The new FDA Approach to

# Analytical Methods Validation of Drugs and Biopharmaceuticals

24 – 25 November 2014, Berlin, Germany

SPEAKERS:

**Dr Chris Burgess**
*Burgess Analytical Consultancy, UK*

**Dr Annick Gervais**
*UCB Biopharma SA, Belgium*

**Dr Gerd Jilge**
*Boehringer Ingelheim Pharma GmbH & Co. KG, Germany*

**Dr Robert de Lange**
*Roche Diagnostics, Germany*

**Dr Xaver Schratt**
*LAT GmbH Dr. Tittel, Germany*

HIGHLIGHTS:

- Key aspects of the new FDA Guidance
- Sources of variability and error in analytical procedures
- Statistical analysis and models in analytical methods validation
- Enhanced method lifecycle approach
- Lifecycle management of analytical procedures
- How to apply the principles of the new Guidance to biopharmaceuticals
- Analytical method comparability studies and transfer of procedures
- Robustness, ruggedness and system suitability tests
- Biological reference standards and materials
- FDA's regulatory expectations

ECA ACADEMY

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

# The new FDA Approach to Analytical Methods Validation of Drugs and Biopharmaceuticals

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## Objectives

The objectives of this Education Course are

- to understand the key aspects to consider in the new FDA Guidance and to get to know FDA's expectations concerning analytical methods validation,
- to learn how to deal with the various sources of variability and error and how to interpret results from methods validation by applying suitable statistical models,
- to discuss the implications of method life cycle management,
- to offer practical solutions on how to apply the principles of the FDA Guidance to biopharmaceuticals,
- to get to know how to deal with biological reference standards and materials,
- to learn how to perform GMP compliant analytical method comparability studies, system suitability tests and method transfers.

In order to improve the understanding and practical application of the contents of the lectures, workshops will be part of the training course.

## Background

In February 2014 the new FDA Guidance for Industry "Analytical Procedures and Methods Validation for Drug and Biologics" was published. This revised draft guidance supersedes the 2000 draft Guidance for Industry on "Analytical Procedures and Methods Validation" and will also replace the 1987 FDA Guidance for Industry on "Submitting Samples and Analytical Data for Methods Validation". It provides recommendations on how analytical procedures and methods validation should be performed and the data should be assembled to be submitted in an NDA, ANDA or BLA and supplements to these applications. Contrary to the 2000 Guidance aspects of life cycle management of analytical procedures and requirements for reporting postmarketing changes have been included in this new Guidance.

## Target Group

This interactive Education Course will be of particular interest to Laboratory Managers, Supervisors and Analysts in pharmaceutical quality control departments who have responsibility for the validation of analytical test procedures. Furthermore, this Course is designed for personnel from Quality Assurance, Regulatory Affairs and Contract Laboratories.

## Moderator

Dr Christopher Burgess

## Programme

### The FDA Guidance on Analytical Procedures and Methods Validation for Drugs and Biologics – What's new?

### Analytical Methods Validation – sources of variability and error

- What is uncertainty?
- Approaches to quantifying measurement uncertainty
- The error budget process
- Major sources of variability
- Simple measurement uncertainty calculation

### How to apply statistical analysis and models in analytical methods validation

- Accuracy, precision and bias
- Error types
- Calculating means and standard deviations
- Intermediate precision using one way ANOVA
- Data models for calibration
- Anscombe's quartet
- $\alpha$- and $\beta$-errors

### Validation for MAA/NDA: Planning and Execution

- Content of analytical procedures
- FDA requirements for method validation
- ICH and USP requirements

### Lifecycle Management of analytical procedures: method development, procedure performance qualification and procedure performance verification

- The Analytical Target Profile (ATP)
- Risk management
- Control strategy
- Knowledge management
- Verification and validation of compendial procedures according to USP <1225> and <1226>
- Defining the life cycle and adoption of the FDA Process Validation model 2011

### How to apply the principles of the FDA Guidance to Biopharmaceuticals – Case Studies

### Workshop: Critique of analytical documents in the lifecycle

The participants will work, in detail, on a typical case study proposing a suitable program of work for a validation dossier.

### Analytical Method Comparability Studies

- Alternative analytical procedures
- Proof of analytical equivalence
- Transfer of analytical procedures
- Analytical significance vs statistical significance
- Demonstration of analytical equivalence
- Alpha and beta errors
- Interval hypotheses

### Robustness, Ruggedness and System Suitability Tests

- Analytical process capability
- Ruggedness and intermediate precision
- Robustness – selecting factors and levels
- HPLC experimental design example
- Robustness testing in development and routine operation
- FDA's requirements on system suitability tests
- USP SST general principles

### Biological Reference Standards and Materials

- Material used for Reference Material (RM)
- Considerations for a RM specification
- Identity, purity and homogeneity
- Assignment of Content and Potency
- Stability considerations
- Sources of biological reference materials

### FDA's Regulatory Expectations concerning Analytical Procedures

## Social Event

On 24 November 2014, you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere

## Speakers

**Dr CHRISTOPHER BURGESS**
*Burgess Analytical Consultancy, UK*
Dr Burgess is a Chartered Chemist and has 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 United States Pharmacopoeia's Council of Experts 2010 to 2015 and is a visiting professor of the University of Strathclyde's School of Pharmacy and Biomedical Sciences (SIPBS). In addition, he is the chairman of the ECA Analytical Quality Control Group and a member of the Executive committee of European Compliance Academy.

**Dr ANNICK GERVAIS**
*UCB Biopharma SA, Belgium*
Chemical engineer by education and Doctor from University Louis Pasteur (Strasbourg, France) specialised in mass spectrometry, Annick has acquired 18 years experience and expertise on Biotech products working in analytical and process development of recombinant proteins first in Switzerland (Serono) for 11 years and currently in Belgium (UCB) for the last 7 years. She is currently Director of Physico-Chemical Method Development in Analytical Sciences for Biologicals in UCB Pharma (Braine L'Alleud, Belgium) dealing with development, validation, transfer of methods and process support from early phase to life cycle management for therapeutic proteins and monoclonal antibodies in the field of immunology. She is also representing UCB in European Biopharmaceutical Enterprises (EBE) biomanufacturing working group (part of EFPIA).

**Dr GERD JILGE**
*Boehringer Ingelheim Pharma GmbH & Co. KG, Germany*
In 1991 Dr Gerd Jilge came to Boehringer Ingelheim working in product development where he was responsible for method development and validation for the application of analytical procedures. In 2000 Dr Jilge took a position in Drug Regulatory Affairs of Boehringer Ingelheim GmbH with the focus on CMC documentation for the submission of new and registered drug products. Since July 2007 he is working in Quality Management on method development for new drug substances.

**Dr ROBERT de LANGE**
*Roche Diagnostics, Germany*

**Dr XAVER SCHRATT**
*LAT GmbH Dr. Tittel, Germany*
Dr Schratt studied Chemistry at the University of Bayreuth, where he specialized in HPLC and HPLC/MS. In 2005 he joined LAT and since 2006 he is head of department R & D 2. In charge of national and international pharmaceutical companies he manages all analytical aspects of projects from preclinical stage up to phase III and post market approval. As an expert for chromatography and mass spectrometry he mainly focuses on method development, validation and qualification of reference substances.

## 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**

Reservation Form (Please complete in full)

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If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
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- until 2 weeks prior to the conference 10 %
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### Date

Monday, 24 November 2014, 10.00 – 18.00 h
(Registration and coffee 9.30 – 10.00 h)
Tuesday, 25 November 2014, 08.30 – 15.00 h

### Venue

InterCityHotel Berlin Hauptbahnhof
Katharina-Paulus-Straße 5
10557 Berlin, Germany
Phone +43 (0)30 288 755 0
Fax +43 (0) 30 288 755 900

### Fees (per delegate plus VAT)

ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable

### Accommodation

CONCEPT 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 course. 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.

### 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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