# An Investigation of the Important Project Management Knowledge Areas in the Life Sciences Sector

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**Abstract**

The application of project management knowledge and skills has historically been focussed on industries such as Construction, Defence and Telecommunications. Because of this, there is an apparent lack of information supporting the use of project management in the life sciences sector and specifically the pharmaceutical industry. As a student of project management working in the pharmaceutical industry, I have a great interest in the ways we, as life sciences project management practitioners can close the knowledge and skills gap between us and the more established industries.
To help identify the means by which the value of project management in the life sciences sector could be increased, I sought to find out which of the standard 9 knowledge areas were currently seen as being the more important than others to project success. An anonymous questionnaire was distributed to a group of pharmaceutical project managers and this paper describes some of the key points of the research data obtained.

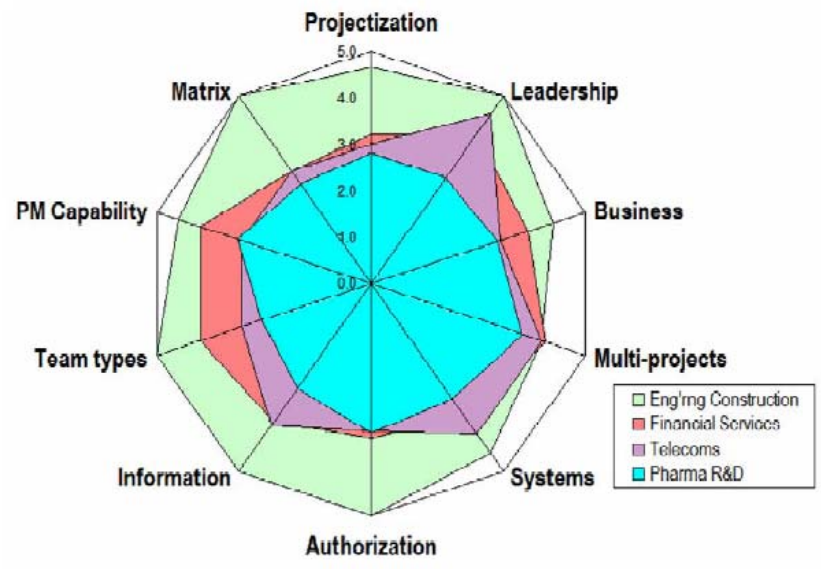
**Keywords:** pharmaceutical, project management, survey

## Introduction

During the completion of my studies toward a master's degree in project management at the University of South Australia I learned the purpose, function and application of the 9 standard PM knowledge areas: Time, Cost, Quality, Scope, Risk, Communication, Human Resources, Procurement, and Integration. While the content of the coursework was extremely enlightening and the numerous guest speakers provided insight into the application of project management in different industries, I felt that for me something was lacking. The case studies presented in class and information in the PMBOK guide [1] were overwhelmingly geared toward the construction/ infrastructure industry. Because of this lack of clear representation of the life sciences sector, I chose to focus my dissertation project on further investigation of the use of project management in the pharmaceutical industry.

Another factor influencing my decision to study the use of project management in the pharmaceutical/ life sciences industry was the results of a recent survey [2]. The results of the survey showed the maturity of project management in the pharmaceutical industry to be lagging behind other industries with respect to generalised aspects of project management.

Figure 1: [2] Cooke-Davies, T (2005), Project Management Maturity in the Biopharmaceutical Industry. How does it Compare with Others?




The aims of my research were to identify specific project management knowledge areas that were considered by experienced project managers to be of high importance in achieving project success. The identification of the "key" knowledge areas and determination of the specific ways these knowledge areas are applied to projects in the life sciences sector was expected to clearly illustrate ways that standard project management practices can be effectively applied to projects in this sector.

To provide data for the original research component of the dissertation, an investigation was made into how project managers in the life sciences sector, specifically in the high-risk pharmaceutical / medical devices / biotechnology sub-sectors, view the importance of project management knowledge areas in the conduct of their projects.

## Methodology

The investigation was conducted through a questionnaire that focussed on how project managers perceive the use of project management knowledge and tools in their industry. Prior to collecting data, the questions were reviewed by the university Ethics Committee and approved for use. The questionnaire was distributed in a manner that mainly covered the Australasian region but also included Europe and North America. Care was taken to limit the number of participants from organisations with many project managers to reduce the influence a single company may have on the results. The results were gathered in a manner that guaranteed the respondent's anonymity and no questions were asked that would possibly identify the individuals. For the purpose of this paper, the data collected is presented in the simplest manner, to focus on the direct results of the questionnaire.

## Results

The following details are selected outcomes from the Dissertation questionnaire and they reflect some of the more interesting and enlightening results.

The number of participants in the questionnaire was 41, a response rate of approximately 37%.

71% of respondents had more than 10 years of experience with projects in the sector and all had 3+ years experience. The level of experience of the respondents gives additional confidence in the validity of the survey results.

44% had also managed projects in the IT industry. This result emphasises the close relationship between the life sciences and IT industries. In a similar survey conducted by the PMI Pharmaceutical SIG in 2005 [3], it was found that overall within the pharmaceutical industry project managers worked on drug development projects 57% of the time and IT projects 26% of the time, with the remainder of the time spent on business transformation (change management) projects.

52% said their organisation performed projects adequately, with some failings, while only 33% saw their organisation as performing projects with a good success rate. Of the respondents that said their company performs projects to a Poor level with critical failures being common, all had five or fewer years experience performing project work.

62% said their industry as a whole performed projects adequately with some failings; while 33% said their industry performed projects with a good success rate overall.

When questioned about benefits of Project Management, the following findings were made:

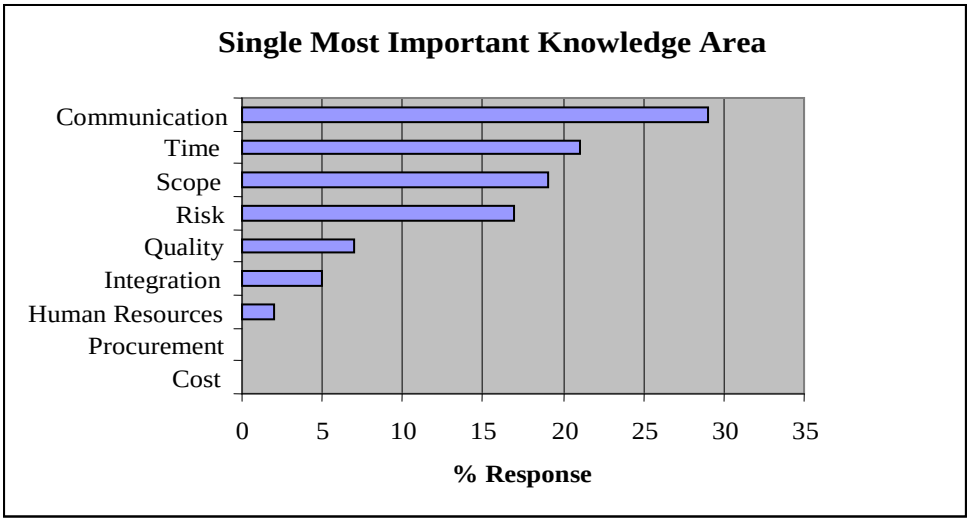
- Approximately two-thirds reported noticeable benefits for Risk, Time and Quality aspects of projects
- 57% said improved Communications was a clearly provided benefit
- 50% believed that benefits for Integration activities were clearly provided
- The least benefit is provided for the control of costs, with 21% reporting a level of "None".

When respondents were asked to choose only 4 of the 9 Project Management Knowledge areas for application to their projects, they chose:
1) Communications Management (81%)
2) Risk Management (79%)
3) Scope Management (71%)
4) Time Management (67%)
Interestingly, Cost Management was the fifth most popular (only 43%).

### Key Knowledge Areas

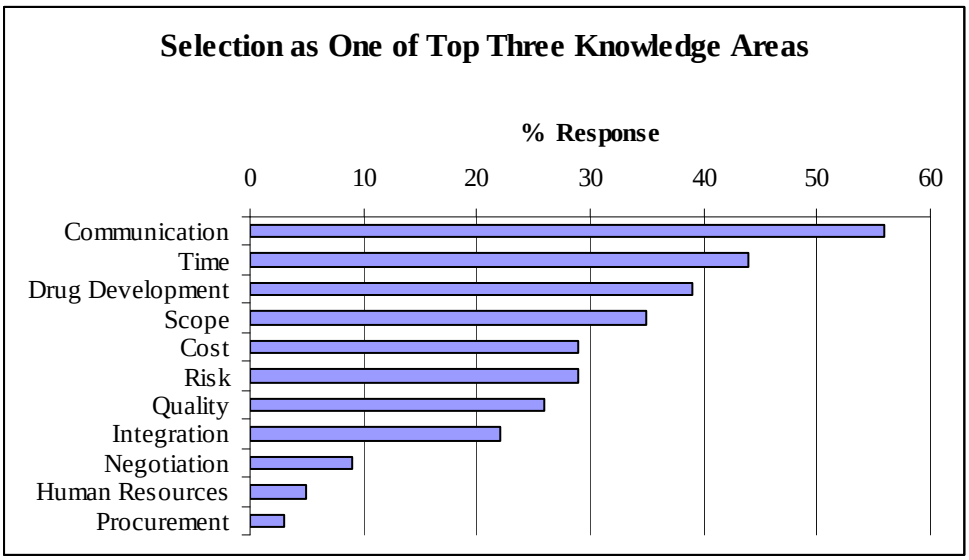
When the participants were asked what they thought the single most important knowledge area was, results are ranked as follows: communication, time, scope, risk, quality, integration, human resources, but procurement and cost are not ranked.

Figure 2: Selection of the Single Most Important Knowledge Area



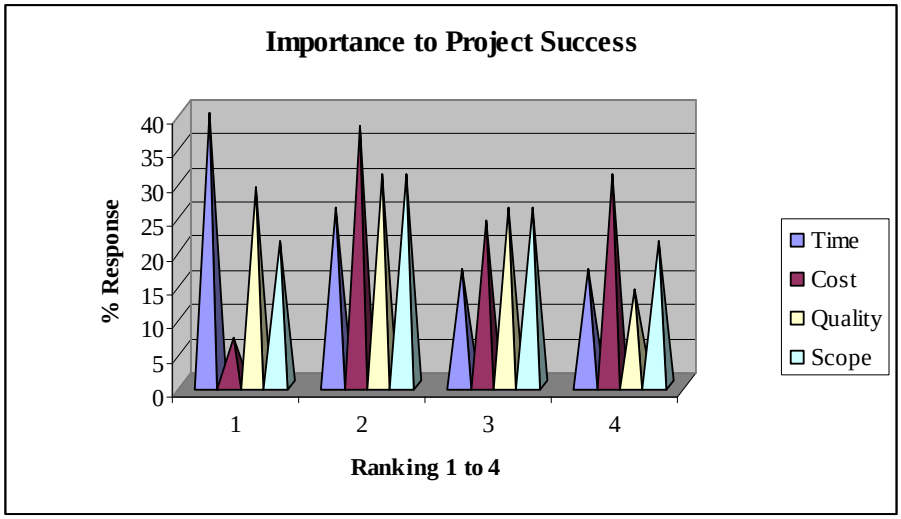

For comparison, in the PMI Pharmaceutical SIG questionnaire [3], respondents ranked the PM knowledge areas according to importance and the results were: Communication 56%, Time 44%, Drug development 39%, Scope 35%, Cost 29%, Risk 29%, Quality 25% only 5% thought HR and 3% said Procurement. See figure 3 below.

Figure 3: Selection of the Top Three Knowledge Areas




The Dissertation questionnaire responses were reviewed to identify the areas of project management that were perceived as being important for project success. As expected these were time, cost, quality and scope. However, the cost element appears to contradict other results seen from the respondents i.e. selection of the four knowledge areas for application to projects and identification of the single most important knowledge area.

Figure 4: Importance of key knowledge areas to project success




## Discussion

The following is a review and discussion of the group of knowledge areas collectively described as being key to project management in the life sciences sector. The grouping is based on the Dissertation questionnaire results for selection of the single most important knowledge area and the four knowledge areas most important to project success. These knowledge areas include: Communications, Time, Quality, Scope, Cost and Risk.

### Communication Management

The results provided an interesting view of Communications management. It was not ranked as being one of the most important for project success, but it was also ranked as the highest rated single most important knowledge area. This seemingly disparate assessment of Communications management is likely based on the substance of the knowledge area. Communications management is not an aspect of a project that is used to assess project success, unlike Time, Cost, Scope and Quality which are direct reflections of common project success indicators. Communications management is instead the one knowledge area that functions with all the other aspects of project management in a continuous and influential way. The way communications are managed in a project can make or break the project, no matter how well the other knowledge areas are managed. Communications can be thought of as the project "glue" that holds parts of the project together. One simple example of this function is the communication of project objective requirements to the individuals performing project tasks and in return, communicating progress and issues occurring at the project WBS level back up to the other aspects of the project such as Time and Scope management. Guidance from authors across several industries includes suggestions ranging from formulating a "communication matrix" to tips on how to ask the "hard questions". Communications management is at the heart of projects and should be given formal consideration on the same level as the other knowledge areas.

**Time Management**

With communications management not able to hold a place in the group of the four most important knowledge areas for project success, Time management shines as possibly being the top knowledge area over all. Having project work packages executed on-time is a key responsibility of the project manager. The likely reason for this is because time is the one thing that there can be no more of. Extra resources can be leveraged, customer expectations can be massaged, but if the project will be delayed by an unacceptable period of time, the impact can be widespread. With poor Time management of a project, other projects can suffer the consequences by being delayed, robbed of resources or placed under increased pressure in relation to time to make up for the delays in the earlier project. The importance of Time management can be visualised if you imagine the typical phases of pharmaceutical development projects to be the stages of a relay race – if the time taken to complete one stage is delayed, the next runner must put strain on their resources or take a short cut in order to remain competitive. Further, in the relay race example, if the runner in next stage of the race begins movement based on the expectation that hand-over is imminent, the runners may falter when the previous stage is delayed, causing more serious delays by compounding the effects.

**Quality Management**

During the early stages of my coursework I was involved in pharmaceutical development projects in the company I was working for as the quality representative. In an effort to apply my newly found project management knowledge, I took on the task of authoring the Quality Plan for the projects I was involved in. I looked at templates and reviewed the text book descriptions of quality management plans but none of them fit the specific requirements of these types of projects. Pharmaceutical development projects rely on an array of regulatory expectations to be met in order to gain approval to move to the next stages of development, leading to eventual sales of product. The quality of the project outcomes required agreed measurements or specifications in order to be assessed for compliance. The authoring of a Compliance Plan was undertaken to clearly define and document the regulatory/ compliance requirements relevant to the project scope and objectives. The Compliance Plan provides a single documented reference that defines the ways regulatory expectations will be met via the outcomes of the project.

The typical Compliance Plan can include information on topics such as:

- Background – general details of the project, with reference made to the specific regulatory guidance(s) relevant to the project, e.g. ICH Q7A GMP Guidance for Active Pharmaceutical Ingredients.
- Project Deliverables – general statement of the main deliverables of the project that will be subjected to regulatory compliance requirements, with milestone dates.
- In-house Analytical Method Qualification – a listing of the product analysis methods that will be required for the project, with reference to the required level of control i.e. qualified or validated.

- Contract Analysis – the list of external laboratories that will be contracted to perform product analysis methods, with reference to the status of the laboratory e.g. approved status, audited, licensed.
- Raw Materials Testing – describes the requirements for the testing of materials constituting the final product, can include the stage of the project that testing will be initiated and which compendia the tests will be based on.
- Reference Standard – defines the product material (batches) that will be used to serve as the reference standard and general details of the quantity, packaging, storage conditions and testing to be done.
- Stability Study Requirements – normally gives a time-line based overview and references a separate protocol that defines the specific requirements of the study(s).
- Retention Samples - defines the product material (batches) and quantities that will be required to serve as retention samples. A reference is made to a separate protocol that manages the stocks of retention materials.
- Cell Banking – gives the general requirements of the number and type of cell banks required, with reference to the documents to be used to generate, qualify and manage the approved cell banks.
- Personnel Training – references the corporate training procedures and alludes to the requirement to document training of personnel on controlled procedures related to the project.
- Descriptions of Plant Process Equipment, Systems and Products – an overview of the utilities and equipment systems that support the manufacture of the project's products. The physical characteristics of the products are described, including excipients and final product form, volume etc. References are usually made to appended equipment systems listing with qualification requirements stated.
- Validation Inclusions and Exclusions – clearly defines which aspects of the project will require validation activities and identifies the parts of the project that do not require this level of proof of control. References should be made to separate validation plans.
- Key Acceptance Criteria – and outline or reference to other documents defining the values the acceptability of the processes and products will be measured against.
- Documentation Types and Format – reference to the general requirements of the documentation created for the project related to the manufacture and testing of products. Is normally the organisation's corporate guidance but may be reference to specific customer requirements.
- Planning and Scheduling – makes a direct reference to the approved project plan and may define the specific requirements for coordinating the compliance aspects of the project. Key milestones and prerequisites/ predecessors are identified to provide a link to the project plan.
- Change Control and Deviations Policy – reference to the applicable corporate practices. May include both project-based procedures and organisational quality system practices.

## Scope Management

The perception that scope management is important for project success is well founded. Like all industry applications of project management, the control of the scope of a project in the life sciences sector is crucial to keeping the balance between time, cost, risk and quality aspects of the project. Defining how to assess possible changes to scope is important to identifying when the scope is actually going to change. Besides the formal requests for scope changes, during the project there can be changes in the tasks being performed which together may constitute a change of scope. There should be a way to collect information about these task-based changes and review the deviations in relation to the scope of the project. It also may be beneficial to define the scope of groups of related tasks to provide a reference that any changes can be measured against. Involving project team leaders in the definition of the scope of task groups will provide a clear communication of the project requirements to the project team and give the project team members an opportunity to establish reliable definitions.

## Cost Management

In an examination by Jacob and Kwak [4] of evaluation approaches for project selection for pharmaceutical R&D projects, some crucial information related to cost management was identified. It was found that there is a perceived requirement to reduce the costs associated with the development of new pharmaceutical products by reducing the risk that the wrong product candidate will be chosen for development. This is described as a movement from a Project Management mentality of doing the project right to one of doing the right project. The importance of selection of the right product candidate was underlined by the statements that it can take between 350 and 500 million US$ to bring a new drug to market and that typically it is required to screen over 5000 compounds to produce one marketable drug. The authors suggest that no matter which approach is taken to manage drug development projects during the early phases, the common theme for success is to have a high quality of information about the project. The wisdom of the decisions made during the project will be based on the quality of information available.

## Risk Management

Risk management for the life sciences industry has gained recognition in recent years. The FDA is taking a risk-based approach when deciding who and what to audit. They are also encouraging manufacturers to make one of their primary considerations the risk to the patient or end user. This acceptance of risk management has also been reflected in the creation of a key guidance document (Q9: Quality Risk Management) developed by the International Conference on Harmonisation (ICH) and fully supported by the FDA. The Q9 guidance covers risk assessment, control, communication and review. It also describes risk management tools and suggests potential applications for quality risk management. With the high costs of performing projects in the life sciences sector and the possible impacts on human life, the adequate performance or risk management is of substantial importance to the industry.

## Summary

The results of the questionnaire provide an insight into how project managers in the sector perceive the use of project management knowledge and tools in their industry. By focusing on the management areas highlighted by this research, project managers in the life sciences sector can hopefully realize improvements in overall project success rates. This focus can also enhance the ability of the project manager to maintain increased levels of control over the project's scope, duration and inherent risk profile – all key factors in achieving overall project success. With an observable increase in project success and the related benefits to the organisation, it will support the formation of stronger PMOs in the life sciences sector. This in turn is a step forward in raising the level of maturity of project management in the industry and underlines the important role project management can play in creating and supporting successful life science sector corporations.

## Acknowledgements

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