ECA Academy
Your GMP/GDP Information Source

Speakers

Dr Helmut Gaus
WinSol, previously Boehringer Ingelheim, Germany

Dr Josef Hofer
EXDRA, Germany

Jiro Okazaki
Bayer Yakuhin, Japan

Werner Pelz
Carl Edelmann, Germany

Dr Jochen Scher
Boehringer Ingelheim Pharma, Germany

Japan Quality

Live Online Training on 21 November 2023

Highlights

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

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 (starting materials, bulk and intermediate products as well as finished 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.

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)

„Japan Quality“ – Specific Requirements for Oral Solid Dosage Forms

- Typical defects and their potential origin
- Defect classification from a Japanese point of view
- Organisational measures in a multi purpose production environment
- Potential improvement measures to minimize defect occurrence

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

- Case studies within Parenterals manufacturing
- Implemented measures in aseptic production
- Increasing requirements for primary packaging materials
- Stragies 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

Speakers

Dr Helmut Gaus
WinSol, previously Boehringer Ingelheim, Germany

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, Germany

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.

Jiro Okazaki
Bayer Yakuhin Ltd., Japan

Head of Site Quality at Supply Center Shiga, Japan. Working for both domestic and international pharmaceutical companies since 1997, engaged in quality control (including 6 years as QC lab testing supervisor) and quality assurance department for 25 years. In 2016 he joined Bayer Yakuhin as head of quality control department and assigned as the current role since May 2021.

Werner Pelz
Carl Edelmann GmbH, Germany

Mr Pelz made his experiences in different positions as a technician for paper converting. He has been working for more than 35 years in the quality department of Edelmann, a producer of folding cartons and product inserts for the pharmaceutical industry. Since 2004 Werner Pelz is the quality manager of the German plants of the Edelmann Group.

Dr Jochen Scher
Boehringer Ingelheim Pharma GmbH & Co. KG, Germany

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 at Boehringer Ingelheim.

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

If the bill-to-address deviates from the specifications on the right, please fill out here:

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GERMANY

Reservation Form (Please complete in full)

Japan Quality
Live Online Training on 21 November 2023 from 09:00 – 16:30 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:
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German law shall apply. Court of jurisdiction is Heidelberg.

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Date of the Live Online Training
Tuesday, 21 November 2023,
09.00 – 16.30 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 € 890
APIC Members € 945
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
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.

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