



Speakers



Dr Joachim Ermer
Sanofi, 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

6 – 8 October 2020 | Copenhagen, Denmark



*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 Ltd., 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 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

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 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

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 2007
- 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
Sanofi, Frankfurt, Germany

Head of Quality Control Services Chemistry, Sanofi-Aventis Deutschland GmbH and Global Reference Standards Coordinator of Sanofi. 25 years of experience in pharmaceutical analytics in development, industrial, and global functions. He is member of the EFPIA Analytical Lifecycle Management working group and of the USP Expert Panel Validation & Verification.

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.

Date

Tuesday, 6 October 2020, 09.00 h - 18.30 h
(Registration and coffee 08.30 h - 09.00 h)
Wednesday, 7 October 2020, 08.30 h - 18.30 h
Thursday, 8 October 2020, 08.30 h - 15.30 h

Venue

Radisson BLU Scandinavia Hotel
Amager Boulevard 70
2300 Copenhagen S, Denmark
Phone +45 33 96 50 00
Email Scandinavia.meetings.events@radissonblu.com

Fees (per delegate, plus VAT)

ECA Members € 1,790
APIC Members € 1,890
Non-ECA Members € 1,990
EU GMP Inspectorates € 995

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.

Conference language

The official conference language will be English.

Organisation and Contact

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

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becker@concept-heidelberg.de.

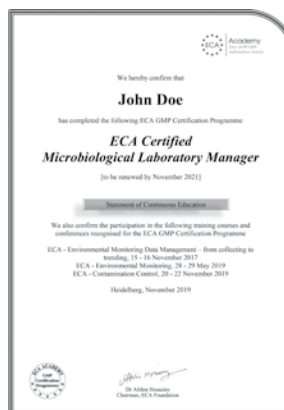
For questions regarding reservation, hotel, organisation etc. please contact:
Ms Nicole Bach (Organisation Manager) at
+49(0)62 21/84 44 22, or per e-mail at
bach@concept-heidelberg.de.

Social Event

On the evening of the first course day all participants and speakers are invited to a guided sight seeing tour and a nice dinner afterwards.

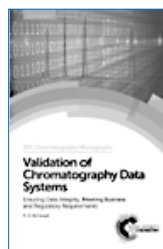


GMP/GDP Certification Scheme



Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. 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.

Literature



Participants of this Course can purchase the 2nd Edition of Dr Bob McDowall's book "Validation of Chromatography Data Systems" (Royal Society of Chemistry) with a discount of 20%!

You will receive the order form for this book at the course.

If the bill-to-address deviates from the specifications on the right, please fill out here:

CONCEPT HEIDELBERG
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GERMANY

Reservation Form (Please complete in full)

FDA Compliance in Analytical Laboratories, 6 – 8 October 2020, Copenhagen, Denmark

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 2 weeks prior to the conference 10 %
 - Cancellation until 1 week prior to the conference 50 %
 - Cancellation within 1 week prior to the conference 100 %
- CONCEPT HEIDELBERG reserves the right to change the materials, instructors,

or speakers without notice or to cancel an event 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.

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 January 2012). German law shall apply. Court of jurisdiction is Heidelberg.

Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at http://www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.