Training Course
Computerized System Validation in the Pharmaceutical Industry
Istanbul, 16-17 January 2003

GxP in the IT Department

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Agenda

Responsibilities

Training

Security / Access control

Back-up

Error logging

Configuration management

Disaster planning

Internal audits

IT infrastructure

Objective

Procedures and plans should be available to

- maintain the validated state
- ensure software and data integrity
- ensure everyone knows their job

Responsibilities of System Owners & Users

Definition in writing (SOP) should be available for

- system ownership
- training
- error reporting
- maintenance of data integrity

Training

Who is to be trained?

- developers
- owners
- users
- operations staff

What is the basis of the training?

- system manuals

Where is the training documented?

- training records

Security / Access Control

Get information on system security by

- monitoring system use
- correction of security weaknesses
- password security
- owners who control access
- administrators who set-up system access

Error logging

What is to be logged?

- all incidents

including

- assessment of criticality
- corrective actions/follow-up
- strategy for preventive maintenance

Change Control

Process should include details for

- raising a change request
- evaluation of the change impact
- authorising the project/work
- documentation
- (re-)validation
- training, if needed

Configuration Management

Questions

Are all items identified?

- ➔ by type and by version

Are all items listed?

Is change control applied?

Ongoing Evaluation

The evaluation process should include

- validation plans and reports
- specifications
- error logs
- change requests
- ownership and responsibilities
- compliance with written procedures

Definition of activities in a SOP covering the evaluation process is recommended

Back-up and Restore

Important questions:

- Responsibilities defined?
- SLAs existing?
- What procedures are existing?
- 21 CFR Part 11 covered?
  - audit trail
  - verification
  - copies

SOP(s) are mandatory

Disaster Planning

Compliance by

- contingency plans
- assessment of impact of failure
- testing of the plans
- training
- periodic review

System Logs

- one per system
- detailing the history of all changes
- providing an audit trail of
  - WHO did
  - WHAT with the system
  - WHEN?

Personnel 1/2

- Adequate number of personnel with necessary qualifications and practical experience
- Organisation chart
- Specific duties recorded in written job descriptions
- Key posts should be occupied by full-time personnel.

Personnel 2/2

- Personnel should receive training appropriate to the duties
- Continuing training should also be given
- Training programs should be available,
- Training records should be kept.

Self Inspections 1/2

- Self inspections should be conducted in order to
  - Monitor the implementation of GMP
  - Compliance with Good Manufacturing Practice principles
  - Propose necessary corrective measures.

- Cover personnel, premises, equipment, documentation
  - Examined at intervals
  - Following a pre-defined audit program
  - Verify their conformity with the principles of Quality Assurance

Self Inspections 2/2

- Self inspections in an independent and detailed way
  - By designated competent person(s) from the company
  - Independent audits by external experts also useful
- Self inspections should be recorded
  - Observations
  - Proposals for corrective measures
- Statements on the actions subsequently taken should also be recorded
- Non disclosure of audit reports, not to be put into validation documentation

Inspections by Health Authorities

- Inform IT departments on inspections
- Prepare IT staff for inspections in an awareness training
- Provide responsibility matrix of IT
- Inform IT staff on the inspection results, even if CSV was not an issue

NEW TOPIC: IT Infrastructure

Why Worry about?

- Extensive use of "corporate" computer systems
- Based on complex IT infrastructure
- High rate of changes
- Documentation within IT existing, but often not according to GMP
- Business reliability and continuity becomes more and more important
- Recent regulatory interest (USA and Europe), warning letters of the FDA, e.g. Pharmacia, Eli Lilly
- 21 CFR Part 11 compliance