ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Control Manager

Speakers

Dr Thomas Backensfeld
Bayer AG, Germany

Dr Raphael Bar
BR Consulting, Israel

Dr Thomas Fürst
Boehringer Ingelheim, Germany

Sue Mann
Sue Mann Consultancy, UK

Dr Bernd Renger
Bernd Renger Consulting, Germany

QC Compliance Manager

Focus on Small-Molecule APIs and Drug Products!

Live Online Training on 02/03 November 2022

Highlights

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

Objective

This Live Online Training 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 training 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 need to be familiar with all these GMP-related topics and need to 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 instrument
- Reference standards
- GMP compliant documentation
- Validation of analytical methods
- Stability program
- Laboratory Data Integrity
- Procedures for handling OOS results

All these key compliance issues will be addressed in this Live Online Training and the main topics are also deepened in workshops.

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

Target Audience

This Live Online Training 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

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

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

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

Transfer of Analytical Methods

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

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

Sampling of Raw Materials, Packaging Components, Devices and Finished Products

- What is Acceptance Sampling?
- Sampling of finished product and packaging
- Sampling Attributes vs. sampling by variables
- ISO 2859-1 sampling standard
- Nonconforming items and non-conformities
- Classification of non-conforming items and non-conformities
- Risks of sampling
- Sampling of starting materials (WHO standard)
- Full testing vs. testing for identity

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

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

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

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)

Speakers

Dr Thomas Backensfeld
Bayer AG, Berlin, Germany

Dr Backensfeld is currently head of Analytical Development – Strategy and Technologies. He is responsible for several analytical labs focussing on small molecules development. The work covers the development and validation of analytical methods, stability testing, quality control and dossier filing. Furthermore, he is in charge of the LIMS system and the CRO 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.

Dr Thomas Fürst
Boehringer Ingelheim, Germany

Dr Fürst joined Schering in 1997 working in a production facility for oral dosage forms. In 2007 he joined Boehringer Ingelheim as a CMC expert. From 2013 – 2018 he was head of development of Consumer Healthcare at Boehringer (from 2017 SANOFI). Since 2018 Dr Fürst is again with Boehringer as head of laboratory of the development department.

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.

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 Vetter Pharma-Fertigung. He was a member of the European Compliance Academy (ECA) Advisory Board and is Immediate Past Chair of the European QP Association.

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Reservation Form (Please complete in full)

QC Compliance Manager, Live Online Training on 02/03 November 2022

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)

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Date of the Live Online Training

Wednesday, 02 November 2022,
09.00 h - approx. 17.15 h CET
Thursday, 03 November 2022,
08.30 h - approx. 16.45 h CET

Technical Requirements

For our Live Online Training Courses and Webinars, we use Cisco WebEx, one of the leading suppliers of online meetings.
At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test.
If the installation is not possible because of your rights for the computer system, please contact your IT department. WebEx is a standard nowadays and the necessary installation is fast and easy.

Fees (per delegate, plus VAT)

ECA Members € 1,590
APIC Members € 1,690
Non-ECA Members € 1,790
EU GMP Inspectorates € 895
The fee is payable in advance after receipt of invoice.

Registration

Via the attached reservation form, by e-mail or by fax message.
Or you register online at www.gmp-compliance.org.

Presentations/Certificate

The presentations will be made available to you prior to the Live Online Training as PDF files. After the event, you will automatically receive your certificate of participation.

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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