ECA Academy
Your GMP/GDP Information Source

Speaker

Dr Joachim Ermer
Ermer Quality Consulting, Bensheim, Germany

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Reference Standards

Establishment, Use and Maintenance of Analytical Reference Substances

Live Online Training on 18 November 2021

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
- Content Assignment for Chemical Reference Standards
- Audits in Quality Control Laboratories with focus on Reference Materials

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

Content Assignment for Chemical Reference Standards

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

Audits in Quality Control Laboratories focussing on Reference Materials

- Storage, labelling and expiry date of Reference Standards in the QC lab
- Documentation requirements
- Handling and use of Reference Standards in analytical test procedures
- Content of the Reference Standard SOP
- Preparing for an audit in QC labs
- Checklist for Reference Standard procedures
- Reference Material – Examples for non GMP compliance

Speaker

Dr Joachim Ermer
Ermer Quality Consulting, Germany

Dr Ermer has 30 years of experience in pharmaceutical analytics including development products, global responsibilities as Director of Analytical Processes and Technology, 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 in Frankfurt. He is member of the USP Expert Committee Measurement and Data Quality, of the Chromatographic Separation Techniques Working Party of the European Pharmacopoeia, and of the EFPIA support team for the update/establishment of ICH Q2/Q14.

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

Jürgen Martin
Martin Consulting, Germany

Mr Martin has more than 25 years of experience in pharmaceutical industry and quality control. After his education at the university of Konstanz he has held different leading positions focusing on quality control topics at Byk Gulden, Altana Pharma and Nycomed. Between 2011 and 2019 he was building up and heading the quality control of the BIPSO GmbH. Since 2019 he is operating his own consultancy and software development office.

Dr Ulrich Rose
Straßburg, 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 Ph. Eur.. After that he became coordinator and auditor for EDQM's Mutual Joint Audit Program. Since 2014 he is head of division A and deputy head of the Ph. Eur. Department where he is overlooking the monograph work on chemically defined APIs, finished products, herbals and general chapters of Ph. Eur. and is involved in the international harmonisation of pharmacopoeias.

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

has completed a two day ECA-Course on 5 to 6 December 2019 in Barcelona, Spain covering the following subject

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

Contents of the course:

- Introduction to Course
- Data Integrity Self Inspections and Audits for Hybrid and Electronic Systems
- Workshop 1
- Workshop 2
- Workshop 3
- Workshop 4
- Workshop 5
- Workshop 6
- Workshop 7
- Workshop 8
- Workshop 9
- Workshop 10
- Workshop 11
- Review of the Course and two Learning Points

Heidelberg, 6 December 2019

ECA Academy

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

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GERMANY

Reservation Form (Please complete in full)

Reference Standards
Live Online Training on 18 November 2021

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.
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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 January 2012).
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
Thursday, 18 November 2021,
10.00 to approx 16.45 h CET

Technical Requirements
For our Live Online Training Courses and Webinars, we use Cisco WebEx, one of the leading suppliers of online meetings. At http://www.webex.com/test-meeting.html you can check if your system meets the necessary requirements for the participation at a WebEx meeting and at the same time install the necessary plug-in. Please just enter your name and email address for the test. If the installation is not possible because of your rights for the computer 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 € 890
APIC Members € 950
Non-ECA Members € 990
EU GMP Inspectorates € 495
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.

Ordering Recordings
Independent from the Live Online Training, you can also order a recording of this training at the same conditions. This recording will be provided on our media server. All you need to watch it is an Internet browser – no additional software. You can order the recording of the Live Online Training at the earliest 10 days after the live performance at https://www.gmp-compliance.org/gmp-webinars/recorded-gmp-webinars.

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

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