Speakers

Dr Thomas Backensfeld
Berlin, Germany

Dr Raphael Bar
BR Consulting, Israel

Dr Thomas Fürst
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Sue Mann
Sue Mann Consultancy, UK

QC Compliance Manager

Focus on Small-Molecule APIs and Drug Products

Live Online Training on 27/28 May 2025

Highlights

- Regulatory Requirements for Analytical Labs (EU and U.S.)
- Analytical Instrument Qualification
- Chromatographic Reference Standards
- Sampling
- Documentation
- Specifications, SOPs, Test Procedures
- Laboratory Data Integrity
- Lifecycle Approach
- Method Transfer and Equivalence Testing
- Managing OOS/OOT Results
- Presenting and Evaluating Stability Data
- QA Aspects Applicable for QC Compliance Managers
- Several Q&A sessions

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. A set of live Q&A sessions will give you the possibility to interact with the speakers and get answers to your questions.

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

- What is acceptance sampling?
- Sampling attributes vs. sampling by variables
- ISO 2859-1 sampling standard
- Nonconforming items and non-conformities
- Risks of sampling
- Sampling of starting materials (WHO standard)
- Full testing vs. testing for identity

Workshop on Sampling with ISO 2859-1

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
- Reprocessing of raw data and re-integration
- 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)

Dr Thomas Backensfeld
Berlin, Germany

Dr Backensfeld is a pharmacist by training and started at Schering AG in 1990 as a lab manager in analytics. After over 10 years in formulation development he was head of a small production facility for oral dosage forms. Since then he held several positions within Analytical Development. In 2022 he completed his career at Bayer and is presently working as a Qualified Person on a consultant basis.

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.

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Reservation Form (Please complete in full)

QC Compliance Manager, Live Online Training on 27/28 May 2025

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:
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Privacy Policy: By registering for this event, I accept the processing of my Personal Data. Concept Heidelberg will use my data for the processing of this order, for which I hereby declare to agree that my personal data is stored and processed. Concept Heidelberg will only send me information in relation with this order or similar ones. My personal data will not be disclosed to third parties (see also the privacy policy at www.gmp-compliance.org/eca_privacy.html). I note that I can ask for the modification, correction or deletion of my data at any time via the contact form on this website.

Date of the Live Online Training

Tuesday, 27 May 2025, 09.00 h - approx. 17.45 h CEST
Wednesday, 28 May 2025, 08.30 h - approx. 17.15 h CEST

Technical Requirements

We use WebEx for our live online training courses and webinars. At www.gmp-compliance.org/training/online-training-technical-information you will find all the information you need to participate in our trainings and you can check if your system meets the necessary requirements to participate. If the installation of browser extensions is not possible due to your rights in the IT 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 EUR 1,690
APIC Members EUR 1,790
Non-ECA Members EUR 1,890
EU GMP Inspectorates EUR 945
The conference fee is payable in advance after receipt of invoice.

Registration

Via the attached reservation form, by e-mail or by fax or search and register directly at www.gmp-compliance.org under the number 21754.

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.

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.

Organisation and Contact

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

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