

ISPE Good Practice Guide: Project Management for the Pharmaceutical Industry

11.1 Web Resources – Sample Checklists

1 Project Initiation: Feasibility Checklist

The following checklist can be used by Project Managers in preparing and reviewing the project business case and feasibility.

Feasibility
Business Case What is the likelihood of this product successfully completing clinical trials? How does this project fit with the organization's supply strategy? E.g., after launch will this product be moved to a lower cost country? What countries will it be marketed in? What are the licensing timelines? Which regulatory bodies will have to be approached? Are there any specific drug potency issues? What are the potential sales volumes? Is there new technology involved? Is there a likelihood of introducing business risk to an existing process? Does the extra cost of validation and the resource taken in submitting a regulatory license modification justify the outlay? Does this project reduce patient risk?
Gatekeeping Why is this project beneficial to the organization (Project Charter)? Does it fit the organization's strategy? What is the business benefit, (and is there an impact on operating costs)? Is there an impending Regulatory change that is driving the need for this project? Are there current Compliance issues that are being addressed by this project? Is there a maximum capital spend above which the project does not become viable? Can the project be delivered for less than this cost? If so what is the capital cost range and accuracy? Have the key stakeholders been consulted? Is there a list of options to investigate during the next stage (not essential)? Is a simple project schedule in place, and are there any long lead items or lengthy activities which will dominate the schedule? Are there any immediate constraints on the project? What are the major risks and what is the strategy for their mitigation? What funding/resources will be required to complete the next stage?

2 Project Initiation: Conceptual Development Checklist

The following checklist can be used by Project Managers in planning and executing the conceptual design phase of a project.

CONCEPTUAL DEVELOPMENT
<p>Scoping and Organization</p> <p>How the success of the project phase will be measured?</p> <ul style="list-style-type: none">• i.e., for the Conceptual phase, a clear indication on which option provides the best capital choice <p>What the team is to deliver?</p> <ul style="list-style-type: none">• i.e., for the Conceptual phase, the deliverable is the capital cost information to allow a decision to be made on options <p>How the team will go about delivering it?</p> <p>How the team will be organized and managed?</p> <p>How the team will communicate internally and with external bodies, including how it will report progress?</p>
<p>Project Strategy</p> <p>Project Purpose</p> <p>Business Objectives</p> <p>Project Objectives</p> <p>Scope Description Overview</p> <p>Schedule Milestones</p> <p>Organization Chart</p> <ul style="list-style-type: none">• Roles and Responsibilities• Project Governance <p>Critical Issues</p> <p>Previous Project Lessons</p> <p>Portfolio/Program Impacts</p> <p>Impact of other Projects</p> <p>Design</p> <p>Procurement and Contracting strategy (high level)</p> <ul style="list-style-type: none">• Internal• EPCM• EP and CM• EP and GC• Design and Build• Turnkey <p>Construction</p> <ul style="list-style-type: none">• Labor Availability• Transport <p>Testing – Commissioning and Qualification strategy (high level)</p> <p>Handover strategy (high level)</p>
<p>Project Phases</p> <p>Feasibility</p> <p>Conceptual Development</p> <p>Project Delivery Planning</p> <p>Detailed Design</p> <p>Procurement</p> <p>Construction</p> <p>Commissioning</p> <p>Qualification</p> <p>Validation</p> <p>Commercial Production</p>

Site

Selection
Confirmation
Country
Location
Ownership
Infrastructure
Utilities
Demographics
Business Environment
Due Diligence
Ecology
Climate
Contamination
Boundary
Topographical
Geotechnical

Regulatory

cGMP
Licensing Authorities
Integrated C&Q
Verification

Permitting

Planning Permission
Fire Safety
Environmental
Water Discharge
Air Emission
Integrated Pollution Control

Technical

Process
Process Equipment
Piping
Clean Utilities
Instrumentation
Automation
Architectural
Civil
Structural
Black Utilities/Mech. Services
HVAC
Fire Protection
Electrical
Life Safety
Environmental
Safety and Health
Commissioning
Qualification
Validation

Design Considerations

Greenfield
Brownfield
Retrofit
Revamp
Demolition
Decontamination
Design Criteria
Corporate Standards
National Standards
Operability
Maintainability
Cleanability
Constructability
Flexibility
Sustainability
Expandability
Exit Strategy
Adjacency
Capacity
Energy Efficiency
Fuels
Redundancy/Standby
Control Philosophy
Shutdown Philosophy

Stakeholders

Business Mgt
Site Mgt
End User
Operators
Maintenance
Labs
Quality
Neighbors
Suppliers

Project Control

Corporate Investment Guidelines
Project Funding Rules
Taxation
Grants
Cost Estimate Accuracy
Cost Contingency
Sensitivity
Approval Authority levels
Cost of Capital
Currencies
NPV
Cash Flows
Project Budget
Capital Approval Dates
Value Management
Master Schedule Accuracy
Schedule Contingency
Risk Management
Benefits Tracking
Bridging Funds

Option Selection

Financial
Technical
Regulatory/Quality
Environmental
Supply Chain Logistics
Timing/Schedule
Risk – Political/Social/Economic
Future Potential
People/Skills

Gatekeeping

Are we agreed on a single option?
Does this option still meet the business objectives?
Is the business idea still sufficiently viable that we want to spend money to go to the next stage of PDP?

3 Pre-Construction Checklist

The following checklist can be used by Project Managers in planning and executing pre-construction checklists.

PRE-CONSTRUCTION
Project Scope Formal description/write up What's included? What's excluded? Unusual elements Repetitive elements
Definitions and Terminology Project Phases Start and Finish Milestones Mechanical Completion Commissioning
Integrated Master Schedule Stage Gate Funding Milestones Design Procurement Construction Commissioning Validation Commercial Production
Capital Cost Estimate Stage Gate Funding Reviews Value Engineering Reviews
Project Organization Structure EP Organization CM Organization Commg. Organization Validation Organization Project Team Responsibility Splits
Design Constructability Reviews Path of Construction Design Zoning philosophy Architectural Civil Structural Process Equipment Utilities Piping Instrumentation Automation HVAC Mechanical Services Air Balance/Zoning Philosophy Fire Protection Electrical HAZOP

<p>Procurement Strategy Procurement/expediting/site acceptance/PO administration to close out Identify Long Lead Equipment Bulk Materials Procurement Philosophy</p>
<p>Construction Location Assessment of Construction Skills profile/deficiencies Industrial Relations strategy Local Site capability re Materials of Construction/Construction Techniques Local Site – Construction “norms”/standard approaches Local Site – Safety Profile/Industry Concerns Local Site – Industry workload assessment</p>
<p>Construction Execution Strategy Site Logistics Plan Modularization Philosophy Module Transportation – route to site “constraints/limits” on module sizing Offsite Fabrication – local Site capacity/capability QA/QC Philosophy</p>
<p>Sub Contracting Strategy Pre Qualification Sub Contractor Bid List Contracting Strategy – split of work scope/no of packages/form of contract</p>
<p>Logistics Temporary Site Establishment Sizing/Layout</p>
<p>Site Environmental Health and Safety Strategy</p>
<p>Construction Field Labor Estimation of Peak Field Manpower Definition of Project Workscope Definition of “exclusions”</p>
<p>Project Risk Assessment</p>
<p>Handover Client Requirements Equipment Manuals Regulatory Documentation</p>
<p>Commissioning Philosophy Integration of Construction and Commissioning Philosophy with Validation Philosophy</p>
<p>Validation Philosophy Life Cycle</p>
<p>Start Up Philosophy Team</p>