

SPEAKERS:

DR OLIVER GROSCHKE
Novartis Pharma

DR JOSEF HOFER
EXDRA GmbH

DR. EVA LINDEMANN
Boehringer Ingelheim

SILKE MAINKA
Anwaltskanzlei Mainka

WERNER PELZ
Carl Edelmann

DR SABINE SCHIEMANN
Boehringer Ingelheim

DR ARMIN SCHWEIGER
Bayer HealthCare
Pharmaceuticals

DR HIROKAZU SUGIYAMA
F. Hoffmann-La Roche

DR LARS SUKOWSKI
F. Hoffmann-La Roche



“Japan Quality”

**14 - 15 May 2012,
Heidelberg, Germany**

HIGHLIGHTS:

- Cultural Differences between Japan and Europe
 - Background “Japan Quality”
 - Effective Communication
- Regulatory Requirements
 - Authorities and Pharmaceutical Laws in Japan
 - GMP Requirements in Japan
 - Regulatory Management for Japan
- Japan-Specific Quality Requirements for
 - APIs / Excipients
 - Printed Packaging Materials
 - Primary Packaging Materials
 - Solid Dosage Forms
 - Parenteralia
- How to Improve Product Quality and Optimize Manufacturing Processes
- Legal Aspects



"Japan Quality"

14 - 15 May 2012, Heidelberg, Germany

Objectives

It is the aim of this conference to point out which measures pharmaceutical companies and suppliers can take today so that the manufactured products achieve "Japan Quality" and can thus compete on the Japanese market. Among them are the sensitisation for "cosmetic" defects or the use of additional visual inspections.

This conference also gives an introduction to the cultural differences between Europe and Japan (Japanese mindset and behaviour, effective communication with Japanese business partners, precautions to avoid misunderstandings).

Furthermore, the general pharmaceutical bases (pharmaceutical legislation and authorities in Japan, Japanese Pharmacopoeia, GMP requirements in Japan) are presented, and the registration of medicinal products for a marketing authorisation in Japan is 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 there complain about the delivered goods even though these products meet the agreed specifications. Soon it becomes clear that 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 term "Japan Quality" to describe this phenomenon.

Target Audience

This conference 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

DR JOSEF HOFER

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)

DR SABINE SCHIEMANN

Information on Cultural Differences between Europe and Japan

- Country information
- Japanese culture and mentality
- General market behaviour
- Pharmaceuticals in Japan

DR HIROKAZU SUGIYAMA

Effective Communication with Japanese Business Partners

- Meeting and Greeting
- Do's and Don'ts during Business Meetings
- Communication
- Building Relationships

DR SABINE SCHIEMANN

Programme (cont.)

Legal Aspects from a Contract Manufacturer's Point of View

- Contractual situations
- Impact of regulatory and other requirements on quality agreements
- Mitigation of legal risks in supply agreements

SILKE MAINKA

How to Achieve „Japan Quality“ in a Pharmaceutical Company?

- Product: customization to Japanese market
- Process: continuous improvement using Kaizen, LeanSixSigma
- Communication: awareness raising for Japanese business style

DR HIROKAZU SUGIYAMA

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

DR OLIVER GROSCHKE

"Quality for the Japanese Market" - The Special Requirements for Secondary Packaging Material

- 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
- Conclusions

WERNER PELZ

Japanese Quality - Case Study in Glass Vial Manufacturing

- Definition of Japanese quality requirements
- Introduction to manufacturing process of tubing glass
- Initial production conditions
- Design of improvement project plan
- Implementation of measures and achieved progress

DR LARS SUKOWSKI



„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
- Opportunities and limitations associated with the use of automated inspection machines

DR ARMIN SCHWEIGER

„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
- Technical innovations in a brand new facility: Parenterals Production Kaiseraugst

DR LARS SUKOWSKI

„Japan Quality“ – Specific Requirements for Pharmaceutical Packaging

- Technical optimisations within the automated packaging process
- Packaging related defects – Introduction of a failure catalogue
- Efficient and reliable visual control of packaging units by operators – How to organize it?
- Development of an inspection machine for packaging units

DR EVA LINDEMANN

Speakers



DR OLIVER GROSCHKE, *Novartis Pharma AG, Basel, Switzerland*

Dr Oliver Grosche works since 2001 as analytical expert in the technical development of small molecules at Novartis Pharma AG Basel, Switzerland. After being involved in the worldwide registration of two innovative drug substances, he moved 2006 to Japan for an international assignment. His main work was to develop on both, the Swiss and the Japanese side a common understanding of analytical processes and requirements required for a Japan specific submission. Since 2008, Oliver Grosche works as global analytical network leader in the technical development of Novartis Pharma Basel. As special role, he is continuing to support the topic "Japan-Specifics".



DR JOSEF HOFER, *EXDRA GmbH, Grafing, Germany*

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



DR EVA LINDEMANN, *Boehringer Ingelheim Pharma GmbH & Co. KG, Ingelheim*

After studying pharmacy at the university of Mainz and doing her PhD thesis Eva Lindemann works since 2003 at Boehringer Ingelheim Pharma GmbH & Co KG. She is responsible for compliance management for Dry Powder Inhalers and Metered Dose Inhalers.



SILKE MAINKA, *Attorney-at-Law, M.B.L.-HSG*

Owner of Law Office in Grünkraut, Germany. Self-employed generalist attorney with more than 10 years substantial legal experience, specialized in pharmaceutical and biotech industry with focus on contract drafting and international negotiations. Award of the degree: Executive Master of European and International Business Law (M.B.L.-HSG) at the University of St. Gallen, Switzerland.



WERNER PELZ, *Carl Edelmann GmbH, Heidenheim, Germany*

Werner Pelz learned starting 1976 the production of folding cartons from the scratch as a mechanic for packaging machines. After some years in the production he continued his education and studied at the academy for the graphic industry in Munich. As a technician for paper converting he made his experiences in different positions. Since 1984 he has been working 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 SABINE SCHIEMANN, *Boehringer Ingelheim GmbH & Co. KG, Biberach, Germany*

After studying biochemistry and doing her PhD thesis at Roche Diagnostics GmbH Dr Sabine Schiemann worked for several years in the production of biotechnological products at Rentschler Biotechnologie GmbH. Since 2007 Dr Sabine Schiemann is responsible for GMP compliance issues in the Quality Assurance Department of the Biopharmaceuticals Division at Boehringer Ingelheim GmbH & Co. KG in Biberach. In 2005, Dr Sabine Schiemann did her master degree in "Master of Drug Regulatory Affairs" at the University of Bonn.



DR ARMIN SCHWEIGER, *Bayer HealthCare Pharmaceuticals, Leverkusen*

Dr Armin Schweiger works since 2007 as plant manager within the solid dosage plant of Bayer HealthCare Pharmaceuticals Leverkusen. In this position he is amongst others responsible for the manufacturing of a variety of products for the Japanese market. After studying pharmacy followed by a Ph.D. in pharmaceutical technology he worked for several years in the galenical department for marketed products at Bayer HealthCare AG.



DR HIROKAZU SUGIYAMA, *F. Hoffmann-La Roche AG, Kaiseraugst, Switzerland*

Born and raised in Tokyo, Hirokazu Sugiyama studied chemical engineering at the University of Tokyo and earned his PhD from ETH Zurich. After his studies he joined F. Hoffmann-La Roche AG as a trainee within Galenical manufacturing in Basel/Kaiseraugst. Since 2009 Dr Sugiyama is responsible for continuous process improvement within Roche's new Parenterals production facility in Kaiseraugst.



DR LARS SUKOWSKI, *F. Hoffmann-La Roche Ltd., Basel, Switzerland*

For the Galenical production at the sites in Basel and Kaiseraugst Lars acted as central contact person for a Japanese partner. The special technical and cultural aspects of this exceptional market were also reflected in the start-up project of a brand new Galenical facility. Today as Technical Operations Support he is responsible for the Biologics Drug Product network of the corporation located in Switzerland, Germany and the US. Since 2001 Lars was holding different positions with the F. Hoffmann-La Roche Ltd in Galenical manufacturing, API development and production as well as quality control in Switzerland and the US.

Social Event

On 14 May 2012, you are cordially invited to a social event. This is an excellent opportunity to share your experiences with colleagues from other companies in a relaxed atmosphere.



Special offer with Lufthansa – up to 20% discounted travel (according to availability) for all ECA Events Attendees.

As an ECA course or conference attendee, you will receive up to 20% discounted travel fares (according to availability). And as Lufthansa German Airlines offers a comprehensive global route network linking major cities around the world you will most likely be able to benefit from these special prices and conditions.

And this is how it works: Once you registered for a course or conference you will receive a link together with your registration confirmation. Opening that link will take you to the Mobility Partner Program website where you can enter a code in the “Access to Event Booking” area you will also receive. This will take you into an online booking platform* that will automatically calculate the discount offered or provide you with an even better offer if another promotional fare is available.

We look forward to welcoming at one of our next events – and we already wish you a pleasant flight!

*Please note: You may have to enable pop-ups on the Mobility Partner Program website – other-wise the booking platform window will not open.

Heidelberg – Optimal Accessibility via Frankfurt

As one of the most beautiful cities in Europe, Heidelberg is at first sight an interesting venue – but is it also easily accessible? The answer is: Yes! The connection to Frankfurt Airport is convenient and fast. Next to London, Frankfurt Airport offers the most frequent air connections in Europe. It takes only about 45 minutes to get from Frankfurt to Heidelberg.

Conference Exhibition

The European Compliance Academy offers you the opportunity to present your company, your products and services to your target group almost without any scattering losses. The costs for an exhibition space at this event are € 1,490 plus VAT. As an exhibitor, you are granted a 50% discount on the registration fee (for one person). You will find details and a registration form on our website www.gmp-compliance.org. Just follow the link "Conferences" and "Exhibition & Sponsoring" on the homepage.

What Is ECA?

The European Compliance Academy (ECA) is an independent educational organisation chaired by a Scientific Advisory Board with members of the pharmaceutical industry and regulatory authorities. The ECA will provide support to the Pharmaceutical Industry and Regulators to promote the move towards a harmonised set of GMP and regulatory guidelines by providing information and interpretation of new or updated guidances.

What Are the Benefits of ECA?

First benefit: During the membership, you enjoy a € 200,- discount on the regular participation fee of any European Conference or Course organised by ECA in co-operation with CONCEPT HEIDELBERG.

Second benefit: The GMP Guideline Manager Software with a large number of guidelines, e.g. EC Directives, FDA Guidelines, ICH Guidelines, will be forwarded to you when you are using your membership for a conference registration.

How Do You Become a Member of ECA?

By participating in one of the European Compliance Conferences or Courses marked with ECA, you will automatically become a member of ECA for two years - free of charge. Conferences and Education Courses organised by ECA will be realised in co-operation with CONCEPT HEIDELBERG. More information about ECA can be obtained on the Website <http://www.gmp-compliance.org>

Easy Registration



Reservation Form:
CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg
Germany



Reservation Form:
+ 49 6221 84 44 34



e-mail:
info@concept-heidelberg.de



Internet:
www.gmp-compliance.org

Date

Monday, 14 May 2012, 09.00 h – 18.00h
(Registration and coffee 08.30 h – 09.00h)
Tuesday, 15 May 2012, 08.30 h – 16.00 h

Venue

Heidelberg Marriott Hotel
Vangerowstr. 16
69115 Heidelberg, Germany
Phone + 49 / (0) 6221 908 0
Fax + 49 / (0) 6221 908 698

Conference fees

ECA Members € 1,490.- per delegate plus VAT
APIC Members € 1,590.- per delegate plus VAT
(does not include ECA Membership)
Non-ECA Members € 1,690.- per delegate plus VAT
EU GMP Inspectorates € 845.- per delegate plus VAT
The conference fee is payable in advance after receipt of invoice and includes conference documentation, dinner on the first day, lunch on both days and all refreshments. VAT is reclaimable.

Accommodation

CONCEPT HEIDELBERG has reserved a limited number of rooms in the conference hotel. You will receive a room reservation form when you have registered for the conference. Please use this form

for your room reservation or be sure to mention "ECA" to receive the specially negotiated rate (single room € 135,- per night, incl. breakfast) for the duration of your stay. Reservation should be made directly with the hotel not later than 13 April 2012. Early reservation is recommended.

Conference Language

The official conference language will be English.

Organisation and Contact

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

CONCEPT HEIDELBERG
P.O. Box 10 17 64
69007 Heidelberg, GERMANY
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.de

For questions regarding content:

Dr. Günter Brendelberger (Operations Director) at +49-62 21/84 44 40, or per e-mail at brendelberger@concept-heidelberg.de.

For questions regarding reservation, hotel, organisation etc.:

Jessica Stürmer (Organisation Manager) at +49-62 21/84 44 43, or per e-mail at stuermer@concept-heidelberg.de.

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

Reservation Form (Please complete in full)

+49 6221 84 44 34

"Japan Quality"

14 - 15 May 2012, Heidelberg, Germany

Mr Ms

Title, first name, surname

Company

Department

Important: Please indicate your company's VAT ID Number

Please indicate the Purchase Order Number, if applicable

Street / P.O. Box

City

Zip Code

Country

Phone / Fax

E-Mail (Please fill in)

CONCEPT HEIDELBERG
P.O. Box 10 17 64
Fax +49 (0) 6221/84 44 34

69007 Heidelberg
Germany

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 2 weeks prior to the conference 10 %
 - until 1 weeks prior to the conference 50 %
 - within 1 week 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)!