Supplementary Training Modules on Good Manufacturing Practice

Validation

Validation

- Part 1. General overview on qualification and validation
- Part 2. Qualification of HVAC and water systems
- Part 3. Cleaning validation
- Part 4. Analytical method validation
- Part 5. Computerized system validation
- Part 6. Qualification of systems and equipment
- Part 7. Non sterile product process validation
Qualification of systems and equipment

Part 6

Validation

Objectives

To discuss the principles of qualification of systems and equipment, with specific focus on:

- The different stages of qualification
- Requalification and
- Qualification of “in use” systems and equipment
Validation Principle

- Systems and equipment: Appropriately designed, located, installed, operated and maintained

- Critical systems and equipment — should be qualified

- May include, where appropriate:
  - Water purification systems, air-handling systems, autoclaves, coating machines

- Continued suitable performance needed
  - Why? To ensure batch-to-batch consistency
Guidelines describe the general aspects of qualification for systems and equipment.

Normally qualification would be applicable to critical systems and equipment whose performance may have an impact on the quality of the product.
General

- Qualification policy for systems and equipment
- To include instruments used in production and quality control
- New systems and equipment: All stages of qualification applicable (DQ, IQ, OQ and PQ)
- In some cases: Not all stages of qualification may be required
  - e.g. electrical supply systems
Validation

General (continued)

- Systems: Qualified before equipment
- Equipment: Qualified before routine use
- Systems and equipment: Periodic requalification, as well as requalification after change
- Certain stages done by the supplier or a third party
- Maintain the relevant documentation, e.g.
  - standard operating procedures (SOPs), specifications and acceptance criteria, certificates and manuals
Validation

General (continued)

- Qualification should be done in accordance with predetermined and approved qualification protocols

- The results of the qualification should be recorded and reflected in qualification reports

- The extent of the qualification should be based on the criticality of a system or equipment, e.g.
  - Blenders, autoclaves or computerized systems
Blender

- Discuss the approach of qualification of a newly installed blender
Validation

Stages of qualification

- Design qualification
- Installation qualification
- Operational qualification
- Performance qualification
Validation

Stages of qualification

- Design qualification
- Installation qualification
- Operational qualification
- Performance qualification
- Change control

3.11.
Design qualification

- User requirements should be considered when deciding on the specific design of a system or equipment

- A suitable supplier should be selected for the appropriate system or equipment (approved vendor)
Installation qualification

- Correct installation as per plan and protocol
- Normally advised to prepare requirements for calibration, maintenance and cleaning at this stage
- Identification and verification of all system elements, parts, services, controls, gauges and other components
- Calibrate the measuring, control and indicating devices
  - against appropriate, traceable national or international standards
Installation qualification (2)

- Documented records for the installation
  - *installation qualification report*

- Indicate satisfactory installation

- Include details, e.g.
  - *The supplier and manufacturer*
  - *System or equipment name, model and serial number*
  - *Date of installation*
  - *Spare parts, relevant procedures and certificates*
The handout shows a typical format for "An installation qualification protocol / report"

- It reflects the minimum information that should be included
- This is an example – and should be used as such
- Specific formats need to be designed for a specific system or piece of equipment
Operational qualification

- Systems and equipment should operate correctly — operation verified as in the qualification protocol

- Studies on critical variable to include conditions encompassing upper and lower operating limits and circumstances (i.e. “worst case conditions”)

- To include verification of operation of all system elements, parts, services, controls, gauges and other components
Operational qualification (2)

- Documented records (Operational qualification report)
- Finalize and approve SOP (operation)
- Training of operators provided – training records
- Systems and equipment released for routine use after completion of operational qualification, provided that:
  - *All calibration, cleaning, maintenance, training and related tests and results were found to be acceptable*
Validation

The handout shows a typical format for:

"An operational qualification protocol / report"

- It reflects the minimum information that should be included
- This is an example – and should be used as such
- Specific formats need to be designed for a specific system or piece of equipment
Performance qualification

- Systems and equipment should consistently perform in accordance with design specifications — verified in accordance with a performance qualification protocol
- Documented records — performance qualification report
- Show satisfactory performance over a period of time
- Manufacturers to justify the selected period
The handout shows a typical format for:
"A performance qualification protocol / report"

- It reflects the minimum information that should be included
- This is an example – and should be used as such
- Specific formats need to be designed for a specific system or piece of equipment
Validation

Requalification

- Defined schedule
- Periodic
- After change
Validation

Defined schedule

Frequency based on Factors

Periodic

After change

Requalification

Results of calibration maintenance, verification

Extent based on Risk assessment

Part of Change control procedure

8.1 – 8.3
What about "old manufacturers" who have not performed DQ, or IQ for existing, in-use systems and/or equipment?
Validation

Qualification of “in-use” systems and equipment

- Data to support and verify the suitable operation and performance of systems and equipment
- Should include operating parameters and limits for critical variables, calibration, maintenance and preventive maintenance, standard operating procedures (SOPs) and records
Group session