ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Control Manager

Speakers

Dr Joachim Ermer
Ermer Quality Consulting, Germany

Dr Manfred Fischer
Skyepharma (member of Vectura Group), Switzerland

Joerg Kastenschmidt
Merck, Germany

Dr Bob McDowall
R D McDowall Limited, UK

FDA Compliance in Analytical Laboratories

Live Online Training on 5 /6 October 2021

How to implement cGMP requirements in the everyday practice of quality control laboratories

Highlights

- FDA Inspections
- cGMP Compliant Sampling and Documentation
- Laboratory Data Integrity
- Analytical Instruments
  - Qualification according to USP <1058>
  - Calibration
  - Computer Validation
- Reference Standards and laboratory reagents: a risk-based Approach
- Analytical Methods
  - Validation
  - Method Transfer
- Out-of-Specification Results
  - FDA OOS Guidance
- Training Case Study

Objective

This Live Online Training provides a comprehensive overview of FDA's current compliance requirements (21 CFR Part 211, Guidances for Industry, Compliance Program Guide, etc.). You will get to know

- FDA's expectations in analytical laboratories and related areas
- The essentials of documentation for QC Labs
- How to calibrate and qualify analytical instruments in QC
- What has to be considered regarding validation and transfer of analytical procedures
- How to handle reference standards and reagents

This training provides guidance about how this all can be managed effectively.

Background

A major consequence of the Barr Ruling in 1993 was the significantly greater emphasis FDA inspections placed on the management and performance of quality control laboratories particularly the handling of Out of Specification results.

As a result of the increased and on-going scrutiny of analytical performance it is hardly surprising that **even today the most frequently cited cGMP non-compliances are still found in laboratories,** particularly:

- General cGMP understanding and particularly relating to compliance with written procedures
- Validation, performance and transfer of analytical procedures
- Data integrity
- Management of out of specification and suspect test results
- Instrument qualification including an explanation of the new version of USP <1058>and calibration
- Computer validation (including the requirements and actual interpretation of 21 CFR Part 11)
- Operator training
- Management of reagents and standards

Target Audience

This Live Online Training will be of significant value to:

- All quality control managers responsible for FDA compliance in their laboratories
- Senior laboratory staff charged with meeting these requirements day-to-day
- All support staff involved in FDA inspections in their companies

Programme

General Aspects: Regulatory Requirements and FDA Inspections

- Regulatory Overview (US, Europe and the world)
- Regulatory requirements in the US (cGMP, CFR, Guidances for Industry, etc.)
- FDA Inspections
- Key issues during laboratory inspections
- 483s and Warning Letters

Sampling in Compliance with FDA Requirements

- Importance of the sampling procedure
- Regulatory requirements
- Sampling statistics / sampling plans
- Sampling procedures
- Sampling equipment and environment
- Training
- Retained samples

Documentation for Quality Control Laboratories

- "Scientifically sound" GMP requirements of QC documents and approaches
- Types of QC laboratory documents:
  - Test specifications and analytical procedures
  - Standard Operating Procedures
  - Instrument qualification protocols
  - Complete data for analytical testing and Certificates of Analysis
- Compare and contrast FDA and EU documentation requirements
- Management of blank forms and data integrity issues

FDA Approaches to Laboratory Data Integrity

- FDA laboratory observations: falsification and fraud
- Compliance Program Guide 7346.832 on Pre-Approval Inspections: Objective 3 - Laboratory data integrity
- FDA inspector training: focus on the computer system not paper printouts
- What controls do you need to have in place to ensure data integrity?

Qualification of Analytical Instruments in the QC

- Legal requirements (cGMP, CFR, etc.)
- USP General Chapter <1058> Analytical Instrument Qualification
- Qualification Phases (DQ/IQ/OQ/PQ)
- Qualification examples (problems and solutions)
- Analytical instrument life-cycle (Requalification, etc.)

Calibration for FDA-Inspected Analytical Laboratories

- General approach to Calibration
- Instrument calibration in the USP
- Contrasting US and European approaches (important in the context of laboratories struggling to meet both requirements)

Transfer of Analytical Procedures

- USP General Chapter <1224>Transfer of Analytical Procedures (TAP)
- Key steps for a successful method transfers:
  - Initiation phase (training method familiarization, etc.)
  - Types of transfer
  - Analytical procedures
  - Materials (samples and standards) and testing design
  - Instruments
  - Data assessment – Acceptance criteria
  - Documentation (transfer protocol / report)
- Summary

Training Case Study

- Legal requirements
- Education / GMP-training / Training on the job
- Training records
- Re-training frequency

Out of Specification Results

- Requirements of the FDA Guidance
- Efficient laboratory investigations
- Reanalysing, retesting, resampling
- Management of variability-caused OOS results
- Investigation of atypical results
- Proactive strategies to prevent OOS results

Validation of Analytical Procedures

- Regulatory requirements (ICH, FDA, compendia)
- Lifecycle approach (3-Stage-Model according to draft USP General Chapter <1220>))
- Verification of compendial procedures
- Rationale design of validation studies
- Identification of relevant performance parameters
- Sensible use of statistics
- Suitable performance parameters for continuous monitoring

Practical Computer Validation in Analytical Laboratories

- Computerised system validation as a critical activity in the analytical laboratory
- 21 CFR Part 11 compliance
- FDA emphasis on data integrity for computerised systems
- GAMP software categories and impact on validation approach
- GAMP Good Practice Guide for Validation of Laboratory Systems second edition
- Case study examples: how to validate systems in a cost effective way and steps of what not to do!

Reference Standards and Reagents for FDA-Inspected Laboratories

- Regulatory requirements
- Types of reference standards: Official/primary/working standards/reference materials
- Traceability, characterisation, and retest date of standards
- Risk-based approach for management, storage and shelf-life of laboratory reagents and solutions
- Stability investigation of solutions for quantitation

Speakers

Dr Joachim Ermer
Ermer Quality Consulting, Germany

Dr Ermer worked for almost 30 years in various positions in industrial Quality Control. His responsibilities included head of laboratory within the analytical drug development at Hoechst AG, Frankfurt, Germany, a global function as Director of Analytical Processes and Technology at Aventis, head of Quality Control and head of QC Lifecycle Management Frankfurt Chemistry, Sanofi, Germany, and Sanofi Global Reference Standard Coordinator. Since December 2020, he serves as consultant for topics of pharmaceutical analytics and Quality Control.

Dr Manfred Fischer
Skyepharma (member of Vectura Group), Muttenz, Switzerland

Director MDI Product Development, SkyePharma (member of Vectura group), Basel, Switzerland. 27 years of experience in pharmaceutical analytics and formulation development. Responsible for the pharmaceutical development of pressurized Metered Dose Inhaler (pMDI) products.

Joerg Kastenschmidt
Merck, Darmstadt, Germany

Joerg Kastenschmidt is an engineer of chemical and bio-technology. He started his career in 2001 as project engineer at the PHAST GmbH in Homburg/Saar. After working in the GMP processes unit within the pharmaceutical analytical development at Merck for 10 years, he joined the development QA in 2016, where amongst other things he is responsible for qualification of analytical instruments, production equipment / facilities and validation of IT systems.

Dr Bob McDowall
R D McDowall Limited, Bromley, Kent, UK
Member of the ECA Data Integrity & IT Compliance Group

Analytical chemist with over 40 years experience including 15 years working in the pharmaceutical industry; Consultant with 25 years' experience, Director of R D McDowall Ltd., UK.

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Reservation Form (Please complete in full)

FDA Compliance in Analytical Laboratories, Live Online Training on 5 /6 October 2021

Title, first name, surname

Department | Company

Important: Please indicate your company's VAT ID Number | Purchase Order Number, if applicable

City | ZIP Code | Country

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Date of the Live Online Training

Tuesday, 05 October 2021,
09.00 h - approx. 16.35 h CEST
Wednesday, 06 October 2021,
08.30 h - approx. 16.20 h CEST

Technical Requirements

For our Live Online Training Courses and Webinars, we use Cisco WebEx, one of the leading suppliers of online meetings.
At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer system, please contact your IT department.
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Fees (per delegate, plus VAT)

ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
The fee is payable in advance after receipt of invoice.

Registration

Via the attached reservation form, by e-mail or by fax message.
Or you register online at www.gmp-compliance.org.

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

Conference language

The official conference language will be English.

Ordering a Recording

Independent from the Live Online Training, you can also order a recording of this training at the same conditions. This recording will be provided on our media server. All you need to watch it is an Internet browser – no additional software. You can order the recording of the Live Online Training at the earliest 10 days after the live performance at https://www.gmp-compliance.org/gmp-webinars/recorded-gmp-webinars.

Organisation and Contact

ECA has entrusted Concept Heidelberg with the organisation of this event.

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