ECA Academy
Your GMP/GDP Information Source

Speakers

Dr Heiko Brunner
HELM AG, Germany

Dr Joachim Ermer
Ermer Quality Consulting, Germany

Dr Rainer Gnibl
GMP Inspector for EMA and local Government, Germany

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

Reference Standards

Establishment, Use and Maintenance of Analytical Reference Substances

Live Online Training on 12 March 2024

Highlights

- Reference Substances of the European Pharmacopoeia – Establishment and Use
- Compendial and Regulatory Requirements
- Qualification, Management and Use of Reference Standards
- Reference Standards – GMP Inspectors' Expectations
- Uncertainty in Content Assignment of Reference Standards
- Reference Standards – a Laboratory View

Objectives

It is the aim of this Live Online Training to provide information on the characterisation, use and maintenance of analytical Reference Substances.

You will get to know

- how to correctly use Pharmacopoeial CRSs,
- which compendial and regulatory requirements have to be considered,
- how to characterise reference standards,
- what GMP inspectors expect when visiting your quality control lab,
- how to assign the content for CRSs.

Finally, you will get recommendations on how to prepare for an audit in the QC lab with focus on reference material.

Background

The establishment, handling and use of reference standards is a key issue for analysts in every quality control laboratory in the pharmaceutical and API industry. The ability to demonstrate compliance of pharmaceutical products with the original licence approval conditions depends on the accuracy of the analytical results. Therefore, the integrity of the reference material is pivotal to the consistency of all analytical determinations.

The application of reference standards is provided for in many monographs of the various pharmacopoeias (Ph.Eur., USP, BP, JP, etc.) as well as in internal test procedures for finished products.

Target Audience

This Live Online Training is designed for Analysts, Laboratory Managers, Laboratory Scientists, QC/QA Managers, Qualified Persons and will also be of significant interest to Regulatory Affairs Professionals and organisations providing a regulated contract laboratory service.

Programme

Reference Substances of the European Pharmacopoeia – Establishment and Use

- Definition of primary and secondary standards
- Analytical techniques and methods used for the establishment
- CRSs for identification tests
- Impurities and impurity mixtures as CRSs
- Assay standards
- Collaborative trials
- Correct use of Pharmacopoeial CRSs
- Storage, manufacture and distribution of CRSs

Qualification, Management, and Use of Reference Standards in Quality Control

- Types of reference standards
- Certificates and documentation
- Appropriate use of reference standards
- Requirements for commercial reference standards

Reference Standards – GMP Inspector's Perspective

- Legal requirements in EU
- How to characterize & qualify standards?
- What is expected in EU-GMP inspection?
- Frequent findings

Uncertainty in Content Assignment of Reference Standards

- Measurement uncertainty
- Mass balance approach or assay vs. primary standards?
- To change or not to change – ensuring reference standard stability

Reference Standards – a Laboratory View

- Ordering – where to get them?
- Shipment and storage
- Handling and documentation
- Audit findings
- Optimizing reference standard consumption

Speakers

Dr Heiko Brunner
HELM AG, Germany

Dr Brunner is a chemist with more the 30 years of experience in the pharmaceutical industry. During his career he worked on development projects in the fields of new chemical entities as well as generic products. Since 2008 he served in several positions in pharmaceutical development, project management and quality control at HELM AG. Dr Brunner is head of quality control and GMP auditor.

Dr Joachim Ermer
Ermer Quality Consulting, Germany

Dr Ermer has 30 years of experience in pharmaceutical analytics, including development products at Hoechst AG, global responsibilities as Director of Analytical Processes and Technology at Aventis, and head of Quality Control and head of QC Lifecycle Management Frankfurt Chemistry at Sanofi. From 2010 till 2020, he was also responsible for the central reference standard group of Sanofi. Since December 2020, he serves as consultant for topics of pharmaceutical analytics and Quality Control. Dr Ermer is member of the Ph.Eur. Working Group "Chromatographic Separation Techniques" and of the USP Expert Committee "Measurement and Data Quality".

Dr Rainer Gnibl
GMP Inspector for EMA and local Government, Germany

Dr Rainer Gnibl is pharmacist and GMP Inspector for the District Government of Upper Bavaria and the EMA and performs GMP-inspections worldwide. Before that, he was working for the Bavarian Ministry of Environment and Health. Rainer Gnibl also holds a lectureship at the University Erlangen-Nürnberg.

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).

Your Benefit:
Internationally Acknowledged Certificate from ECA Academy

The EU GMP Guide requires: „... All personnel should be aware of the principles of Good Manufacturing Practice that affect them and receive initial and continuing training,...". This is why you receive an acknowledged participant certificate, which lists the contents of the seminar in detail and with which you document your training.


CERTIFICATE

Mr John Doe

ECA - Lab Data Integrity – Meeting FDA & EU Concerns
Part 2: Self Inspections and Audits to Confirm Effective Data Integrity Controls

This could be of interest for you as well

Would you like to train a larger group of participants in your company?

We offer practice-oriented GMP/GDP training courses on:

- Basic GMP
  - APIs (ICH Q7)
  - Medicinal Products
  - Biopharmaceuticals
- Quality Assurance
- Quality Control
- Validation/Qualification
- Regulatory Affairs
- Sterile Manufacturing
- IT / Computer Validation
- Good Distribution Practice (GDP)
- Data Integrity
- Packaging
- Medical Devices und
- Technical Operations

You will find a time schedule for each training course at https://www.gmp-compliance.org/training/gmp-gdp-in-house-trainings

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)

Reference Standards
Live Online Training on 12 March 2024

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 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 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 of the Live Online Training

Tuesday, 12 March 2024,
09.00 to approx. 16.45 h CET

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.

Fees (per delegate, plus VAT)

ECA Members € 990
APIC Members € 1,090
Non-ECA Members € 1,190
EU GMP Inspectorates € 595
The fee is payable in advance after receipt of invoice.

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.

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.

Organisation and Contact

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

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

For questions regarding content please contact:
Ms Anne Günster (Operations Director) at
+49(0)62 21/84 44 50, or at
guenster@concept-heidelberg.de.

For questions regarding organisation please contact:
Ms Julia Grimmer (Organisation Manager) at
+49(0)62 21/84 44 44, or per e-mail at
grimmer@concept-heidelberg.de.