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GMP Certification Programme
Certified Quality Control Manager

Speakers

Dr Raphael Bar
BR Consulting, formerly with Teva

Nicolas Bardy
Sanofi, France

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

NEWS

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Ph. Eur., USP and other Pharmacopoeias

Dealing with different compendial methods

Live Online Training on 05/06 November 2025

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
- Reference Standards - similarities and differences
- Verification of Compendial Procedures
- Alternative methods to pharmacopoeial methods
- Equivalence testing of two methods
- Multicompendial Testing Strategies

- Including Workshops
- Implementation & Comparability of Pharmacopoeial Procedures
- Revised harmonised chapter on chromatographic separation techniques

Programme

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

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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 Ph. Eur. monographs
- What the Pharmacopoeia does not say about a procedure

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

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

General Texts and General Chapters

- Meaning of general texts and chapters
- Harmonisation efforts
- Recent revisions, e. g. elemental impurities and nitrosamine control

Revised Harmonised General Chapter on Chromatography (incl. Workshop)

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

Workshop 1: Reporting Compendial Test Results

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 / Implementation of Compendial Procedures

- USP <1226> *Verification of Compendial Procedures* and Ph. Eur. Chapter 5.26 *Implementation of Pharmacopoeial 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
- Documentation of procedure verification

Q&A Session 3

Pharmacopoeial Policy of Impurities Testing

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

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)

Multicompendial Testing Strategies

- Divergent and conflicting pharmacopoeial requirements
- How to proceed in case of missing harmonization?
- Full Testing, Worst Case Testing, Alternative Testing
- How to proof equivalence?

Workshop 2: Meeting Challenges of Pharmacopoeial Compliance

Q&A Session 4

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

Speakers

Dr Raphael Bar,
BR Consulting, Israel

Dr Bar headed the Analytical R&D Laboratory at Teva Pharmaceuticals and the QC Laboratory at Pharmos. He has been involved with the Pharma industry for the last 30 years. He served as a member of the Scientific Advisory Board of global PDA (USA). He is past president and now a member of the Israel PDA Chapter as well as a member of the organizing committee of Israel Society of Analytical Chemistry. For the last fifteen years, Raphael Bar has been a pharmaceutical consultant for the Pharma and bio-Pharma industries.

Nicolas Bardy
Sanofi, France

Nicolas Bardy started his career as Analytical development manager in a Veterinary company and joined Sanofi more than 15 years ago to hold the position of a QC manager. Since then, he has evolved in Global Quality and is currently Phamacopoeia manager for Sanofi. With this position, he has acquired expertise and global knowledge on major Pharmacopoeias, their content and ways of working.

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).

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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 05/06 November 2025

Title, first name, surname

Department | Company

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Date of the Live Online Training
Wednesday, 05 November 2025,
09.00 h – 17.30 h CET
Thursday, 06 November 2025,
09.00 h – 17.15 h CET

Fees (per delegate, plus VAT)
ECA Members € 1,890
APIC Members € 1,990
Non-ECA Members € 2,090
EU GMP Inspectorates € 1,045

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

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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 21991.

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.

CONCEPT HEIDELBERG
P.O.Box 10 17 64
69007 Heidelberg, Germany
Phone +49(0)62 21/84 44-0
Fax +49(0)62 21/84 44 34
info@concept-heidelberg.de
www.concept-heidelberg.de

For questions regarding content please contact:
Dr Andrea Kühn-Hebecker (Operations Director)
at +49(0)62 21/84 44 35 or per e-mail at
kuehn@concept-heidelberg.de.

For questions regarding organisation please contact:
Mr Ronny Strohwald (Organisation Manager)
at +49(0)62 21/84 44 51, or per e-mail at
strohwald@concept-heidelberg.de.