Global CompliancePanel

Netzealous
Knowledge, a Way Forward…

2-day In-person Seminar:

Preparing the Marketing Authorization Application in the EU, with a focus on the product information

Zurich, Switzerland

April 18th & 19th, 2018

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~~

Register for 10 attendees

Price: **$10,422.00** You Save: $8,528.0 (45%)*

~~$18,950.00~~

ENROLL

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

Adriaan Fruijtier

Regulatory Affairs Consultant,
CATS Consultants GmbH

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 :

In this seminar, we will look into all elements of the MAA dossier, in particular module 1, and within this module the Product Information. In addition, the various meetings with the Health Authorities in the centralized procedure will be discussed.

Regular review and monitoring of product information for medicines is important, to support awareness of relevant updates/changes which may affect prescribing, dispensing, administration or monitoring practices. It is also important that patients and caregivers, as appropriate, are made aware of the information contained in the Package Leaflet (PL) and should be encouraged to read it prior to and during their treatment.

Agenda:

Day One

Lecture 1: "GxP" Computer Systems and FDA Oversight

- 1.0 Cover Letter
- 1.1 Comprehensive Table of Contents
- 1.2 Application Form
- 1.3 Product Information
- 1.4 Information about the Experts
- 1.5 Specific Requirements for Different Types of Applications
- 1.6 Environmental Risk Assessment
- 1.7 Orphan Market Exclusivity
- 1.8.1 Pharmacovigilance system, where appropriate
- 1.8.2 Risk-Management System
- 1.9 Information relating to clinical trials
- 1.10 Information relating to Paediatrics

Lecture 2: In-dept review of requirement for product information

Areas Covered in the Session:

- SmPC
- Package Leaflet
- Labelling
- Readability testing
- How to conduct presubmission meetings with the EMA and Rapporteurs

Who will benefit:

- Regulatory Affairs personnel involved in Development of medicinal products

Day Two

Lecture 1: In dept review of requirement for product information (continued)

Lecture 2: Pre-submission meetings with EMA and Rapporteurs

Why should you attend:

This seminar is specifically designed for personnel that will have to prepare a Marketing Authorisation Application in the EU. It is important to do this correctly, as otherwise the application may be rejected at validation (at the time of submission) or there may be delays later in the process

Product Information is a key part of the marketing authorisation of all medicines authorised in the European Union

The product information is comprised of the Summary of Product Characteristics (SmPC) and the PL. These documents are issued when a medicine is first licensed for use and are reviewed and updated as necessary throughout the lifetime of a medicine, to reflect the current state of knowledge of the medicine and the risks associated with its use. The SmPC is mainly intended for use by healthcare professionals

SmPCs are also the basis for the preparation of package leaflets, so are important documents in enabling information on medicines to reach patients.

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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

Payment Option

1. Credit Card: Use the Link to make Payment by Visa/Master/American Express card click on the register now link
2. Check: Kindly make the check payable to NetZealous DBA GlobalCompliancePanel and mailed to 161 Mission Falls Lane, Suite 216, Fremont, CA 94539, USA
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Contact Information: Event Coordinator

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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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