



EUROPEAN PHARMACEUTICAL REGULATORY ENVIRONMENT

13 – 16 SEPTEMBER 2011
FREIBURG I. BR., GERMANY

- The European Pharmaceutical Legislation
- The Regulatory Institutions and other stakeholders
- Interaction of international Agencies
- The general requirements for the Common Technical Document (CTD), the Marketing Authorisation Dossier (Module 1, Module 2)
- Special legal provisions for biopharmaceuticals
- Orphan Drug Designation
- SME
- Principles of registration and certification of medical devices and device/drug combinations

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

The subject area Regulatory Affairs ensures that the quality, safety and efficacy of the medicinal product is in line with legal requirements for the purpose of marketing safe and efficacious medicinal products solely in the interests of public health. Regulatory affairs is primarily a specialty of the pharmaceutical industry. The function encompasses all strategic, operational and administrative activities required to obtain official authorisation for Clinical Trials, marketing and distributing of medicinal products, post-marketing changes and obligations and manufacture and the activities related to pharmacovigilance. Seminar 1 provides the basis for all activities of a regulatory affairs professional since it imparts detailed knowledge on the pharmaceutical legislation, the regulatory institutions and stakeholders and their interaction and on the Modules 1 and 2 of the marketing authorisation dossier. Modules 3, 4 and 5 of the marketing authorisation dossier are dealt with in Seminar 4 of this course, specifically describing what is relevant for biopharmaceuticals. This Seminar furthermore deals with the particulars of small and medium size enterprises, and all regulations related to biopharmaceuticals. It also provides the legal details on orphan drug regulations and on the role and activities of the ICH process.

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 European regulatory environment.

UPCOMING SEMINARS

SEPTEMBER, 29 – 30:

Good Regulatory Affairs practice: communication skills, project management and tools for the daily practice

OCTOBER, 25 – 28:

Regulatory procedures for CTA, MAA, Variations in the EU, USA, Japan, Switzerland, China

DECEMBER, 07 – 09:

Key features of biopharmaceuticals illustrated by practical cases

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



Judith Creba

Head of EU Liaison and Policy in Drug Regulatory Affairs at Novartis Pharma AG



Gabriele Dallmann

Study Director EUCRAF, CEO Pharmatching GmbH, Former PEI



Hoss Dowlat

Vice President, Technical, Drug Development Global Strategy Services, responsible for EU, USA, Japan, China, Korea, and Latin America drug development and regulatory submissions at PAREXEL



Anne Dupraz-Poiseau

Voisin Consulting



Monika Eck-Schaupp

Deputy General Manager and Director Regulatory Affairs at NDA Regulatory Service GmbH

Rembert Elbers

Head of Section Oncology, Immunology Blood at Federal Institute for Drugs and Medical Devices



Marielle Fournier

Director of Voisin Consulting



Geneviève Michaux

Counsel at Covington & Burling LLP



Gesa Pellier

Head Drug Regulatory Affairs Europe at Novartis Pharma AG



Silvia Pfaff

Head Drug Regulatory Affairs at Novartis Pharma AG



John Purves

Former EMA



Jürgen Regenold

CEO Dr. Regenold GmbH

Course Leaders: Geneviève Michaux and John Purves

13 SEPTEMBER 2011, 10.00 – 18.30

GABRIELE DALLMANN

- **Welcome and Introduction to the whole MSc EUCRAF course on biotech-related regulatory affairs**

GENEVIÈVE MICHAUX, GABRIELE DALLMANN

- **Introduction into the European regulatory system**
 - How are medicines and devices regulated and why?
 - What is regulatory affairs?

GENEVIÈVE MICHAUX

- **The European Pharmaceutical Legislation**
Essential terms and provisions of the framework defining the marketing of pharmaceutical medicinal products in the EU/EEA
 - The Common market in the EU/EEA
 - Approval and distribution of medicinal products in the EU
 - Regulations and Directives determining the pharmaceutical legislation applicable to the EU/EEA and national pharmaceutical law of the EU Member States
 - Notice to applicants
 - Obligations of the marketing authorisation holder
 - Global Marketing Authorisation
 - Data Protection and patents
 - Types and procedures of referrals

REMBERT ELBERS

- **Orphan Medicinal Products in the EU/EEA**
 - Legal basis and provisions
 - Orphan Designation
 - Orphan Status
 - Market Exclusivity and Further Incentives
 - Annual Report

- Register
- Marketing Authorisation Procedure
- Strategy

GABRIELE DALLMANN

- **Legal particulars for biopharmaceuticals**
 - Advanced therapies
 - Emerging Therapies and technologies
 - Biosimilars
 - Plasma and Vaccine Antigen Master Files
 - Genetically Modified organism (GMO)
 - Batch release

14 SEPTEMBER 2011, 08.30 – 18.30

GESA PELLIER, JUDITH CREBA, SILVIA PFAFF

- **Regulatory Institutions and other Stakeholders of the European System of Pharmaceuticals, their functions and role**
 - Role of the Parliament, Council, EU Commission, Enterprises DG, Pharmaceutical Committees
 - Working effectively with the EMA
 - Legal Basis, role, structure and procedures
 - Executive Director
 - Management Board
 - Secretariat: EMA's support of the authorisation process of medicinal products
 - Involvement of external experts
 - QRD product information, Invented name requests
 - Transparency, communication and publications
 - European Public Assessment Report (EPAR)
 - Annual Report
 - EMA Scientific Committees, their interaction and their Working Parties
 - CHMP, COMP, HMPC, CAT
 - Expert committees SAG

- The National Agencies of the EU/EEA Member States
- The HoA Network
- The Industry Learning Societies
- Involvement of patient organisations

JÜRGEN REGENOLD

■ Small and Medium Size Enterprises (SME)

- The particular conditions applicable to Small and Medium Size Enterprises (SME) and the SME office of the EMA
- SME Regulation and Incentives
- Type of companies assigned SME status
- What does the SME Office deliver
- Scientific advice

15 SEPTEMBER 2011, 09.00 – 18.00

THE COMMON TECHNICAL DOSSIER (CTD)

MONIKA ECK-SCHAUPP

■ Format and content of the marketing authorisation Application: The Common Technical Dossier (CTD)

- General aspects of the harmonised CTD
- eCTD

■ Module 1 of the CTD: General information

- Application Form
- Application Numbering
- Multiple applications: co-marketing and co-promotion
- Strengths
- Fees and reduced fees
- Proposals (Mock-ups) for packaging, labelling and package inserts
- Specimens
- INN
- ATC codes
- Environmental Risk Assessment (ERA)

■ Labelling, Package Leaflet and Summary of Product Characteristics (SmPC)

- Readability test, Braille, Blue Box

16 SEPTEMBER 2011, 09.00 – 17.00

MONIKA ECK-SCHAUPP

■ Module 2 of the CTD

- Table of Contents (Module 2 – 5)
- Introduction
- Module 2.3 Quality Overall Summary
- Module 2.4 Nonclinical Overview
- Module 2.5 Clinical Overview
- Module 2.6 Nonclinical Summary
- Module 2.7 Clinical Summary

■ Risk Management Plan (RMP)

HOSS DOWLAT

■ International collaboration of agencies

- ICH process: collaboration of the three regions EU, US and Japan
- Collaboration with FDA
- Collaboration with other agencies: China, India, Brazil

ANNE DUPRAZ-POISEAU, MARIELLE FOURNIER

■ The regulatory framework for drug/device combination products

- The EU regulatory framework for drug/device combination products
- The specific case of combined ATMP
- The US regulatory framework for drug/device combination products
- The key challenges raised by drug/device combination products

BIOTECH RELATED REGULATORY AFFAIRS
SEMINAR 1: EUROPEAN PHARMACEUTICAL REGULATORY ENVIRONMENT

Please send your registration form to: **BOOKING FORM FOR SEMINAR 1**
EUCRAF Ltd.,
Wippertstr. 2
79100 Freiburg,
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or via homepage: www.eucraf.eu

or via email to:
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	Fee	VAT 19%	Total
<input type="checkbox"/> Industry	1.720,00 €	326,80 €	2.046,80 €
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<input type="checkbox"/> Academic Institution	1.140,00 €	216,60 €	1.356,60 €

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On receipt of your booking form we will confirm your provisional place and provide you with the details of the payment method via Email. An invoice will be sent separately. Payment must be received prior to the meeting.

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Signature Date

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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THE VENUE

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