



## Speakers



Dr Raphael Bar  
BR Consulting, formerly with Teva



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



Dr Lance Smallshaw  
UCB, Belgium

NEWS

Stay informed with the GMP  
Newsletters from ECA

The ECA offers various free of charge  
GMP newsletters for which you can sub-  
scribe to according to your needs.

To subscribe, simply scan the  
QR code on the right or visit  
[www.gmp-compliance.org/  
gmp-newsletter](http://www.gmp-compliance.org/gmp-newsletter)



# 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

## 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](http://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 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.



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).



Dr Lance Smallshaw  
UCB Biopharma, Belgium

Lance Smallshaw is Head of Pharmacopoeial Affairs at UCB and member of the EFPIA Pharmacopoeia WG. He is also Co-Chair of the Executive Board of the ECA.

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)



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

Important: Please indicate your company's VAT ID Number

Purchase Order Number, if applicable

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 4 weeks prior to the conference 10 %,
  - Cancellation until 3 weeks prior to the conference 25 %,
  - Cancellation until 2 weeks prior to the conference 50 %,
  - Cancellation within 2 weeks prior to the conference 100 %.

CONCEPT HEIDELBERG reserves the right to change the materials, instructors, 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 deductions within 10 days after receipt of invoice. Important: This is a binding registration and above fees are due in case of can-

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 July 2022). 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 <https://www.gmp-compliance.org/privacy-policy>). 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 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.

Technical Requirements

We use Webex 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 – or **search and register directly at [www.gmp-compliance.org](http://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.

You cannot attend the Live Event?

We also offer many of the training courses and conferences as recordings. This means that you can watch the videos of the event „on demand“ – whenever it suits you – on our web server. It is quite uncomplicated and doesn't require any software – you simply watch the video on your browser. You can find all recorded events at [www.gmp-compliance.org/recordings](http://www.gmp-compliance.org/recordings).

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](mailto:info@concept-heidelberg.de)  
[www.concept-heidelberg.de](http://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](mailto: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](mailto:strohwald@concept-heidelberg.de).