

# FDA Compliance in Analytical Laboratories

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

## SPEAKERS:



**Dr Joachim Ermer**  
*Sanofi, Germany*



**Dr Manfred Fischer**  
*Skyepharma (member of Vectura group), Switzerland*



**Joerg Kastenschmidt**  
*Merck, Germany*



**Dr Bob McDowall**  
*Member of the ECA Data Integrity & IT Compliance Group, UK*



**4 Interactive Workshops**

28 - 30 October 2019, Berlin, Germany

## LEARNING OBJECTIVES:

- 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



# FDA Compliance in Analytical Laboratories

28 - 30 October 2019, Berlin, Germany

## Objectives

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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 expectation 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

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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 Group

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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

## Programme

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### 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

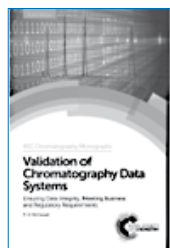
## Training Case Study

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

## Moderator

[Dr Bob McDowall](#), R D McDowall Ltd., UK

## Literature

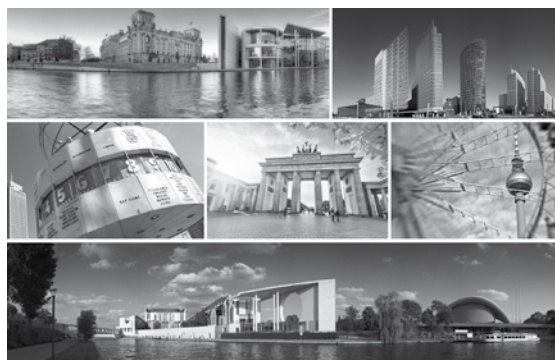


Participants of this Course can purchase the 2nd Edition of Dr Bob McDowall's book "Validation of Chromatography Data Systems" (Royal Society of Chemistry) with a discount of 20%!

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

## 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.



## Speakers



### Dr Joachim Ermer

*Sanofi, Frankfurt, Germany*

Head of Quality Control Services Chemistry, Sanofi-Aventis Deutschland GmbH, Frankfurt, Germany 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*

Jörg 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.



## Organisation and Contact

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

CONCEPT HEIDELBERG  
P.O. Box 10 17 64  
69007 Heidelberg, Germany  
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info@concept-heidelberg.de,  
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**For questions regarding content please contact**  
Dr Günter Brendelberger (Operations Director)  
at +49-62 21 / 84 44 40 or per e-mail at  
brendelberger@concept-heidelberg.de.

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

## GMP/GDP Certification Programme

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This seminar is recognised within the GMP Certification Programme for the module “Certified Quality Control Manager”. By attending selected seminars, the participant can acquire an additional certificate. We offer the following modules:

- ECA Certified Validation Manager
- ECA Certified QA Manager
- ECA Certified API Production Manager
- ECA Certified Quality Control Manager
- ECA Certified Technical Operations Manager
- ECA Certified Computer Validation Manager
- ECA Certified Regulatory Affairs Manager
- ECA Certified Microbiological Laboratory Manager
- ECA Certified Sterile Production Manager
- ECA Certified Biotech Manager
- ECA Certified Pharmaceutical Development Manager
- ECA Certified GMP Auditor
- ECA Certified GDP Compliance Manager
- ECA Certified Packaging Manager
- ECA Certified Data Integrity Manager

On the Internet at [www.gmp-compliance.org](http://www.gmp-compliance.org) you will find a text explaining which seminars are recognised for which certificates.

Or you send an e-mail to [info@gmp-compliance.org](mailto:info@gmp-compliance.org) or a fax to +49-6221- 84 44 64 with the request for information about the GMP Certification Programme. We will then send you our brochure on the topic.

## What are The ECA Foundation and the ECA Academy?

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The European Compliance Academy Foundation (ECA Foundation) is an independent professional organisation chaired by a Scientific Advisory Board with members from the pharmaceutical industry and regulatory authorities. The ECA Foundation's goal is to support to the Pharmaceutical Industry and Regulators to promote the move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidances. The ECA Academy offers professional basic and advanced education (training) programmes. All services offered by the ECA Academy and with regard to ECA Academy Memberships are solely managed by Concept Heidelberg (a leading European training and information services provider). The ECA Foundation is conceptual sponsor of the ECA Academy.

## How Do You Become a Member of ECA?

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By participating in one of the ECA Academy Conferences or Courses you will automatically become a ECA Academy Individual Member for two years - free of charge. More information about ECA Academy can be obtained on the Website <http://www.gmp-compliance.org>

## What Are the Benefits of ECA?

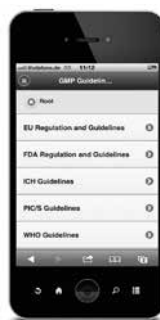
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During the membership, you enjoy

- free access to the members' area where you always find the latest update of the “GMP Guideline Manager” online version – allowing you to access a GMP tree with guidelines sorted by topics or by authority. It lets you find relevant guidelines quick and easy. And as member you can also get to this detailed tree with the GMP WebApp on your smartphone or tablet PC.
- a 200,- Euro rebate for any ECA course and conference, plus the opportunity to complete the GMP Certification Programme with an internationally recognised certificate.

## Use the GMP App at no costs!

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The ECA Foundation has developed a GMP App which offers a comprehensive GMP Guideline database with more than 1,400 GMP Guidelines and ten thousands of pages. Check relevant Guidelines (full text versions) during internal audits, regulatory inspections or GMP compliance meetings – simply on your smartphone or tablet PC. In addition to this wealth of guideline information the GMP App also comprises features like GMP News, a comprehensive GMP Search Engine. To open the app just enter [app.gmp-compliance.org](http://app.gmp-compliance.org) in your browser and the WebApp opens immediately.

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

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Reservation Form (Please complete in full)

## FDA Compliance in Analytical Laboratories,

28 - 30 October 2019, Berlin, Germany

Mr  Ms

Title, first name, surname

Company

Department

**Important: Please indicate your company's VAT ID Number**

**PO Number if applicable**

Street/P.O. Box

CONCEPT HEIDELBERG

P.O. Box 101764

Fax +49 (0) 62 21/84 44 34

City

Zip Code

Country

Phone

Fax

D-69007 Heidelberg  
GERMANY

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 %
  - until 1 week prior to the conference 50 %
  - 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 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](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.

 + 49 6221 84 44 34



## Easy Registration



Reservation Form:  
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Reservation Form:  
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e-mail:  
[info@concept-heidelberg.de](mailto:info@concept-heidelberg.de)



Internet:  
[www.gmp-compliance.org](http://www.gmp-compliance.org)

### Date

Monday, 28 October 2019,  
09.00 h - 18.30 h  
(Registration and coffee  
08.30 h - 09.00 h)  
Tuesday, 29 October 2019,  
08.30 h - 18.30 h  
Wednesday, 30 October 2019,  
08.30 h - 15.30 h

### Venue

Titanic Chaussee Berlin  
Chausseestraße 30  
10115 Berlin, Germany  
Telephone: +49 30 311 6858-0  
E-mail: [info.tcb@titanic-hotels.de](mailto:info.tcb@titanic-hotels.de)

### 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 all days 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 event. 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](http://www.gmp-compliance.org).

### Conference Language

The official conference language will be English.

