, M., 2024. Elevating Visibility of Project Management Knowledge: Artificial Intelligence (AI) may lead the way. *PM World Journal,* XIII(V), pp. 1-7	N/A
Q7	Have you any experience (positive or negative) of using lean or six sigma in projects, and if so how did it impacted the performance of the project	*Do project management methodologies impact project cost control performance?*	Pyzdek, T., 2003. *The Six-Sigma Handbook.* 2nd ed. New York: The McGraw-HIll Companies, Inc..	N/A
Q8	Is there anything else you would like to mention that could help cost overruns on projects from a project management perspective	*Do project management methodologies impact project cost control performance?*	N/A	N/A

Figure 7.0 Research Questions Interview Matrix

Appendix 4 – Research Interviews- Consent & Audio Recording Forms

Participation Letter

Dear Participant,

I hope this email finds you well.

I am writing to invite you to participate in a research study. Please take the time to review the following information carefully to understand the purpose of the research and your potential involvement.

My name is Leon Burns (Student Number 23156031), and I am pursuing a Master's Degree in Business Administration at the National College of Ireland, Dublin. As part of my dissertation, I need to conduct a research project.

The study aim is to understand if there is a relationship between different types of project management methodologies and cost overruns on engineering capital projects within the pharmaceutical industry. The study involves conducting online interviews, which are estimated to be approximately 45 minutes long, and will be conducted by myself. These interviews will be recorded and transcribed, with access limited to my supervisor and myself. Recordings will be deleted after the final report is submitted and graded, and transcripts will remain stored on a password-protected computer for the duration of the research.

Participation in this study is voluntary, with no incentives or rewards offered. Participants can withdraw at any time without any consequences. Confidentiality and anonymity will be maintained through the use of pseudonyms.

To ensure clarity, participants will be required to sign two consent forms: one to confirm their understanding of the study requirements and another to acknowledge that the interview will be recorded. Participants may also request a feedback summary of the study findings if desired.

If you have any questions or require additional information, please do not hesitate to contact me.

Thank you for considering this invitation and for reviewing the participant information sheet.

If you are happy to proceed the signature can be applied virtually using a Docusign envelope that I will send.

Kind Rgds,

Leon Burns

x23156031@student.ncirl.ie

Please fill out the information below as proof that you have read and understood the participant information sheet:

Participant Name(s): _____ Date: _____

Signature: _____

Audio Recording Consent Form

I, _____ (name/s), consent to Leon Burns recording my interview using an audio device via the Microsoft teams platform.

I acknowledge that:

- Only the researcher and his supervisor will have access to the transcribed interview and audio recordings.
- Identifying details will remain confidential through the use of pseudonyms.
- The recordings will be permanently deleted after the research report is completed and graded.
- Interview transcripts will be securely stored on a password-protected computer for the duration of the research.

Date: _____ Signature: _____