



Good Practice Guide

Project Management for the Pharmaceutical Industry



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Good Practice Guide

Project Management for the Pharmaceutical Industry

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Preface

The practice of Project Management within the highly regulated world of the pharmaceutical industry provides unique challenges and opportunities. The ISPE Good Practice Guide: Project Management for the Pharmaceutical Industry promotes the integration of GxP with relevant project management activities to ensure that compliance risk is managed both effectively and proactively.

The Guide aims to provide a reference source of good practices for project management for a wide variety of project types within the pharmaceutical industry and benefit to Project Managers and other professionals working on such projects.

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Table of Contents

1	Introduction	9
1.1	Background	9
1.2	Purpose	9
1.3	Benefits	10
1.4	Industry Context	10
1.5	Scope	11
1.6	Structure of the Guide	14
1.7	Key Concepts	15
2	People Management	23
2.1	Introduction	23
2.2	Roles and Responsibilities: The Project Manager	23
2.3	Roles and Responsibilities: Senior Stakeholders	28
2.4	Roles and Responsibilities: The Project Team	37
2.5	Roles and Responsibilities: Consultants and Contractors	47
2.6	Knowledge Management	52
2.7	Language, Culture, and Communication	55
3	Risk Management	61
3.1	Introduction	61
3.2	Pharmaceutical Risk Types	65
3.3	Pharmaceutical Quality Risk Management	71
3.4	Integrated Project Risk Management	76
4	Project Initiation	85
4.1	Introduction	85
4.2	The Importance of Good Front End Definition	85
4.3	Stage Gate Project Approval Process	86
4.4	Stage 1 – Project Feasibility– Is this a Good Idea?	89
4.5	Stage 2 – Project Conceptual Development – Identifying the Best Option	95
5	Project Delivery Planning	107
5.1	Project Sponsor	107
5.2	Project Scope	108
5.3	Project Schedule	110
5.4	Project Cost	113
5.5	Project Controls	119
5.6	Project Team	121
5.7	Communication Plan	122
5.8	Design Management Strategy	123
5.9	Technology Strategy	125
5.10	Procurement Plan	127
5.11	Construction Plan	127
5.12	Testing and Commissioning Strategy	128
5.13	Project Start-Up Strategy	128
5.14	Project Close-Out and Handover Strategy	130
5.15	Completion of Project Delivery Planning	131

6	Design Planning and Delivery	133
6.1	Introduction	133
6.2	Project Stage 1 Feasibility – Design Activities	134
6.3	Project Stage 2 Conceptual Development – Design Activities	134
6.4	Budget and Schedule Objectives	136
6.5	Project Stage 3 Project Delivery Planning – Design Activities	138
6.6	Project Stage 4 – Detailed Design Activities	140
6.7	Completion of Design	148
7	Implementation: Procurement	149
7.1	Introduction	149
7.2	Procurement Strategy	152
7.3	Procurement Planning	153
7.4	Procurement Delivery	166
7.5	Procurement Completion	178
8	Implementation: Construction	179
8.1	Introduction	179
8.2	Who Provides the Construction Input?	179
8.3	Preconstruction	180
8.4	Construction Delivery	189
8.5	Construction Completion	192
9	Implementation: Testing and Commissioning	195
9.1	Introduction	195
9.2	Pre-Requisites for Testing Success	197
9.3	Delivery of the Testing Phase	210
10	Project Close-Out	211
10.1	Introduction	211
10.2	Handover Activities	211
10.3	Financial and Contractual Close-Out	212
10.4	Knowledge Management	214
10.5	Summary – Example Close-Out Checklist	217
11	Appendix 1 – Supplementary Material	221
11.1	Web Resources	222
11.2	Testing Phase Supplementary Guidance	223
11.3	Example Project Report	242
11.4	Example Project Charter	243
11.5	Additional QRM Background	244
12	Appendix 2 – Case Studies	245
12.1	Product Launch Project Case Study	246
12.2	API Capital Project – Project Initiation Case Study	247
12.3	Oral Solid Facility Project – Project Delivery Planning Case Study	248
12.4	Electronic Batch Record (EBR) Project – Design Case Study	249
12.5	Biotech Facility Project – Procurement Case Study	250
12.6	Tech Transfer Project Case Study	251
12.7	Facility Project – Risk Management Case Study	253
12.8	IT Project – Construction Case Study	255
12.9	GAMP Inspection Readiness Project Case Study	256

13	Appendix 3 – References	259
14	Appendix 4 – Glossary	263
14.1	Acronyms and Abbreviations	264
14.2	Definitions	267

1 Introduction

1.1 Background

The practice of Project Management within the highly regulated world of the pharmaceutical industry provides unique challenges and opportunities. It is considered good project management practice to integrate GxP with relevant project management activities to ensure that compliance risk is managed effectively and proactively. This ISPE Good Practice Guide (GPG): Project Management for the pharmaceutical industry provides good practice approaches which promote the successful integration of these additional requirements.

Throughout the Guide, references to the “pharmaceutical industry” are intended to include all aspects of the industry, including biopharmaceuticals and medical devices.

1.2 Purpose

The purpose of this Guide is to provide a reference source of good practices for project management for a wide variety of project types within the pharmaceutical industry.

The Guide considers how appropriate tools and techniques can support and promote good project management practices and aims to help in sharing of these good practices to facilitate their use within the pharmaceutical industry.

This Guide aims to:

- provide specific guidance on project management in the pharmaceutical industry
- provide a resource for Project Managers and other professionals who are involved in projects in the pharmaceutical industry
- provide a link to project management bodies of knowledge for industries other than the pharmaceutical industry (References 1, 2, and 3, Appendix 3)

The Guide aims to support the:

- development of a common language across the pharmaceutical Project Management community
- access to good project management practice information to enable Project Managers to complete a gap analysis
- development a culture of good project management practice throughout an organization
- development of organizational project management capability, e.g.:
 - a reproducible project delivery system
 - an understanding of the project management requirements for successful project execution
 - enabling project stakeholders to understand the complexities of running a project
 - regular training and skill development for the personnel delivering a project
- development of organizational and individual pharmaceutical project management capabilities through expanding the project management body of knowledge (References 1, 2, and 3, Appendix 3) specific to the pharmaceutical industry

- integration of different aspects of a pharmaceutical project which cross both functional and organizational boundaries, which need to be managed proactively
- integration of risk management into specific aspects of a project

This document contains good practice guidance, and any stated recommendations or requirements should not be regarded as mandatory (except where regulatory or legal requirements are directly referred to).

*The use of terms such as **must** is intended to indicate that these aspects are essential for maximum project effectiveness or success, and not that such aspects are mandatory from a regulatory or legal perspective.*

*Similarly, the use of **critical** (except when used as part of a defined term such as Critical Quality Attribute) is intended to indicate that these aspects are essential for maximum project effectiveness or success, and not that such aspects are necessarily critical from a product quality perspective.*

1.3 Benefits

This Guide is intended to be of benefit to Project Managers and other professionals working within the pharmaceutical industry.

It aims to provide the pharmaceutical context to project delivery and address unique aspects of project management within the pharmaceutical industry. The key benefit is intended to be an increased potential for successful completion of a pharmaceutical project.

A key purpose is to provide a common language and a way to use generic and specific tools in the context of a pharmaceutical project.

Additional benefits include:

- the collation of a comprehensive list of current good practices to aid project delivery success
- the development of a broader knowledge of pharmaceutical projects and project management for a wider variety of stakeholders
- knowledge to help to mitigate or eliminate risks common to pharmaceutical projects

1.4 Industry Context

This Guide is specific to Project Management within the global pharmaceutical industry and to projects typical within that environment. The main focus of the Guide is facility and engineering projects, including facility, improvement, and IT projects.

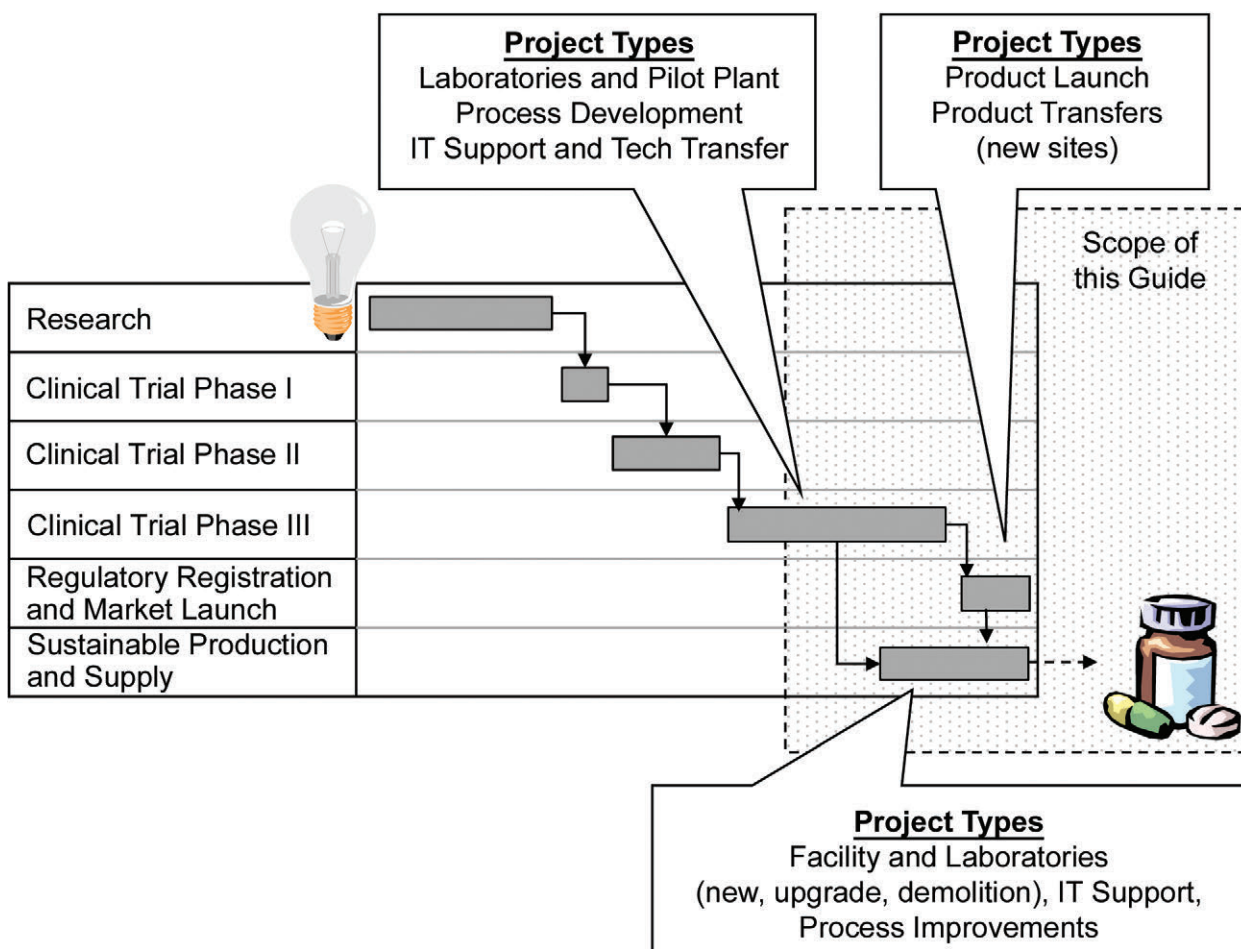
The concepts, principles, approaches, and tools are also relevant to other project types. The specific terminology of each type of project may differ, but the methods discussed in this Guide are applicable. For sources of further guidance on specific terminology, see Appendix 4.

The industry context and scope of the Guide was defined through considering the stages within the product life cycle (ICH Q10; Pharmaceutical Quality Systems (Reference 4, Appendix 3)) and Figure 1.1:

- Pharmaceutical Development
- Technology Transfer

- Commercial Manufacturing
- Product Discontinuation

Figure 1.1: Typical Pharmaceutical Drug Product Life Cycle and the Scope of this Guide

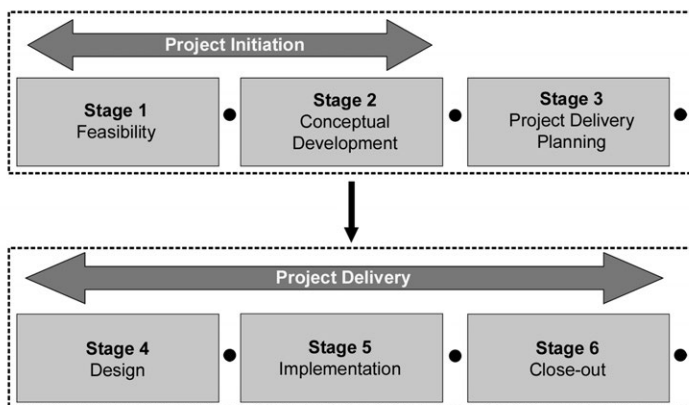


1.5 Scope

The Guide will cover:

- the tools and techniques supporting project delivery
- the life cycle of a typical project (Figure 1.2) in the pharmaceutical industry
- how compliance to pharmaceutical industry regulations should be integrated with the project life cycle

Figure 1.2: Typical Project Life Cycle



This Guide considers new or novel aspects of project management which, although not unique to the pharmaceutical industry, are fundamental to pharmaceutical project success.

Generic areas of project management knowledge (e.g., project controls, safety, health and environmental, etc.) which, although not specifically covered in individual chapters, are discussed in chapters where they have a specific pharmaceutical relevance.

This Guide does **not** cover:

- Generic project management tools and methodologies that are not applied differently nor have a different context within a pharmaceutical environment.
- The technical challenges within any part of the project life cycle: Only the management of those challenges are covered, **not** the technical solutions. Technical Guides are referenced, where applicable.

This Guide is **not** intended to be a comprehensive or generic project management body of knowledge. For further information regarding general project management, see (References 1, 2, and 3, Appendix 3).

1.5.1 Project Types

In terms of the type of projects which occur in the pharmaceutical industry, this Guide is intended to be applicable to most types with the exception of pure discovery or research projects (see Appendix 1). These project types could include:

- Facility
 - New and Retrofit Facilities
 - New Equipment or Equipment Systems
 - Decommissioning and Demolition
 - Estate (whole site projects: purchase, development, sale)
- Improvement
 - Product, Facility, and Equipment
 - Audit (Safety or Quality) Preparation and subsequent improvement (typically linked to a facility)

- Product
 - New Product and Product Transfer
 - Technology Transfer
- IT
 - ERP Implementation
 - System Functionality Upgrade
- Automation
 - Process Control System

Case studies, for a variety of the above project types, are included in Appendix 2.

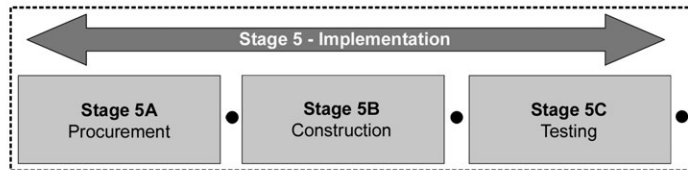
The lack of inclusion of any particular subject is not a reflection on its lack of importance within pharmaceutical projects, but a recognition that it is a generic subject and existing project management guidance is available (see References 1, 2, and 3, Appendix 3).

1.5.2 Terminology

The terminology in Figure 1.2 is generic and where specific terminology is used within a certain project type, then this will be introduced, explained, and defined in the glossary (Appendix 4) and also summarized in the Project Type Matrix (for further information, see Appendix 1). For example:

- Within Computerized System Projects, delivered following the GAMP approach, (Reference 5, Appendix 3) the life cycle stages are:
 - Concept
 - Planning
 - Specification, Configuration, and Coding
 - Verification
 - Reporting and Release
- In Facility Projects, the design can be broken up into distinct stages:
 - Concept Design or Conceptual Development (as used in this Guide)
 - Front End Design, Preliminary Design, Scheme Design, or Basis of Design (as used in this Guide)
 - Detailed Design and Engineering
- In Facility Projects, implementation involves three distinct phases following detailed engineering design (Figure 1.3):
 - Procurement

- Construction and Installation
- Testing (also called commissioning and qualification and also verification)

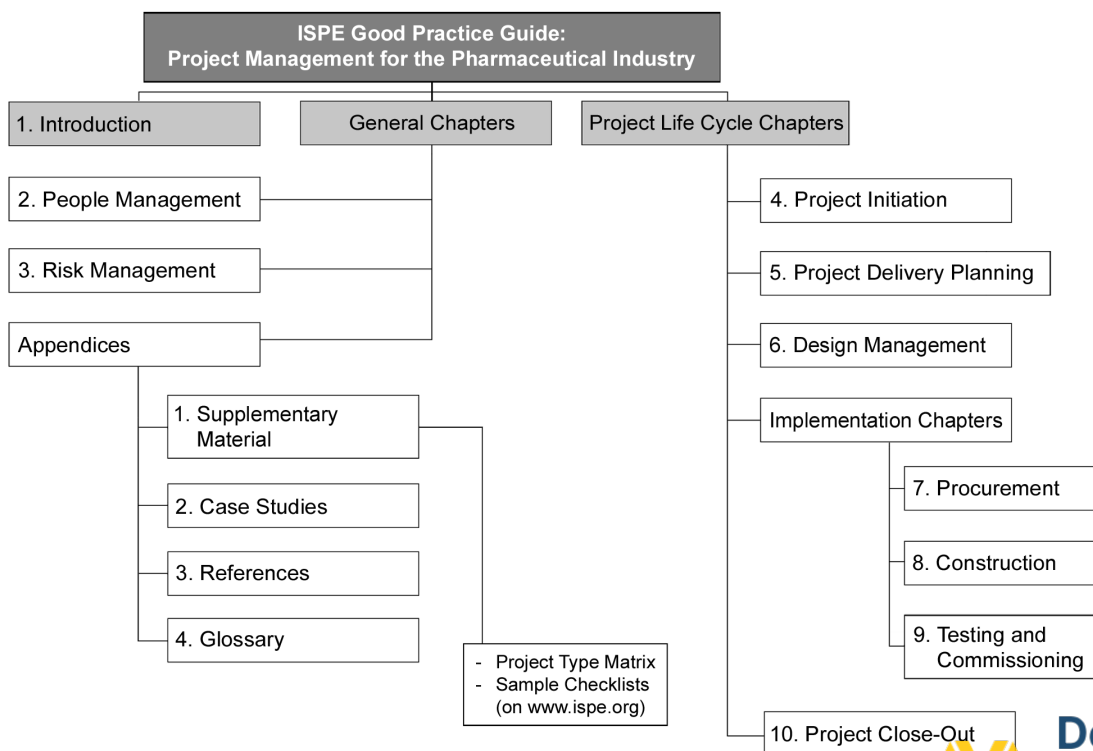
Figure 1.3: Typical Facility Project Implementation Stages

- In Improvement Projects, close-out involves not only demonstrating that the project deliverables are complete, but that the benefits from the project are also being realized sustainably, i.e., project closure and handover do not represent the end-point for the Project Manager although it will be for most of the Project Team.

1.6 Structure of the Guide

Figure 1.4 shows the structure of the Guide. Chapters 2 and 3 are applicable across an entire project life cycle. Other chapters cover a distinct phase of a project life cycle. Appendices are used to provide further information and background, e.g.:

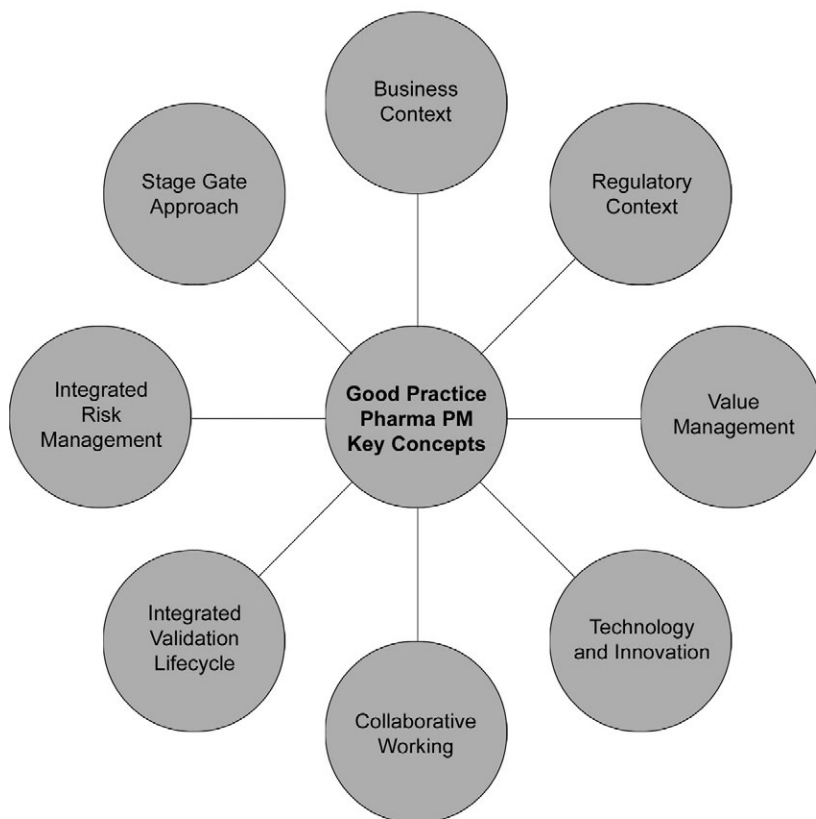
- Appendix 1 – either includes or provides reference to supplementary materials to give additional guidance in specific areas of project management.
- Appendix 2 – provides short case studies for a variety of projects to demonstrate how the guidance in this Guide can be applied.

Figure 1.4: Guide Structure

1.7 Key Concepts

The following key concepts (see Figure 1.5) are those which apply to all pharmaceutical project types and all parts of the project life cycle. They form the basis on which this Guide has been developed.

Figure 1.5: Key Concepts Summary



1.7.1 Business Context

A project is the result of an approved business case which demonstrates that its delivery will satisfy a business need within an acceptable cost-benefit analysis. Within a stable external environment, this cost-benefit analysis can be clearly linked to a defined scope and delivery approach which changes only in a minor way during the lifetime of the project.

Within the pharmaceutical industry, there are a large number of drivers which can affect the cost and benefit of a project. Project Managers have, therefore, a greater requirement (and responsibility) to have a formal benefits management process. This process can guide interaction with project sponsors and enable the management and delivery of the business case.

Benefits management in this context allows an organization to evaluate repeatedly all aspects of a traditional business case:

- **Cost** – the cost estimated at funding approval may be challenged as the external economic and political environment changes. Projects need to deliver cost effective solutions in an increasingly cost competitive environment. Organizations are cost conscious and operate in dynamic economic and political environments.
- **Scope** – as technology, regulatory, and competitive issues occur, the scope of a project has to be repeatedly challenged.

- **Time** – the importance for increased speed to market for new drugs has meant that most projects are under pressure to deliver faster while maintaining agreed cost and scope objectives.

The pharmaceutical industry is highly dynamic, with critical cost and time constraints within a shifting regulatory environment. Business expectations for a project often require consideration of risk and future needs on an ongoing basis, particularly where product pipeline flexibility is a key management goal.

The Project Manager's role involves managing the project business plan and linking that plan to regulatory requirements. A key part of that is to link several stakeholders through effective communications planning and delivery. If conflict or contradiction between business needs and regulatory requirements occur, Project Managers should educate stakeholders, including project sponsors, so that regulatory requirements are met.

1.7.2 *Regulatory Context*

Where applicable, GxP should be integrated into relevant activities to ensure that compliance risk is managed effectively and proactively. Regulatory policy can be dynamic. Project Managers should take note of changes in the regulatory climate that will be fundamental to a project's success.

Regulatory requirements are of high importance within the pharmaceutical industry. Compliance with specific industry regulations and local codes, legislation, and regulations is required. Failure to abide by these regulations can result in significant financial and operational penalties for a manufacturer. Managing a project's compliance to regulations is an essential undertaking to achieve success, but ensuring compliance can be complicated by fast track product and project development.

The pharmaceutical industry has adopted and embraced a systematic quality risk management process (as described by ICH (References 4, 6, 7, and 9, Appendix 3)). This process involves the assessment, control (risk acceptance or reduction through mitigating activities), communication, and review of risks to the quality of a product across its life cycle, and therefore, the risk to the patient. A quality risk management process provides an organization with effective and consistent risk-based decisions that will complement compliance activities and approaches.

Regulatory requirements should be managed throughout a project life cycle to ensure compliance. The key regulatory management functions include:

- **Regulatory Definition** – the identification of regulatory requirements early in the project life cycle and then the confirmation of the processes (see below) which will maintain these during the project. This includes compliance with GxP and other codes and regulations.
- **Management of Change** – the identification, analysis, and documentation of change occurs throughout the project and product life cycle. Within a project this process should proactively identify the extent to which a change may impact the ability for the project to successfully meet the regulatory requirements.
- **Management of Scope** – the identification and management of the scope required to successfully achieve the regulatory requirements. Within a project, this process should challenge the scope required to successfully meet the regulatory requirements while not necessarily essential to the success of the business case.
- **Quality Management** – to define the intended quality objectives and how to best deliver them (and the link to Quality Risk Management – ICHQ9 (Reference 7, Appendix 3)). This would typically involve processes to manage traceability and validation, for example.

Within a project management context, a Project Manager would not distinguish between the latter three functions; they are a part of the "business as usual" for a Project Manager:

- Change control is a process to manage cost, time, and scope.

- Scope management is a process to manage all aspects of the scope: quantity, functionality, **and quality**.

1.7.3 Value Management

Value management is a multi-disciplined process aimed at enhancing the value of a project from concept design through to final handover and use of the project outcome. The purpose of value management is to achieve the maximum benefit of an investment over the expected useful life of the project outcome based on resource availability and/or constraints. Value management is specifically targeted at the “business solution” rather than the “technical solution” (synonymous with Value Engineering). This methodology aligns with the principles of lean six sigma and requires the full participation from the customer, project team, and other key stakeholders.

The starting point for successful value management is a comprehensible scope, which allows the consideration of value from a specific project context. The value management process is a scope challenge process, i.e., the process aims to identify non-value adding activities, deliverables, or approaches, etc. Table 1.1 shows examples of what “is” and “is not” value management:

Table 1.1: Value Management Definition

IS Value Management	IS NOT Value Management
A cross-functional team based process that provides a ‘forum’ for the identification and evaluation of all design and project delivery options without constraint based on the definition of value for that project	A simple cost cutting process
The identification and elimination of unnecessary product cost (through elimination of non-value adding scope or approaches)	A design review
Encourages creativity, imagination, ingenuity and inventiveness with no restraints	Quality Control
A process that synergizes a better (a value added) solution	A consensus process
A Kaizen event	A regular project team meeting
A way of confirming and communicating project goals in support of an aligned project vision of success	A forum for individual agenda or preferential engineering

When performed successfully, value management can provide benefits such as:

- all assumptions are challenged
- documented proof that value has been added and integrated into the project at an early stage (typically pre final funding approval)
- a technique that recognizes both economic and intangible value
- the identification of missing cost or scope items
- the identification of risks and early discussions of how to manage them in a value-added manner
- a more competitive solution
- improved sustainability with respect to the environment

- emphasis on life cycle cost and equipment reliability

Life cycle cost is becoming an increasingly important aspect of value management and within this Guide, the term is used to describe the total cost of ownership over the life of an asset (e.g., building or equipment). Typical areas of expenditure which are included in calculating a complete life cycle cost include construction and acquisition, operations, maintenance, depreciation, and cost of finance.

1.7.4 Technology and Innovation

When managing projects, the introduction of technology and innovation should be considered in terms of its application to:

- The internal running of a project – when applied successfully, the performance of a project can be improved while reducing required investment.
- The project outcomes – in an environment where speed to market and cost are often conflicting primary drivers, technological and innovative solutions can become strategic enablers.

Key drivers for the introduction of technology and innovation include:

- a varied and expanding portfolio of products
- product and/or process improvement and remaining competitive (constantly reduce the cost of goods)
- the ability to accommodate new platforms and future generation technologies
- adaptability, flexibility, and interchangeability
- lower emissions and less environmental impact
- supply assurance with a less costly and simpler supply chain
- development of sustainable solutions
- innovative ways of working, including improved collaboration, communication, and information sharing for project teams
- streamlined approaches to technology transfer, process and equipment design, and testing of products, facilities, and processes

Optimum and innovative solutions may be achieved by avoiding traditional technologies; a solution which matches the context should be identified. For example, labor cost, product margins, and product volumes are considered when determining the appropriate level of process automation for a project.

Risk associated with using technology and innovation should be managed, e.g., confirmation that suppliers can provide appropriate support during ongoing use for the technology.

1.7.5 Collaborative Working

Collaborative working promotes the sharing of information and exchange of ideas to enhance overall understanding and enable stakeholders to achieve superior solutions.

A stakeholder is considered to be anyone who is influenced or affected by the project or who could influence or affect the project.

Senior stakeholders, the Project Manager, Project Team members, and Subject Matter Experts (SMEs), from stakeholder organizations, should be committed to collaborating constructively to help to bridge geographic, cultural, and technological boundaries. This working model should provide value-based solutions that are generated by the team, combining team success to solutions, and reducing time, effort, and cost over the project lifetime.

Characteristics of a collaborative working environment include:

- reciprocal respect of each stakeholder's viewpoints and expertise
- reduced risk of individual stakeholder failure and reward driving stakeholder ownership
- early and continuous involvement of all stakeholders with clearly defined roles and responsibilities
- communal decision making and innovation generation
- mutual perception of the project parameters and objectives
- avoidance of the duplication of effort and activities
- appropriate, timely, informative, and accurate communication
- an appropriate infrastructure

Processes which integrate these characteristics into a collaborative approach include:

- good communications planning and delivery
- robust development of team member roles and responsibilities
- development of pre-agreed business objectives for personnel involved in a collaboration

Project Managers and project sponsors should have the appropriate level of authority and capability to manage these processes (see Chapter 2 of this Guide).

1.7.6 Integrated Risk Management Approach

A risk-based approach should consider the variety of risks related to a project. This may include risks to the project, the process, or the product.

Chapter 3 provides details of the process of applying a risk-based approach across the project life cycle and how this links in with regulatory requirements. The project life cycle chapters demonstrate good practices within the context of the project stage being discussed.

1.7.7 Integrated Validation Life Cycle

The integrated validation process supports the management of the interaction between project management good practices and regulatory requirements. Validation requirements should be defined early and managed throughout the project life cycle. This approach is usually termed the “management of the integrated validation life cycle.”

The integrated validation life cycle should ensure that, where possible, validation activities are integrated into normal project activities. The project team, with SME support, should identify where GEP and GxP are applicable.

A Validation Master Plan (VMP) may be used to define and document a validation strategy at the start of a project. The VMP should:

- Define processes, testing, and documentation required.
- Define Critical Quality Attributes (CQAs).
- Define Critical Process Parameters (CPPs).
- Allow resource requirements to be determined (in terms of capability and capacity).
- Set the strategy to obtain documentary evidence and traceability from defined user requirements through design, testing, and acceptance.

Validation management can help Project Managers to:

- Integrate validation planning into the overall project delivery planning activities.
- Identify the SMEs required to support the validation process.
- Manage GxP risks through early development of mitigation strategies.
- Be assured that GxP has been integrated into the project outcome from an early stage.
- Streamline activities and avoid duplication during the project life cycle.
- Simplify project documentation, document approvals, and the flow of project information.
- Integrate reviews, checks, and decisions which assure that a project is moving forwards appropriately.

The integrated validation life cycle should continue after handover of the project outcome. Project Managers should ensure that requirements are defined to maintain the validated state of the project outcome following deployment.

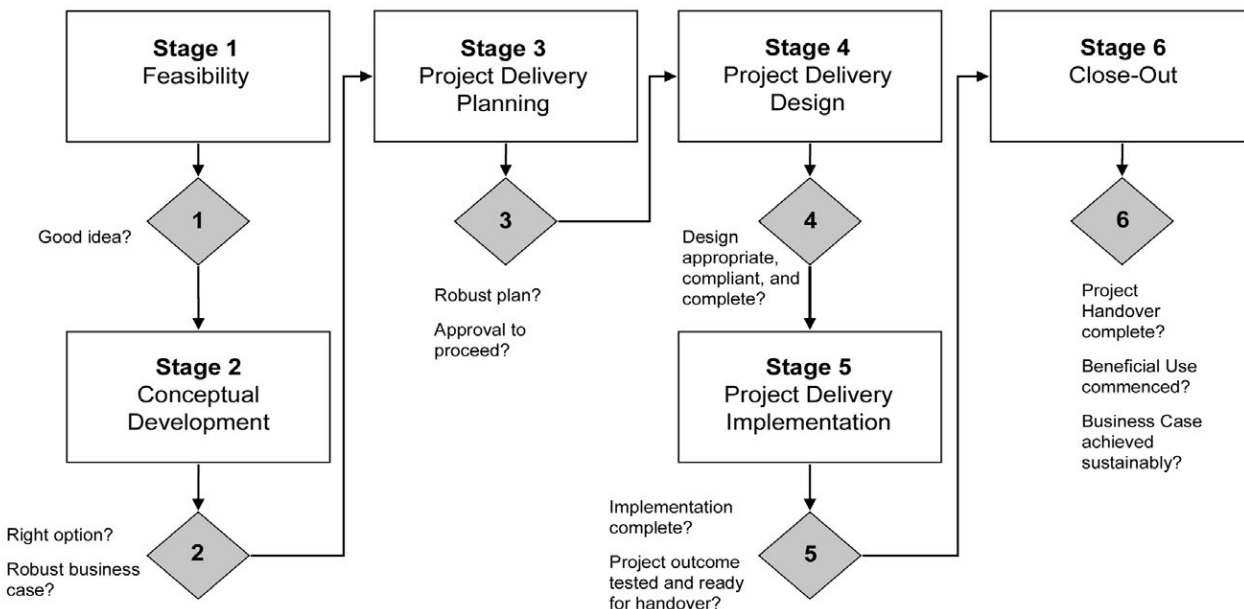
A key project management tool which supports the integrated validation life cycle is stage gate definition.

1.7.8 Stage Gate Approach

A stage gate approach is a project management good practice. Figure 1.6 shows an example of a project life cycle which has been divided into discrete stages.

Each stage is a bounded set of activities which deliver data to a stage gate decision. The stage gate decisions are go/no go points: A project has to pass through each stage gate to proceed to the next stage.

Figure 1.6: A Typical Project Stage Gate Approach



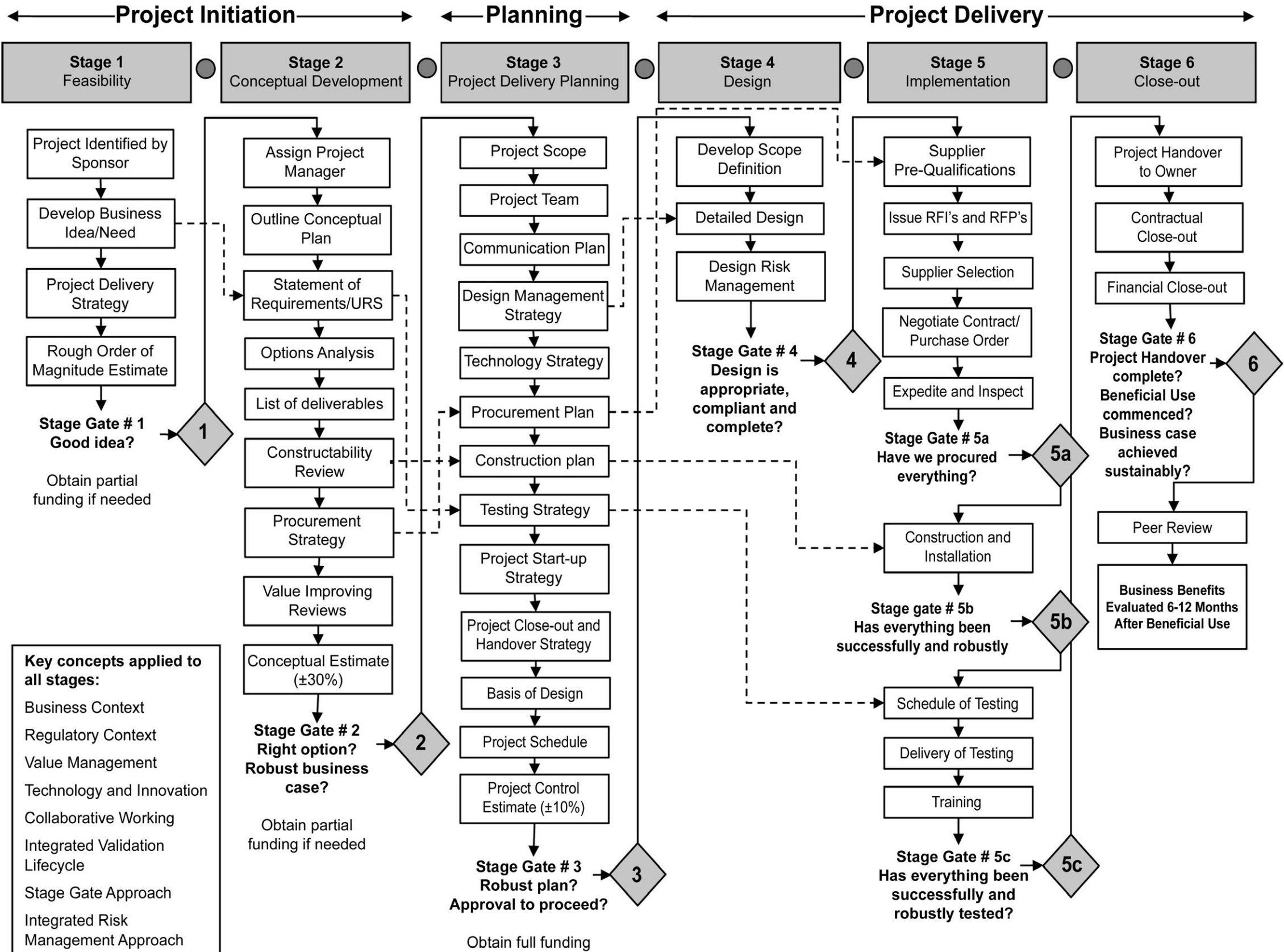
For this approach to be effective, each stage gate should have:

- **Inputs:** what needs to have been achieved before a decision can be made.
- **Acceptance Criteria:** the level at which the achievements are deemed to have been sufficient.
- **Value:** a reason why the hold point is required; why it adds value to an organization.

A project stage-gate approach can be used to develop clarity of scope and approach for a project team and key stakeholder groups. It can be used to develop an early view of the overall project time-line based on the key data needed at each stage gate and the decisions that the data can support.

This approach has been used throughout this Guide and Figure 1.7 expands upon Figure 1.6 making links to the contents of the Guide and the stage gate decisions within each part of the project life cycle.

Figure 1.7: Project Management Flowchart



2 People Management

2.1 Introduction

In a regulated environment, a wide variety of people and functions will typically be brought into a project, i.e., the project stakeholders as well as specialist subject matter experts. The interdependency of issues requires this wider variety of people and disciplines to interact, communicate, and collaborate effectively to deliver the intended project outcome.

The key areas of people management are:

- Roles and Responsibilities:
 - Defining the categories of project stakeholders, their roles and responsibilities, for effective management: The Project Manager, Senior Stakeholders, The Project Team, Consultants, and Contractors
- Knowledge Management
 - The extent of critical and/or confidential project information requires the definition of a project Knowledge Management Plan that addresses knowledge capture, knowledge sharing, and knowledge change management.
- Language, Communication, and Culture
 - Effective communication throughout a project requires the definition of a Communication Plan that addresses communication processes, defines the terminology and establishes the basis for a project culture.

2.2 Roles and Responsibilities: The Project Manager

Project Managers should manage communication, knowledge transfer, project goals, and maintain a conflict-free project delivery.

Within projects in the pharmaceutical environment, no matter the type, there is often a greater diversity of expertise required – both what and when. This is a challenge for the Project Manager who needs to be selected based on being able to cope with this diversity. A Project Manager has a continually moving team and is constantly making and realigning relationships; often managing through influence rather than power as matrix teams with part-time team members are used. Sometimes a Project Manager may not even be managing a face-to-face team – virtual teams are becoming more common when dealing with major organizational change projects where there is no one focal point in the organization for all the required resource. The establishment of a Project Management Office (PMO) is one way that organizations are handling this challenge; it allows implementation of a consistent project management process across an organization.

Some projects have part-time Project Managers or managers with minimal project management skill: they are selected for their technical expertise. While this is not an ideal situation, and may introduce risks to project success, it is often the reality. The Project Sponsor has a role to play in mitigating this risk and this is often through establishment of a Project Team with appropriate capabilities to manage any gaps.

Titles used for role of Project Manager can depend on project type and organization, e.g.:

- Project Leader (or Product Leader) may be used in R&D type projects.
- Project Director may be used in larger capital engineering projects.

- Program Manager may be used for large IT projects or programs.

Titles used may reflect the scale of the project or the hierarchy within an organization; roles or responsibilities can be comparable.

For other titles, see the Project Type Matrix (see Appendix 1). Within this Guide, the term Project Manager is considered to be the person responsible for delivering the successful project outcome.

2.2.1 **Project Management Capability**

Project Managers may need to coordinate a wide range of knowledge in pharmaceutical industry projects and may not be a Subject Matter Experts (SME) for the project type. Project Managers usually require the ability to ask the correct questions and to respond to those questions appropriately, by having an understanding of:

- how to deliver successful projects in this highly regulated industry
- the challenge of science driven projects

The criteria for the selection of Project Managers, the organization around the role, and the responsibilities within the role may vary considerably.

The complexity and criticality of a project in relation to its size, duration, and project type should be understood when considering appointment of a Project Manager. Aspects to consider include the:

- required project management capability
- required leadership skills

Example

A complex project for a new drug launch which is critical to an organization's future sustainability requires a different level of project management capability to that for a small maintenance shutdown project on an API Manufacturing Facility.

Criteria for project management capability in the pharmaceutical industry include:

Knowledge:

- Has knowledge of the regulatory context in which a project is to be delivered.
- Has knowledge of the project type in terms of the typical life cycle, risks, and key success criteria.
- Has knowledge of the critical pharmaceutical processes or technologies that constitute a large part of the project (desirable, but not essential), e.g., the validation process and requirements.
- Understands how to engage with people.
- Understands business drivers.
- Understands when to apply value managements tools and concepts.

Skills:

- Able to manage at all levels throughout the organization with strong communication skills and good cultural awareness.

- Possesses appropriate project management skills:
 - Hard skills, e.g., project delivery strategy development, cost, and schedule planning, risk management techniques, negotiation, progress management, etc.
 - Soft skills, e.g., team building and management, facilitation, communication, motivation, influencing, decision making, stakeholder management, etc.
- Has good business acumen and the ability to manage the project throughout the project life cycle or has good business acumen and ensures that the project delivers the specified benefit to the stakeholders.
- Possesses appropriate leadership skills, e.g., thinking strategically, resolving conflict, and managing key business relationships.

Behavior:

- Encourages innovative thinking and the exploration of ideas and approaches.
- Able to drive engagement, via team based decisions and other approaches, encouraging input and involvement while keeping the team focused on the primary objective of the project.
 - Project Managers should drive team commitment and steer that team toward achieving a project's objectives.
 - Project Managers should create and manage a team that will meet, and where possible, exceed expectations.
- Able to focus on the business goal.
 - Project Managers should work closely with the Project Sponsor and stay connected with an organization's strategic plans.
 - This normally requires strong communication skills and the ability to effectively manage both up and down an organization.
- Can build a project team whether in the same location or virtually.
 - Project Teams should be encouraged to think innovatively and should be provided with an environment for the exploration of concepts such as sustainability and life cycle cost. This may be assisted by familiarity with value management tools and techniques.
- Is an effective leader; demonstrates leadership behavior such as honesty and integrity and has the ability to be strategic and inspirational and to engage the team in the longer term vision of success.

Performance:

- Is experienced in managing senior stakeholders from a diverse scientific and business background.
- Has proven ability to understand and manage the expectations of a diverse group of stakeholders.
- Has demonstrated success in managing projects within the pharmaceutical industry (or similar highly regulated industries).

- Where a Project Manager has experience of project management, but not of the pharmaceutical industry or specific project type (e.g., subject matter expertise), a project organization should be created with the required subject matter expertise and a robust process for the Project Manager to engage with that expertise.
 - For smaller projects, a Project Manager may be responsible for delivering technical work packages or content in addition to project management duties. In such cases, project activities may be delegated to other members of the project team to allow sufficient time for the Project Manager to manage the project,
 - Where an SME is appointed as a Project Manager, the Project Sponsor (with project steering team support, if applicable) should provide additional support to manage the project management capability gap.
- Has proven success in delivery of project outcomes which generate sustainable business benefits,
 - Meets responsibilities in an ethical manner,

Project management capability can be developed by, e.g.:

- Knowledge accumulated by learning and experience in other project roles.
- Skills acquired through training and practice.
- Behavior adapted by changing attitudes or values.
- Performance enhanced through new experiences.

The key responsibility of a Project Manager is delivering the required project outcomes (Table 2.1), i.e.:

- Achieving the project objectives by balancing, cost, scope, and schedule.
- Enabling the realization of business benefits.
- Developing and managing a project team and all stakeholder groups.
- Management of all regulatory and compliance aspects through appropriate management of risk.

A basic project management tool which supports clarity in role definition is the RACI Chart. A RACI Chart (see Table 2.1) defines:

R = Responsible – who does the work to complete an activity or task

A = Accountable – who is ultimately accountable for the correct completion of the activity or task

C = Consulted – whose opinion is sought during the completion of the task

I = Informed – who is kept up to date about the progress of a task and/or its completion

Only one person can be accountable for an activity and only one person can be responsible (this can be the same person, if appropriate). The level of consultation (2-way discussions with others) and informing (1-way communication at completion of an activity) should equate to that necessary for the success of an activity and the project. Table 2.1 is an extract from a typical RACI Chart used to clarify the role of a Project Manager.

Table 2.1: Example RACI Chart – The Role of the Project Manager

Role →	Project Sponsor	Process Owner	End User	Project Manager	Project Team
Activity ↓					
Development of the project delivery plan (see Chapter 5 of this Guide)	A	I	I	R	C
Delivery of the project outcomes	C	I	I	AR	C
Achievement of project objectives (cost, schedule, scope)	C	I	I	AR	C
Enable the benefits to be realized	C	I	I	AR	C
Develop and manage team performance	I	-	-	AR	C
Develop stakeholder management plans	C	-	-	AR	I
Manage project risk	I	-	-	AR	C
Deliver regular project reports	I	I	I	AR	C

The RACI Chart would typically be an Appendix within the Project Delivery Plan (PDP) (see Chapter 5 of this Guide). The PDP is a core tool for a Project Manager; it is considered a “contract” with the Project Sponsor and a key communications tool for the Project Team.

Project Managers are usually expected to have a diverse range of skills and experience. A suitably qualified Project Manager may need to be appointed from outside an organization if none are available internally. All candidates should be interviewed in a similar way to ensure the appropriate person is appointed to the role.

- **The “Internal” Project Manager** – if expertise is available within an organization, a Project Manager may be appointed to the role of Project Manager.
 - This is frequently the case for smaller projects, especially those in which the Project Manager might also be responsible for delivering some of the technical work packages in addition to managing and leading the work of others.
 - When an internal Project Manager is appointed based on their technical expertise their project management expertise can be supported/developed by the use of a part-time project management consultant.
- **The “External” Project Manager** – when an organization does not have the expertise to manage projects it typically appoints an experienced consultant to perform the project management role.
 - Selected based on their experience in managing the type of project to be delivered..
 - Consultant Project Managers should have a suitable personality, attitude, and leadership style to deliver a project within an organization’s corporate culture.
 - The Project Sponsor should provide the context and support necessary to:
 - > Ensure the consultant Project Manager undergoes induction training and understands organizational ways of working.

- > Clarify that the consultant Project Manager is leading the project within the organization.
- > Allow the consultant Project Manager to manage the organization's staff effectively.

2.2.2 Key Project Management Challenges

Key challenges for the Project Manager include:

- The management of a diverse, science-focused team.
- The operation of virtual, matrix, or co-located task teams that are potentially diverse in language, culture, and capability.
- The management of complexity across a lengthy product life cycle often managed as distinct projects in series to deliver a robust process, an operational facility and a sustainable manufacturing business.
- The clarity needed in assigning responsibilities for effective project delivery (using tools such as the RACI Chart).

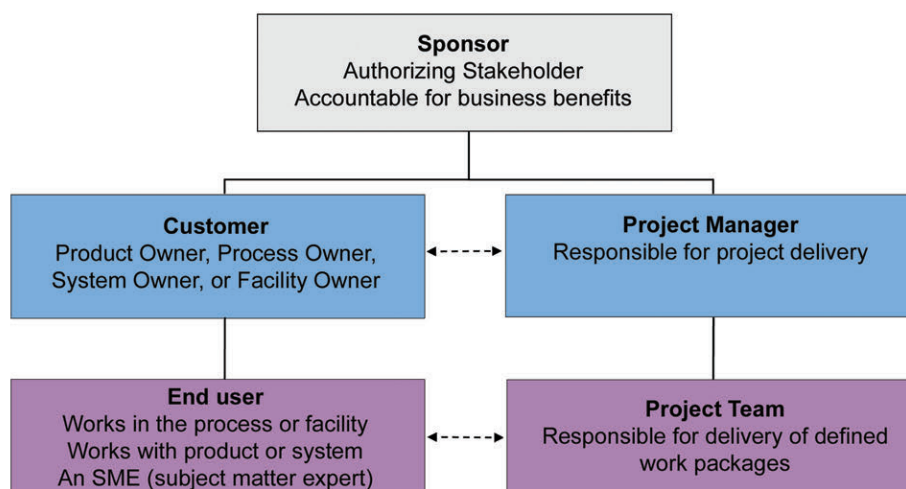
2.3 Roles and Responsibilities: Senior Stakeholders

Senior project stakeholders within the pharmaceutical industry normally have a technical background and focus on the patients for whom their products are intended. An effective partnership should be developed. The process of stakeholder management should involve the identification of those senior stakeholders who have both the authority and influence on the resources, pace, and direction of the Project and who have a technical or business driver for their involvement. The three key senior stakeholders can be categorized as:

- The Project Sponsor
- The Customer
- The End User

Figure 2.1 shows the relationship between these key senior stakeholder groups.

Figure 2.1: Stakeholder Relationship Map

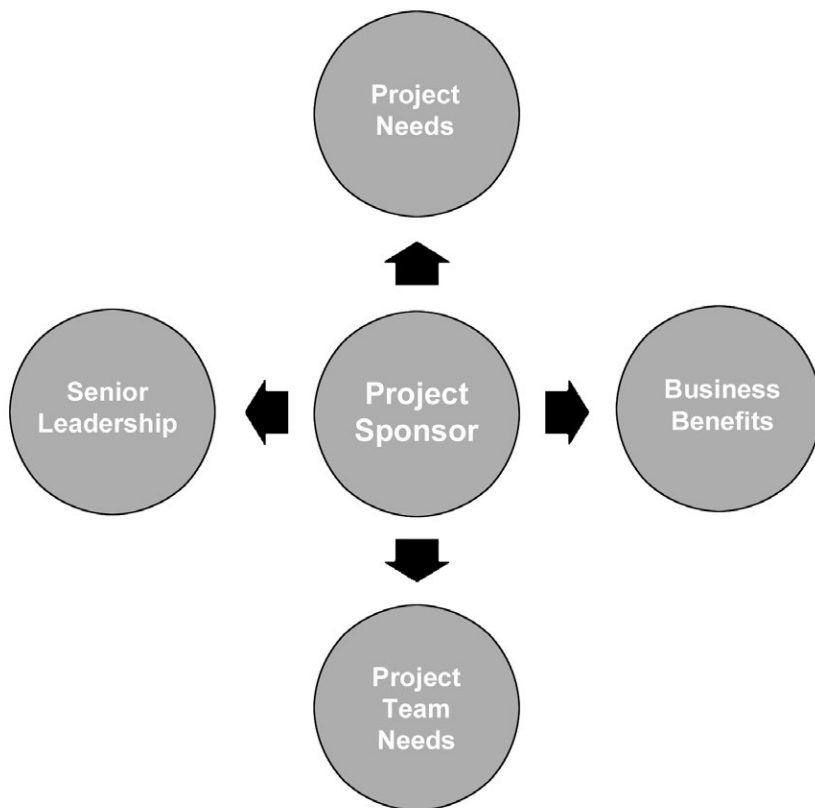


2.3.1 *The Project Sponsor*

The Project Sponsor should have the authority over the part of the organization being changed by the project. The Project Sponsor should:

- ensure the Project Team receives all the support and resources necessary for a successful delivery and is managed appropriately
- be an advocate for the Project Manager and Project Team
- provide guidance and support to the Project Manager
- manage Senior Stakeholders in line with the Stakeholder Management Plan
- act as a buffer between the Project Team and Senior Stakeholders to prevent the Team from being distracted or receiving information or guidance that could be misleading
- remove obstacles to project success: this may require close interaction with Senior Stakeholders
- mitigate all organizational issues which could undermine a successful outcome for a project
- approve the scope of the project and conducts regular reviews to ensure that the project meets both its technical and business objectives while being managed appropriately
- develop the External Communication Plan for the Project in liaison with the Project Manager and handle communication to and from the senior stakeholders within an organization
- create and ensure commitment to the project within the Customer's organization
- champion the project through the approval process and thereafter to completion/handover
- be a link between the project and the business at all times: remain actively engaged and identify current strategic information that could affect the project
- monitor the external environmental: assessing the "fit" of the project to the business on an ongoing basis
- obtain additional funds from the original approving authority (once the scope of the project is established and final funding received) before making substantial scope changes outside the approved/funded scope of a project

The role of a Project Sponsor can be summarized in four key areas, described in Figure 2.2.

Figure 2.2: Role of the Project Sponsor

The Project Sponsor is:

- accountable for the delivery of sustainable business benefits from the project
- responsible for confirming that the project meets business needs and is delivered within cost and time parameters within the customer's organization
- responsible for key decisions:
 - stage gates (project go/no go points)
 - resources (people, funds, assets)

Project sponsors may require training to help them prepare for the role. Project sponsors need to balance their project sponsorship role with their primary business role. This potential conflict of objectives can be detrimental to a project. Lack of support and guidance from a Project Sponsor may prevent a project from achieving its objectives.

2.3.2 The Customer

Within this Guide, the term "customer" refers to the actual group who will use the project's outcome to support achievement of business objectives. From a project perspective, the product, process, system, or facility owner is the customer. On smaller projects, the customer and Project Sponsor could be the same person. The Customer:

- requires the project outcome: the project deliverable
- should be able to express the benefits of the project and set the business acceptance criteria by which the project's completeness can be assessed at the end of the project

2.3.3 *The End User*

The End User is the customer's representative who has detailed knowledge about how the project's key deliverables should perform during operation. Key End Users (i.e., SMEs) have knowledge or experience which is valuable to the project team. In this regard, they are also key customers for the project team. The End User and the project team should collaborate to ensure that user required functionality is integrated into the project design and testing. The End User group should include representatives from other functions within the customer organization, as required by the project scope. For example, manufacturing projects end users would include Quality and Compliance. The End User:

- helps the Project Manager and Project Sponsor to define the project's objectives and develop the business case
- works with the Project Team to develop the User Requirements Specification (URS) (see Chapter 6 of this Guide)
- provides expert guidance and advice to the project team during design and delivery to reduce risk
- has access to SMEs in other areas of an organization and ensures their involvement, as required
- may have a role in the review and acceptance of activities during the project such as acceptance testing or formally accepting ownership of the project's deliverables once the project has been completed
- may have a role in confirming the business acceptance criteria have been met (this depends on the role of the Customer)

2.3.4 *Senior Stakeholder Management*

A Project Manager should develop a Stakeholder Management Plan to manage stakeholders, based on the analysis of:

- involvement of stakeholders in the project or in the use of the project outcome
- stakeholder influence on the project outcome
- stakeholder authority to give or withhold critical resources which the project requires
- stakeholder support or resistance to the project

Stakeholder management then goes through four basic phases:

1. Gaining Entry – making initial contact.
2. Contracting – clarifying and agreeing roles and responsibilities, decisions and information flows, etc.
3. Engagement – meeting the agreed “contract.”
4. Disengagement – agreeing that the “contract” is complete (at project end and/or when benefits have been realized).

Stakeholder management tools include:

- Role Identification Tool: Stakeholder Mapping
- Role Definition Tool: RACI Chart (see Table 2.2)
- Role Management Tools: Stakeholder Maps, Relationship Maps, RACI Charts, etc.

The RACI Chart is a good practice tool for the definition of responsibilities. The RACI Chart can also be used at project launch to help to plan how the group of senior stakeholders and the project team will work together, and to agree and communicate definitions on key activities. The RACI Chart may be considered a customer communications plan and a first step in customer relationship management.

Table 2.2: Example RACI Chart – Defining the Role of Senior Stakeholders

Role →	Project Sponsor	Customer	End User	Project Manager	Project Team
Activity ↓					
Defining the projects objective, business context, and rationale	A	R	C	C	I
Establishing and prioritizing the projects business objectives	A	R	C	C	I
Representing the projects interests and ensuring the project is allocated sufficient resources and priority within the customers organization	AR	C	C	C	I
Chair the Project Steering Committee	AR	C	I	C	I
Develop the Projects Business Case	AR	C	C	C	I
Define and establish the roles required to complete the project	C	C	C	AR	C
Manage project progress	C	I	I	AR	C
Remove organizational road blocks that might impede the progress of the project	AR	C	C	C	I
Endorse any Project scope changes	AR	C	C	C	I
Communicate impact of project on the business	AR	C	C	C	I
Ensure project benefits are realized throughout the life of the project outcome (immediate post project review)	A	R	C	C	I
Formally accept the completed project	A	R	C	C	I

Note for Table 2.2: The example RACI Chart represents a situation where all senior stakeholder and project team roles are within one organization. When defining roles and responsibilities, the potential effect of contractual boundaries should be considered.

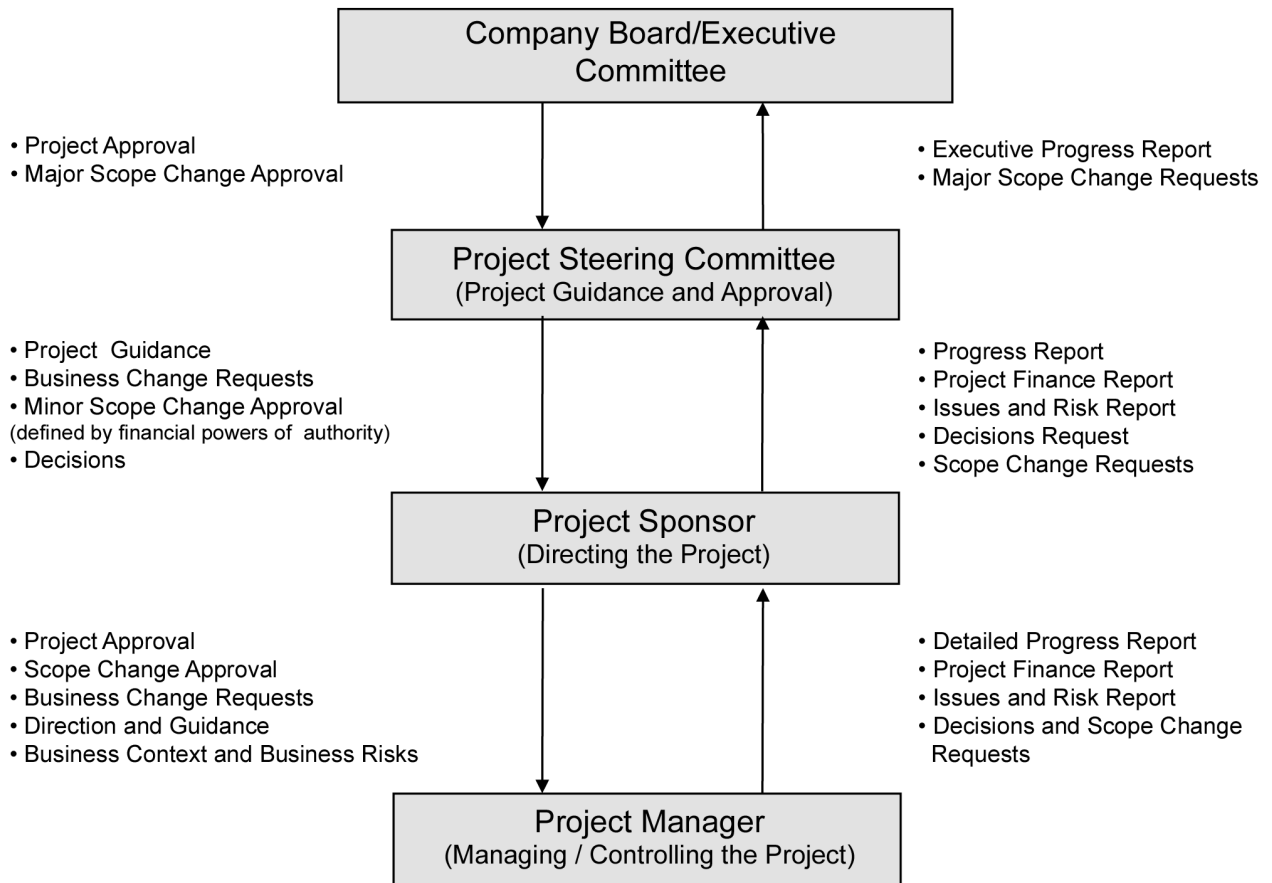
The defined roles form the Project Manager's basic stakeholder map. A stakeholder is anyone who is influenced or impacted by the project or who could influence or impact the project. The stakeholder map is considered a key customer relationship management tool and can be fundamental to managing business change issues.

2.3.5 Project Steering Groups

A project specific steering group or committee may be created to support management of key customer relationships. Figure 2.3 shows an example communication map and reporting structure for a typical project steering committee.

Steering committees should be formed at the beginning of a project and typically consist of senior stakeholders. The Project Manager should report to the Project Sponsor who chairs the steering committee.

Figure 2.3: Project Steering Group Structure



The roles and responsibilities of the steering committee typically include:

- acting as the ultimate decision taking body for critical project issues
- ensuring that adequate resources are available
- deciding on appropriate contracting models
- deciding on the utilization of the cost contingency
- providing recommendations to the organization's board/executive committee for investment approval
- steering the direction of the overall project
- nominating a Project Manager

- decisions regarding any changes to the project budget, timeline, and scope (quantity, quality, and functionality) following approval
- select the most suitable alternatives (usually presented by the Project Manager on behalf of the project team)
- providing guidance and feedback to the Project Manager and team, resolving disputes and ambiguity

In systems or process change projects that cover multiple areas of a business, it may be beneficial for the steering committee to remain together after delivery to allow on-going decisions related to system changes and updates.

Example

During the delivery of a new ERP system to controls production, sales, and financials, it was impossible to assign a single system owner; therefore, a steering committee was formed. This group of Senior Stakeholders was effective in steering the direction of the project and making timely decisions. Upon project completion, the group decided to remain “active” in order to steer any future system changes and ensure the sustainability of the project benefits.

2.3.6 Project Ownership

The handover of the project outcome should be discussed by the Project Manager, Customers, and End Users from the very start of a project. Early stakeholder discussions should include the transition of the project outcome into the business, e.g.:

- identify the business changes needed and responsibilities for their delivery, i.e., are they within the project scope or are they to be delivered by the business at handover
- identify potential compliance risks
- identify people and business process issues, e.g., the need for operational documentation to be developed, such as manufacturing procedures
- identify infrastructure issues, e.g., the need for more purified water

Example

A newly developed drug product is handed over for production within an existing manufacturing facility.

- Additional operators were recruited to operate the new process due to an increase in the number of manual operations.
- The new operating procedures were handed over.
- In process sampling and testing procedures were agreed.
- The facility team trained operators to manufacture to the new procedures.
- The support functions (quality, warehouse) were involved in handover discussions so that they could manage their own business changes.

2.3.7 Business Change Management

When a project is approved, it is typically because the business requires some form of business change. The project delivers outcomes which, when used by the business, supports delivery of this change thus realizing benefits of value to the organization.

Completed projects can lead to:

- new ways of working
- requirements for new capabilities and skills
- new organization structures and responsibilities
- new roles and will have an impact on resource levels

Managing the related business changes is a part of the project management scope. This includes the identification of the business change and also gaining support for successful delivery, often by resources outside of the Project Team.

Within the pharmaceutical industry, changes to the business also have to ensure compliance to regulatory requirements. This requires:

- Organizational change control documentation. This is documented proof that the project's outcomes meet regulatory requirements; that quality risk have been eliminated or reduced to an acceptable level, and that the new ways of working are reproducible and repeatable.
- Training – to enable people to operate according to the revised ways of working.
- Sustainability – checks that the new ways of working are being maintained.

Example

A laboratory business change project was implemented to decrease the time it took to test final drug products. The project changed the laboratory layout, the way samples were managed, and the way testing was completed. The success of the project was due to the early identification of key areas of business change requiring support from the laboratory team:

- an understanding of current ways ("as is") of performing tests
- an understanding of Good Laboratory Practices (GLP) or other applicable regulatory requirements
- assurance that the team would implement the new ("to be") ways of working

The Project Manager developed a project delivery strategy which engaged and involved the laboratory end users:

- The laboratory team, SMEs in this area, and representatives were asked to join the Project Team.
- The initial workshops involved all of the laboratory team as a way to collate issues or any differences in current ways of working.
- The laboratory team was involved in the design of the "future state."
- 2-way communication using the lab team representatives was a continuous process during the project delivery.

As a result of the business change strategy used, the project successfully delivered the required reduction in testing time and was able to sustain this improvement following project completion.

Inevitably, there can be resistance to change. Resistance is a natural human reaction to change; however, in a project, it needs to be managed so that the project's goals (both compliance and business objectives) are achieved and sustained. Key strategies to minimize and manage change resistance include:

- open communication with the affected business area through all phases of the project
- participation from all or some representatives of the business area; these may be SMEs and should be part of the project team

- development of handover strategies from the start of the project
- development and delivery of training programs
- robust stakeholder management planning and engagement (see Section 2.3.4 of this Guide)

The project team should develop the project scope with a clear understanding of the current (“as is”) business situation, so that the project is seen as solving current issues, and to highlight the benefits regularly throughout the project to maintain engagement of the End Users.

2.3.8 Key Project Management Challenges

Key senior stakeholder management challenges for a pharmaceutical project can be summarized as shown in Table 2.3.

Table 2.3: Key Customer Management Challenges

Challenge	Comments	Impact?	Mitigation Plans
Project alignment with business objectives	Business objectives change over time. Project sponsors are responsible for ensuring the project objectives remains aligned with the business objectives and to initiate any scope changes that may result from the changes in these objectives.	High	Regular Project Manager-Project Sponsor meetings should be held to ensure alignment between the internal project environment and the external business environment.
Poor communication between the Project Sponsor and project team	Project sponsors can also be an SME and involved on a day to day basis with the team.	Medium	The Project Sponsor should understand the dichotomy of these roles. This should be managed, as Team members may not see the distinction.
Changing key project members during the project delivery	Key SMEs can be moved from project to project due to changing priorities. This can cause risks to individual projects, if done without adequate knowledge transfer and without regard to impact on a project team.	Medium	The Project Manager should outline key SME roles and agree how SME redeployment (if necessary) should be managed.
Selecting the wrong Project Sponsor	Project sponsors need to have the appropriate authority in the area being changed by the project. This may not be the most senior person available or person who has the most interest, knowledge, or expertise in a project is selected.	High	Project sponsors should be selected from persons who have the appropriate authority in the business area being changed by the project. The Project Sponsor may need to be changed to someone with the appropriate authority.
Key stakeholder not adhering to the agreed terms of engagement	Inexperienced project stakeholders can be involved in projects.	Medium	A specific RACI Chart should be developed and a “contracting” session should be conducted.

Table 2.3: Key Customer Management Challenges (continued)

Challenge	Comments	Impact?	Mitigation Plans
No defined Project Sponsor	Small projects or large complex technical project may not have a single point of accountability.	High	A Project should have a Project Sponsor who is accountable for realization of the project deliverable and benefits, who is “active” and understands the role.
Poorly defined roles and responsibilities	The Project Manager should ensure that the project team understands their roles and responsibilities, to avoid duplication of effort, conflicting priorities, and aspects of the project being missed.	High	Formal roles and responsibilities should be developed, preferably using the RACI process described in Section 2.3.3 of this Guide.
Insufficient project team members with the correct expertise	Project team members should be appointed based on skills and/or authority to operate in the role, rather than status.	High	Project sponsors should understand and support the Project Manager in the selection of staff with the appropriate level of skill and authority.
Have resource available with strong knowledge of GxP and other regulations	A resource with knowledge of GxP and other regulations should be available to ensure the project is compliant with regulatory requirements and regulatory deliverables are optimized.	Medium	Appropriate regulatory expertise should be engaged when establishing the project team. Expertise may be obtained from within an organization or outside an organization.
Unrealistic expectations of project cost and schedule	Inexperienced Project sponsors may set unrealistic “stretch” goals with regard to a project’s schedule and budget.	High	The process of building project budgets and schedules should be transparent to both the Project Sponsor and Project Manager and methods of schedule acceleration should be openly discussed.
Diverging Process Owner priorities	Customers can be two different process owners, e.g., in developing and transferring a drug to a scale up facility there is usually a facility owner and a product owner.	High	Recognize that the project deliverables are going to two different owners. The Project manager should contract with both owners to understand, define, and align priorities.

2.4 Roles and Responsibilities: The Project Team

Team members need to understand their Subject Matter Expert (SME) role, and also the need to balance deliverables and expectations with cost and schedule, as the Project Manager does. They may need to be coached into joint ownership of project delivery within the sanctioned project constraints and this requires selection of a suitable coach and possibly provision of additional formal training. Being a member of a project team is different from the role of supporting production from a QA, Validation, or Operations position, yet team members might not understand this. Project success can depend upon this cross functional participation and team members may need additional training or support to contribute properly. These and several other people considerations will be discussed further in this chapter. However, above all, for project team members to be successful they need to be capable, available, and have the authority to undertake their defined roles and responsibilities. The Project Manager must ensure that this happens and recognize and manage the risks when it doesn't.

This section looks at the team structure for a project, but it should be noted that the structure may change as a project matures. For the purposes of this Guide, a “team” is defined as:

- “Two or more individuals or functional units that join together to achieve a common goal, either under a permanent or temporary organizational structure.”

As the scope of a project increases the number of people supporting the project (either full or part time) and the number of relationships to be maintained also increase. Project Managers have a key role in the management of people and these relationships:

- The Project Manager defines a team structure which is communicated by project organizational chart. This is led by the project manager and any team member within the chart is managed by the Project manager. This is the vertical structure that defines the team depth.
- The Project Manager also determines additional support needs. These are not typically documented within the project organizational chart and may not be managed by the Project Manager. This is the horizontal structure that defines the team breadth.

The scope of work may be divided into specific areas or sub-projects with each being assigned a defined set of deliverables. A resource plan, such as supported by a RACI Chart or Role Profiles, should be developed for each area and sub-project; this should state the roles and responsibilities of team members.

In larger projects, the project life cycle may be divided into phases. As a project evolves, project participants may change or their roles may change within the project. This process needs to be defined and managed.

In a given project phase, the Project Manager can decide to divide the resource plan and/or organizational chart differently than in earlier or later phases. For example, during the engineering design phases of a Facility Project, it is usual to organize a project by function, whereas during the construction or implementation phase, a project may be divided into geographic areas or systems.

It is the intent of this section to reinforce existing concepts and introduce new ones that will address the following questions:

- How should a Project Manager structure the project team roles and responsibilities to deliver project scope?
- How should a Project Manager determine the size and type of team required to meet the project objectives?
- How should a Project Manager determine which roles are most critical to project success and how best to staff those roles?
- How should a Project Manager determine and manage the needs of the project team and balance those against project objectives?

These questions are critical activities which should be considered early and re-evaluated regularly throughout a project's life cycle. The term “team” should be predefined. The Project Manager should identify, formulate, and manage the team, including delegating activities appropriately to team members.

2.4.1 Critical Activity #1 – Structuring the Project Team’s Roles and Responsibilities to Ensure Delivery of the Project Scope

Project Managers should:

- Understand the scope of a project and be able to assess resources needed, establish budgetary estimates, and determine schedule duration. The project scope should be documented.

- Ensure that a project team has a clear and complete understanding of the scope of a project.

Team member's roles and responsibilities should be established early in a project life cycle to help ensure a project's success. Using a RACI Chart can be beneficial, e.g., the definition of responsibilities supports the establishment of communication and reporting structures.

Typically, an outline project scope is developed by a small team of experienced senior staff. The Project Manager should use the outline scope to develop an executable plan which identifies the expertise and resources required to deliver the project. For further information on the development of scope, see Chapters 4 and 5 of this Guide.

Once the scope has been allocated by functional groups and resource types, the roles and responsibilities should be clearly documented and communicated to team members. This is the basis of establishing a team.

Where external resources are used extensively as Subject Matter Experts (SMEs), team members from within the organization may "shadow" the external SMEs. This practice can support project turnover (see Chapters 9 and 10 of this Guide), but should be evaluated against the project schedule and budget, as well as demands placed on other responsibilities of team members from within the organization.

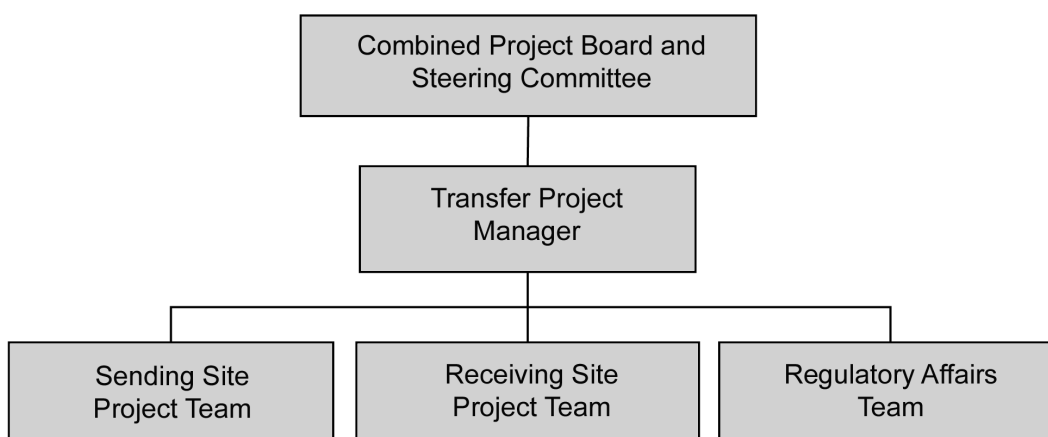
Assigning specific tasks to team members from within the organization, with SMEs providing mentoring and training, can be a more effective relationship.

2.4.2 **Critical Activity #2 – Determining the Size and Type of Team Required to Meet the Project's Objectives**

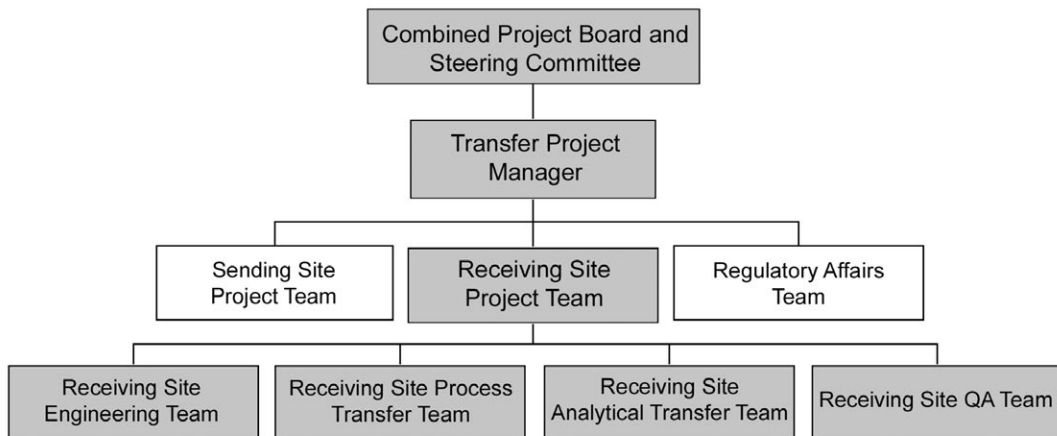
The project scope determines the type, size, budget, and duration of a project team. This is demonstrated using an example of a project for transferring production from one manufacturing site to another.

At a high level, the project may be organized into teams as shown in Figure 2.4.

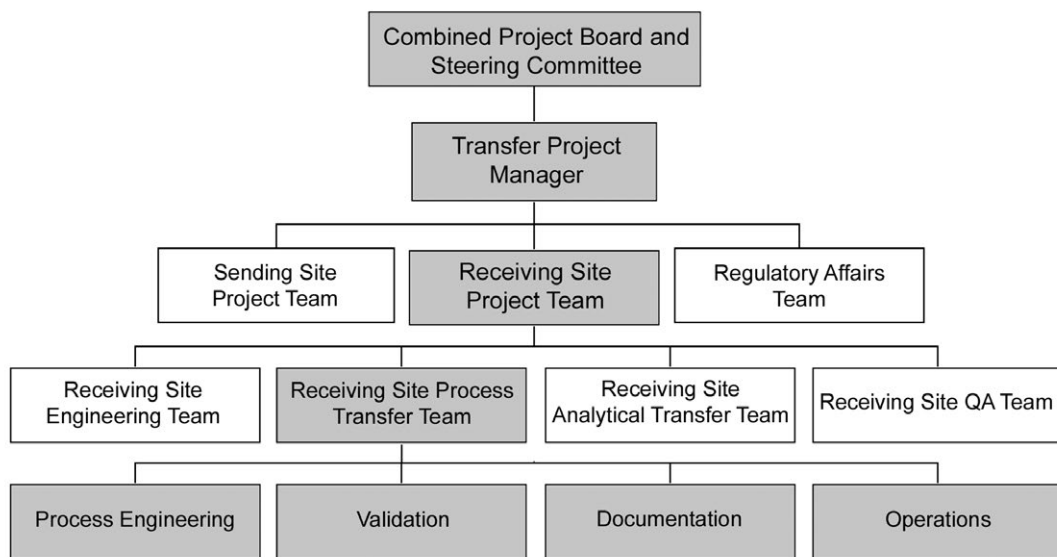
Figure 2.4: Typical Technology Transfer Project Team Structure



As shown in Figure 2.5, this team structure can be broken down into the sub-teams required to deliver various aspects of the project's scope.

Figure 2.5: Typical Technology Transfer – Receiving Site Project Team Structure

Each of these sub-teams may have a further sub-set of smaller teams, as shown in Figure 2.6.

Figure 2.6: Typical Receiving Site Process Transfer Team Structure

Project Managers should determine the best way to structure a project, regardless of the size of the project team.

The following steps provide an **example** for determining the size and type of team required to meet a project's objectives.

Step #1 – Determining Functional Needs

Functional areas needed to support the project should be listed. This list should help to define the skill sets and expertise required, but without determining hours of effort, budgets, or schedules. Roles and responsibilities for the project should have been identified previously to allow the required functional areas to be established.

The conceptual structure, defined during this step, may contain functions that can be achieved by the Project Manager or the project management team.

Step #2 – Defining the Project Management Role

Project Managers should develop the organizational structure considering the project requirements and the tools and methods appropriate to the stakeholder organization. Tasks such as scheduling, cost control, procurement, and document control may be included in the Project Manager's role, depending on the size and/or complexity of the project. Project Managers should balance such a workload with the requirements of managing the project. When staffing the project, Project Managers should ensure that other team members are able to provide support for these project management tasks.

Leadership is a core competency for Project Managers; management of activities is as critical as the execution of those activities.

Step #3 – Consolidating Remaining Functional Roles

For the remaining functional roles, the Project Manager should try to group like tasks into organized groups. These groups may be aligned with typical project responsible areas, e.g., in a Facility Project:

- Project Management (PM)
- Design (D)
- Construction (C)
- Testing (T)
- Operations (O)

Depending on the project type, other responsible areas may be required, e.g., Regulatory Affairs, R&D, or IT.

Step #4 – Re-Evaluation of Roles and Responsibilities

It may be beneficial for Project Managers to re-evaluate the roles and responsibilities to demonstrate the appropriate division of labor across the functional groups. The roles and responsibilities should be sufficiently detailed to identify any gaps or responsibilities not aligned with the project's scope.

Step #5 – Determining Contract Scope

This step allows the Project Manager to determine which functions can be managed internally by a Customer's personnel, and which functions need to be contracted out.

Identified functions can be organized into two groups within the project team:

- one for identified functions **“to be managed internally”**
- one for identified functions **“to be contracted out”**

This is a critical activity and will be the basis for determining a project's associated labor budget and the Project Manager should gain commitment for the “to be contracted out” scope of work.

Projects may be staffed entirely internally by an organization. Where projects require additional contract support, the internal versus contract scope of work needs to be defined and agreed in order to determine an accurate estimate of associated costs. For further information on the development of an appropriate contract strategy, see Chapter 7 of this Guide.

The internal groups and resource required to support a project should be determined early in a project. Draft roles and responsibilities should be shared with internal groups to enlist their support. Internal capabilities should be verified to ensure that assumptions made in developing roles and responsibilities of internal groups are addressed before outside support is contracted. Potential additional contract needs should also be identified.

The reporting structure and employee evaluation of internal staff assigned full-time to a project should be moved temporarily to the Project Manager. This should allow the Project Manager to manage full-time team members and assign team members' job function and goals. A matrix management approach to personnel management may be required in virtual, multi-site, and multi-national teams.

Example

During a facility improvement project, the overall project budget was established prior to the development of the detailed labor estimates. This delivered a staffing approach that met the available funding, but not necessarily the technical or compliance requirements.

The Project Team should be staffed with individuals having the necessary technical competencies to deliver the project scope. Less experienced individuals should be placed with those with more experience. Project Managers should identify skill sets required and conduct value management activities to correctly size the team, offer project specific training, mentor project team members, and maintain a project team focused on scope delivery.

Step #6 – Determining Duration of Functional Support

The duration of functional support required to support the project should be determined independent of how much time is needed at each stage. One approach is to mark on an outline project milestone schedule the functional groups required to support each project stage.

Typically, major milestones align with project life cycle stages, e.g., for a Facility Project:

- Conceptual Development
- Project Delivery Planning
- Detailed Design
- Procurement
- Construction – if a capital engineering project
- Testing
- Close-Out and Handover

This activity can help to develop an understanding of the hours of effort required to deliver each project life cycle stage and establish project staffing requirements. Functions may span multiple life cycle stages or may appear in non-sequential stages. This exercise should form the basis for identifying the structures of the project team throughout the life of the project.

The six steps above should allow Project Managers to organize team structures defined by Team Depth (Project Assigned Staff), Team Breadth (Project Support Staff), and Team Length (Duration of Assignment).

Step #7 – Determining Team Depth (Project Assigned Staff)

Steps #1 to #6 should help Project Managers determine the functional areas that will fall under their management structure. Typically, project structures are shown as top down reporting schemes; however, alternative methodologies can be employed. For the purposes of this Guide, a general structure of an organizational chart is assumed (see Figures 2.4, 2.5, and 2.6) with the intent to show both the reporting structure and the functional division of labor and responsibilities. Organizational charts should be included in the Project Delivery Plan (PDP) and communicated to all team members and the Project Sponsor. For further information on PDPs, see Chapter 5 of this Guide.

The depth of the team should be based on an evaluation of the level of staffing and level of skills required in completing the scope of work of a project. For example, a senior procurement manager may support the project throughout its entire life cycle, but it may be supported during peak workloads by a sub-team of procurement experts, etc.

The number of team members required to support a project is dependent on:

- the scope of work
- workload estimates
- available resource schedule analysis
- identification of roles and responsibilities
- skills and experience of key team members
- the division of available budget

Step #8 – Determining Team Breadth (Project Support Staff)

The functional areas not managed directly by the Project Manager, but supporting the delivery of the project, such as quality assurance, finance, or maintenance management, etc., form the breadth of a project and represent how the project scope can affect many areas of an organization. Communication should be managed, as these functional groups may not have close contact with the core project team. Individuals should be designated in the vertical (core) team structure with responsibility for maintaining linkage with the wider team so that information and communication can be managed and distributed as needed.

Correct sizing of communications becomes important where there is a mix between part-time and full-time team members. Full-time members are usually better informed. Part time members may lose connectivity and may become inefficient. A comprehensive communications plan should be developed to mitigate potential inefficiencies (see Section 2.7 of this Guide).

Project team members from a customer's functional organization may support more than one project in addition to normal working. The time required to be committed to a particular project, as a team member, should be planned, allocated, and documented in their annual objectives. Project team activities should be integral to an individual's annual objectives and be evaluated during performance reviews. This should help to ensure the team member's contribution is understood by both the project and customer leadership.

Other functional areas may not appear on the project structure or organizational chart. However, the activities that those areas need to perform to deliver a project should be identified and communicated to ensure that their roles and responsibilities are included in the PDP. For further information on PDPs, see Chapter 5 of this Guide.

Step #9 – Determining Team Length (Duration of Assignment or Support)

The duration of the different project life cycle stages may not be fixed during the early stages in project planning, but the level of effort required during the specific stages should be estimated.

There are several methods for communicating and representing the durations needed for functional groups during a project timeline. One of the simplest is to connect the start and end of involvement to specific project milestones and to highlight which milestones are on the schedule critical path.

These milestones should bookmark the major level of effort required by the functional groups. Groups may need to become involved prior to the start of their activities, especially during schedule development, or planning activities where time is required to significantly increase resource levels for a specific activity. Functional groups may also be involved after their primary responsibilities have been completed. The staffing plan should account for this.

These steps help the Project Manager develop a detailed view of the overall project team structure.

2.4.3 Critical Activity #3 – Determine Which Roles are Most Critical to Project Success and Determining How Best to Staff Those Roles

For functional groups with the longest time span across a project's life cycle, the Project Manager should consider performing a capability and capacity risk assessment to evaluate and mitigate any potential risk associated with lack of appropriate resources.

Functions identified as critical to project success are likely to have the highest resource budget and most scheduled items to manage. Typically, they will be on the schedule critical path, and represent potential risk to the project schedule and quality. The critical requirements of the key positions within project teams should be identified. The Project Manager should ensure that individuals chosen to fulfill these roles are suitably qualified, experienced, and sufficiently skilled to perform the designated function.

A project culture which aligns philosophies and management practices should be established early in the staffing life cycle. This should help to ensure ownership from key project team members and allow them to build sub-teams with team members who fit the project culture and can work together as necessary (see Section 2.7).

Key project team members form the core project team in the vertical project structure and should commit to the project scope and vision of success. The Project Manager should act as the interface between the core project team and the horizontal cross-functional team.

The core project team should communicate effectively with others and be available for the complete duration of their assigned roles and responsibilities. This may be achieved through the development and distribution of the project charter by the core team (See Appendix 1).

2.4.4 Critical Activity #4 – Determining and Managing the Needs of the Team and Balancing Those Against Project Objectives

Team members may be required to follow rigid processes in their daily job function, whereas in a project role, they may be required to adopt a more flexible way of completing their responsibilities. These differing role requirements can lead to conflict, as:

- Projects are less predictable and have a higher level of uncertainty.
- Projects can have changes of direction, as uncertainty is clarified.
- The project team has a definite start and end date and a focus on project outcomes.

- Project team members usually have differing skills and experience.
- Processes may be customized for a specific project (defined within the PDP).
- The Project Manager may not be an SME or an expert on the business area or the technology.
- Project participants may not have sufficient time allotted for project work.

Resource gaps can occur where insufficient time is allotted for project work.

Project environments are usually:

- high pressure, and therefore, more stressful
- less certain and require more flexibility, and problem solving and creative skills
- more transient in terms of developing relationships

Issues to be considered include:

- personnel being unclear about their role
- frustration from repetitive changes of direction
- loss of perspective
- lack of availability of key personnel
- splintering of a team into small groups who work independently and inadvertently deviate from project scope
- insufficient time to complete tasks
- exhaustion of personnel through increased workload as the project progresses

The impact of these issues can be mitigated by the use of good project management practice and general management tools and techniques, e.g.:

- RACI Charts and Role Profiles
- Project Charter
- Team Health-Check
- Time Management Tools (Importance/Urgency Matrix)
- Effective Meeting Checklist

Where personnel are in a new environment defined roles and responsibilities should be communicated, solving two problems:

- Two project members trying to do the same job because each believes they are responsible. This can lead to stress and a breakdown in working relationships.
- Omissions, where each project member believes someone else is responsible.

Roles and responsibilities should be discussed with the project team and adjusted, as required. As a project progresses, roles and responsibilities should be re-visited to ensure that they remain current.

Project leadership should be maintained. It can be beneficial for the Project Sponsor explain to the project team why the project is being undertaken and how it will change the organization.

Project Manager Role in Critical Activity #4

Project Managers should consider activities that will increase commitment and promote project ownership to the individual level, e.g., project team workshops to develop the detailed RACI and schedule based on the high-level predefined requirements.

Project Managers should manage their own workload as well as the workload associated with direct reports. There should be a balance in how the project maintains focus and absorbs increasing workload, e.g., flexibility in working hours or working from home (where company policy allows) may help to mitigate increased project workload.

Project Managers should use an appropriate change control process to evaluate change and determine the impact on project objectives such as schedule, quality, and cost as well as on the project team (capacity and capability).

Project Managers should develop methods that best fit their own project management style and keep each member of the project team engaged. Turnover of team members may be necessary for personal or disciplinary reasons, but can have a negative impact on a project.

Where issues arise that cannot be resolved within the team, but have not escalated to a point of conflict, a level of authority beyond that mandated to the team may be required. Plans should be established to address such issues and can have two clear benefits:

- provides a defined escalation process, ensuring problems can be addressed quickly
- defines authority levels and personnel understand who is making decisions

Conflict resolution planning should be part of a Project Delivery Plan. Conflict can prevent delivery of a successful project. The Project Manager should have the experience and skill to resolve conflict or the project should have a designate that has the experience and skill to resolve conflict. The Project Manager should be able to enforce the established project policies and agreed team ways of working. Example techniques to resolve conflict are given in Section 2.5.6.

Team Meetings

Interaction should occur within an individual team and between separate project teams. The full project team should meet on a regular basis, e.g., starting the week with a team meeting for all members of the project team. An overview of progress is usually presented and then each attendee (or team leads of the sub-teams) should discuss what they have planned for the week. If a team lead is the only person representing that sub-team's scope of work, that sub-team lead should mimic the weekly meeting process for their sub-team. This achieves:

- making team members focus on their goals for the week and encouraging good work practices
- giving team members a sense of commitment - they have stated their goals, and the following week they will have to explain if these have not been met
- alerting the Project Manager to problems
- enabling team members to see how the work of other people may be affected by what they are doing

- raising issues between different project team members
- providing a chance to set action items and follow-up the following week

The Project Manager should determine which methods work best for them, and allow for feedback and constructive criticism to focus their style to the project team's needs.

Example

A facility improvement project was approved and involved a large package of changes to an existing facility to be delivered over 18 months. The Project Manager identified a number of methods to maintain team communications and delivery focus over this time:

- A Project Team Meeting – to occur at a regular time each month and have an agenda and minutes. Where action items are created, they were documented in the minutes. The minutes were communicated by the afternoon of the same day.
- “Weekly Stand-up” only meetings – around project dashboards and used to convey project status in a visible way so that team members immediately got a “signal” to act or react in a specific way to maintain appropriate progress.

A Project Manager should recognize that management is the application of skills and experience. Project Managers should understand that people can be unpredictable and influenced by factors outside the project. An effective Project Manager should be patient and understand the personalities, skills, and capabilities within the project team members.

2.4.5 Key Project Management Challenges

Typical challenges faced by a Project Manager as a team is selected, formed, and managed include:

- Developing a “streamlined” team with the required capacity and capability, particularly with respect to an SME to address the GxP or specific technical considerations. For example, the design team needs to integrate compliance with and consideration of GxPs effectively into the detailed design and be able to support qualification/verification efforts to support validation.
- Working with technical experts – in terms of the technology challenges – who do not have the relevant compliance background; ensuring personnel who may be from other industries and not have the appropriate understanding of GxP and compliance receive the appropriate training.
- Using QA resources effectively (while maintaining their independence from commercial aspects of the project), e.g., QA personnel with an appropriate background in risk assessment working to develop a risk-based verification approach. Motivating team members and ensuring accountability for individual responsibilities.
- Decision making – recognizing that decisions with significant impact have to be made and ensuring appropriate team commitment to these.

2.5 Roles and Responsibilities: Consultants and Contractors

This section discusses the people aspects of the relationship between an organization and its key external resources: consultants and contractors. It focuses on communications from an internal Project Manager perspective to give an example of the type of challenges faced and how to mitigate risks. The exact nature of contracts is not discussed.

For further information on using external resources and strategies, see Chapter 7 of this Guide.

Communication is discussed from the point at which:

- A scope of work has been approved.
- A design consultant has been selected (if appropriate to project type).
- A contract has been signed.
- The Project Manager and design consultant are embarking on design.

Design is an iterative process and requires significant collaboration between the parties. A team of consultants with their own Project Manager may be contracted to provide project services to a Customer. In this case, the Customer's Project Manager may communicate contractual changes only with the consultants' Project Manager - as a single commercial point of contact. The consultant's Project Manager takes responsibility for managing the team of consultants and ensuring their adherence to quality, schedule, and budget. The consultants' Project Manager is responsible for reporting to Customer's Project Manager.

Contracts should contain clauses which make explicit what should happen where communications start to be challenged or breakdown; however, no contract can predict every situation or cover every contingency so the Project Managers' tasks are dependent upon their communications skills and processes.

2.5.1 Selection

Key criteria for selection of consultants and contractors include:

- previous experience in the specific type of project
- track record in the pharmaceutical industry
- adequate in house resources Client references for similar projects
- alignment of contractor and Customer's culture

In addition, each organization may have specific procurement policies for consultants and contractors, e.g., consultants and contractors may need to:

- be an approved supplier before being used on a project within an organization
- undergo specific training before commencing work on a project

For further information on selecting external resources, see Chapter 7 of this Guide.

2.5.2 The Contractual Relationship

The formal nature of contracts should ensure that they align to the way that a project needs consultants and contractors to behave (see Chapter 7 of this Guide).

Partnering and alliance approaches can be used to link the contractual relationship with an appropriate communication process by reducing or eliminating the adversarial nature of contracts. These typically involve the development of performance measurement applicable to both organizations, and appropriate to the contract type, e.g.:

- In a capital project the desire to achieve a key milestone for completion within a budget can be aligned in the contract through some form of sharing of the savings from good ideas. The incentive drives appropriate behaviors – looking for cost saving ideas – which support project success.