ECA Certified Quality Control Manager Course*

4 Interactive Workshops

FDA Compliance in Analytical Laboratories

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

10 - 12 November 2010, Amsterdam, The Netherlands

SPEAKERS:

Dr Wilfried Arz
Sanofi-Aventis

Dr Christopher Burgess
Burgess Analytical Consultancy

Dr Joachim Ermer
Sanofi-Aventis

Dr Manfred Fischer
SkyePharma

Jürgen Martin
Nycomed

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
  - The final FDA OOS Guidance
- Training Case Study
- Stability Testing

ECA
EUROPEAN COMPLIANCE ACADEMY

* This education course is recognised for the ECA GMP Certification Programme „Certified Quality Control Manager“. Please find details at www.gmp-certification.eu

FDA Compliance in Analytical Laboratories

10 - 12 November 2010, Amsterdam, The Netherlands

Objectives

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 Manual, 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

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

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 Christopher Burgess
Burgess Analytical Consultancy, UK

Programme

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
- A risk based life-cycle approach for reference standards
- Purity and testing of standards
- Handling and storage of standards and reagents
- Documentation

Jürgen Martin
Nycomed, Germany

Validation of Analytical Procedures

- Regulatory requirements (ICH, FDA)
- Holistic validation approach
- Rationale design of validation studies
- Relevant performance parameters
- Sensible use of statistics

Dr Joachim Ermer
Sanofi-Aventis, 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 Final FDA Guidance
- Efficient laboratory investigations
- Reanalysing, retesting, resampling
- Handling of atypical (out-of-trend) results

Dr Joachim Ermer
Sanofi-Aventis, Germany

Documentation in the Pharmaceutical Quality Control

- Procedures
  - Control tests and SOPs
  - Structure, contents, administration
- Documentation of raw data
  - Receipt of samples, testing and calibration of instruments
  - Definitions, principles, documentation systems, storage
- Issuing of test results
  - Analytical reports and certificates of analysis
  - Structure, contents

Dr Wilfried Arz
Sanofi-Aventis, Germany

Sampling in Compliance with FDA Requirements

- Importance of the sampling procedure
- Regulatory requirements
- General sampling procedure
- Sampling statistics
- Sampling
  - of raw materials, intermediates, active ingredients and excipients,
  - of drug products,
  - of packaging materials,
  - for IPCs,
  - for process and cleaning validations
- Sampling equipment / Sampling environment
- Personnel
- Documentation
- Retained samples

Dr Wilfred Arz
Sanofi-Aventis, Germany

Practical Computer Validation in Analytical Laboratories

- Computerised system validation as a critical activity in the analytical laboratory
- 21 CFR Part 11 compliance
- GAMP® software categories and impact on validation approach
- GAMP® Best Practice Guides for Laboratory Systems and for Part 11: pros and cons
- 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

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

- Legal requirements (ICH-guidelines, etc.)
- ISPE Good Practice Guide to Technology Transfer
- Standard procedure for method transfers
  - Initiation phase (transfer checklist, etc.)
  - Methods being transferred
  - Materials (samples and standards)
  - Instruments
  - Acceptance criteria, data assessment
  - Documentation
- Frequent problems of method transfers

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 proposed 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
- Training programme updates
- Handling non-compliance situations observed or reported in a 483 as a result of an FDA Inspection

Jürgen Martin
Nycomed, Germany

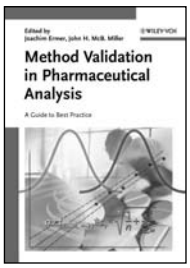
USP Chapter <1010> Analytical Data – Interpretation and Treatment

On 8 - 9 November 2010, i.e. on Monday and Tuesday of the same week, there will be another ECA GMP Education Course in Amsterdam about **Analytical Data – Interpretation and Treatment**. This course is intended as a practical introduction to the requirements of USP General Chapter <1010>.
The course is an ideal precursor to the Education Course **FDA Compliance in Analytical Laboratories** (10-12 November 2010). Further information about this course can be received at www.gmp-compliance.org. Participants who register simultaneously **for both courses** will receive a **€ 350 discount** (not valid for EU GMP Inspectorates).

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



Participants of this Course can purchase Dr Ermer's book „Method Validation in Pharmaceutical Analysis" (Wiley VCH, Weinheim 2005, ISBN: 3-527-31255-2) at a 15% reduced price! 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 of Amsterdam and a nice dinner afterwards.

Speakers

Dr Wilfried Arz, *Sanofi-Aventis Deutschland GmbH, Germany*
Group Head of Industrial Quality & Compliance Chemistry / Biotechnology at Sanofi-Aventis Deutschland GmbH, Frankfurt. Member of the expert group 10C of the Ph.Eur. and of the Committee for Pharmaceutical Chemistry of the German Pharmacopoeia Commission.

Dr Christopher Burgess, *Burgess Analytical Consultancy, UK*
Chartered Chemist with more than 30 years experience in the pharmaceutical industry primarily with Glaxo in Quality Assurance and Analytical R & D. He is a "Qualified Person" and a qualified ISO 17 025 Guide assessor and was member of the PDA (USA) OOS Task Force.

Dr Joachim Ermer, *Sanofi-Aventis Deutschland GmbH, Germany*
Head of Quality Control Chemistry, Sanofi-Aventis Deutschland GmbH, Frankfurt, Germany.

Dr Manfred Fischer, *SkyePharma AG, Switzerland*
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.

Jürgen Martin, *Nycomed GmbH, Germany*
Head of quality control laboratory responsible for testing of non-sterile products at Nycomed GmbH in Singen, Germany. Over 15 years of experience in pharmaceutical quality control. Additionally, Jürgen is operating his own software development enterprise.

Dr Bob McDowall, *McDowall Consulting, UK*
Analytical chemist with over 30 years experience including 15 years working in the pharmaceutical industry; Principal of McDowall Consulting, UK.

Organisation and Contact

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69007 Heidelberg, Germany,
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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 Is ECA?

The European Compliance Academy (ECA) is an independent educational organisation chaired by a Scientific Advisory Board with members of the pharmaceutical industry and regulatory authorities. The ECA will provide 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.

What Are the Benefits of ECA?

First benefit: During the membership, you enjoy a 10 % discount on the regular participation fee of any European Conference organised by ECA in co-operation with CONCEPT HEIDELBERG.

Second benefit:
The GMP Guideline Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines, will be forwarded to you when you are using your membership for a conference registration.

How Do You Become a Member of ECA?

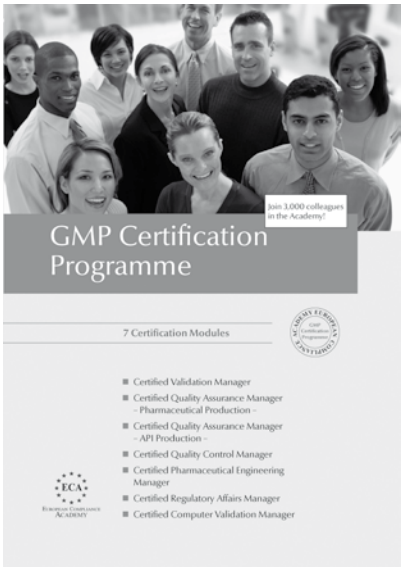
By participating in one of the European Compliance Conferences or Courses marked with ECA, you will automatically become a member of ECA for two years – free of charge. There are no obligations for the
member! Conferences and Education Courses organised by ECA will be realised in co-operation with CONCEPT HEIDELBERG. More information about ECA can be obtained on the Website http://www.gmp-compliance.org.

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
you will find a text explaining which seminars are recognised for which certificates. Or you send an e-mail to 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.



Easy Registration

Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany

Reservation Form:
+ 49 6221 84 44 34

e-mail:
info@concept-heidelberg.de

Internet:
www.gmp-compliance.org

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

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

☐ **FDA-Compliance in Analytical Laboratories,** 10 - 12 November 2010, Amsterdam, The Netherlands

☐ I would also like to register for the ECA Education Course
Analytical Data – Interpretation and Treatment, 8-9 November 2010, Amsterdam, The Netherlands

☐ 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

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 %,
- until 1 weeks 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)!

Date

Wednesday, 10 November 2010, 09.00 h - 18.30 h
(Registration and coffee 08.30 h - 09.00 h)
Thursday, 11 November 2010, 08.30 h - 18.30 h
Friday, 12 November 2010, 08.30 h - 15.30 h

Venue

Mövenpick Hotel Amsterdam City Centre
Piet Heinkade 11
1019 BR Amsterdam
The Netherlands
Phone + 31 20 519 12 00
Fax + 31 20 519 12 49

Fees

Non-ECA Members € 1,990.- per delegate plus VAT
ECA Members € 1,791.- per delegate plus VAT
APIC Members €1,890.- per delegate plus VAT
(does not include ECA membership)
EU GMP Inspectorates € 995.- per delegate plus VAT
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.

If you register for the ECA Education Course "Analytical Data – Interpretation and Treatment" from 8-9 November 2010 at the same time, you will receive a 350€ discount. This is not valid for EU GMP Inspectorates.

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 or be sure to mention "Concept Heidelberg" to receive the specially negotiated rate for the duration of your stay. Reservation should be made directly with the hotel not later than 29 September 2010. 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.