GMP Training Course
Quality Control

20 - 21 October 2009

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Quality Control

- GMP in the QC Laboratory
- Certificates of Analysis
- Dealing with out of specification results
- Parametric Release and Real Time Release Testing

GMP in the QC laboratory

GMP in the QC Laboratory

- Manufacture in relation to medicinal products includes any process carried out in the course of making that product
- Quality control testing is regarded as part of the process of manufacture (GQCLP)
- Don’t confuse GLP with GQCLP (GMP) - there is no requirement to comply with Principles of GLP (OECD)

h1

Slide 4

h1 Would you want to say be part of a GLP monitoring programme as they may get confused about the principles.
harrisonr, 05/10/2009

GMP in the QC Laboratory

- Sampling inspecting and testing
- Controlled documents, i.e. validated methods, SOPS
- Trained personnel
- Clear and traceable records
- Validated computerised systems
- Calibrated and maintained equipment

GMP in a Contract QC Laboratory

- Compliance with EU GMP isn't optional
- Subject to inspection
- Contract labs still need their own quality systems

GMP in a Contract QC Laboratory

- All the GMPs still apply (where applicable)
  - Technical agreements
  - Control of contract giver supplied information
  - Change control
  - Self Inspection
  - GMP specific training

GMP in the QC Laboratory

Deficiencies

- Lack of data recording
  - Method parameters, equipment used
- Equipment calibration by external engineers
  - No review of information supplied
  - Not compatible with the pharmacopeia

GMP in the QC Laboratory

Deficiencies

- No evidence of GMP specific training
- Ineffective QC checking of data
- Not in compliance with the pharmacopeia

GMP in a Contract QC Laboratory

Deficiencies

- Technical agreements

  - no agreements, insufficient detail, no system

- No system for controlling contract giver information

  - specifications, methods

- No method validation (microbiology)
- No technical transfer

Certificates of Analysis

Certificates of Analysis

- Mainly for starting materials and finished products
- Should include specific detail:
  - the organisation issuing it
  - material name & batch number
  - the specification & result
  - date of testing
  - authorisation by a competent person

Certificates of Analysis

- Part of a system for ensuring quality
  - audit, questionnaire & other checks
- Does not eliminate the need to confirm identity
- C of A acceptor is responsible for the correctness of the material

Certificates of Analysis

Deficiencies

- Uncontrolled template used for C of A
- Lack of detail
  - Doesn’t state site of manufacture
  - No indication of the role of the approver
  - No clear indication of the specification

Out of Specification Results

Out of Specification (OOS) Results

- OOS, anomalous/out of trend result
  - Not meeting the specification
  - Irregular result
  - Lower or higher than expected result

Out of Specification Results

- Expectations
  - Acknowledged and logged
  - Investigated
  - Impact assessed
  - Corrective actions & preventative actions
  - SOP
  - Documented

Out of Specification Results

- Expectations
  - All test results reported unless evidence to invalidate
  - If there is a decision to reject the batch, still need an investigation
  - Hypotheses testing
  - Sound scientific evidence to support decisions

Out of Specification Results

Deficiencies

- SOP isn't clear or contains errors
- Never had any OOS!!!
- Poorly documented

Out of Specification Results

Deficiencies

- Insufficient evidence to support conclusion
- In appropriate use of averaging
- Contract QC lab - doing as the contract giver asks an ignoring their SOP!

Parametric Release & Real Time Release

Parametric Release

Definition

"A system of release that gives assurance that the product is of the intended quality based on the information collected during the manufacturing process and on the compliance with specific GMP requirements related to parametric release"

Parametric Release

- Must be approved by the Competent Authority
- Original guidance applied to terminally sterilised products
- Ongoing update to current EMEA guidance doc

Real time Release Testing

Definition

"The ability to evaluate and ensure the quality of in process and/or final product based on process data, which typically include a valid combination of measured material attributes and process control"

Real time Release Testing

- Testing is performed on line, rather than at the end of the process
- In process tests that evaluate critical quality attributes
- May still perform still end product testing
- Not to be confused with batch release

Thank You

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