ECA Academy
Your GMP/GDP Information Source

EP - USP and other Pharmacopoeias

Dealing with different compendial methods

Workshop on testing for organic impurities according to Ph.Eur. and USP

SPEAKERS:

Dr Raphael Bar
Consultant, formerly with Teva, Israel

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

Dr Ulrich Rose
EDQM, France

14-15 May 2019, Barcelona, Spain

LEARNING OBJECTIVES:

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

This education course is recognised for the ECA GMP Certification Programme „Certified Quality Control Manager“.
Please find details at www.gmp-certification.eu

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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, EP 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 Education Course 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 manadatory whereas compliance with EP is mandatory in 38 countries and the 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 Education Course addresses employees and managers from Quality Control Labs. It also addresses colleagues working in Quality Assurance and Regulatory Affairs department.

Programme

▶ Session 1: Introduction to Pharmacopoeial Testing

Structure, General Methods and challenges of EP and USP and their enforcement

- Structure of EP 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 EP monographs
- What the Pharmacopoeia does not say about a procedure
- Dietary Supplements, API and CEP of EP

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

▶ Session 2: Important Monographs: Harmonisation, Differences, Solutions

Harmonisation of EP, USP, JP –General methods and excipients

- Mechanisms of harmonisation between Pharmacopoeias
- History of PDG
- Examples for harmonised monographs and general chapters
- Typical obstacles and examples
- New PDG process

Workshop
Testing for Organic Impurities according to Ph.Eur. and USP

Analytical Instrument Qualification according to EP and USP

- USP General Chapter <1058> Analytical Instrument Qualification and EP
- 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

▶ 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
- Uncertainty
- 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

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

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

Dr Ulrich Rose, EDQM, France
Dr Rose works since 1991 at the EDQM in Strasbourg. Until 2011 he was responsible for establishment and monitoring of the Ph. Eur. reference standards. Moreover he was involved in the elaboration and revision of monographs of the European Pharmacopoeia. After that he became coordinator and auditor for EDQM's Mutual Joint Audit Program. Within this function he had to audit the Official Medicines Control Laboratories (OMCLs) in Europe. Since 2014 he is head of division A and deputy head of the European Pharmacopeia Department where he is overlooking the monograph work on chemicals, excipients, herbals and general chapters of Ph. Eur. and is involved in the international harmonisation of pharmacopoeias.

Social Event

In the evening 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:

Reservation Form (Please complete in full)

+ 49 6221 84 44 34

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Title, first name, surname

Company | Department

Important: Please indicate your company's VAT ID Number | **P.O. Number (if applicable)**

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City | Zip Code | Country

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If you cannot attend the conference you have two options:
1. We are happy to welcome a substitute colleague at any time.
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German law shall apply. Court of jurisdiction is Heidelberg.

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Date

Tuesday, 14 May 2019, 09:00 h – 18:00 h
(Registration and coffee from 08:30 h – 09:00 h)
Wednesday, 15 May 2019, 08:30 h – 15:15 h

Venue

Barcelo Sants Hotel
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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 and includes conference documentation, dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotels. You will receive a room reservation form/POG when you have registered for the event. Reservation should be made directly with the hotel. Early reservation is recommended.

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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