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
Manfred Fischer Consulting, Germany

Joerg Kastenschmidt
Merck, Germany

Dr Bob McDowall
R D McDowall Limited, UK

GMP/FDA Compliance in Analytical Laboratories

23 – 25 October 2024 | Barcelona, Spain

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

Highlights

- FDA Inspections
- cGMP Compliant Documentation
- Laboratory Data Integrity
- Analytical Instruments
  - Qualification according to USP <1058>
  - Calibration
  - Computer Validation
- Practical Ways to Validate Excel Spreadsheets
- Reference Standards and Laboratory Reagents: a risk-based Approach
- Analytical Methods
  - Validation
  - Method Transfer
- Out-of-Specification Results
  - FDA OOS Guidance
- Training Case Study
- Stability Testing

4 Interactive Workshops

Objective

The purpose of this three-day education course is to give participants **a comprehensive overview of FDA's current compliance requirements** (21 CFR Part 211, Guidances for Industry, Compliance Program Guide, etc.) and expectations in these and related areas, and how they can be managed effectively.

The format allows each of our speakers to give an overview of the specific regulatory requirements associated with their topic prior to describing the approach to managing the issues with respect to philosophy, documented procedures, SOPs, etc.

In addition, the programme includes **four workshop sessions** covering:

- Method Validation
- Out of Specification Results
- Validation of Excel Spreadsheets
- Method Transfer

The course will also discuss the implication of new developments resulting from recent FDA and USP initiatives, such as analytical lifecycle management with continuous monitoring, data integrity, ...

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

Take advantage of this course to discuss all these issues.

Target Audience

This course 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

Moderator

Dr Bob McDowall, R D McDowall Limited, UK

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

Qualification of Analytical Instruments in QC Laboratories

- 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)

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

Validation of Analytical Procedures

- Regulatory requirements (ICH, FDA, compendia)
- Lifecycle approach (3-Stage-Model according to 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

Stability Testing

- Regulatory requirements for stability testing of drug substances and drug products
- Types of stability studies
- Storage conditions requirements according to climatic zones
- Stability protocol and reports
- Establishment of storage conditions and shelf-life
- Stability testing for post-approval changes

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

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

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

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!

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?

FOUR WORKSHOPS

Some of the most important laboratory compliance topics will be further discussed in interactive workshops:

Topic I: Method Validation
Moderator: Dr JOACHIM ERMER

Topic II: Out of Specification Results
Moderator: Dr JOACHIM ERMER

Topic III: Validation of Excel Spreadsheets
Moderator: Dr BOB McDOWALL

Topic IV: Method Transfer
Moderator: Dr MANFRED FISCHER

Transfer of Analytical Procedures

- USP General Chapter <1224>Transfer of Analytical Procedures (TAP)
- Key steps for a successful method transfer:
  - 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

Validation of Excel Spreadsheets

- Excel spreadsheets are used widely in analytical laboratories as it is easily available and easy to use - and equally so, it is easy to misuse
- Technical features available in Excel
- Practical ways to validate Excel spreadsheets
- Protection of the electronic records produced
- Problems of complying with 21 CFR Part 11 and the new EU GMP Annex 11 Requirements

Training Case Study

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

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
Manfred Fischer Consulting, Germany

Former 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.

Date
Wednesday, 23 October 2024, 09.00 h - 18.15 h
(Registration and coffee 08.30 h - 09.00 h)
Thursday, 24 October 2024, 08.30 h - 18.15 h
Friday, 25 October 2024, 08.30 h - 15.00 h

Venue
Barceló Sants Hotel
Plaça dels Països Catalans, s/n
08014 Barcelona, Spain
Phone: +34 (93) 503 53 00
E-mail: sants@barcelo.com

Fees (per delegate, plus VAT)
ECA Members € 2,090
APIC Members € 2,190
Non-ECA Members € 2,290
EU GMP Inspectorates € 1,145

The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on every day and all refreshments. VAT is reclaimable.

Accommodation
CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form/POG when you have registered for the conference. Reservation should be made directly with the hotel. Early reservation is recommended.

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 for this event will be available for you to download and print before and after the event. Please note that no printed materials will be handed out on site and that there will not be any opportunity to print the presentations on site. After the event, you will automatically receive your certificate of participation.

Conference language
The official conference language will be English.

Social Event
At the end of the first course, all participants and speakers are invited to a social event. This is an excellent opportunity to share experiences with colleagues from other companies in a relaxed atmosphere.

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

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For questions regarding reservation, hotel, organisation etc. please contact:
Ms Marion Grimm (Organisation Manager) at
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This Training Course is recognized for the GMP/GDP Certification Programme Certified Quality Control Manager

Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. This training course is the first element for your additional certification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance. Please find more information at www.gmp-certification.org

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Reservation Form (Please complete in full)

GMP/FDA Compliance in Analytical Laboratories | 23 – 25 October 2024, Barcelona, Spain

Title, first name, surname

Department Company

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

City ZIP Code Country

Phone / Fax

E-Mail (Please fill in)

General terms and conditions
If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
2. If you have to cancel entirely we must charge the following processing fees:
- Cancellation until 4 weeks prior to the conference 10 %,
- Cancellation until 3 weeks prior to the conference 25 %,
- Cancellation until 2 weeks prior to the conference 50 %
- Cancellation within 2 weeks prior to the conference 100 %.

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If the event must be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. CONCEPT HEIDELBERG will not be responsible for discount airfare penalties or other costs incurred due to a cancellation. **Terms of payment**: Payable without deductions within 10 days after receipt of invoice.
Important: This is a binding registration and above fees are due in case of cancellation or non-appearance. If you cannot take part, you have to inform us in writing. The cancellation fee will then be calculated according to the point of time at which we receive your message.
In case you do not appear at the event without having informed us, you will have to pay the full registration fee, even if you have not made the payment yet. Only after we have received your payment, you are entitled to participate in the conference (receipt of payment will not be confirmed)! (As of July 2022).
German law shall apply. Court of jurisdiction is Heidelberg.

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