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
Supplementary Training Modules on Good Manufacturing Practice

Computerized systems validation

Part 5

Validation

Objectives

To discuss validation of computerized systems including:

- System specifications
- Functional specifications
- Security
- Back-ups
- Validation:
  - Hardware
  - Software
Validation

General

- Validated - level appropriate
  - or their use and application.

- Production and quality control.

- Computer systems used in planning, specification, programming, testing, commissioning, document operation, monitoring and modifying.

- Validation: Evidence and confidence
  - intended use, accuracy, consistency and reliability.
Both the system specifications and functional specifications should be validated.

Periodic (or continuous) evaluation should be performed after the initial validation.
Written procedures for:
- performance monitoring, change control, programme and data security, calibration and maintenance, personnel training, emergency recovery and periodic re-evaluation

During validation, consider:
- networks
- manual back-ups
- input/output checks
- process documentation, monitoring
- alarms, and
- shutdown recovery
In place, stating:
- objectives of a proposed computer system
- the data to be entered and stored
- the flow of data
- how it interacts with other systems and procedures
- the information to be produced
- the limits of any variable
- the operating programme and test programme

(Examples of each document produced by the programme should be included)
System elements that need to be considered in computer validation include:

- **hardware (equipment)**
- **software (procedures)**
- **people (users)**
Validation

Functional specification (Performance specification)

- Provide instructions for:
  - testing, operating, and maintaining the system
  - names of the person(s) (development and operation)
- When using computer systems, consideration:
  - location
  - power supply
  - (Fluctuations in the electrical supply can influence computer systems and power supply failure can result in loss of memory).
  - temperature
  - magnetic disturbances

3.1 – 3.2
GMP requirements for computer systems:

- **Verification and revalidation**
  - After a suitable period of running a new system
  - Independently reviewed and compared with the system specification and functional specification

- **Change control**
  - Alterations made in accordance with a defined procedure
  - Provision for checking, approving and implementing the change

- **Checks**
  - Data checked periodically
  - Confirm accurate and reliable transfer
Validation

Security

- Production as well as in quality control
- Data entered or amended - authorized persons
- Security systems to prevent unauthorized entry or manipulation of data
- SOPs for entering data, changing or amending incorrect entries and creating back-ups
- Security procedures in writing
Traceability is of particular importance

Audit trail:
- identify the persons who made entries
- identify the persons who made changes
- identify the persons who released material
- identify the persons who performed other critical steps in production or control
(continued)

- Entry of critical data by an authorized person
- Independent verification and release for use by a second authorized person
  - e.g. for entry of a master processing formula.
- SOPs for certain systems or processes validated
  - e.g. action in case of system failure or breakdown including disaster recovery procedure in the event of a breakdown
Validation

Back-ups

- Regular back-ups of all files and data
  - Secure storage (prevent intentional or accidental damage)

Validation

- Validation process should include:
  - Planning
  - Validation policy
  - Project plan and SOPs
Validation (2)

- Define computer-related systems and vendors
- Vendor and product evaluated
- System designed and constructed
  - Consider types, testing and quality assurance of the software
- Extent of qualification depends on complexity of the system
Qualification includes:

- Installation
- Evaluation of the system
- Performance
- Change control, maintenance and calibration, security, contingency planning, SOPs, training, performance monitoring and periodic re-evaluation
Validation of hardware

- Appropriate tests and challenges to the hardware
- No influence of static, dust, power-feed voltage fluctuations and electromagnetic interference
- Hardware is considered to be equipment
  - focus on location, maintenance and calibration as part of the qualification

7.1.1 – 7.1.2
Validation

Validation of hardware (2)

It should prove:

- Appropriate capacity
- Operational limits
  - e.g. memory, connector ports, input ports
- Performance under worst-case conditions
  - e.g. long hours, temperature extremes
- Reproducibility/consistency
  - e.g. by performing at least three runs under different conditions
Validation of hardware (3)

- Written qualification protocols; results in qualification reports kept
- Revalidation – in case of significant changes
- Validation may be performed by the vendor – but ultimate responsibility remains with the company
- If records kept by supplier, manufacturer still has to have sufficient records to allow assessment of the adequacy of the validation
- A mere certification of suitability from the vendor, for example, will be inadequate
Summary: Validation requirements for Hardware (See table 1 in notes)
Validation

Summary: Validation requirements for Hardware (See Table 1 in notes)

- Location: environment, distances
- Maintenance
- Key aspects To consider
- Command overrides
- Signal conversion
- I/O operation

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Summary: Validation requirements for Hardware (See Table 1 in notes)

- Revalidation
- Function
- Limits
- Worst case
- Reproducibility
- Consistency and documentation
Validation of Software

Software:

- is the term used to describe the complete set of programmes used by a computer, and which should be listed in a menu
- Records are considered as software
- Focus should be placed on: accuracy, security, access, retention of records, review, double checks, documentation and accuracy of reproduction
Key computer programmes to be identified:

- *language, name, function (purpose of the programme)*
- *input (determine inputs), output (determine outputs)*
- *fixed set point (process variable that cannot be changed by the operator), variable set point (entered by the operator)*
- *edits (reject input/output that does not conform to limits and minimize errors, e.g. four- or five-character number entry), input manipulation (and equations) and programme overrides (e.g. to stop a mixer before time)*

Identification of authorized personnel

- *to write, alter or have access to programmes*
Points to be considered may include:

- **Consistency in performance**: Within pre-established limits
- **Function**: Matching the assigned operational function (e.g. generate batch documentation, different batches of material used in a batch listed)
- **Worst case**: Validation under different conditions (e.g. speed, data volume, frequency)
- **Repeats**: Sufficient number of times (e.g. replicate data entries)
- **Documentation**: Protocols and reports
- **Revalidation**: In case of significant changes made
Summary: Validation requirements for Software (See Table 1 in notes)
Validation

Summary: Validation requirements for **Software** (See Table 1 in notes)

- Programme overrides
- Language
- Edits, input manipulation
- Name, function
- Fixed and Variable Set points
- Input, output

**Software identification**
Validation

Summary: Validation requirements for **Software** (See Table 1 in notes)
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Validation

- Group session