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Maintaining Equilibrium between Project Success and Team Well-Being: Pharmaceutical Project Management

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Maintaining Equilibrium Between Project Success and Team Well-being: Pharmaceutical Project Management

Shu-Han Chang （張書菡） – CCT College, Dublin, Ireland - 2021

Abstract

Projects of all types bring with them their own set of challenges and risks. Those within the pharmaceutical industry are subject to heavy regulation, high risk of failure, and the requirement of having very specialised knowledge. High-pressure projects like this also puts much stress on the individual team members working to ensure the project's success. In order to delve into what it takes to maintain equilibrium between project success in a timely and cost effective manner, and the well-being of the project teams themselves, this research takes a look at what are the common issues with these types of projects. Issues such as unrealistic timelines and budgets, unclear requirements, and inadequate resources, will be explored to determine what affect they have on the workers, and how might these issues be addressed in a structured and repeatable way, regardless of project type.

Keywords: *Project Management, Stage-Gate Methodology, Pharmaceutical, Heavy Regulation, Risk Management*

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Introduction

Pharmaceutical projects of all types are well-known for their reliance on specialised knowledge, their innovative nature, being heavily regulated, as well as having a high risk of failure (Chiou, et al., 2016). Like most projects, planning and control are critical functions of their successful management. According to (Pellerin & Perrier, 2018) this involves representing a project through a set of requirements, scheduling project activities, allocating project resources, analysing the various risks involved, evaluating time and cost performance, forecasting cashflow, etc.. The question arises then, as to what can be done differently in order to mitigate the higher levels of risk, and navigate through the various regulatory requirements while managing to maintain an acceptable success rate and prevent churn in the specialised workforce.

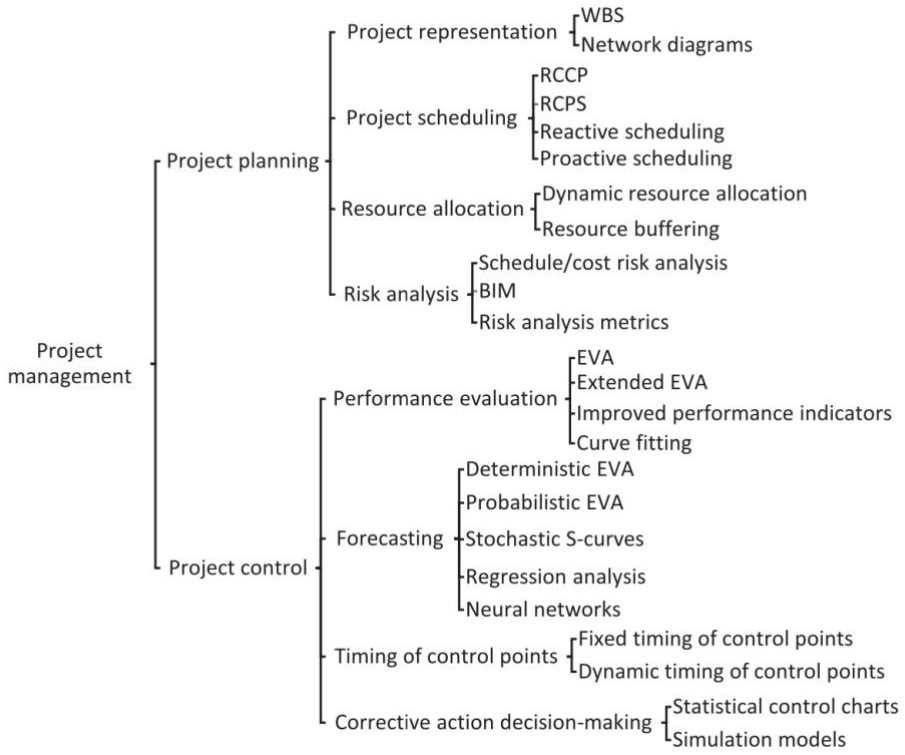

Figure 1- Methods and techniques for project planning and control (Pellerin & Perrier, 2018)

Research Question(s), Goals and Objectives

This research is on the use of the Stage-Gate framework for managing pharmaceutical projects, with a particular focus on an implementation to both deliver projects successfully in a high-risk and heavily regulated industry, and improve team morale, culture and motivation.

This project aims to:

- Identify and discuss the impact of heavy regulation on the success of a project and the well-being of the team
- Identify project management frameworks in use in the industry
- Discuss the benefits of Lean/Agile/Stage-Gate frameworks and how learnings from them might be adapted for use in pharmaceutical projects
- Highlight correlations between team well-being and successful project delivery
- Discuss improvements to team well-being and successful project delivery through strategic restructuring of teams, communication channels and feedback processes.

Research Design Methodology

This study is a qualitative research which is supported through a probing into academic papers and an interview conducted with an industry expert. The primary data has been collected using recent academic papers mostly from the last 5 years, but no later than 10 years old. Research from different countries has been considered in order to reduce bias towards particular culture based implementations. Secondary supporting data has also been collected from websites, books, digital news sources, journals and university lectures. The literature review was conducted in September 2020, using research papers and slides from CCT College EBSCO, as well as Google Scholar. The interview was conducted in early April with an expert, having over 30 years' experience in R&D, IT, construction, and PM consultancy within the pharmaceutical sector.

Literature Review

Much time is spent in the initial planning phases of traditional projects, with complex and extensive requirements documents being drafted in negotiation with clients in order to understand their needs and make commitments for the delivery of the project. It is not at all uncommon for clients to request alterations to the initial plan however when, for example their own business needs or priorities shift. There is a consensus among researchers (Cooper & Sommer, 2016) and (Kuruvilla, 2019)that when this happens it can be very costly to make these changes, especially if the project is in the later stages of its development life-cycle. This often results in compromises needing to be made by the client, which is less than ideal from the clients perspective, as well as a drop in team morale, where they must re-do or disregard work that they have previously done. (Scolding, et al., 2020) mentions the importance of team morale in being able to effectively respond to developments in high pressure situations, and how regular retrospectives can help improve processes and increase efficiencies iteratively. These retrospectives normally happen at the end of a long project when using traditional management approaches, which means the benefits won't be seen in the current project and issues that arise and bad practices can often persist until a project is completed.

(Kuruvilla, 2019) also mentions that traditionally managed projects in the pharmaceutical industry often suffer from unrealistic commitments to timelines made in the initial planning stages. This naturally leads to situations where development teams are under pressure to deliver products before their ready, but regulatory obligations obviously don't allow for this, and so deadlines are frequently missed. Allocation of resources is also an issue where hierarchical management structures introduce competing priorities of managers looking to reduce costs, and development team members requiring sufficient resources to reliably manage the throughput of work in progress (Cooper & Sommer, 2016).

As its name suggests, Agile project management aims to tackle these issues that causes development to be slow and cumbersome. It does so by laying out a guiding set of principals in the Agile Manifesto to reduce wasteful processes with continuous improvement while increasing a team's ability to adapt to changes through an iterative approach to development (DeBenedictis, 2019).

Agile however, is often seen as fundamentally incompatible with regulated environments where robust documentation and decision making is a necessity (Batenburg, et al., 2015).

Other barriers to adopting an Agile approach to development, identified by (McHugh, et al., 2012) are traceability issues, lack of up-front planning, and managing multiple releases. As such, many researches such as (Cooper & Sommer, 2016), (Batenburg, et al., 2015), (Jones, 2020) and (Lechler & Thomas, 2015) suggest that incorporating methodologies from the Stage-Gate framework is successful in addressing these shortcomings.

It seems while there is a steep learning curve associated with the mindset shift needed to make the move to a more agile approach to project management, it is very likely to be more beneficial in the long run. With a simple implementation, and clear guidelines for gates and gate-keepers, it can be easier to pilot these new working methodologies in a way that's flexible enough to empower team rather than restrict them, while still maintaining the important decision making stages to ensure regulatory compliance. With a set of guiding principles, it is then possible to scale the implementation to suit the needs of the team and bring further benefits.

Results (Research Findings)

Stage Gate Methodology

The Stage-Gate methodology is a widely used framework which, as the name implies, breaks projects into a series of stages and gates. The stages delineate different critical phases of the project which have their own requirements, risks, etc., and the gates in between every stage represent a period of review and due-diligence which aims to evaluate the viability of moving forward given the current state of the project and its environ. (Johnston, 2021) seems to agree with (Jones, 2020) description of Stage Gate as "The Quintessential Decision Factory" as both have argued that Stage-Gate projects have an increased speed to market and profitability rate over their non-Stage Gate counterparts, speeding up and energizing an organization's projects (Johannesson, 2016).

(Johnston, 2021), in this author's interview with him, describes the use of the Stage-Gate framework in the scenario of a capital project for building a new facility for the production of pharmaceutical products. The Stage-Gate model for this example project can be seen below in Figure 2 and this example will be referenced throughout this research paper.

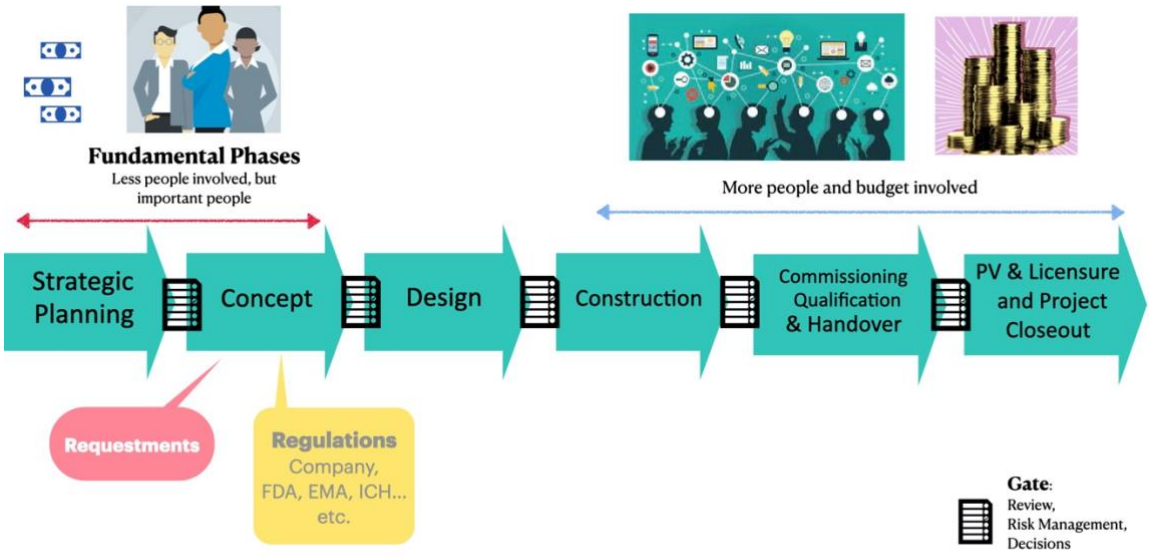

Figure 2- Example Stage-Gate model for pharmaceutical capital project

(Johnston, 2021) argues that the most important phases of this proposed Stage-Gate model, and likely any projects according to (Cooper & Sommer, 2016) and (Kuruvilla, 2019), are the

initial planning stages. In this case that would be the Strategic Planning and Concept Design phases. It is at these stages that fundamental questions are asked and decisions and estimates are made which will affect the entire project going forward to the point that provided these fundamental questions can be answered correctly, with sufficient time and due-diligence given to ensure such, that almost 50% of the potential benefit of a project can be secured after the Strategic Planning Phase. The additional benefit, up to 80% - 90%, can also be secured after the Concept Design phase provided it is done to a high standard and proper consideration is given to all the different ways of achieving what was laid out in the strategic design and the project team at this point performs the various costings and high-level designs in order to ensure they are choosing the most optimum option for the organisation (Johnston, 2021).

It is clear that with such a high value given to the planning phases that the sentiment is such that even if the project is poorly executed in the later phases, because there is a certainty that the correct path to completion was chosen, the impact of this is a lot smaller than it otherwise might have been.

The stage-gate structure and approach help give project teams the granularity they need throughout a project, because at each gate-review step there is a cross-functional review team set up to ask two important overarching questions.

The first question is “have we done everything we should have done in this phase to the correct standard?”. At the end of the concept phase, for example, the review team might look at whether or not they have produced all the necessary documents, have these documents all been appropriately reviewed and approved, has the industry expectations for deliverables been met, have the clinical trial timelines been benchmarked against the industry average, are the timelines or budgets set out to ambitious, and how much risk is being carried over into the next phase, etc. (Rocque & Viali, 2004).

Next, the project team ask themselves “how well are we prepared for the next phase?”. This should take into account things like, have resources been appropriately planned, how is risk management going to be done in the next stage, how are clinical trials to be properly run, has a contract manufacturing organisation been lined up to take on the production of the tens of millions of vaccine doses once approval is received, and such.

(Shah, 2017) mentions the importance of documenting such things and preparing them in a format for review at each gate so that they can be quickly used as materials for supporting decisions. This decision could be yes, we have sufficiently completed this stage and are ready to move to the next stage, confident that there is minimal risk. It could also be no, as, for example, the gate review team may feel that some critical components of the current phase have not been completed. The outcomes of this could be that the project will be put on hold until those failings have been sufficiently addressed, or else they might decide to continue on to the next phase at-risk, but putting into place agreements that those components must be properly completed within the next two weeks, for example.

Figure 3- Risk management conducted at each stage

It is evident that taking this approach, it empowers project teams to take a well-documented body of best practices and regulatory requirements and insist that due diligence is done at each stage of the process. (Johnston, 2021) states that ideally, this allows for what's referred to as "unhindered execution" with minimal changes to the plan. Oftentimes strict measures will be put in place that after a certain point no changes can be made to a project's scope without going through an obscene amount of red-tape in order to prevent scope-creep and minimise risk by taking away this avenue for potential costs and scheduling impacts altogether. It also helps with communication as everyone involved in the project should be very clear about what needs to be done.

Internal factors aren't the only consideration during a gate review however. (Iqbal & Suzianti, 2020) also identifies that pharmaceutical companies emphasize the external risks of the regulatory environment and other competitors during the gate review process.

While Stage-Gate by no means prescribes to any specific organisational structure as such, some organisations have arrived at their own optimum structures in order to manage the complex nature of these projects with a need for specialised skillsets. These structures

revolve around three roles at their core; the Sponsor, the Project / Program Manager, and the Facility Owner / Lead End User. These three core roles have been found to work well with most project types (Johnston, 2021).

It is the Sponsor who is accountable for ensuring that the investment into the project is not only initially viable, and that the benefits proposed can actually be achieved, but that these benefits continue to be viable throughout the project, right up until its completion and launch.

In the strategic planning phase, the Sponsor will be lead the drafting of the Business Case document which details the reasons for a particular investment being made. At each of the gate reviews, the review team will always go back and check that the business case for the project is still valid. Consider the capital project example again, and imagines at one of the gate reviews about halfway through the project it is discovered that there are three other competitors after making a similar vaccine, and that they are at a further stage of their clinical trials and have achieved better results in their trials than ours. The Sponsor will be in charge then of determining what the possibility is that our capital project can be completed in time in order to be first to market, or if it is reasonable that the efficacy or use case of our product can distinguish us from our competitors such that it is still a viable option to continue with the capital project unhindered. This resonates with what is happening at the time of writing, as we see multiple pharmaceutical companies promoting their vaccines for the COVID-19 virus with varying efficacy rate, or different requirements for correct storage leading the some being more feasible than others in certain circumstances (Dunleavy, 2021).

At this point, it may not make sense to continue investing into the project, and it may be better to pause and re-evaluate, or else to cancel the investment altogether if the benefits initially planned are no longer valid and the return on investment has been drastically reduced.

With respect to the other two major roles, the Facility Owner (capital projects) otherwise known as the Lead End User (product / service projects) is responsible for the future state of the project, for example, what the new facility being built should look like, or what the go-to-market strategy is for the new vaccine. The Project Manager then is responsible for helping the Facility owner achieve that future state, by managing the various contractors and designers involved, etc..

These division of labour into different categories correspond with what (Brandl, et al., 2018) called the “macroplanning horizon” of Stage-Gate, where they divide a project into three planning levels: strategical, tactical, and operational with a different methodology for tackling each developing a “healthy tension” between fixed and iterative planning. (Cooper & Sommer, 2016) takes this further in suggesting a new high-level management model called Scrum-Stage-Gate.

Both (Aristodemou, et al., 2020) and (Cooper, 2007) point out that particular projects, like pharmaceutical ones, are fragile, unique, and knowledge-built. This leads to the mismanagement of such projects, and these researchers advocate for Stage-Gate to better manage. (Sabbaghi & Allahyari, 2020) puts it well by saying:

> *“risk management is inevitable, and it also exists in unorganized projects in an unsystematic and intuitive manner. The point is to achieve the most positive results from the risk management by making it a systematic activity.”*

This splitting the work into three categories is further supported by (Kuchta & Skowron, 2016) where they suggest concept control structures of Product Breakdown, Work Breakdown, and Organisation Breakdown. It may be evident to the reader that these structures align somewhat with the responsibilities of the three core roles mentioned previously.

One of the topics this research paper wants to address was regarding the culture of pharmaceutical projects, how that can be enhanced, and whether the regulatory environment makes it more difficult for the project culture to develop positively.

(Johnston, 2021) finds that, especially for those who are used to working in pharmaceuticals, and have grown up with regulatory expectations ingrained in the culture, it is no different when they begin to work as part of a project.
Where this is not the case, however, and the regulations can become a problem, third-parties with no experience working in pharmaceuticals are brought in to the project. This is even true where the third-parties have experience in other heavily-regulated industries, such as nuclear or aeronautics. The reason is that different industries can have vastly different regulatory

styles, with some being very prescriptive, and some being more conceptual and open to interpretation. As such, where these types of partners are onboard, it is even more important to ensure that there is a solid communication plan so that everyone is operating under the same specific understanding of the requirements, and that this is reviewed on a regular basis to ensure there is no deviation between the teams understanding.

Failing to complete the necessary due diligence and following the laws and regulations laid out be each of the regulatory bodies with authority over the markets the product will be operating in can have an effect on the future trust of owners, partners and employees, and so the risks of such failures should not only be considered in the short term, but also for the at the "big-picture" level over longer time frames (Kendrick, 2015).

(Sangshetti, et al., 2017) notes that the FDA inspection team, during pre-license or preapproval inspections under a QbD (Quality by Development) concept assess the implementation and efficacy of the process design submitted as part of the application, as well as the successful transfer of knowledge between the design phases through to the manufacturing ones.

Regulatory affair organisations however will help a project team to understand the regulatory requirements and, due to the strict nature of how these regulations must be followed, they often actually help to clearly define the structure of a project and all the necessary stages that the new product lifecycle needs to go through (U.S. FDA; CDRH; CBER, 2002).

The overarching stages of our example project would be for the research and development of a new vaccine. These would surely be much different than those for the capital sub-project of building the facility to produce the vaccine. As such, there would be a whole other set of regulatory requirements that need to be considered, and a completely different body of work that needed to be done. The Stage-Gate model however can be adapted so that it still provides the same confidence in planning and executing the project with minimal risk.
In this example, the first stage would still be strategic planning, with the aim being to define the requirements such as, the market(s) in which the product will be launched, the data that must be collected and submitted to each of the regulatory agencies in those markets, how those submissions must be done, what the lead time is for the agencies to review the

submissions, should applications be made for any rapid-review schemes with the agencies, how those can be applied for, etc…
The following stage then might involve pre-clinical work, and then the subsequent three stages would delineate different phases of clinical trials, with the proceeding stage being for filing applications with the various regulatory agencies, and so on and so forth.

So while there are stark contrasts between the two example projects, by adopting the stage-gate process, a project team can be confident that they understand the requirements and periodically address the risk to ensure adequate resources are made available to keep the project within budget and timeframe, or to adjust the budget and timeframe of the project accordingly (Aristodemou, et al., 2020).

Top Causes of Stress for Project Teams

According to (Johnston, 2021) there are three main causes of stress on project teams that stand out as warranting the most concern and are often ignored to the detriment of a project's success and the well-being of those involved. These are unrealistic timelines and budgets, unclear requirements, and inadequate or poorly managed resources.

Beginning with unrealistic timelines and budgets, this is a symptom that can be found across projects of all types. What is often the cause of this seems to be either insufficient, or in some cases a complete lack of strategic planning. (Edgett, 2018) states that the failure or success of a project is more often than not determined before it has even begun development, as what they call the "critical upfront activities" that define the attributes, features and benefits of the project will either have succeeded or failed in lining the path to success at the end of the planning phase. (Johnston, 2021) refers to this concept as "front-loading" where a substantial

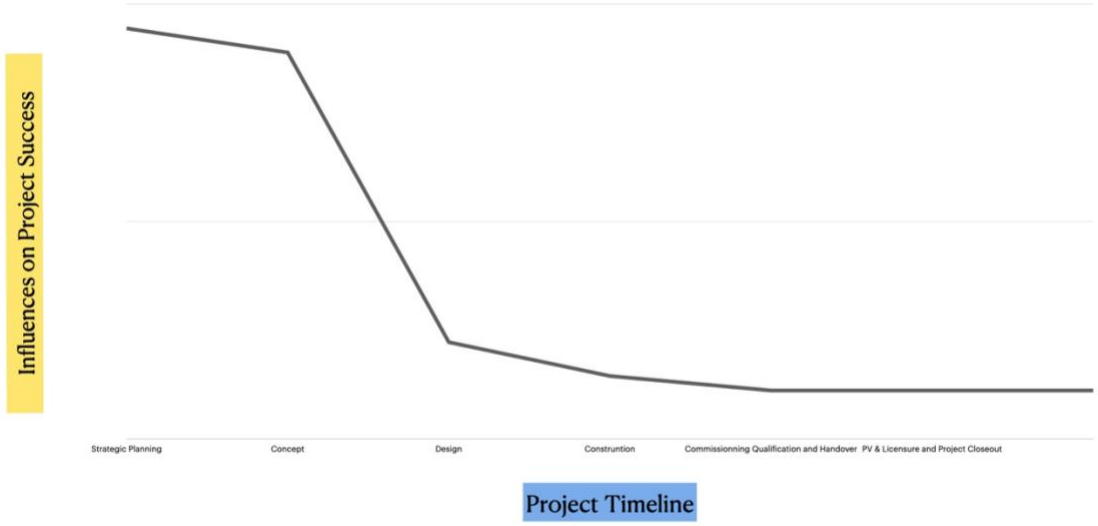

Chart 1- Project Stage Vs Influence on Project Success

amount of time and resources should be spent on doing the initial stages of a project correctly where the influence on the success of the project is much higher Chart 1, and the cost of change is significantly lower Chart 2.

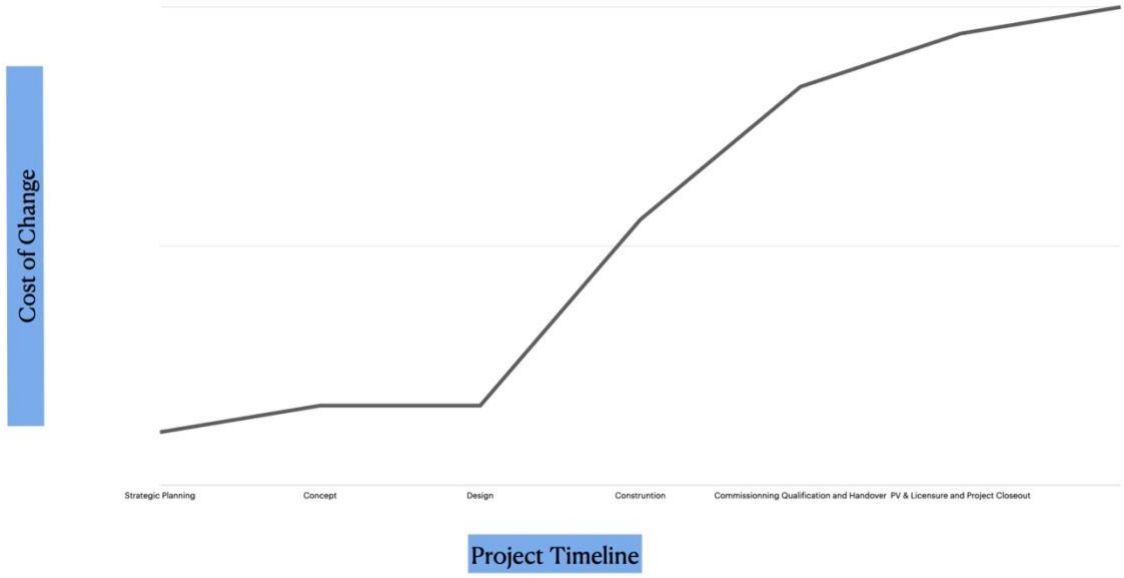

Chart 2- Project Stage Vs. Cost of Change

During the interview, (Johnston, 2021) recalls being called in to advise on many projects where someone might have had a good idea, and there was an opportunity to do something with it. They might have then, for example, called the head of engineering on a site advising they were interested in making an investment. After giving very little detail on a set of hypothetical requirements, they would ask for a quick tender to be drafted up within a very short deadline. The site head then, not wanting to miss out on a lucrative opportunity would

agree to do so, and then rush to put together a high-level proposal, with many huge assumptions made regarding cost, timelines, and risks. The issue then is when the company would come back and advise that they will proceed with the proposed project. The site is then held to these unrealistic budgets and timelines, and given a “fait accompli” where they are expected to deliver on a project that is likely doomed to fail from the beginning. This is where stress and difficulties very much come to the fore as in a situation like this the workers know that the project is not credible or realistic, and that they can’t change it, or that they must bear with it and potentially overwork themselves as the reputation of the site is at stake.

While this example is somewhat contrived, the sentiment stands that where Strategic Planning isn’t done, options aren’t looked at, no benchmarking is done, it would not be uncommon for the project to reach a certain stage before anyone realises the cost of the project has gone up 50%, and the project team is playing catch up throughout (Johnston, 2021). (Kendrick, 2015) describes these scenarios as “ready-shoot-aim” tactics where the work is begun before there is an understanding of the scope. This research conducted a case study where a project had begun while 75% of the requirements were initially unknown by the team and what had been initially in scope was never even signed off by upper management. This lead to numerous regulatory obligations not being met, something which was not identified until the mid-project review.

In order to avoid situations like this, (Johnston, 2021) advises that regular “Risk Workshops” be conducted during each of the individual phases in order to understand how the project is evolving. By doing this at each stage, a better understanding can be gained as to how risks identified in previous stages have either persisted, or been mitigated away. It’s very difficult for teams to identify and understand the full extent of risks for a project, especially one that may span a number of years. Certain individuals with a lot of experience might have the ability to advise on risk based on past experiences, however, each project brings with its own unique set of challenges and so regular periodic risk workshops, and a well-defined risk management plan can assist greatly in simplifying and anticipating what might happen in the coming stages as designs mature, requirements are further defined, and as more and more workers and organisations join the project. This last point also brings with it a benefit, as with more parties joining the project comes a pearl of greater collective wisdom regarding specialised tasks. By doing risk workshops across the project and iteratively at each phase this knowledge can be leveraged and communicated effectively to reveal the blind spots of

the core project team. Risk registers can also be updated to prepare as input into gate reviews. This becomes a powerful knowledge-bank that can be very easily assessed by those in charge of managing the project's schedule and cost so that mature discussion can be had about the upfront cost of mitigating risks, or the subsequent cost of failing to do so (Johnston, 2021).

The second cause of stress, unclear requirements was already touched on above, however, this author feels it warrants further discussion. The onus is not only on management to provide clear requirements, but also on those executing the tasks to ensure that they themselves understand the requirements. (Drakeman & Oraiopoulos, 2020) mentions a problem that big pharma has in that the signal to noise ratio is massive. And that getting the right information to the right small number of people at the right time is very difficult given the large number of resources and complex information filtration systems that are often put in place. They later go on to say that a parallel search process, where two parties are operating off of different understandings of the one requirement is likely to lead to a large number of failures.

This can sometimes be found when dealing with third-party contractors that might approach a project in a way that suits their needs, rather than the needs of the project or the contracting company. Clear, unambiguous requirements can help circumnavigate these types of issues.

(Kendrick, 2015) talks about change being unavoidable as legitimate needs are uncovered later in a project, and how even if productivity is unaffected, there is the potential for discord on the team. A project's success tends to rely on the teamwork. The conflict, strained relationships, low morale, and lack of cooperation that arises from the absence of good teamwork can have a detrimental effect on the success of a project. This is partly the reason why many stage-gate projects tend to tightly lock the scope of a project after the strategic and concept phases have completed. (Johnston, 2021) advises that red-tape can also be purposefully put into place to make it extremely difficult to make any changes or introduce anything new into the scope of the project in order to avoid costly late changes Chart 2 and project delays. This is easier said than done, however, as being able to commit to a project scope so strictly requires great maturity in the organisational culture and very strong leadership so that people can trust that the ones making the decisions have the best interests of the project and the project team in mind.

(Sabbaghi & Allahyari, 2020) define in their research three types of supply risk. Process risk, when the product is not produced to the specified deadline, quantity or quality. Demand risk, when the demand for a product outweighs its availability. Control risk, when the quality control is not sufficient. As a project grows so too does the level of uncertainty around things like resource allocation, which leads to the third main issue of stress for project teams, inadequate resources.

While the above is specifically to do with the product itself being a resource, which can put stress on supply teams, customer relationship managers, factory staff, etc., this is not the only scenario where inadequate resources can be an issue. At the beginning of a project, especially during the concept phase, (Johnston, 2021) suggests that it is vital to the success of the project that the project team has access to the specialists it needs who have the expertise to thoroughly understand the new design, the product, and the best way forward for the project. This however, is invariably difficult as specialists such as this will nearly always be required by the organisation on other tasks at the same time.

Going back to the capital project example. If the specialists are, for example, only contracted later on in the project, it is likely that they will be missing the very specific knowledge of how this particular site operates, how and to what standard things should be done, how maintenance must be facilitated, etc... This goes back to what was mentioned before about front-loading projects. The insights from these specialists into the commercial viability of a project are essential and ensures a better transition between stages as they might identify opportunities for the project to be protected through patents, trade secrets, or have special access to raw materials, opening up new possibilities, etc. (Cooper, 2007). As such, before the project even begins there should be commitments in place that the necessary people will be released to the project for a sufficient amount of time as without sufficiently diverse perspectives with regards to resource allocation, the “innovation funnel”, as (Drakeman & Oraiopoulos, 2020) puts it, becomes too narrow too quickly for it to be able to achieve the necessary diversity of opportunities.

It can be difficult, however, to manage resources without the proper supply and demand metrics in place. The methodologies a project uses in order to measure its various components and track progress should be clearly defined in the Progress Measurement section of the Project Execution Plan. The requirements for metrics being tracked and how they are analysed will invariably change between each stage of the project, as well as for each discipline, or resource category. Consider a team of electricians working at one of the later

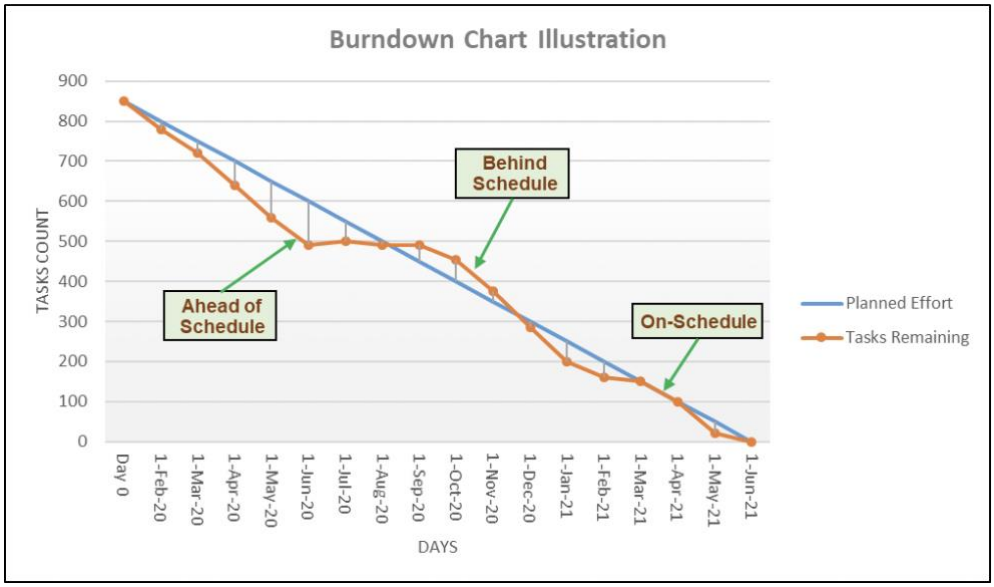

Chart 3 - Example Burndown Illustration (Firnanto, et al., 2020)

stages of the capital project laying cables. Their performance might be measured using meters of cables laid per day. This metric could also be used to track the burndown of the cabling resource, with some adjustments made for waste. However, this metric would make no sense for a team of clinicians conducting the clinical trials. A project control team is usually put in charge of determining the most appropriate way of taking, recording, and analysing such measurements. Part of this work can also be to procure any systems that may be required to store and visualise this data appropriately. Common system requirements might be the ability to produce burndown charts, progress or earned-value curves, schedules, and the ability to monitor progress against these schedules, as well as to perform various aggregations atop the different metrics and schedules. Once these metrics are in place, resource levelling methods which aim to reduce peak requirements and minimise fluctuations in resource utilization becomes a much simpler process (Pellerin & Perrier, 2018).

Giving a Voice to the Team

It has been well documented in the IT industry how Agile practices, such as retrospectives sessions, serve to give a voice to the individual members on project teams, allowing them to contribute to developing better processes and team methodologies in the spirit of continuous improvement (Scolding, et al., 2020). This research not only boosts team morale, but also addresses one of the major concerns (Kuruvilla, 2019) pointed out in their research which was accountability. It is said here that traditional pharmaceutical project teams with hierarchical management structures face this issue where members are afraid to speak up about mistakes, delays, or future risk.

In order to foster a similar organisational culture of transparency and accountability without reprimand, pharmaceutical Stage-Gate teams have adopted the practice of "Lessons Learned" sessions, which can be a part of daily or weekly meetings, needs dependant, with a larger session conducted towards the end of each stage. This helps prepare a very useful bank of information that can be used as input into the gate reviews so that knowledge can be rolled over into the next stage, but more importantly, on an individual level, it is an opportunity for team members to reflect, and for kudos to be given for jobs well done. By not only focussing on the negative, but also on the positive like this, the project team can create a body of best practices, as well as problem solutions which can be carried forward into the next project (Chiou, et al., 2016). High-functioning companies even go so far as to ensure these lessons learned are shared between projects so that different project teams that could be based around the globe can learn from each other's successes and failures without having to go through them themselves (Johnston, 2021).

Conclusions and Further Work References

The successful management of a complex pharmaceutical project and the well-being of its project teams is less correlated to what was originally perceived as a struggle against strict and heavy regulations, but more so with the maturity, transparency, and timeliness by which decisions are made. This such that learnings on these matters in any type of industry project can well be applied to pharmaceutical projects, with the caveat that their specific characteristics are taken into account. A well-defined project with mature leadership, rigorous planning and monitoring, as well as modern communication processes which promote trust and a collaborative culture can greatly reduce the risk of such investments and lead to better profitability overall.

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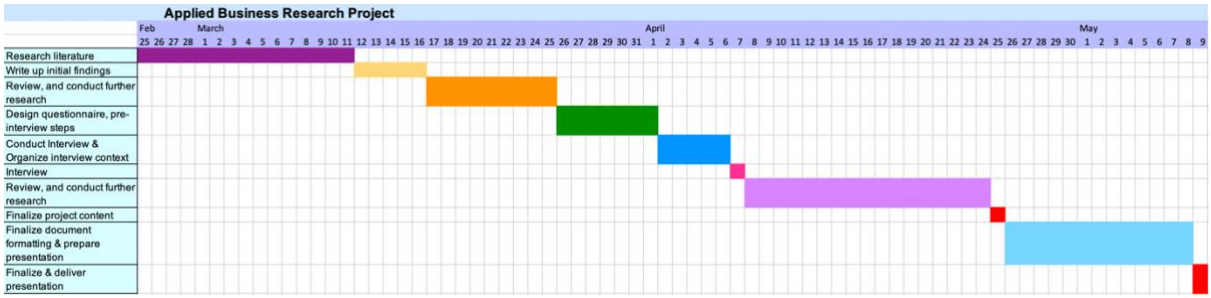
Appendix A: Project Planning and Gantt Chart

Research Timetable

Week 1	Research literature
Week 2	Write up initial findings
Week 3	Review, and conduct further research
Week 4	Design questionnaire, pre-interview steps (deliver questions, consent, etc.)
Week 5	Conduct Interview & Organize interview context
Week 6	Review, and conduct further research
Week 7	Finalize project content
Week 8	Finalize document formatting & prepare presentation
Week 9	Finalize & deliver presentation

Gantt Chart



Risk Analysis

When conducting the initial literature review, while there was a lot of material on project management, and delivering projects in the pharmaceutical industry, a lot of the information was extremely specific and it was difficult to generalize some of the research to infer industry best practices in-use. As such, the focus has shifted more towards the benefits of the frameworks themselves, and how they can be applied to challenges within the industry.

This research will also include an interview with an industry expert (lead project manager consultant within the pharma industry) in order to make up for any industry specific knowledge gaps. As with any interview, however, there comes with it some risks regarding

interview ethics, consent, and availability of the interviewee. A consent form has been drafted, and research has been done into ethical considerations to ensure I am well informed as to how best to conduct the interview and handle information and communications pertaining to the interviewee. The interviewee has also made assurances regarding their availability; however, it is understood that this can never be fully guaranteed, due to a good relationship with the interviewee it might be possible to arrange for a suitable substitute if there are any issues.

Appendix B: Interview Questions

Question 1

Themes: PM framework / managing risk & failure / delivering value

Why choose Stage-Gate for pharma projects over other PM Frameworks such as Agile, Lean, or PRINCE2?

- How does stage-gate help with managing risks?
- When choosing stage-gate, are you also choosing a trade-off between speed of delivering value and reducing risk? How does this affect the profitability of projects?
- What is the main driver of cost associated with pharma projects? How do you approach minimising these costs as well as the risk of going over budget?

Question 2

Themes: positive team culture / managing risk & failure / communication / heavy-regulation

A growing trend is observed in other industries where a focus is being put on team culture and empowerment, as well as overall employee well-being as it has been found to boost productivity and innovation while also having a positive affect on reducing stress, burn-out and turnover of employees. Is a similar focus given to this in pharma products? If so, what are some of the strategies implemented and have the results been positive?

- What are the main points of stress / difficulty for teams / individuals within pharma projects?
- How does the heavily regulated nature of pharmaceutical projects affect team morale / performance? Is it difficult to maintain employee motivation when projects get delayed / cancelled due to regulatory matters? How do you manage this?

Question 3

Themes: positive team culture / balancing speed and quality / cross-functional team / delivering value

Does the structure of teams, leadership, and reporting hierarchy differ much in a stage-gate pharma project that you might see in a traditional hierarchical bureaucracy?

- Are cross-functional teams used? How are teams generally structured? What is the purpose of the chosen team structure?
    - Are there any improvements that might be made to team structures that might improve the speed at which projects can be delivered using better communication strategies etc.? What are some of the roadblocks in implementing these new structures?
- Retrospectives in Agile and Lean are vital to continuous improvement. Retros provide huge benefits to teams allowing them to fine-tune processes, flag risks, reflect on what went wrong. They can also help greatly in boosting team morale as everyone gets a chance to put their suggestions forward. They are particularly useful with cross-functional teams where issues with communication, handovers and over/under-utilization can be flagged. It is much easier to see how this type of ceremony fits in with Agile projects that tend to be shorter and more iterative, and so my question is, do you utilise any form of retrospectives throughout a pharma stage-gate project, and if so when are the best times do conduct them?

Question 4

Themes: best practices / heavy-regulation / PM framework / managing risk & failure

How do you go about determining the stages, gates, and decision criteria for a project?

- At what stage of the project are these generally decided upon?
- Who is responsible for making the above decisions?
- Is the stage-gate model tailored specifically to every pharma project or are their templates that are used for different categories, for example “Drug R&D”, “Medical Device Development”, and “Regenerative Medicine Research”?

Question 5

Themes: Delivering Value / Managing Innovation / Measuring Performance

Other frameworks like Agile & Lean put an emphasis on development driven by the needs of the consumer / client, iterating on the product in order to meet their changing needs or adapt to their feedback. On pharma projects, which are more drawn out and regulated, what is the main driver of value and innovation?

- How is performance best measured? Are there specific metrics you heavily rely on in order to track performance?
- How do you determine value and priority when considering a project?
- Do you use any frameworks or methodologies for managing innovation such as the Pentathlon model, or the Six Paths framework from blue ocean strategy?

Appendix C: Interview Notes

(Johnston, 2021)

Question 1 - PM framework / managing risk & failure / delivering value

In our company, we only use the Stage-gate project management framework instead of others, as well as a standard for us to follow and operate every programme. The programme range could be very wide, such as maintaining capital environments, improving IT sectors, erecting a new factory, planning a new programme, R&D for new products, and daily project management practices in process. Stage-gate is a framework with a fast track, which suits a team / company has a considerably tight time limit, bustling working environment, receives order from many clients at the same time, and special designs are requested, while the pharmaceutical industry operates like this.

And the reason we use Stage-gate is that it is more flexible to adapt every new idea from different sectors; it is well structured to follow easily; once the project is well planned in the early stages, it has a fairly high percentage to reach the project goal and make great benefit to the firm.

This is a basic framework we use to explain to our clients in the company. Instead of 5 stages and 4 gates, this is simpler to give a process baseline for explaining the elements are needed in a project.
As I mentioned earlier, the first two phases which are “Strategic planning” and “concept” are the most vital fundamental stages in the whole project. If the team can come up a plan with some great influences, for instance, certain resources, understanding customers/shareholders requirements, and drafting the project abide by EMA/ FDA/ Clinical Trial standards…etc, above components would lead the project operate into a right direction and likely to have 80-90% successful rate to bring benefits back to company.

There were a few past clients we had, while they were concepting the project, they didn’t consider all the requirements, follow the company/ government /industrial regulations, or didn’t manage the resources very well. When the project moved on the mid-stage, more problems and issues had shown, they had to pause the action, hire more people and went back to the earlier stages. It wasted time, budget, and also brought the negative reputation to themselves.

Question 2 - positive team culture / managing risk & failure / communication / heavy-regulation

Risk management is vital in every phase/stage/gate which has the same duty as an administrator. We often use “Risk Workshop” to identify the things that are likely to derail the project. During every stage, it is important to anticipate what is happening, estimate the

matureness of team performance to find defects/weakness/problems/ blind spots/boundaries. By doing the risk management across each phase, update the registers, comparing with past risk logs, and weighing out the impacts of risk. The results from the risk workshop are reflecting the actual workforce and performance from the project, it could help the manager forecast the further risk might happen, how much budget is needed to add on and try to mitigate the risk, reduce the potential cost.

In this case, sometimes, heavy regulation is actually a good helper as a best practice guideline to let the project progress smoother. The regulation means a standard people must follow; a structure people must take; and expectations people must achieve. It helps the team to define the necessary steps/elements/requirements that need to be kept or removed to meet market's expectations. For example, many pharma companies are trying to produce vaccine and relative medicines/devices for Covid-19 usage. Covid-19 is a new virus which has higher difficulty to do background research. At this stage, One of the FDA/ ICH/ IOS 9001/ EMA guidelines would help the new project work with a benchmark, how they need to operate the product life cycle and ensure the product would be qualified before launch.
The Stage-gate provides a structured discipline around the project, compose the requirements and external potential impactors, and make sure every member understand their duties, cross-function, equipment checking, remain the resources supply steadily and being critical on every stage/gate review which can save more time for further phases.

There are 3 things we found out that have brought profound negative impacts in the project process in general, which are *unrealistic timeline & budget*, *unclear requirements* and *inadequate resources*. Without clear definitions/record details/timetable/cost, the difficulties have increased to deliver the information and the team has to come back forward to redo the same tasks over a few times; overall, unclear requirements affected the effectiveness.

Question 3 - positive team culture / balancing speed and quality / cross-functional team / delivering value

Frontline loading has a key job to mitigate the risks, conflicts and reduce the late changes. As a manager or project leader, there are some tips can help, for instance, encouraging all team member to involves decision-making, creating and analysing information; spending more time to repetition of information and make sure the members fully understand it, it would have a better result compare with cramming numerous information in a short period of time; knowing your team members' preference in learning type, some people are doing better in individual learning, some people have greater performance while they are paired with others.

We didn't do retrospectives activities in our company, however, we do weekly briefing and it has worked out perfectly for us. By concise information to call out the good/bad findings, key points of learnings and input key notes into gate reviews. Those activities would help the team understand the whole project better and map up the benefit for further phase/steps/gates.

We often use a phrase “Go Slow to Go Fast” to remind team members or managers that a well-structured project management proposal and comprehensive plan is crucial. The expertise, specialties, shareholder, sponsors are the people who lead the early phases of the project which are not many but very important, they really need to take time to find a balance between company culture, market demand, regulations, recruiting good people, managing available facilities and stable supplier with high quality materials to conduct the project and guide the team to achieve success. As many examples, most reasons for failure in a project are total cost over the budget, return back to the previous stage to redo partial elements, didn’t follow certain regulation guidelines and find out some defects in the design. Those factors would lead the project to either spend more time, raise budget to fix the issues or totally cancel the project.

Here I would like to point out that *positive company culture* and *strong leadership* are important to help the team operate the project abide by the PMI, minimise the unrealistic factors and adapt the challenges. Especially during the “concept” phase, a nice leadership would create an open communication platform, pay attention to every sectors’ advice and voice, find the agreements in between and well-deliver to the design time.

Question 4 - best practices / heavy-regulation / PM framework / managing risk & failure

Project Execution Plan(PEP) from PMBOK is highly recommended to use, the most basic one but suits for every project, and it is also the one we use for risk management. It includes the project definition(Introduction background and history), project objectives, project scope, project interfaces, project assumptions, project governance, key roles and responsibilities, project responsibility matrix, and project schedule (Schedule hierarchy) must be documented clearly and in order. With a standardized record and easy-read PEP template, the whole team would know what are their own duties and who would be the to-go person when they have questions. As I mentioned before, PEP would be vital for early stages(Concept), it guides us to know how many risk workshop are needed, the bast practices from regulations, illegal items, facilitate factors, when would the reported risk be solve and closure it.
Not only can finding blind spots easier but also can improve the communication system, especially when two different background sectors work together.
It sounds easy but not every project does have a clear PEP template to follow.

Question 5 - delivering value / managing innovation / measuring performance

As I mention in the previous question, PEP would be the one to measure the team performance. Another meth we use in the company is similar to the Burndown Chart. Firstly, making up a table(graph) with the goal lines; secondly, record every steps or results in the project and numerate it ; thirdly, uploading the operationally data into the table with line graph; finally, comparing the goal lines and operationally lines, and dissect the difference

in between. Using this method can easily see which gate/phase/step has issues, who is in charge of the task, and how the team should avoid the same issue for the future.