Validation

Before, during and after construction

Good and not-so-good practise

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Overview

- Validation Sequence
- Requirements & Specifications
- Validation Plans
- Design Review
- Qualification Protocols
- When it goes wrong

Validation

Establishing **documented evidence**, to provide a high degree of assurance, that in accordance with GMP, any specific process, equipment, facility, activity or system will consistently produce a 'product' that meets pre-determined acceptance criteria

Qualification

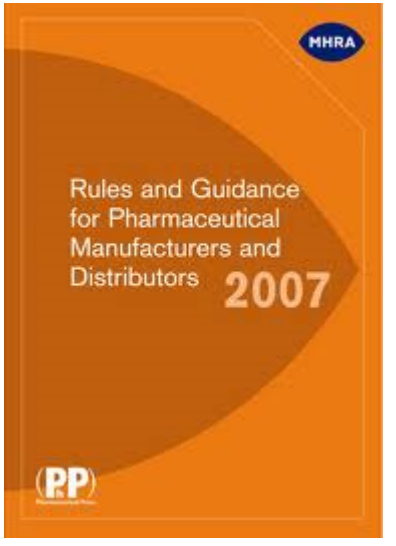
An action proving and **documenting** that equipment or systems are properly installed, work correctly and actually lead to the expected results.

Qualification is part of the validation process

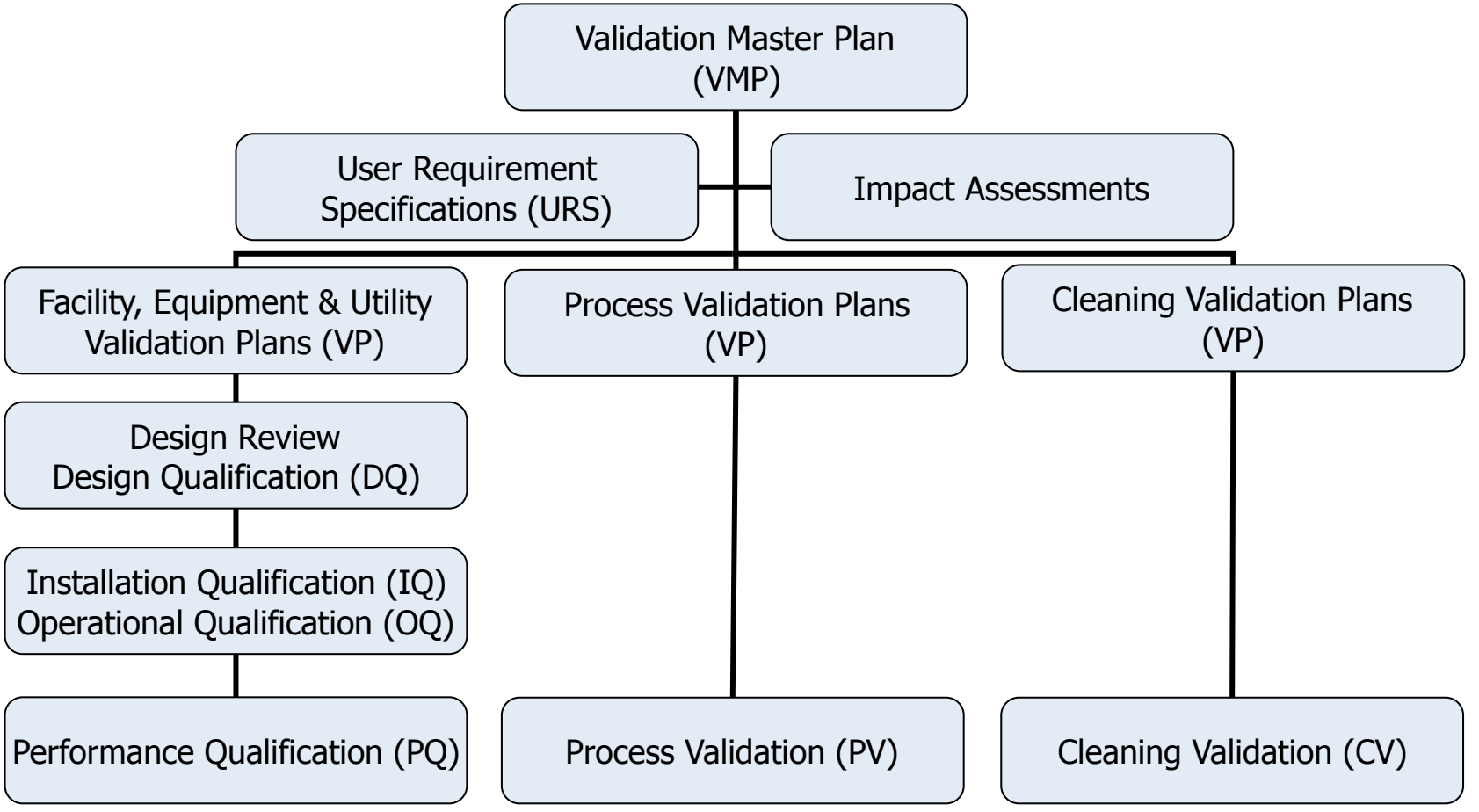
Why Validate?

Orange Guide Annex 15
Qualification & Validation

Significant changes to the facilities, the equipment and the processes, which may affect the quality of the product, should be validated



Sequence



Project Approval	Contractor Selection	Detail Design	Construct & Install	Commission & Test	Handover Completion	Users Occupy

Validation Master Plan

Critical high level document which establishes an over-arching validation plan for the project

It's the

"WHAT? HOW? WHY? WE'RE VALIDATING"

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VMP Content

- Validation policy
- Organisational structure of validation activities
- Roles & responsibilities
- Summary of facilities, systems, equipment and processes to be validated
- Documentation format to be used for protocols and reports
- Planning and scheduling
- Change control system
- Reference to existing documents

BRIEF **CONCISE** **CLEAR**

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User Requirement Specification

It's the

"WHAT WE WANT"

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URS Content

- Objective/description
- cGMP requirement
- Construction standards
- Engineering requirement
- Performance parameters
- Documentation requirement
- Computer hardware/software
- Commissioning
- Validation
- Training

A key defining document against which validation and qualification, to verify compliance, is based.

Without a URS?

- How will the contractor know **what we want**?
- How will we get **what we want**?

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Design Qualification

Enhanced Design Review

Verification that the proposed designs for the facilities, equipment, and systems are suitable for their intended purpose

Contractor Specifications

Functional Design Specification

- Material Specifications
- Equipment Specifications
- Brochures
- Data Sheets
- Drawings & Schematics
- Programme

It's the contractor's

"How we are going to do it"

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Design Review Process

"How we are going to do it"

(FDS)

Versus

"What we want"

(URS)

(including GMP & regulatory requirements)

Allow sufficient time!

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Interrogating the Design

Concentrate on critical direct impact systems, selecting key components to review

- HVAC (AHU, ductwork, filters, grilles, supply, extract)
- Construction (fabric, radiation protection, hatches, benching)
- Finishes (doors, vision panels, floor, wall, ceiling, lights)
- Personnel/Product/Waste Flows
- Access (interlocks, security, alarms)
- Service/Equipment Interfaces
- Control Systems
- Monitoring (continuous environmental monitoring)
- Environmental Conditions (classification, pressure, temperature)
- Commissioning, Qualification & Validation
- Training

DQ Sign Off

- Once satisfied that the design meets user, GMP and regulatory requirements
- Outstanding issues assessed and risks evaluated
- Unified team (contractor / user)
- ‘Change control’ kicks in

Protocol Generation

- Completion of DQ allows IQ OQ PQ protocols to be prepared and approved
- Scope determined by the VMP already in place
- Relevant content confirmed by the DQ completion

Installation Qualification

Documented verification that the equipment or systems have been installed in accordance with the approved design

“They installed what we agreed”

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Discrepancies

IQ is not snagging!

Categorise the discrepancy

Low

Continue qualification

High

Stop qualification activities
until discrepancy resolved

Operational Qualification

Documented verification that the installed equipment and systems operate and function as specified, within agreed parameters and anticipated operating ranges

“It works as we agreed”

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Qualification Sign Offs

Review protocol result content and approve each protocol on its completion

Do not start the next stage of qualification until you have approved the current stage

Performance Qualification

Documented evidence that the facility, equipment and processes will perform repeatedly and consistently within pre-determined parameters during operational use

Plus

Cleaning Validation

Gowning Validation

Process Validation

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Where was my design review?

HVAC ISSUES

No access to air system dampers for on-going maintenance

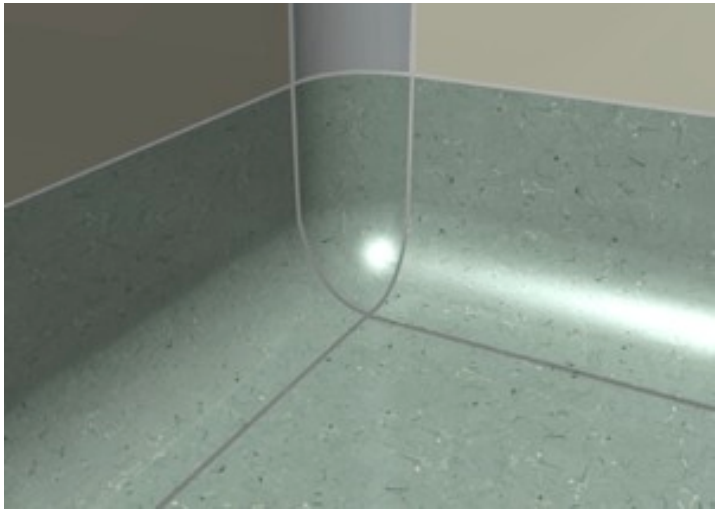
Filtered and unfiltered grilles on the same air system

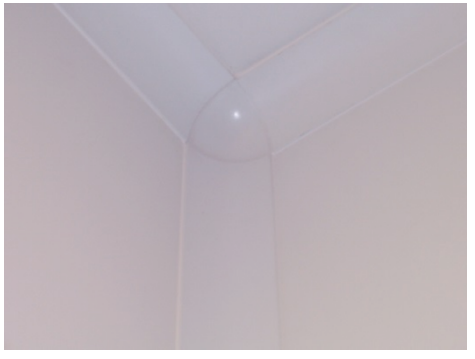
No supply fan fitted to the system

Non compliant AHU (HTM03-01)

Unacceptable odours from fresh air intake

No ‘benchmarking’ for finishes





Door interlocks with push button to unlock the door

Timber battening used for cleanroom benching support

Incorrect door sizes and orientation

Transfer hatches too small for items

Incorrect transfer hatch trolley heights

No air bleed through transfer hatch

Controls Programming Issue – Identified at PQ

AHU turned off at night!

Validair

Thank you for listening