

ISPE Good Practice Guide: Project Management for the Pharmaceutical Industry

PROJECT TYPE MATRIX : Key Activities per Life Cycle Phase

Phase	Aspects within phase	PROJECT TYPE				
		Facility - New Build / Revamps / Upgrades	Product Transfer	Process Improvement / Development	IT	Automation
General	PROJECT MANAGER	Project Manager	Product Transfer Project Manager	Business Change Manager	Project Manager	Project Manager
	PROJECT FOCUS	Engineering				
	PROJECT GOAL	Completion of a facility to a specified level	Transfer manufacture and/or packing from one site to another	Improving supply chain & equipment/process rather than product	Delivery of a new or improved IT system	Completion of automation project (H/W or S/W) to a specified level
Initiation	INPUTS	Business Opportunity / Requirement	Business Opportunity / Requirement	Business Opportunity / Requirement	Business Opportunity / Requirement	Business Opportunity / Requirement
		Business Sponsor	Business Sponsor	Business Sponsor	Business Sponsor	Business Sponsor
		Project Governance	Project Governance	Project Governance	Project Governance	Project Governance
	KEY ACTIVITIES and Deliverables	FEASIBILITY / CONCEPT DESIGN	FEASIBILITY	FEASIBILITY	REQUIREMENTS ANALYSIS	FEASIBILITY / CONCEPT DESIGN
	User Requirements	Based on target facility capability	Based on pilot studies or data	Use Cases / User Requirements	User Requirements	
	Cost Estimate to +/-30%	Cost Estimate	Cost Estimate	Cost Estimate to better than +/-30%	Cost Estimate to +/-30%	
	Benefits Estimation	Benefits Estimation	Benefits Estimation	Benefits Estimation	Benefits Estimation	
	PROJECT PLANNING	PROJECT PLANNING	PROJECT PLANNING	PROJECT PLANNING	PROJECT PLANNING	
	Project Delivery Strategy	Project Delivery Strategy	Project Delivery Strategy	Project Delivery Strategy	Project Delivery Strategy	
	Plan for PDP Development Phase	Plan for PDP Development Phase	Plan for PDP Development Phase	Plan for PDP Development Phase	Plan for PDP Development Phase	
OUTPUTS	Business Case	Technical Feasibility / Business Case	Technical Feasibility / Business Case	Business Case	Business Case	
STAGE GATE	Is the project viable?	Is the project viable?	Is the project viable?	Is the project viable?	Is the project viable?	
PDP	INPUTS	Approved pre-project funding	Approved pre-project funding	Approved pre-project funding	Approved pre-project funding	Approved pre-project funding
		All previous development & planning	All previous development & planning	All previous development & planning	All previous development & planning	All previous development & planning
		Appropriately resourced team	Appropriately resourced team	Appropriately resourced team	Appropriately resourced team	Appropriately resourced team
	KEY ACTIVITIES and Deliverables	FRONT END DESIGN	FRONT END DESIGN	FRONT END DESIGN	FUNCTIONAL SPECIFICATION	FRONT END DESIGN
	Outline drawings	Outline drawings	Scope of changes	Functional Specification	Functional Specification	
	PFD's	Scope of changes	PFD & P&ID modifications	Pilot / Prototyping	Hardware Architecture / Spec	
	P&ID's	PFD & P&ID modifications	Cost Estimate +/- 10%	Hardware Architecture / Spec	Cost Estimate +/- 10%	
	Cost Estimate +/- 10%	Cost Estimate +/- 10%	Specifications	Cost Estimate +/- 10%		
	Specifications	Specifications				
	PROJECT PLANNING	PROJECT PLANNING	PROJECT PLANNING	PROJECT PLANNING	PROJECT PLANNING	
	Project Execution Plan	Project Delivery Plan	Project Delivery Plan	Project Execution Plan	Project Execution Plan	
	Procurement Strategy	Procurement Strategy	Procurement Strategy	Procurement Strategy	Procurement Strategy	
	Validation Master Plan	Validation Master Plan	Validation Master Plan	Validation Master Plan	Validation Master Plan	
	Project Schedule	Project Schedule	Project Schedule	Project Schedule	Project Schedule	
	Risk Assessment	Risk Assessment	Risk Assessment	Risk Assessment	Risk Assessment	
QA/QC Plan	QA/QC Plan	QA/QC Plan	QA/QC Plan	QA/QC Plan		
OUTPUTS	Defined Technical Scope	Defined Technical Scope	Defined Technical Scope	Defined Functional Scope	Defined Technical Scope	
Refined Business Case	Refined Business Case	Refined Business Case	Refined Business Case	Refined Business Case	Refined Business Case	
STAGE GATE	Should this project go ahead?	Should this project go ahead?	Should this project go ahead?	Should this project go ahead?	Should this project go ahead?	

Implementation	INPUTS	Fully approved funding	Fully approved funding	Fully approved funding	Fully approved funding	Fully approved funding
		Appropriately resourced team	Appropriately resourced team	Appropriately resourced team	Appropriately resourced team	Appropriately resourced team
		All previous development & planning	All previous development & planning	All previous development & planning	All previous development & planning	All previous development & planning
	KEY ACTIVITIES and Deliverables	DESIGN	DESIGN	DESIGN	DESIGN	DESIGN
		Specifications	Specifications	Specifications	Detailed Designs	Detailed Designs/Drawings
		Detailed Designs/Drawings	Detailed Designs/Drawings	Detailed Designs/Drawings		
		PROCUREMENT	PROCUREMENT	PROCUREMENT	PROCUREMENT	PROCUREMENT
		Bid & Award Equipment	Bid & Award Equipment	Bid & Award Equipment	Bid & Award Equipment	Bid & Award Equipment
		Bid & Award Contracts	Bid & Award Contracts	Bid & Award Contracts	Bid & Award Contracts	Bid & Award Contracts
		CONSTRUCTION	CONSTRUCTION / MODIFICATION	CONSTRUCTION (modification)	CONSTRUCTION	CONSTRUCTION
	Building construction	Building construction	Equipment modifications	Server / Software Installation	System Build	
	Equipment FAT	Equipment modifications	Equipment testing	Software Coding / Configuration	Software Configuration	
	Equipment installation	Equipment testing		Module / Unit Testing	System FAT	
		Equipment installation		System Testing / User Acceptance Testing	System Installation	
	COMMISSIONING	COMMISSIONING	COMMISSIONING	COMMISSIONING	COMMISSIONING	
	Verification Protocols	Verification Protocols	Verification Protocols	Verification Protocols	Verification Protocols	
	Verification Records	Verification Records	Verification Records	Verification Records	Verification Records	
OUTPUTS	Qualified facility ready for beneficial use	Qualified facility ready for beneficial use	Qualified facility ready for beneficial use	Qualified system ready for beneficial use	Qualified system ready for beneficial use	
STAGE GATE	Ready for handover?	Ready for handover?	Ready for handover?	Ready for handover?	Ready for handover?	
Handover & Closure	INPUTS	Completed facility	Modifications complete	Modifications complete	Completed system	Completed system
		Qualification documentation	Qualification documentation	Qualification documentation	Qualification documentation	Qualification documentation
		Operating documentation	Operating documentation	Operating documentation	Operating documentation	Operating documentation
	KEY ACTIVITIES and Deliverables	HANDOVER	HANDOVER	HANDOVER	HANDOVER	HANDOVER
		Customer acceptance	Customer acceptance	Customer acceptance	Customer acceptance	Customer acceptance
		Project final documentation	Project final documentation	Project final documentation	Project final documentation	Project final documentation
		Project closure	Project closure	Project closure	Project closure	Project closure
		CLOSURE	CLOSURE	CLOSURE	CLOSURE	CLOSURE
		Learning review	Learning review	Learning review	Learning review	Learning review
		Business case review	Business case review	Business case review	Business case review	Business case review
	Beneficial Use review	Beneficial Use review	Beneficial Use review	Beneficial Use review	Beneficial Use review	
OUTPUTS	Facility in beneficial use	Facility in beneficial use	Facility in beneficial use	System in beneficial use	System in beneficial use	
STAGE GATE	Can the project be closed?	Can the project be closed?	Can the project be closed?	Can the project be closed?	Can the project be closed?	