Global CompliancePanel

Netzealous
Knowledge, a Way Forward…

2-day In-person Seminar:

Product Information for Medicinal Products in the EU

Zurich, Switzerland

June 19th & 20th, 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

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 :

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.

The PL reflects the more comprehensive information described in the SmPC, but is required to be presented in an abbreviated and easyto-read format for patients.

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Agenda:

Day One

Lecture 1: The SmPC

- The role of the SmPC (including use as Pharmacovigilance Document)
- Where does the information come from?
  - Structure of the Common Technical Document
  - Structure of SmPC in reference to difference Modules
  - Structure of SmPC in reference to departmental responsibilities (PV, Clinical, Quality, etc.)
  - Relationship between Modules, SmPC, PIL, Labelling - the last three being the only key information seen by general public / med practitioners
- How to write an SmPC from scratch
- Presentation and discussion of key guidance documents (including templates) from EMA/CHMP
- The importance of writing the SmPC so that it will be precise, exact, readable, and unambiguous
- Clarifying the therapeutic indications
- Listing contraindications
- Defining the warnings and precautions for use
- Highlighting potential drug interactions
- Defining instructions for proper use, improving tolerance to medicines by communicating necessary safety information and avoiding untoward effects
- Describing adverse reactions from clinical studies and spontaneous reporting and how it may influence pharmacovigilance
- Describing instructions for storage, shelf life and in use stability claims,
- Timing of reporting the date of last revision
- Translations
- The package leaflet
- Relationship between SmPC / Package Leaflet
- differences
- what is reflected where and in what format?
- The perception of risk of a medicinal product
- Guidelines for package leaflets

Day Two

Lecture 1: Examining the legal issues surrounding the European regulations

- How must safety information be presented to the patient that would prevent very severe consequences such as foetus deformity - be included in leaflets?
- How does a company manage this by region?
- How often should a SmPC leaflet be reviewed? Relationship with PSURs.
- Risk-Management Plans and how they affect product information

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Lecture 2: Readability Testing

- Legal requirements
- Language requirements
- Where to test
- Pitfalls in developing a test
- Interviewing focus groups
- Bridging tests
- Inclusion and exclusion criteria

Lecture 3: Practical exercise 4

- Conduct readability testing with the participants

Lecture 4: Product Information during the registration procedures

- Before submission
- Steps to consider after submission and before marketing approval
- What to agree to and what not to agree to when negotiating with the Health Authorities
- What to do after CHMP opinion until EU Commission authorisation

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Day One

Lecture 1: The SmPC

- Combining package leaflets for different pharmaceutical forms, presentations and strengths of a medicinal product
- The package leaflet as a marketing tool, what is allowed?

Lecture 2: Practical exercises: Successfully working through the Regulations

- In this session, participants will be able to analyse the regulatory requirements and will gain an in-depth knowledge of how to meet them. The emphasis will be on grasping what information is required. This is a unique opportunity for the participants to ensure they fully understand and comply with the regulations in place.

Lecture 3: Participants will work on the following points:

- Understanding what must be included in your Patient Information Leaflets (PLs) with a focus on safety
- Overcoming the special challenges when drafting the safety sections on contraindications, warnings and precautions

Lecture 4: Practical exercise 1

- Writing a package leaflet, based on an SmPC

Lecture 5: Practical exercise 2

- Improving a package leaflet, making it more clear and patient-friendly

Lecture 6: Labelling

- Relationship between SmPC / Labelling
- Requirements for labels
- Minimum information on small labels
- Additional secondary packaging, e.g. Lilly contraceptives
- Labelling as a marketing tool, what is allowed?

Lecture 7: Practical exercise 3

- Writing the label text, based on an SmPC

Day Two

Lecture 5: Product Information after approval

- Overview of Variations
- Variations involving Product Information
- Variations for generic/hybrid/biosimilar products
- Variations following referrals
- Implementation of Pharmacovigilance requirements
- What to do with editorial changes?
- When to submit the translations
- Article 61(3) Notification

Lecture 6: International situation

- Comparing US labelling, the Package Insert; also the complementary Medication Guide for the high risk drugs under a REMS

Why should you attend:

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.

The labelling and package leaflet are important tools to achieve correct use of the medicinal product.

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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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