



REGULATORY PROCEDURES FOR:

- CLINICAL TRIAL APPLICATIONS
- MARKETING AUTHORISATIONS
- VARIATIONS

IN THE EU, USA, JAPAN, SWITZERLAND AND CHINA



25 – 28 OCTOBER 2011, FREIBURG I. BR., GERMANY

- European centralized procedure at EMA
- MRP and DCP
- CTA in Europe – Process, VHP, particulars for biopharmaceuticals
- Variations – changes to the CTD, procedures, data particulars for biopharmaceuticals
- Changes to the SmPC
- Data and document management
- Approval in other regions – process and essentials of the relevant agencies USA, Japan, Switzerland, China

EUCRAF - the European Center of Regulatory Affairs Freiburg offers in collaboration with University of Strasbourg the postgraduate Diploma „Regulatory Affairs for Biopharmaceuticals” developed by distinguished experts from authorities, universities and companies. EUCRAF is also a platform for Regulatory Affairs experts to facilitate the exchange on current matters related to biopharmaceuticals.

LIMITED NUMBER OF PLACES ONLY – REGISTER EARLY

BIOPHARMACEUTICALS ARE SPECIAL – STAY UP TO DATE!

CONTENT

This seminar provides in-depth knowledge on the procedures for marketing authorization applications, clinical trial authorisations and variations in the EU, USA, Japan, Switzerland and China. These regions are most important markets for pharmaceutical products and the appropriate agencies such as the European national agencies, the EMA, the FDA and the Japanese MHLW have major influence on the regulatory strategy in pharmaceutical companies used to develop and submit new medicines. In order to authorise products in these markets successfully, companies need to act according to the requirements and procedures of the different regions since they are not harmonised despite increasing efforts. For the EU, the centralised procedure and the national mutual recognition and decentralised procedures are described in detail. Furthermore, the documentation and steps required to obtain and maintain authorisations for clinical trials are discussed. During the life cycle of products their marketing authorization dossier is changed and the changes are subject to regulatory processes. For biopharmaceuticals, these variations are frequently demanding in terms of data and dossier requirements. The Seminar focuses in detail on product life cycle activities related to Europe but also provides an overview on the principles to be followed in other regions.

WHO WILL ATTEND:

All who start a career in Regulatory Affairs and CEOs and CSOs of small and midsize companies to get the essentials of the regulatory procedures in the EU, USA, Japan, Switzerland and China

UPCOMING SEMINARS

DECEMBER, 14 – 16:

Key features of biopharmaceuticals illustrated by practical cases

JANUARY, 24 – 27:

Pharmaceutical development of biopharmaceuticals and particulars of the CMC dossier

MARCH, 06 – 09:

Non-clinical and clinical development of biopharmaceuticals including biosimilars and the Module 4 and 5 requirements

APRIL, 19 – 20:

Requirements for the development and authorizations of medicinal products for children

FULL PROGRAMME: WWW.EUCRAF.EU

TAKE THIS SEMINAR AS FIRST IN THE SERIES OF NINE TO GET THE POSTGRADUATE DIPLOMA ON BIOTECH RELATED REGULATORY AFFAIRS.

SPEAKERS

Christine Degeling

Senior Consultant/Manager at Xendo

Karen van Graevenitz Buser

Senior Regulatory Program Manager



Steffen Gross

Deputy Head of the Section Monoclonal and Polyclonal Antibodies, Laboratory Head as well as Scientific Assessor at PEI



Esther Imboden

Director of REGULIX LTD



Hartmut Krafft

Head of the section clinical trials at PEI



Leyna Mulholland

Director of Global Product Development Regulatory Affairs at Hoffman-La Roche, Inc.



Tilo Netzer

Senior Vice President and Head of Global Regulatory Affairs at Merck Serono



Ruth Rettenmeier

PAREXEL International GmbH



Dunja Schumacher

Senior Regulatory Consultant at NDA Regulatory Science Ltd.

25 OCTOBER 2011, 10.00 – 18.00

GABRIELE DALLMANN

■ **Welcome and Introduction**

DUNJA SCHUMACHER

■ **European Centralised procedure at the EMA**

- Mandatory and optional scope of the centralised procedure
 - Eligibility request
 - Pre-submission activities
 - Conditional marketing authorisation
 - Marketing authorisation under exceptional circumstances
 - Accelerated assessment
 - Appointment and Role of the (Co)Rapporteurs and their assessment teams, of the EMEA PTL and of Agencies' experts
 - Involvement of Working Parties and Scientific Committees other than CHMP

 - Review process
 - Procedure
 - Validation of the MAA
 - Time lines
 - Assessment report
 - CHMP Peer Review
 - Oral explanation
 - CHMP Opinion
 - Withdrawal
 - Re-examination
 - Commission decision

 - Life-cycle of European Marketing Authorisations
 - Actual marketing
 - Cessation of placing a product on the market
 - Suspension
 - Revocation
 - Withdrawal
 - „Renewal“
 - Sunset clause
 - Annual Re-assessment
 - Time lines, Procedures, Documents, Exemptions
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26 OCTOBER 2011, 09.00 – 18.15

HARTMUT KRAFFT

■ **Clinical Trial Application (CTA) in Europe: legal basis and relevant procedure**

- The Clinical Trials Directive
 - European and national Guidelines and publications
 - National authorisation procedures and their particulars
 - Content and format
 - Procedures, timelines, submission to regulatory authorities and ethic committees
 - EUDRACT and EUDRACT tracking number
 - Notification of amendments
 - Safety reporting requirements
 - Annual Safety Report
 - End of Trial Notification
 - Summary Clinical Trial Report
 - „Grounds for Non-approval“(GNA) letter and appeal procedure
 - Interventional and non-interventional trials
 - Exploratory CTAs
 - Experience with different authorities
 - Role and responsibilities of CROs
 - Harmonisation of CTAs
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LEYNA MULHOLLAND

■ **USA**

- Legal basis for medicinal products and medical devices
 - Types and Procedures of Regulatory Submissions
 - Role and function of and interaction with the FDA
 - The FDA's review process
 - The Investigational New Drug Application (IND)
 - Pre-submission process
 - The New Drug Application (NDA)
 - The Biological License Application (BLA)
 - Accelerated Development options
 - FDA's approach to the CTD
 - Supplements
 - Post-marketing obligations
 - Regulations for biopharmaceuticals, follow-on products and advanced therapies
 - Orphan Drugs
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TILO NETZER

■ **The PDUFA process at FDA**

LEYNA MULHOLLAND

■ **Japan**

- Pharmaceutical legislation in Japan
 - Organisation of and interaction with the MHLW
 - Types and procedures of regulatory submissions
 - Pre-submission procedures
 - Relevance of clinical bridging studies
 - KIKO consultation – Clinical Trial Notification (CTN)
 - Regulations for biopharmaceuticals, biosimilars and advanced therapies
 - Orphan Drugs
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27 OCTOBER 2011, 09.00 – 17.30

GABRIELE DALLMANN

- **Strategic considerations on selecting the authorisation procedure**
 - How is flexibility determined and where does it end
 - How to select the right process for the company's strategic considerations, CP vs DCP
 - Factors of success

ESTHER IMBODEN

- **Marketing Authorisation and Clinical Trial Authorisations Applications in other regions (focus on biopharmaceuticals)**
 - Switzerland
 - Legislation and Stakeholders
 - Procedures
 - Regional Part of the Application
 - Handling Variations
 - Post-marketing obligations

STEFFEN GROSS

- **Variations-European Regulations and national legal provisions for changes to the CTD**
 - Classifications, documentation
 - Procedures and time lines
 - Contact points
 - Downgrading, pooling and consequential changes
 - Multiple agency submissions
 - Appeals

STEFFEN GROSS

- **Changes to the Biotech CTD**
 - Data and documentation requirements
 - Typical changes and their handling

28 OCTOBER 2011, 09.00 – 17.30

RUTH RETTENMEIER

- **Changes to the SmPC**
 - Line extensions (composition, formulation, indication, posology)
 - Safety information
 - Quality changes
 - SmPC harmonisation

CHRISTINE DEGELING

- **European National Mutual recognition (MRP) and Decentralised procedure (DCP)**
 - Network and resources of the Agencies: Role and activities of the RMS, CMS, CMD(h)
 - Filing, Validation, Time lines, Process Management, Fees
 - Review Process
 - Assessment report
 - CMD(h) and CHMP referrals
 - Referral

KAREN VAN GRAEVENITZ BUSER

- **The regulatory System in China**
 - Pharmaceutical legislation
 - Organisation of the S-FDA
 - Types and procedures of regulatory submissions
 - Pre-submission procedures
 - Clinical Trials
 - Regulations for biopharmaceuticals, biosimilars and advanced therapies
 - Orphan Drugs

BIOTECH RELATED REGULATORY AFFAIRS

SEMINAR 2: REGULATORY PROCEDURES VALID FOR: CLINICAL TRIAL APPLICATIONS, MARKETING AUTHORISATIONS, THE LIFE CYCLE OF AUTHORISATIONS

Please send your registration form to: **BOOKING FORM FOR SEMINAR 2**

EUCRAF Ltd.,
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Freiburg, Germany

For any questions, please contact us by phone: +49 (0)761 13 73 44 24
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or via homepage: www.eucraf.eu

or via email to:
booking@eucraf.eu

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HOW TO REACH

Freiburg:

Freiburg i. Breisgau is located in the Southwest of Germany, in the tri-national region of France-Germany-Switzerland.

By plane:

Freiburg is served by EuroAirport Basel-Mulhouse-Freiburg (<http://www.euroairport.com>). There is an airport shuttle bus to Freiburg. Zurich or Frankfurt airports are other options.

By train:

Freiburg has an excellent connection via ICE express trains (www.db.com).

By car:

By car, you reach Freiburg via highway A5.



YOUR CONTACT PERSON



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