ECA Academy
Your GMP/GDP Information Source

GMP Certification Programme
Certified Quality Control Manager

Speakers

Dr Raphael Bar
BR Consulting, formerly with Teva, Israel

Dr Bernd Renger
Member of the Analytical QC Working Group of the ECA Foundation, Germany

Dr Ulrich Rose
Former Deputy Head of the European Pharmacopoeia Department, EDQM, France

Ph. Eur., USP and other Pharmacopoeias

Dealing with different compendial methods

Live Online Training on 20/21 September 2022

Highlights

- Structure of Ph. Eur. and USP and their enforcement
- Additional Pharmacopoeias around the world – Japan, China, India, Int. Ph. (WHO)
- Harmonisation of Ph. Eur., USP, JP
- Ph. Eur., USP Testing for Organic Impurities
- Implementation of ICH Q3D – differences and similarities
- Analytical Instrument Qualification according to Ph. Eur. and USP
- Life cycle approach to compendial methods
- Reference Standards - similarities and differences
- Verification of Compendial Procedures
- Alternative methods to pharmacopoeial methods
- Equivalence testing of two methods
- Multicompendial Testing Strategies

- With Case Studies:
  Meeting Challenges of Pharmacopoeial Compliance
- 2-Step Process for the Implementation of Pharmacopoeial Procedures
- Revised harmonised chapter on chromatographic separation techniques

Objectives

It is important to understand the structure and the procedures of the different Pharmacopoeias. Some general chapters and the monographs of some widely used excipients have already been harmonised between the most important Pharmacopoeias, USP, Ph. Eur. and JP in the context of the Pharmacopoeial Discussion Group (PDG). But for a large number of general methods differences still exist. Therefore some of the frequently asked questions are:

- How to use alternative procedures and interchangeable methods?
- What are the allowed exceptions to the obligation to perform all tests?
- How can multi-compendial testing strategies look like?
- How to prove equivalence?

In addition, PDG harmonisation does not include upcoming important pharmacopoeias like Indian and Chinese Pharmacopoeias.

This Live Online Training will discuss these issues and provides support in order to successfully deal with compendial methods and their differences.

Background

Pharmaceutical companies have to follow Pharmacopoeia standards in order to meet regulatory requirements. However, there is no single Pharmacopoeia which can be applied in all regions. The US FDA may enforce USP monographs which then become mandatory whereas compliance with Ph. Eur. is mandatory in 39 member states and the European Union (EU) and is applied in over 100 countries worldwide. Moreover, also other Pharmacopoeias exist in the world like the Japanese (included in the PDG harmonisation process) , Chinese, Russian or Indian Pharmacopoeias.

But what are the differences and how to deal with quality standards and test methods if products are manufactured and released for different markets?

Target Audience

This Live Online Training addresses employees and managers from Quality Control Labs. It also addresses colleagues working in Quality Assurance and Regulatory Affairs department.

This Live Online Training Course is recognized for the GMP/GDP Certification Scheme

Building on your education the ECA GMP/GDP certification programmes provide you with the appropriate supplement to acquire this qualification. The Live Online Training is the first element for your additional certification. Simply choose any three courses within the programme according to your professional interest. Your certificate is then valid for two years. To renew it, you can pick any training from the ECA courses and conferences list within that two-years period – allowing you to broaden your knowledge in GMP and GDP compliance. Please find more information at www.gmp-certification.org

Programme Day 1

Session 1: Introduction to Pharmacopoeial Testing

Structure, General Methods & Challenges of Ph. Eur.

Structure, Monographs and Activities of USP

- Structure of Ph. Eur. and USP
- Meeting Pharmacopoeial standards and Pharmacopoeial designation
- The USP approach: Single Testing
- Structure of USP monographs:
  - modern monograph
  - flexible monograph
- Structure of European Pharmacopoeia
- Structure of Ph. Eur. monographs
- What the Pharmacopoeia does not say about a procedure
- Dietary Supplements, API and CEP of Ph. Eur.
- Mechanisms of harmonisation between Pharmacopoeias

Additional Pharmacopoeias around the World – Japan, China, India, Int. Ph. (WHO), BP

- Historical developments
- The development of the International Pharmacopoeia
- JP, ChP, Russian Ph., and IP – similarities and differences
- Legal status and enforcement
- WHO Good pharmacopoeial Practices

Q&A Session 1

Session 2: Important Monographs: Harmonisation, Differences, Solutions

Revised Harmonised General Chapter on Chromatography

- History and background of Ph. Eur. 2.2.46, JP <2.00>, USP <621>
- Definitions and adjustment of chromatographic conditions
- Important changes

Pharmacopoeial Policy of Impurities Testing

- Which impurities are controlled?
- Analytical techniques and general texts/monographs
- Control of organic impurities
- What about validation?

Analytical Instrument Qualification according to Ph. Eur. and USP

- USP General Chapter <1058> Analytical Instrument Qualification and Ph. Eur.
- Type of instruments and risk assessment
- Qualification steps: DQ, IQ, OQ and PQ
- Roles and responsibilities
- Computerized data systems in laboratory
- Examples: Qualification of HPLC and analytical balances

Life Cycle Approach to Compendial Methods

- USP chapter <1220> & Measurement Uncertainty
- USP Chapters <1224>, <1225>, <1226>
- Analytical Target Profile and Analytical Control Strategy
- ICH Q2(R2) Revision
- ICH Q14 Analytical Procedure Development

Q&A Session 2

Programme Day 2

Session 3: Dealing with Testing Challenges

General Notices – Definitions and Requirements

- Use of alternative procedures & interchangeable methods
- Waivers to the obligation to perform all tests
- Scope of general monographs
- Definitions

Reference Standards - Similarities and Differences

- Definitions and guidelines
- Legal status of reference standards
- Types of standards
- Establishment and use/Testing and value assignment
- Similarities and differences between pharmacopoeias

Verification of Compendial Procedures

- Difference between Verification and Transfer of an analytical procedure
- Chemical vs microbiological procedures
- Minimal performance characteristics to be verified
- What to verify in procedures for high-level (Assay by HPLC) and low-level analytes (Impurities by HPLC and TLC)
- When procedure verification is not required
- ISO 17025 requirements for method verification
- Documentation of procedure verification

Q&A Session 3

Multicompendial Testing Strategies

- Divergent and conflicting pharmacopoeial requirements
- CDER's MAPP 5310.7 "Acceptability of Standards from Alternative Compendia"
- How to proceed in case of missing harmonization?
- Full Testing, Worst Case Testing, Alternative Testing
- How to proof equivalence?

Alternative Methods to Pharmacopoeial Methods: Equivalence Testing of two Methods

- Is a compendial procedure equivalent to an in-house validated procedure?
- Critical performance characteristics to be compared
- Plotting the results of comparative testing
- Traditional way of comparison of two procedures
- Equivalence testing with two one-sided t-test (TOST)

Case Studies: Meeting Challenges of Pharmacopoeial Compliance

Q&A Session 4

Speakers

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 lasts ten years, Raphael Bar has been a pharmaceutical consultant for the Pharma and bio-Pharma industries.

Dr Bernd Renger
Member of the Analytical QC Working Group of the ECA Foundation, 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 is a member of Analytical QC Working Group of ECA and is Immediate Past Chair of the European QP Association. Dr Renger is presently working as a consultant, auditor and trainer.

Dr Ulrich Rose
Former Deputy Head of the European Pharmacopoeia Department, EDQM, France

Dr Rose was Deputy Head of the European Pharmacopoeia Department at the EDQM in Strasbourg and in this context responsible for the preparation of monographs on chemical defined APIs, finished products, herbal drugs & preparations, and general chapters. He was also involved in the harmonization of international pharmacopoeias. Previously, he was responsible for the establishment and control of Ph. Eur. Reference Standards, and later served as coordinator and auditor for EDQM's Mutual Joint Audit Program, which audits Official Medicines Control Laboratories in Europe (OMCLs).

Participant comment of September 2020 Live Online Training Course:
„Excellent Speakers."
Dr. Benjamin Schinor, LTS Lohmann Therapie-Systeme AG, Germany

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Reservation Form (Please complete in full)

Ph. Eur., USP and other Pharmacopoeias: Dealing with different compendial methods
Live Online Training on 20/21 September 2022

Title, first name, surname

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Date of the Live Online Training
Tuesday, 20 September 2022,
09.00 h – 17.30 h CEST
Wednesday, 21 September 2022,
09.00 h – 17.00 h CEST

Fees (per delegate, plus VAT)
ECA Members € 1,690
APIC Members € 1,790
Non-ECA Members € 1,890
EU GMP Inspectorates € 945

The conference fee is payable in advance after receipt of invoice.

Technical Requirements
We use Webex Events for our live online training courses and webinars. At https://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.

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.

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

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