



# QC Compliance Manager

Focus on Small-Molecule APIs and Drug Products!

## SPEAKERS:



**Dr Thomas Backensfeld**  
Bayer AG, Germany



**Dr Raphael Bar**  
BR Consulting, Israel



**Dr Kerstin Hartisch**  
Bayer AG, Germany



**Mathieu Materne**  
UCB BioPharma, Belgium



**Sue Mann**  
Sue Mann Consultancy, UK



Participate in 4 Workshops

27 – 29 March 2019, Vienna, Austria

## PROGRAMME:

- 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



# QC Compliance Manager

27 – 29 March 2019, Vienna, Austria

## Objectives

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 US, 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 US. 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
- 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.

This year's programme has been further updated to include the current challenges of Laboratory Data Integrity issues in analytical labs about reporting and invalidating laboratory results.

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 spectrophotometer
  - Dissolution apparatus

### Sampling

- EU GMP Part 1, Chapters 4, 5, 6
- EU GMP Part 2, Chapter 7 (7.1 – 7.5)
- EU GMP 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-test (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: Validation of Analytical Test Procedures

Moderator: Dr Raphael Bar

### Topic III: Method Transfer

Moderator: Dr Kerstin Hartisch

### 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*

Thomas Backensfeld studied Pharmacy at the University of Muenster and received his PhD in Pharmaceutical Technology at the University of Kiel. He joined Schering AG in 1990 and held different positions in Analytical and Pharmaceutical Development. He has more than 10 year experience in formulation development of solid dosage forms including GMP manufacturing of clinical trial materials. After leading a production plant he returned back to Analytical Development. In his current position as head of an Analytical Development T. Backensfeld 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, tech transfer, dossier filing and support of life cycle management.



### Dr Raphael Bar

*BR Consulting, Israel*

Raphael Bar is presently a pharmaceutical consultant for the Pharma and bio-Pharma industries. He is consulting various companies and provides development and analytical support to investigational, generic, new drugs as well as combination device-drug products and CMC project management. With a doctorate in Chemistry (1984), Dr Bar joined Teva Pharmaceuticals (1995) and headed for three years the Analytical R&D Laboratory. He was involved in preparation of ANDA files. He then joined Pharmos where he managed the quality control and R&D laboratory till 2007. As Senior Director of Analytical Development he was actively involved in preparation of CMC packages for clinical trial studies. From 2009 until June 2015, he was a member of the scientific advisory board of global PDA (USA).



### Dr Kerstin Hartisch

*Bayer AG, Berlin, Germany*

Kerstin Hartisch studied Food Chemistry and Pharmacy at the University of Bonn and received her PhD in Pharmaceutical Analytics. In her position as head of Analytical Development within Bayer, Global Chemical and Pharmaceutical Development she is responsible for all aspects regarding special analytical techniques in product development, i.e. dissolution testing, particle identification, packaging material and excipient testing and also sample and data management (LIMS). She is specialized in the area of dissolution testing including all aspects of automation (Robot Technology).



### Mathieu Materne

*UCB BioPharma sprl, Belgium*

*IT Compliance Lead, Global TO, NewMeds & Patient Solutions (Medical Device), IT Strategy & Technology Solutions,*

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



### Sue Mann

*Sue Mann Consultancy, UK*

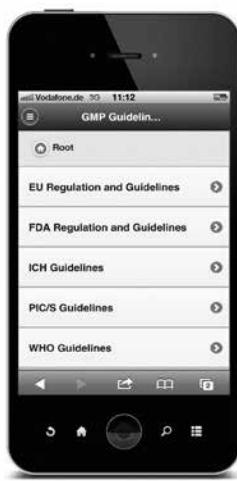
Sue Mann is a Pharmacist and a Qualified Person, and has spent over 35 years in the industry in various roles including technical support, clinical trial supplies and quality assurance/management. She has worked for many different types of company including multinational, contract manufacturing, Japanese and virtual. Sue has worked with both commercial and investigational medicinal products and most major dosage forms. Sue is presently a pharmaceutical consultant working for Pharmaceutical and Biopharmaceutical companies. She has a passion for developing simple, efficient, effective quality systems to support all operational activities including those performed in the analytical laboratory.

## 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.



## Use the GMP App at no costs!



The ECA Foundation has developed a GMP App which offers a comprehensive GMP Guideline database with more than 1,400 GMP Guidelines and ten thousands of pages. Check relevant Guidelines (full text versions) during internal audits, regulatory inspections or GMP compliance meetings – simply on your smartphone or tablet PC. In addition to this wealth of guideline information the GMP App also comprises features like GMP News, a comprehensive GMP Search Engine.

To open the app just enter [app.gmp-compliance.org](http://app.gmp-compliance.org) in your browser and the WebApp opens immediately.

## What are The ECA Foundation and the ECA Academy?

The European Compliance Academy Foundation (ECA Foundation) is an independent professional organisation chaired by a Scientific Advisory Board with members from the pharmaceutical industry and regulatory authorities. The ECA Foundation's goal is to support 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. The ECA Academy offers professional basic and advanced education (training) programmes. All services offered by the ECA Academy and with regard to ECA Academy Memberships are solely managed by Concept Heidelberg (a leading European training and information services provider). The ECA Foundation is conceptual sponsor of the ECA Academy.

## How Do You Become a Member of ECA?

By participating in one of the ECA Academy Conferences or Courses you will automatically become a ECA Academy Individual Member for two years - free of charge. More information about ECA Academy can be obtained on the Website <http://www.gmp-compliance.org>

## What Are the Benefits of ECA?

During the membership, you enjoy

- a EUR 200,- discount on the regular participation fee of any European Conference or Course presented by the ECA Academy.
- free access to the members' area where you always find the latest update of the "GMP Guideline Manager" online version – allowing you to access a GMP tree with guidelines sorted by topics or by authority. It lets you find relevant guidelines quick and easy.

## 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 – otherwise the booking platform window will not open.

## GMP Certification Programme

This seminar is recognised within the GMP Certification Programme. 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
- ECA Certified GMP Auditor
- ECA Certified GDP Compliance Manager
- ECA Certified Packaging Manager
- ECA Certified Data Integrity Manager

On the internet at [www.gmp-compliance.org](http://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](mailto: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

Reservation Form (Please complete in full)

### QC Compliance Manager

27 - 29 March 2019, Vienna, Austria

Mr.  Ms.

Title, first name, surname

Company

Department

**Important: Please indicate your company's VAT ID Number**

P.O. 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 %, - within 1 week prior to the conference 50 %.  
CONCEPT HEIDELBERG reserves the right to change the materials, in-

structures, 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 deduction 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, German law shall apply. Court of jurisdiction is Heidelberg.

**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 <http://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.

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

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D-69007 Heidelberg  
GERMANY

## Date

Wednesday, 27 March 2019, 09.00 h - 18.30 h  
(Registration and coffee 08.30 h - 09.00 h)  
Thursday, 28 March 2019, 08.30 h - 18.30 h  
Friday, 29 March 2019, 08.30 h - 15.30 h

## Venue

Radisson Blu  
Park Royal Palace Hotel Vienna  
Schlossallee 8  
1140 Vienna, Austria  
Phone +43/1/89110 - 0  
info.parkroyalpalace.vienna@radissonblu.com

## 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 three 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 with all further information when you have registered for the event. 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](http://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.

CONCEPT HEIDELBERG  
P.O. Box 10 17 64  
D-69007 Heidelberg, Germany  
Phone +49 (0) 62 21 / 84 44 0  
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[www.concept-heidelberg.de](http://www.concept-heidelberg.de)

## For questions regarding content:

Dr Günter Brendelberger (Operations Director) at phone +49-62 21 / 84 44 40, or per e-mail at [brendelberger@concept-heidelberg.de](mailto:brendelberger@concept-heidelberg.de).

## For questions regarding reservation, hotel, organisation etc.:

Ms Nicole Bach (Organisation Manager) at +49-62 21 / 84 44 22, or per e-mail at [bach@concept-heidelberg.de](mailto:bach@concept-heidelberg.de).