Global CompliancePanel

Netzealous
Knowledge, a Way Forward...

2-day In-person Seminar:

The New Clinical Trials Regulation and Regulatory Affairs Aspects of Medicinal Product Development in the EU

Zurich, Switzerland

June 15th & 16th, 2017

9:00 AM to 6:00 PM

Price

Price: **$1,895.00**

(Seminar for One Delegate)

Register for 5 attendees

Price: **$5,685.00** You Save: $3,790.0 (40%)*

~~$9,475.00~~

ENROLL

***Please note the registration will be closed 2 days (48 Hours) prior to the date of the seminar.*

Adriaan Fruijtier

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Adriaan Fruijtier has graduated as a pharmacist at the University of Utrecht, The Netherlands.

He is currently Director Regulatory Affairs at CATS Consultants. Until March 2004 he has been Head of the Oncology Group within Global Regulatory Affairs at Bayer AG, Wuppertal, Germany, and Bayer Corporation, West Haven, CT, USA. Between 2001 and 2003 he was Director of Regulatory Affairs at Micromet AG, a biotech company in Munich, Germany. Prior to joining Micromet he has worked during four years as a Project Manager for Oncology Projects at the European Medicines Agency in London, United Kingdom.

Overview :

The main document from a regulatory perspective in the development of a medicinal product is the regulatory plan. In this Seminar it is explained how to write the regulatory plan, and which aspects to consider.

The regulatory plan describes the regulatory strategy, as well as pricing and reimbursement issues in your development. Orphan medicinal Products will be discussed, and the advantages of having a status as an orphan medicinal product will be explained.

Scientific advice is a vital element in the development of a medicinal product, and knowledge of the how to choose between national and EU scientific advice, as well as the preparation and procedure is vital for a successful outcome

Agenda:

Day One

Lecture 1: Introduction
- Elements of development regulatory affairs
- The regulatory plan
- Overview of the European Medicines Agency

Lecture 2: Regulatory strategy and regulatory plans (including target SmPC)
- Structure of the regulatory plan
- Sources for the regulatory plan

Lecture 3: Pricing and reimbursement
- What is Health Technology Assessment (HTA)?
- Who decides on pricing and reimbursement: the HTA bodies

Lecture 4: Orphan medicinal products
- Rare diseases: orphan medicinal products?
- Main incentives
- Applying for orphan medicinal product designation

Lecture 5: Scientific advice
- Why and when is scientific advice needed and useful?
- Topics for scientific advice
- Briefing document, timelines and planning: from submission to final scientific advice by CHMP
- National versus EMA
- Joint scientific advice CHMP + HTA bodies: benefits and issues to consider

Lecture 6: Paediatric development
- Research and development programme for medicines in children: Paediatric Investigation Plans
- Cases in which studies in children are not needed or will be done later: Waivers/deferrals
- What is a paediatric use marketing authorisation (PUMA)?

Lecture 7: SME status
- Advantages of micro-, small- and medium-sized-enterprise (SME) status
- How to apply for SME status

Day Two

Lecture 1: Advanced Therapy Medicinal Products (ATMP)
- Definitions
- Early scientific evaluation of quality and non-clinical data: Certification procedure
- Guidelines
- Practical exercise: Determine for various products if they fall under the ATMP definition

Lecture 2: Oncology
- Why is development of oncology products different?
- Preclinical considerations: Which animal studies are needed for oncology products?
- The new clinical oncology guideline

Lecture 3: Practical session: regulatory plan
- Case study: New oncology product
- Does it qualify for orphan drug designation?
- How to propose the optimal orphan indication
- Paediatric studies necessary?
- Scientific advice: Topics, selection of authorities

Lecture 4: How to apply for a clinical trial authorisation in the EU
- The clinical trial directive
- Outline of the procedure
- Content of the Investigational Medicinal Product Dossier and important guidance documents

Lecture 5: Voluntary Harmonisation Procedure (VHP)
- Harmonisation of assessment of clinical trial applications in several EU countries through the VHP:

Lecture 6: Overview of the process
- Advantages and disadvantages

Lecture 7: Future changes to the clinical trial authorisation process in the EU
- The Clinical Trial Regulation
- Impact on the pharmaceutical and biotech Industry

Lecture 8: Interactive discussion: what are the advantages and disadvantages of the new Regulation?

Group Participation

10%	2 Attendees to get offer
20%	3 to 6 Attendees to get offer
25%	7 to 10 Attendees to get offer
30%	10+ Attendees to get offer

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Kindly get in touch with us for any help or information.

Look forward to meeting you at the seminar

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