Participate in 4 Workshops

QC Compliance Manager

Focus on Small-Molecule APIs and Drug Products!

16 – 18 March 2016, Prague, Czech Republic

SPEAKERS:

Dr Raphael (Raphy) Bar
BR Consulting, Israel

Eric De Maesschalck
UCB, Belgium

Sue Mann
Sue Mann Consultancy, UK

Dr Kerstin Pauli
Bayer HealthCare Pharma AG, Germany

Dr Alexander Pontius
Bayer HealthCare Pharma AG, Germany

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
  - Development and Validation
  - Method Transfer and Equivalence Testing
- Managing OOS/OOT Results
- Stability Testing
- QA Aspects Applicable for QC Compliance Managers

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

QC Compliance Manager

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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 updated to include the current challenges of Laboratory Data Integrity issues (both documentation and computerized systems) and the Handling of OOT results.

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

Target Adience

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

Sue Mann

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

Dr Alexander Pontius

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)

Sue Mann

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

Sue Mann

Analytical Methods: Development and Validation
- Developing robust, stability indicating methods
- Implementation of QbD in development of analytical methods
- Life-cycle of an analytical method

Dr Raphael (Raphy) Bar

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

Dr Raphael (Raphy) Bar

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

Sue Mann

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

Eric De Maesschalck

Stability Testing
- Overview of ICH storage programs for new drugs
- Generic drugs
- Mean kinetic temperature
- Presenting stability data
- Derivation of shelf life

Dr Raphael (Raphy) Bar

Transfer of Analytical Methods
- Regulatory Requirements (EU GMP Chapter 6 Draft, WHO recommendations, USP General Chapter <1224>)
- ISPE Guide
- Case Studies

Dr Kerstin Pauli

Method Comparison – Equivalence Testing of Two Methods
- Is a newly issued pharmacopeial method equivalent to an in-house validated and practiced method?

Dr Raphael (Raphy) Bar

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)

Sue Mann

Four Workshops

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

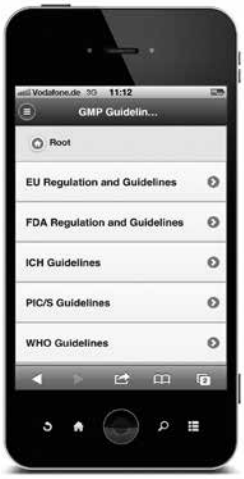
Topic I: Analytical Instrument Qualification
Moderator: Dr Alexander Pontius

Topic II: Validation of Analytical Test Procedures
Moderator: Dr Raphael (Raphy) Bar

Topic III: Method Transfer
Moderator: Dr Kerstin Pauli

Topic IV: Sampling of Raw Materials, Packaging Components, Devices and Finished Products – Practicing with the Sampling Standard ISO-2859-1
Moderator: Dr Raphael (Raphy) Bar

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 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 to 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. In addition you will receive the GMP Guideline Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines.

Lufthansa is Mobility Partner for all ECA Events

Lufthansa Mobility Partner

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.

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

On the internet at 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 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.

Speakers

Dr Raphael (Raphy) 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 (1995) Teva Pharmaceuticals 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. Since 2009, he has been a member of the scientific advisory board of global PDA (USA) till June 2015.

Eric De Maesschalck

UCB, Belgium

Eric De Maesschalck graduated in Clinical Chemistry and Medical Biology. He has spent 25 years in highly regulated pharmaceutical companies: GSK, Pfizer, Phibro Animal Health and UCB Pharma. Eri de Maesschalck has 20 years of experience in computerized systems qualification and validation including IT infrastructure (GMP, GCP, GLP, GPvP) and his current position at UCB Pharma is Head of Global e-Analytics, Corporate Analytical Sciences, where he has to define the long term strategy for electronic analytical tools supporting business processes to be implemented across UCB sites (e.g. GLIMS, ELN, statistical application, central chromatography, scientific data management system, etc.).

Sue Mann

Sue Mann Consultancy, UK

Sue Mann is a Pharmacist and a Qualified Person, and has spent over 30 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.

Dr Kerstin Pauli

Bayer HealthCare Pharma AG, Berlin, Germany

Kerstin Pauli 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 Global Chemical and Pharmaceutical Development she is responsible for different laboratory groups working on all aspects regarding special analytical techniques in product development, i.e. NIR and Raman Spectroscopy, AAS, LC/MS, GC, but also sample and data management (LIMS). She is specialised in the area of dissolution testing including all aspects of automation (Robot Technology).

Dr Alexander Pontius

Bayer HealthCare Pharma AG, Berlin, Germany

Dr Alexander Pontius is a pharmacist by training and did his PhD graduation in biopharmaceutical analytics. He is heading a QC group in the global pharmaceutical development division and is responsible for all aspects of the dissolution methodology. The work covers the development and validation of dissolution methods, bio-pharmaceutical evaluations, dossier submission of innovative drug products, handling of post approval changes as well as support of life cycle management and patent protection of market products.

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.

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

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

CONCEPT HEIDELBERG
P.O. Box 101764
Fax +49 (0) 62 21/84 44 34

D-69007 Heidelberg
GERMANY

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

QC Compliance Manager
16 – 18 March 2016, Prague, Czech Republic

☐ 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 %,
- until 1 weeks prior to the conference 50 %
- within 1 week prior to the conference 100 %.

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Terms of payment: Payable without deductions 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, 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)

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.

Date

Wednesday, 16 March 2016, 09.00 h - 17.30 h
(Registration and coffee 08.30 h - 09.00 h)
Thursday, 17 March 2016, 08.30 h - 18.00 h
Friday, 18 March 2016, 08.30 h - 15.30 h

Venue

Corinthia Hotel Prague
Kongresova 1
10069 Prague, Czech Republic
Phone + 420 261 191 111
Fax + 420 261 225 011

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.

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

For questions regarding reservation, hotel, organisation etc.:
Ms Marion Weidemaier (Organisation Manager) at +49-62 21 / 84 44 46, or per e-mail at weidemaier@concept-heidelberg.de.