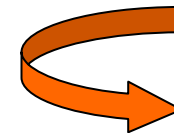


# VMP

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VMP is a summary intention document stating the scope of the validation and outlining the methods to be used to establish the performance adequacy.



# VALIDATION MASTER PLAN CONTENT

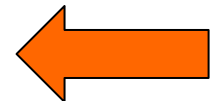


- Introduction
- Objective
- Approach
- Scope & Justification
- Acceptance Criteria
- Support programs
- Organisation
- Schedules
- Appendix

# INTRODUCTION

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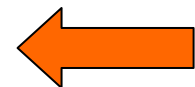
- Synopsis of the project and of individual unit operations
- Flow sheets / flow diagrams as references



# OBJECTIVE

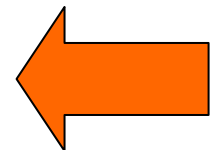
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- A concise statement of the task to allow complete understanding of the validation.



# APPROACH

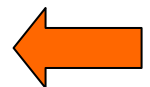
- Approach as to how the validation is to be conducted
- Define the documents to be produced and the formal approval method



# SCOPE & JUSTIFICATION

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- Scope and justification for what is included and what is excluded from the programme.
  - \* Outline critical item to be tested
  - \* Qualification matrix
  - \* Outline critical parameter to be evaluated



# ACCEPTANCE CRITERIA



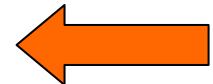
- Acceptance criteria stated in general terms.



# SUPPORT PROGRAMMES



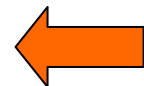
- Support programmes such as training, calibration, change control procedures must be in place before PQ.





# ORGANISATION

- Define responsibility for validation
- Define organisation and management of the validation (responsibility matrix)
- Define the team



# SCHEDULE



## ■ The schedule could list

- \* Man power
- \* Supplies
- \* Services required
- \* Document preparation
- \* Document handling
- \* Validation test equipment
- \* Support service
- \* Work time scale.



# APPENDIX

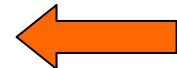
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- \* Glossary
- \* Validation method references
- \* Facility site plans
- \* Process flow sheets
- \* Equipment layout
- \* People and product flow
- \* Air conditioning zone program diagram
- \* etc.



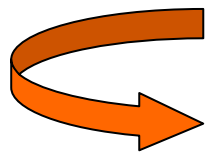
# VALIDATION PLANNING

- Prepare & Approve Project Brief
  - \* Define responsibility for the project
  - \* Define project function
  - \* Define responsibility for validation
  - \* Convene project and validation team
- Prepare Preliminary Project Design and Specification
  - \* Flow sheets / flow diagrams
  - \* Layouts
  - \* Broad specifications
  - \* Rationale



# FAMILY TREE

A family tree is a useful document for showing the hierarchy of areas, services and equipment to be validated and for ensuring that all the validation implications of a given project have been considered and included as necessary.





- Design Qualification
- Installation Qualification
- Operational Qualification
- Performance Qualification



## **SCOPE**

### **Requirements Summary**

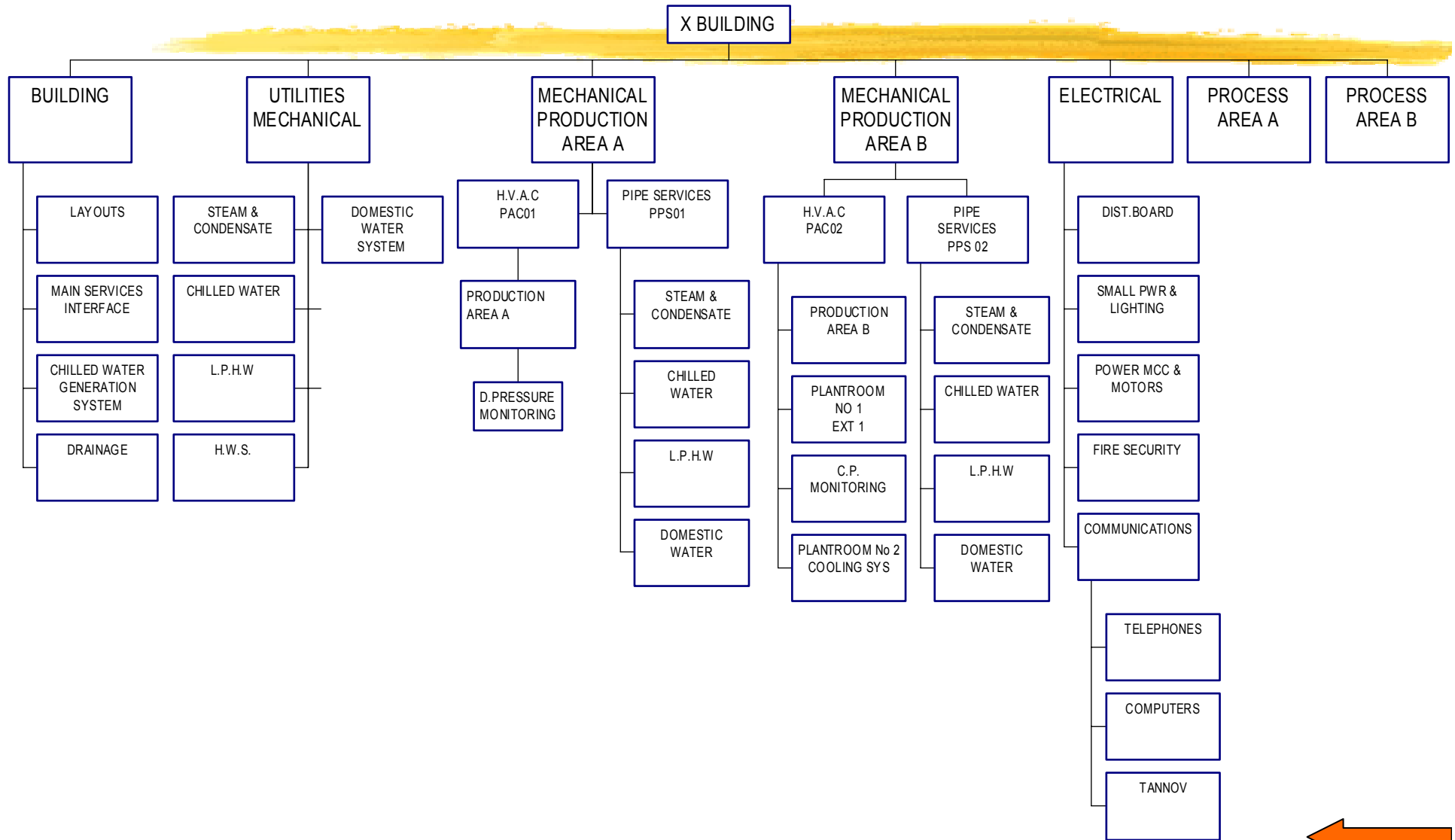
C - Calibration required before Operational Qualification DQ - Design qualification IQ - Installation qualification OQ - Operational qualification PQ - Performance qualification						
		<b>C</b>	<b>DQ</b>	<b>IQ</b>	<b>OQ</b>	<b>PQ</b>
<b>Building</b>						
	Building	X	X	X	X	
<b>Services</b>						
	HVAC (Critical systems)	X	X	X	X	X
	Industrial Steam (Non - critical )	X	X	X		
	Pure Steam (Critical)	X	X	X	X	X
	Potable Water (Critical)		X	X	X	
	Purified Water (Critical)	X	X	X	X	X
	Distilled Water (Critical)	X	X	X	X	X
	Chilled Water (Non-critical)	X	X	X	X	
	Gases (Critical )	X	X	X	X	X
	Compressed Air (Product contact critical )	X	X	X	X	X
<b>Equip.</b>						
	Autoclave	X	X	X	X	X
	Vial Washer	X	X	X	X	X
	Sterilizing Tunnel	X	X	X	X	X
	Filling Machine	X	X	X	X	X
	Check Weigher	X	X	X	X	X
	Garment Washing Machine		X	X	X	X
	Labelling Machine	X	X	X	X	X
	Semi-auto Cartoner	X	X	X	X	X
	Laminer Flow Cabinets	X	X	X	X	X
	Blister Packing Machine	X	X	X	X	X
	Leutos Bar Codes	X	X	X	X	X
	Tablet Pressing Machine	X	X	X	X	X
	Lab. Equipment	X	X	X	X	

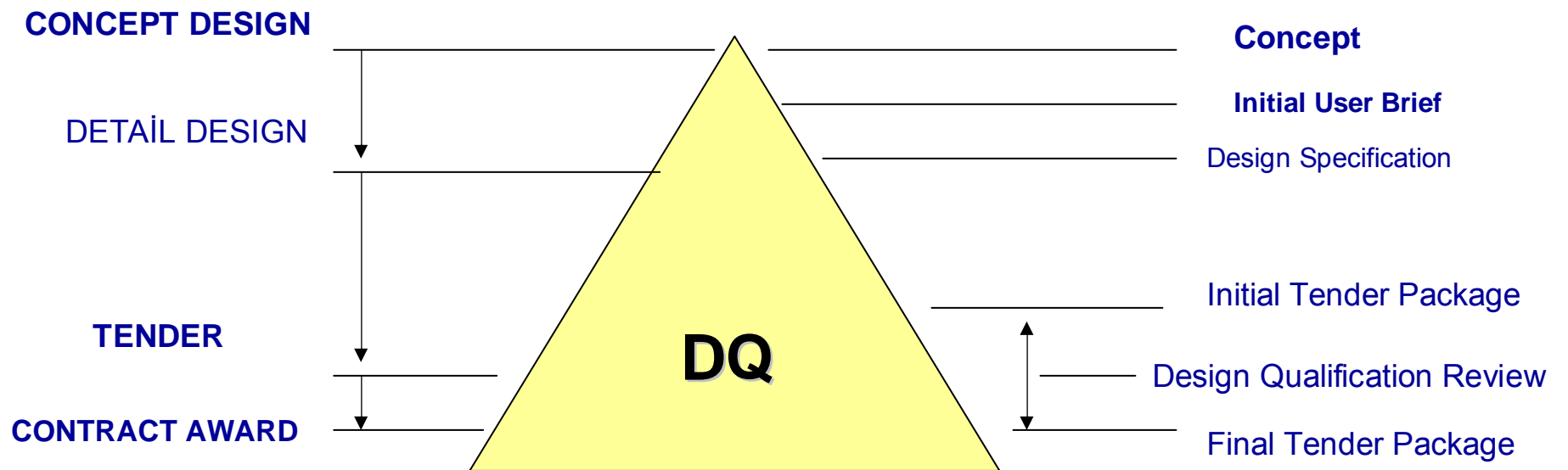
C - Calibration required before Operational Qualification DQ - Design qualification IQ - Installation qualification OQ - Operational qualification PQ - Performance qualification						
		C	DQ	IQ	OQ	PQ
Process						
	Cleaning Areas					X
	Cleaning Equipments					X
	Cleaning Machine Parts					X
	Cleaning Garments					X
	Filling Operation					X
	Vial Washing					X
	Plugging					X
	Capping					X
	Inspection					X
	Test Methods					X
	Packing					X
Systems						
	Building Management System	C	X	X	X	X
	Fire Protection		X	X	X	X
	Computer System		X	X	X	X
People						
	Training					X
	Health&Safety					X
	Performance					X





FAMILY TREE





# How to do DQ

Ask relevant Questions

■ **What** do you want this for

is the best way of doing this

do you need to make this

**Where** do you want to put this

**When** do you want this

do you need this

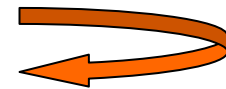
**Why** do you want this and not a slide

do it this way

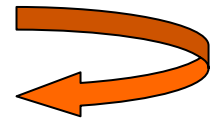
**How** will you pay for this

will you build it

will you find the time



<b>GlaxoSmithKline</b>	
Site.	FunctionalDescription:
Project.	Location Dig.No.
	Schematic Dig.No.
Project No.	Plant No.
Item RefNo.	System No.
<div style="background-color: yellow; width: 100%; height: 20px; margin-bottom: 10px;"></div>	
Installation inspected and details recorded by:	Sign:                  Date:
Installation complies with design:	Sign:                  Date:
Comments on IQ\OQ:	
<b>DECLARATION:</b> Installation and Operation Inspected, Tested and found to be satisfactory	Sign:                  Date:



<b>GlaxoSmithKline</b>			
Site.	Functional Description:		
Project.	Location Drg. No.		
	Schematic Drg. No.		
Project No.	Plant No.		
Item Ref No.	System No.		
		<b>O</b>	
		<b>Q</b>	
		Checked by:	Witnessed by:
			Date:
Comments on IQ/OQ:			
<b>DECLARATION:</b>		Sign:	Date:
Installation and Operation Inspected, Tested and found to be satisfactory			



<b>GlaxoSmithKline</b>		
Site.	Functional Description:	
Project.	Location Drg. No.	
	Schematic Drg. No.	
Project No.	Plant No.	
Item Ref No.	System No.	
		<b>P</b>
		<b>Q</b>
		Checked by:
		Witnessed by:
		Date:
Comments on PQ/OQ:		
<b>DECLARATION:</b>		
Installation and Operation Inspected, Tested and found to be satisfactory		Sign:                      Date:

