ECA Academy
Your GMP/GDP Information Source

Speakers

Dr Helmut Gaus
WinSol, previously Boehringer Ingelheim

Dr Josef Hofer
EXDRA

Dieter Mößner
Gerhard Schubert

Dr Jochen Scher
Boehringer Ingelheim Pharma

Japan Quality

Live Online Training on 03 December 2025, 09:00 – 17:15 h CET

Highlights

- Regulatory Requirements in Japan
- Regulatory Management for Japan
- Specific Japan Requirements Regarding Analytical Testing
- Specific Requirements and Solutions for Oral Solid Dosage Forms
- Specific Requirements for Liquid/Sterile Dosage Forms (Parenterals)
- Specific Requirements for Secondary Packaging Materials

Objectives

The purpose of this Live Online Training is to provide an overview on measures pharmaceutical companies and suppliers can take in order to achieve "Japan Quality" for their products.

The general pharmaceutical principles (pharmaceutical legislation and authorities in Japan, Japanese Pharmacopoeia, GMP requirements in Japan) as well as current developments will be presented and the registration of medicinal products for a marketing authorisation in Japan will be discussed.

Background

All pharmaceutical companies that deliver their products to Japan for the first time are familiar with the situation that the recipients and the customers of the market complain about the delivered goods even though these products meet the agreed specifications.

Japanese customers attach much more importance to the visual/outward appearance of goods than the average European or North American customer. The pharmaceutical environment has coined the phrase "Japan Quality" to describe this phenomenon.

Target Audience

This Live Online Training is addressed to executives and employees from the pharmaceutical and its supplier industries who work in the fields of Regulatory Affairs, Research & Development, Quality Assurance, Quality Control or production and are involved in the manufacture and distribution of products for the Japanese market.

Moderator

Sarah Schmidt, CONCEPT HEIDELBERG
(on behalf of ECA)

Programme

Regulatory Management for Japan

- Management of Japan – specific requirements in marketing authorisation procedures
- Establishment of regulatory documentation for and from Japan, international challenges
- Japanese oriented organisation and structures in drug regulatory affairs

Regulatory Requirements in Japan

- Japanese pharmaceutical authorities
- Development of Japanese pharmaceutical law
- Japanese system of law
- Revised pharmaceutical affairs law (r-PAL)
- GMP regulations in Japan (J-GMP)

Specific Japan Requirements Regarding Analytical Testing

- Pharmacopoeias in Japan (JP, JPE, JPC, JPED)
- JP requirements on APIs and excipients
- Specific requirements for analytical methods (method description, test procedure, method validation, specific test methods)
- Harmonisation

„Japan Quality“ – Requirements and Solutions for Oral Solid Dosage Forms

- Typical defects and their potential origin
- Defect classification from a Japanese point of view
  - Technical optimizations to minimize defects
  - Operational optimizations to minimize defects

„Japan Quality“ – Specific Requirements for Liquid/ Sterile Dosage Forms (Parenterals)

- Case studies within parenterals manufacturing
- Implemented measures in aseptic production
- Increasing requirements for primary packaging materials
- Strategies to reduce unnecessary rejects in visual inspection

„Quality for the Japanese Market“ – The Special Requirements for Secondary Packaging Materials

- General expectations to folding cartons and inserts
- Defect evaluations of printing and finishing issues
- Development of a defect list specification
- Strategy of the packaging material producers
- Realisation in the daily practice

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 I: Risk Assessment and Prioritization
- Workshop II: Audit of an Excel Spreadsheet
- Workshop III: Auditing a Hybrid Standalone System
- Workshop IV: Auditing a Networked Laboratory System – Audit Trail Review
- Workshop V: Electronic Signature Auditing
- Workshop VI: Preparing for the Data Integrity Audit
- Workshop VII: Observations and Findings during a Laboratory Audit and Planning the Closing Meeting
- Workshop VIII: Feedback to the Auditees
- Review of the Course and the Learning Goals

Heidelberg, 6 December 2019

ECA Academy

Speakers

Dr Helmut Gaus
WinSol GmbH, previously Boehringer Ingelheim

Dr Gaus was Head of Quality Control Service at Boehringer Ingelheim, Biotechnology. He has also been working as Vice President Quality Control and Qualified Person for Novartis Generics, Vetter-Pharma and Rentschler Biotechnologie were he gained an extensive knowledge in the field of visual inspection. In 2018, he founded his own company WinSol.

Dr Josef Hofer
EXDRA GmbH

Dr Hofer is Managing Director of EXDRA GmbH (Excellence in Drug Regulatory Affairs). Working for and in international pharmaceutical industry since 1980. Dr Hofer holds a lectureship at the University in Bonn for the Master Course in Drug Regulatory Affairs.

Dieter Mößner
Gerhard Schubert GmbH

Dieter Mößner is working as a Global Key Account Manager at a leading German manufacturer of packaging machines. Before that he was working as Project Engineer Pharma and Key Account Manager at a leading manufacturer of folding boxes and package leaflets for the pharmaceutical and cosmetics industries.

Dr Jochen Scher
Boehringer Ingelheim Pharma GmbH & Co. KG

Dr Scher joined Boehringer Ingelheim Pharma GmbH & Co. KG in 2005 and worked for 12 years in different areas of Drug Product Analytics (including 3 years as dissolution lab head and 3 years as Drug Product Analytics group manager at the development site in Kobe, Japan). In 2017 he joined the global R&D Project Management for 6 years at Boehringer Ingelheim. Since 2022 he is leading the team Early Development in Pharmaceutical Development.

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GERMANY

Reservation Form (Please complete in full)

Japan Quality
Live Online Training on 03 December 2025, 09:00 – 17:15 h (CET)

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 %.

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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
Wednesday, 03 December 2025,
09.00 – 17.15 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 € 1,090
APIC Members € 1,190
Non-ECA Members € 1,290
EU GMP Inspectorates €645
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
Via the attached reservation form, by e-mail or by fax – or search and register directly at www.gmp-compliance.org under the number 22035.

Conference language
The official conference language will be English.

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

You cannot attend the Live Online 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.

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