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Speakers



Dr Helmut Gaus
WinSol, previously Boehringer
Ingelheim



Dr Josef Hofer
EXDRA



Dieter Mößner
Gerhard Schubert



Dr Jochen Scher
Boehringer Ingelheim Pharma



Dr Harald Stahl
Romaco

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)



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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.



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 where 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.



Dr Harald Stahl
Romaco Holding GmbH

Dr Stahl is a physicist, worked in the Pharmaceutical Development of Schering and was responsible for evaluating new technologies for many years as Group Director Application & Strategy Management at GEA. He is currently Head of Strategy & Business Development at Romaco.

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

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Date of the Live Online Training

Wednesday, 03 December 2025,
09.00 – 17.15 h CET

Technical Requirements

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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.

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Organisation and Contact

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

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