



4 Interactive Workshops

# FDA Compliance in Analytical Laboratories

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

29 - 31 October 2014, Copenhagen, Denmark

## SPEAKERS:

**Dr Christopher Burgess**  
*Burgess Analytical Consultancy*

**Dr Joachim Ermer**  
*Sanofi*

**Dr Manfred Fischer**  
*SkyePharma*

**Dr Bob McDowall**  
*McDowall Consulting*

## LEARNING OBJECTIVES:

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



# FDA Compliance in Analytical Laboratories

29 - 31 October 2014, Copenhagen, Denmark

## 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 initiatives.

## 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, and 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
- Equipment qualification and calibration
- Computer validation (including the requirements and actual interpretation of 21 CFR Part 11)
- Operator training

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 requirements (cGMP, CFR, Guidances for Industry, etc.)
  - FDA Inspections
  - Quality System Inspections (QSIT)
  - Key issues during laboratory inspections
  - 483s and Warning Letters
  - FDA's 'Pharmaceutical cGMPs for the 21st Century: A Risk-based Approach' Initiative
  - 'Process Analytical Technology' (PAT) initiative
- Dr Christopher Burgess, Burgess Analytical Consultancy, UK

### 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)
  - Case study: Qualification of a NIR-spectrophotometer
    - NIR Monograph: USP vs. EP
    - Change Control
  - Analytical instrument life-cycle (Requalification, etc.)
- Dr Manfred Fischer, SkyePharma, Switzerland

### Calibration for FDA Inspected Analytical Laboratories

- Requirements in the USP for instrument calibration
  - Contrasting US and European approaches (important in the context of laboratories struggling to meet both requirements)
  - ISO Guide 17 025 requirements
- Dr Christopher Burgess, Burgess Analytical Consultancy, UK

### Reference Standards and Reagents for FDA-Inspected Laboratories

- Regulatory requirements
  - Official/primary/working standards
  - Traceability of standards
  - Purity and characterisation of reference standards
  - Handling, storage and shelf-life of reference standards and reagents
  - Documentation
- Dr Joachim Ermer, Sanofi, Germany

### Validation of Analytical Procedures

- Regulatory requirements (ICH, FDA, compendia)
  - Holistic validation approach
  - Rationale design of validation studies
  - Relevant performance parameters
  - Sensible use of statistics
- Dr Joachim Ermer, Sanofi, Germany

### Stability Testing

- Stability testing of drug substances and drug products
- Stability testing for NDAs, ANDAs, and INDs
- Stability protocol
- Reporting stability data
- Specific stability requirements
- Stability testing for post-approval changes

Dr Christopher Burgess, Burgess Analytical Consultancy, UK

### Out of Specification Results

- Requirements of the FDA Guidance
- Efficient laboratory investigations
- Reanalysing, retesting, resampling
- Handling of atypical results

Dr Joachim Ermer, Sanofi, Germany

### Documentation for Quality Control Laboratories

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

Dr BOB McDOWALL, McDowall Consulting, UK

### 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

Dr Christopher Burgess, Burgess Analytical Consultancy, UK

### 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!
- Validation Lite for low risk systems

Dr Bob McDowall, McDowall Consulting, UK

### 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

Dr BOB McDOWALL, McDowall Consulting, UK



### 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 Christopher Burgess

#### 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

Dr Manfred Fischer, SkyePharma, Switzerland

## 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

Dr Bob McDowall, McDowall Consulting, UK

## Training Case Study

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

Dr Manfred Fischer, SkyePharma, Switzerland

## Literature

Each participant will receive the following together with the conference material:

- FDA's Human Drug cGMP Notes (including the parts that are not available via Internet)
- The complete BARR Ruling

## Integrating Analytical Instrument Qualification and Computerised System Validation

On 27 - 28 October 2014, i.e. on Monday and Tuesday of the same week, there will be another ECA GMP Education Course in Copenhagen about Integrating Analytical Instrument Qualification and Computerised System Validation.

The course is an ideal precursor to the Education Course FDA-Compliance in Analytical Laboratories (29 - 31 October 2014). Further information about this course can be received at [www.gmp-compliance.org](http://www.gmp-compliance.org).

Participants who register simultaneously for both courses will **receive a 350 € discount** (not valid for EU GMP Inspectorates).

## 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.



## Moderator

Dr Christopher Burgess

Burgess Analytical Consultancy, UK

## Speakers



**Dr Christopher Burgess**

Chartered Chemist with more than 36 years experience in the pharmaceutical industry primarily with Glaxo in Quality Assurance and Analytical R & D. He is a "Qualified Person" and a member of the European QP Association advisory board. He has been appointed to the USP Council of Experts 2010 to 2015.



**Dr Joachim Ermer**

Head of Quality Control Services Chemistry, Sanofi-Aventis Deutschland GmbH, Frankfurt, Germany and Global Reference Standards Coordinator of Sanofi. Over 20 years of experience in pharmaceutical analytics in development, industrial, and global functions. He has been appointed to the USP Validation and Verification Expert Panel 2010-2012.



**Dr Manfred Fischer**

Head Analytical Department / Quality Control at Skye-Pharma, Basel (Switzerland). Responsible for development, validation / transfer of analytical methods and quality control of clinical trial material.



**Dr Bob McDowall**

Analytical chemist with over 40 years experience including 15 years working in the pharmaceutical industry; Principal of McDowall Consulting, UK.

## Organisation and Contact

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

CONCEPT HEIDELBERG  
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### For questions regarding content:

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.:

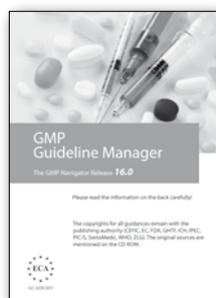
Ms Marion Weidemaier (Organisation Manager)  
at +49-62 21 / 84 44 43 or per e-mail at  
weidemaier@concept-heidelberg.de.

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

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?

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?

During the membership, you enjoy a EUR 200,- discount on the regular participation fee of any European Conference or Course presented by the ECA Academy. In addition you will receive the GMP Guideline Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines.

## GMP Certification Programme

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

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.

## Special offer with Lufthansa – up to 20% discounted travel for all ECA Events Attendees



As an ECA course or conference attendee, you will receive up to 20% discounted travel fares (according to availability).

And as Lufthansa German Airlines offers a comprehensive global route network linking major cities around the world you will most likely be able to benefit from these special prices and conditions.

And this is how it works: Once you registered for a course or conference you will receive a link together with your registration confirmation. Opening that link will take you to the Mobility Partner Program website where you can enter a code in the "Access to Event Booking" area you will also receive. This will take you into an online booking platform\* that will automatically calculate the discount offered or provide you with an even better offer if another promotional fare is available.

We look forward to welcoming at one of our next events – and we already wish you a pleasant flight!

\*Please note: You may have to enable pop-ups on the Mobility Partner Program website – other-wise the booking platform window will not open.

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,

29 - 31 October 2014, Copenhagen, Denmark

Integrating Analytical Equipment Qualification and Computerised System Validation,

27-28 October 2014, Copenhagen, Denmark

Please tick if you want to register for this course, too.

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

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### 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)

## 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.

## 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 when you have registered for the event. Please use this form for your room reservation to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel. Early reservation is recommended.

## Venue

Radisson BLU Scandinavia Hotel  
Amager Boulevard 70

2300 Copenhagen S, Denmark

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## Date

Wednesday, 29 October 2014, 09.00 h - 18.30 h  
(Registration and coffee 08.30 h - 09.00 h)

Thursday, 30 October 2014, 08.30 h - 18.30 h

Friday, 31 October 2014, 08.30 h - 15.30 h

## Easy Registration



Reservation Form:  
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