



Speakers



Dr Thomas Backensfeld
Bayer AG, Berlin, Germany



Dr Raphael Bar
BR Consulting, Israel



Sue Mann
Sue Mann Consultancy, UK



Mathieu Materne
UCB BioPharma sprl, Belgium



Dr Bernd Renger
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QC Compliance Manager

Focus on Small-Molecule APIs and Drug Products!

15 – 17 June 2021 | Heidelberg, Germany



Highlights

- Regulatory Requirements for Analytical Labs (EU and U.S.)
- Analytical Instrument Qualification According to USP <1058>
- Computerised Systems in Analytical Labs
- Sampling of APIs and Excipients
- Documentation
- Specifications, SOPs, Test Procedures
- Laboratory Data Integrity
- Analytical Methods
 - Lifecycle Approach
 - Method Transfer and equivalence testing
- Managing OOS/OOT Results
- Stability Data: Presenting and Evaluating
- QA Aspects Applicable for QC Compliance Managers

Participate in 4 Workshops!

Objective

This Education Course will give a comprehensive overview of the main GMP requirements for quality control laboratories, from a European as well as from the U.S. (FDA) perspective. It is the aim of the course to address the challenges that QC Compliance Managers face today regarding the relevant regulatory requirements and how to successfully implement these requirements in the analytical lab.

Background

Due to changing regulatory requirements pharmaceutical Quality Control Compliance Managers are continuously facing new challenges. There are many regulatory requirements relevant for the pharmaceutical quality control, both in EU and in the U.S., for instance:

- EU GMP Guide (Part 1 / Part 2 / Annexes)
- 21 CFR Part 210/211 (USA)
- Guidances (EMA and FDA)
- ICH Guidelines
- WHO and PIC/S Recommendations
- Pharmacopoeias (Ph.Eur., USP)

QC Compliance Managers must be familiar with all these GMP-related topics and must be aware of the latest updates and the current interpretation of all these guidance documents.

In addition, analytical QC laboratories are increasingly in the focus of GMP inspections, both in Europe and in the U.S.. For instance after FDA inspections, many laboratory-specific citations can be found in 483s and Warning Letters. And many findings related to the laboratory can also be found after inspections of European GMP supervisory authorities. Key compliance requirements include:

- Change control systems
- Calibration and qualification of analytical instruments
- Reference standards
- GMP compliant documentation
- Validation of analytical methods
- Stability program
- Validation of computerised systems
- Procedures for handling OOS results

All these key compliance issues will be addressed in this course and the main topics also deepened in workshops.

Please note that the emphasis of this course is on small-molecule pharmaceuticals. The course will not focus on biotech products.

Target Audience

This Education Course will be of significant value to

- Laboratory managers
- Quality control managers
- Analytical scientists
- Senior laboratory staff

from quality control units in the pharmaceutical industry who are responsible for GMP Compliance in the analytical laboratory.

Programme

Regulatory Requirements for Analytical Labs and QC (EU and US)

- EU GMP Guide Part 1
- EU GMP Guide Part 2
- US 21 CFR Part 210/211
- FDA Guidances for Industry with relevance for labs
- Inspection of analytical labs (EMA, FDA, etc.)
- FDA Warning Letters relating to QC

Analytical Instrument Qualification

- USP General Chapter <1058> Analytical Instrument Qualification
- Risk analysis
- Qualification steps: DQ/IQ/OQ/PQ
- Practical Qualification of typical instruments such as
 - Balances
 - HPLC
 - UV
 - Dissolution

Sampling

- EU GMP Part 1, Chapters 4, 5, 6
- EU GMP Part 2, Chapter 7 (7.1 – 7.5)
- EU GMP Draft Chapter 4
- Statistical sampling – requirements and interpretation
- EU GMP Annex 8
- EU GMP Annex 19
- US / FDA Requirements
- WHO
- PIC/S
- ISO (former Military Standard)

Documentation in QC Laboratories

- Regulatory requirements (EU / US)
- Specifications, test procedures, SOPs, etc.
- Handling of data (paper, electronic, hybrid)
- Laboratory Data Integrity
- Analytical results (raw data, raw data check, averaging, rounding of results)
- Case Studies
- Laboratory Data Integrity issues related to documentation
 - issues to be aware of

The Analytical Aspects of Laboratory Data Integrity

- Overview of deficiencies in laboratory data integrity
- Structure of a typical assay in a QC laboratory
- When system suitability requirements are not met
- Is there a system suitability test based on samples?
- When sample variability criteria are not met
- QC samples for method validity check
- Integration of chromatographic peaks: Automated versus manual
- Reprocessing of raw data and re-integration
- Accepting or invalidating test results?
- Review of audit trail of an analytical run

Lifecycle Approach to Analytical Procedures

- Developing robust, stability indicating methods
- Analytical Target Profile
- Implementation of QbD in development of analytical methods
- Life-cycle of an analytical method
- Are we estimating the real method precision?
- The concept of Assay Format

Handling and Qualification of Primary and Secondary Chromatographic Reference Standards

- Procedure for qualification of a primary reference standard
- Procedure for qualification of a secondary reference standard
- Pharmacopeial standards: handling and re-use
- Will the certified reference standards (CRM) come to the QC lab?
- Assigning purity values to reference standards
- Calculation examples of assigning purity

Managing Out of Specification and Out of Trend Results

- OOS / OOE / OOT
- FDA and MHRA Guidance
- Reportable Value
- Case Study: Practical approach for handling OOS results
- Issues with OOT results and how to manage these

Computer Validation and Integrity of Electronic Data in Analytical Labs

- Regulatory requirements (EU Annex 11 / US 21 CFR Part 11)
- GAMP / GAMP Laboratory Guide
- PIC/S Guide Computerised Systems in GXP Environments
- Validation of Excel spreadsheets
- UCB Case Study: Implementation of a computerised system at UCB from IT infrastructure components to final VSR and periodic review
- Facilitating and ensuring data integrity through validated paperless processes

Presenting and Evaluating Stability Data

- Overview of ICH storage programs for new drugs
- Generic drugs
- Presenting stability data
- Derivation of shelf life according to ICH Q1E

Transfer of Analytical Methods

- Definition and regulatory requirements
- How to perform a method transfer
- Case studies
- Typical and critical issues

Method Comparison – Equivalence Testing of Two Methods

- Is a newly issued pharmacopeial method equivalent to an in-house validated and practiced method?
- Traditional way of comparison
- Equivalence testing with two one-sided t-tests (TOST)
- Examples

QA Aspects in QC (relevant for QC Compliance Managers)

- Defining responsibilities for analysts, head of analytical lab, QPs (EU and US)
- Release of APIs, excipients, packaging materials, finished products, etc.
- Contract labs
- CAPA (Corrective Actions and Preventive Actions)
- Change Control (regulatory framework)
- PQR
- Training (GMP training / training on the job, training records)



Four Workshops

Some of the most important laboratory compliance topics will be further discussed in interactive workshops:

Topic I: Analytical Instrument Qualification

Moderator: Dr Thomas Backensfeld

Topic II: Method Transfer

Moderator: Dr Bernd Renger

Topic III: Validation of Analytical Test Procedures

Moderator: Dr Raphael Bar

Topic IV: Sampling of Raw Materials, Packaging Components, Devices and Finished Products – Practicing with the Sampling Standard ISO-2859-1

Moderator: Dr Raphael Bar

Speakers



Dr Thomas Backensfeld
Bayer AG, Berlin, Germany

Dr Backensfeld is head of Analytical Development within Global Chemical and Pharmaceutical Development. He is responsible for several analytical project groups developing pharmaceutical products of small molecules. The work covers the development and validation of analytical methods, stability testing, quality control, dossier filing and support of life cycle management.



Dr Raphael Bar
BR Consulting, Israel

Dr Bar headed the Analytical R&D Laboratories at Teva Pharmaceuticals and the analytical QC laboratory at Pharmos. He served in the Scientific Advisory Board of global PDA (USA) and is presently a board member of Israel PDA Chapter as well as a member of the organizing committee of the Israel Society for Analytical Chemistry. For the last ten years, Raphael Bar has been a pharmaceutical consultant for the Pharma and bio-Pharma industries.



Sue Mann
Sue Mann Consultancy, UK

Sue Mann is a Pharmacist and a Qualified Person, and has spent over 35 years in the industry in various roles including technical support, clinical trial supplies and quality assurance/management. She has worked with both commercial and investigational medicinal products and most major dosage forms. She is presently a pharmaceutical consultant working for pharmaceutical and biopharmaceutical companies.



Mathieu Materne
UCB BioPharma sprl, Belgium

Mathieu Materne is Quality, Compliance and IT Professional with over 15 years of experience in BioPharma industry for international Technical and Supply Chain Operations. He has strong experiences in GMP/GDP (Engineering, Manufacturing, Laboratory and Supply Chain) and Medical Device projects and data management.



Dr Bernd Renger
Bernd Renger Consulting, Germany

Dr Bernd Renger started at Hoechst AG. Since then, he has held several quality management positions at Mundipharma, Byk Gulden (now Takeda) and Baxter BioScience in Vienna and Veter Pharma-Fertigung. He was a member of the European Compliance Academy (ECA) Advisory Board and is Immediate Past Chair of the European QP Association.

Date

Tuesday, 15 June 2021, 9.00 – 18.30
(Registration and coffee 8.30 – 9.00)
Wednesday, 16 June 2021, 8.30 – 18.00
Thursday, 17 June 2021, 8.30 – 15.30

Venue

NH Heidelberg
Bergheimer Strasse 91
69115 Heidelberg, Germany
Phone +49(0) 6221 1327 0
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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 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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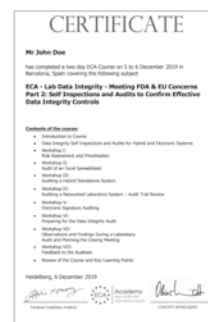
For questions regarding reservation, hotel, organisation etc. please contact:
Ms Sonja Geppert (Organisation Manager) at
+49(0)62 21/84 44 16, or at
geppert@concept-heidelberg.de.

Social Event

At the end of the first course day 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.



Internationally Acknowledged Certificate from ECA Academy



The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...“. This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.

Lufthansa is Mobility Partner for all ECA Events



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:

CONCEPT HEIDELBERG
P.O. Box 101764
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D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

QC Compliance Manager, 15 – 17 June 2021, Heidelberg, Germany

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 %
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Important: This is a binding registration and above fees are due in case of can-

cellation 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.

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