

**VMP**  
**VALIDATION**

PROTOCOLS

Validation is a documented program that provides high degree of assurance that a specified facility or operation will consistently produce a given product meeting pre determined specification.

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# VALIDATION PLANNING

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PROTOCOLS

- **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

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**VMP**

PROTOCOLS

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

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# VALIDATION MASTER PLAN VMP CONTENT

PROTOCOLS

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

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# INTRODUCTION

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- **Synopsis of the project and of individual unit operations**

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- **Flow sheets / flow diagrams as references**

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**OBJECTIVE**

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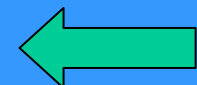
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- **A concise statement of the task to allow complete understanding of the validation.**

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**APPROACH**  
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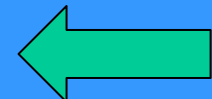
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- **Approach as to how the validation is to be conducted**

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- **Define the documents to be produced and the formal approval method**

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# SCOPE & JUSTIFICATION

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## PROTOCOLS

- **Scope and justification for what is included and what is excluded from the programme.**

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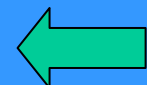
- \* **Outline critical item to be tested**

- \* **Qualification matrix**

- \* **Outline critical parameter to be evaluated**

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# ACCEPTANCE CRITERIA

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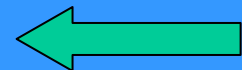
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- Acceptance criteria stated in general terms.

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# SUPPORT PROGRAMMES

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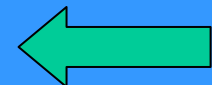
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- Support programmes such as training, calibration, change control procedures must be in place before PQ.

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# ORGANISATION

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## PROTOCOLS

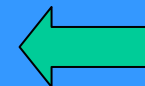
- Define responsibility for validation

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

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- Define the team



# SCHEDULE VMP

- **The schedule could list**

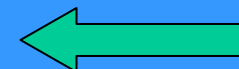
- \* **Man power**
- \* **Supplies**
- \* **Services required**
- \* **Document preparation**
- \* **Document handling**
- \* **Validation test equipment**
- \* **Support service**
- \* **Work time scale.**

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# APPENDIX

## VMP

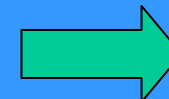
### PROTOCOLS

- \* **Glossary**
- \* **Validation method references**
- \* **Facility and site plans**
- \* **Process flow sheets**
- \* **Equipment layout**
- \* **People and product flows**
- \* **Air conditioning zone pressure diagrams.**

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# FAMILY TREE

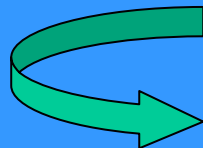
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A family tree is a useful document for showing the hierarchy of areas, services and equipment to be validated and for ensuring that all the validation implications of a given project have been considered and included as

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necessary.  
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- **Design** Qualification

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- **Installation** Qualification

- **Operational** Qualification

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- **Performance** Qualification

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**SCOPE**

**Requirements Summary**

		C	DQ	IQ	OQ	PQ
C - Calibration required before Operational Qualification DQ - Design qualification IQ - Installation qualification OQ - Operational qualification PQ - Performance qualification						
Building	Building	X	X	X	X	
Services	HYAC (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
	Compresed Air (Product contact critical )	X	X	X	X	X
Equip.	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	

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		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

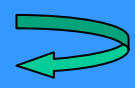
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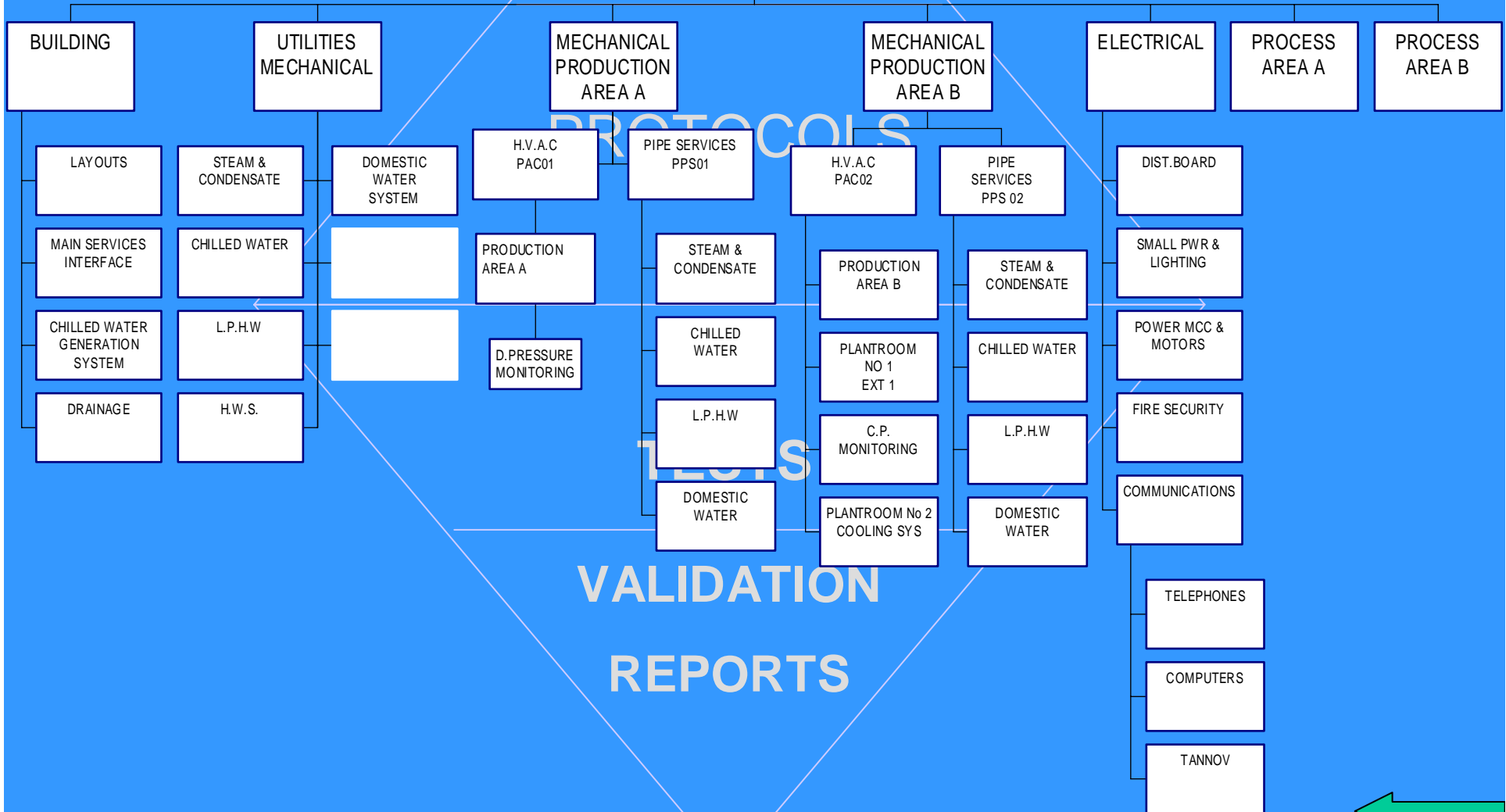
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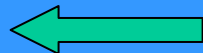
FAMILY TREE

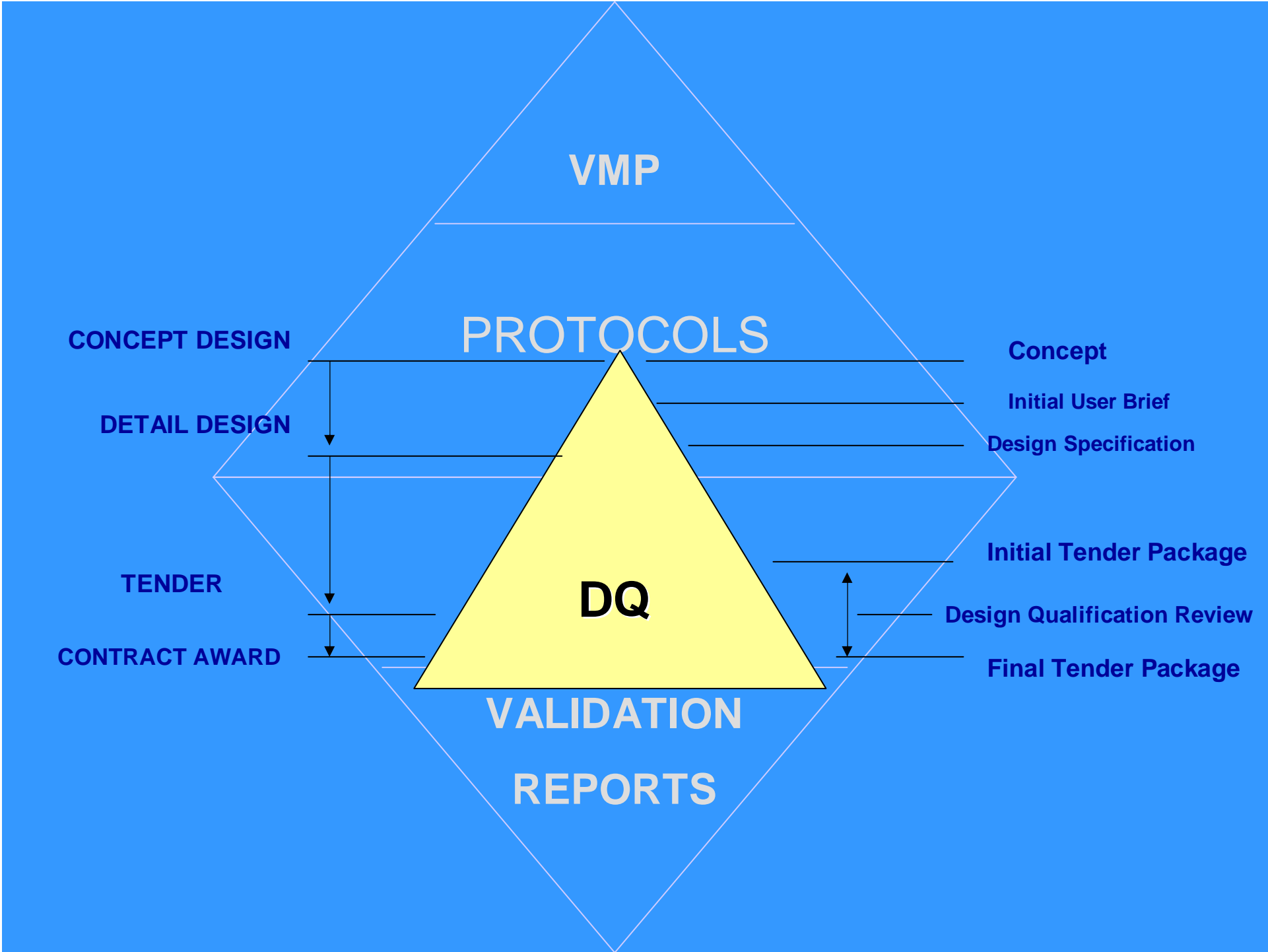
VMP

X BUILDING



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# How to do DQ

VMP

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

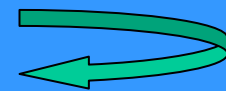
will you find the time

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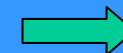
REPORTS



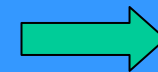
<b>GlaxoSmithKline</b>	
Site.	Functional Description:
Project.	Location Drg. No.
	Schematic Drg. No.
Project No.	Plant No.
Item Ref No.	System No.
<b>VMP</b>	
<b>IQ</b>	
<b>PROTOCOLS</b>	
<b>TESTS</b>	
<b>VALIDATION</b>	
Installation inspected and details recorded by:	Sign:                      Date:
Installation complies with design:	Sign:                      Date:
Comments on IQ/OQ:	
<b>REPORTS</b>	
<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>VMP</b>		<b>IQ</b>		
		Checked by:	Witnessed by:	Date:
		<b>PROTOCOLS</b>		
		<b>TESTS</b>		
<b>VALIDATION</b>				
Comments on IQ/OQ:				
<b>REPORTS</b>				
<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:
<b>PROTOCOLS</b>				
<b>TESTS</b>				
Comments on PQ/OQ:		<b>VALIDATION</b>		
<b>DECLARATION:</b>		<b>REPORT</b>		
Installation and Operation Inspected, Tested and found to be satisfactory		Sign:	Date:	



VMP

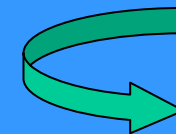
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<b>Glaxo</b>	<b>GAUGE (MAGNEHELIC)</b>
Site: GLAXO SUSTAS/GEBZE	Functional Desc.: P AHU HEPA'S
Project.: CEPHALOSPORINS BUILDING	Location Drg. No.: N/A
	Schematic Drg. No.: 94-01/C-48
Project No.: <i>GWTR101</i>	Plant No.: N/A
Item Ref No.: MG-M11/15-04	System No. M11/15

**GAUGE (MAGNEHELIC)** **IQ**

Manufacturer *JWYER* Type *MAGNEHELIC* Serial No. ....

Dia. *100* mm Range *0-700* Pa Others.....

Position *A.H.U.*

Installed to specification YES/NO\* ~~NO~~

Tag Label attached YES/NO\* ~~NO~~

Installation inspected and details recorded by: Sign: *Just* Date: *18-09-95*

Installation complies with design: Sign: ~~Just~~ Date: *18/09/95*

*Inclined Manometer* **SITE CALIBRATION TEST** **OQ**

Actual injected	Readings	Limit % $\pm 10$
<i>0</i>	<i>0</i>	<i>- % 12.5 acceptable</i>
<i>80</i>	<i>90</i>	<i>✓</i>
<i>190</i>	<i>190</i>	<i>✓</i>
<i>385</i>	<i>390</i>	<i>- % 12 ✓</i>
<i>480</i>	<i>490</i>	<i>- % 20 ✓</i>

Test Instrument *Air flow Inclined Manometer* Serial No. *68424*

Test carried out by: Sign: *Just* Date: *18-09-95*

Test witnessed and results accepted by: Sign: ~~Just~~ Date: *18/09/95*

Comments on IQ/OQ: \* = Delete as applicable

**DECLARATION:**  
Data recorded above has been reviewed and found to be satisfactory Sign: ~~Just~~ Date: *21/09/95*

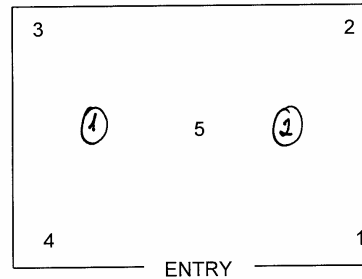


<b>Glaxo</b>	<b>ROOM PERFORMANCE PARTICLE COUNTS</b>
Site.GLAXO SUSTAS/GEBZE	Functional Description:STERILE LAUNDRY
Project.CEPHALOSPORINS BUILDING	Location Drg. No.N/A
	Schematic Drg. No.94-01/C-48
Project No. <i>GWTR/01</i>	Plant No. N/A
Item Ref No.-- <i>N/A</i>	System No.M11/15

**ROOM PERFORMANCE PARTICLE COUNTS**

**PQ**

All measurements to be taken 1m above floor level in positions indicated.



*Room Class - 10.000*

Design Particles per m<sup>3</sup>  
0.5 micron                      5 micron

Results	0.5 micron	5 micron
X ①	91	1
X ②	66	2
X		
X		
X		

Test Instrument: *Malvern Particle Counter* Serial No. *3151*  
*APC 300 A*

Test carried out by:

Sign: *[Signature]* Date: *11/09/15*

Test witnessed and results accepted by:

Sign: *[Signature]* Date: *11/09/15*

Comments:

**DECLARATION:**

Data recorded above has been reviewed and found to be satisfactory

Sign: *[Signature]* Date: *21/09/15*

