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EU & US REQUIREMENTS FOR PHARMACEUTICAL LABELLING & PACKAGE LEAFLETS

LIVE Online Academy
23-25 June 2021

Further your understanding of the latest requirements for labelling and packaging according to EU and FDA guidelines

COURSE OVERVIEW

This course will clarify the European and US regulatory requirements for developing labelling and package leaflets and clearly interpret the latest Directive. The course will also provide practical advice on designing and writing Patient Information Leaflets and Package Inserts to meet regulatory requirements and satisfy readability and compliance needs. In the face of increasing regulatory and consumer demand, the need for accurate and complete product information has never been stronger. This course will provide you with key practical information on devising successful labelling strategies to guarantee complete compliance.

MEET
THE
TRAINER

Sumaiya Patel

Sumaiya Patel is a director of a regulatory consultancy with over 11 years' experience in both pre and post-approvals for generic, CRO and big pharma organisations. Sumaiya has experience in regulatory implementation and training, focusing on CMC, clinical development, strategy and manufacturing. She has extensive experience in writing Module 3 of CTD, Module 2 of the CTD and also Quality Expert statements to support dossiers and Type II Quality variations. She has a track record of providing regulatory inputs related to CMC aspects during the development product lifecycle.

MODULE ONE

Key background information surrounding the pharmaceutical regulatory environment for European SmPC and PIL, as well as gaining insights into American labelling.

A thorough analysis of the legal and regulatory framework that governs pharmaceutical product information in the European Union. Your chance to clarify all the outstanding issues you have.

MODULE TWO

Understanding and clarifying the latest regulations and best EU practices on the SmPC, package leafl ets and product labelling; also comparing and contrasting EMA and FDA perspectives

- Presentation and discussion of key guidance documents from EMA/ CHMP and FDA
- Gaining unique insights into the SmPC, with emphasis that it is the source document of a PL

MODULE THREE

The importance of writing the SmPC so that it will be precise, exact, readable, and unambiguous

- Communicating proper use and risk of a medicine by both the SmPC and PL
- Examining the Directives and guidance on human product information
- Defining the requirements for labels and leaflets
- Meeting standard criteria for identifying a medicinal product

MODULE FOUR

Achieving a single label and leaflet version across Europe and reflections on American developments

- Writing a single version of a SmPC, PL or package labels in all European languages using the EMA template
- Comparing US labelling, legally the physicians Package Insert also intended for the patient; also the complementary Medication Guide for the high risk drugs under a REMS

MODULE FIVE

Combining PLs for different pharmaceutical forms, presentations and strengths of a medicinal product

- Combining PLs for different pharmaceutical forms, presentations and strengths of a medicinal product
- Steps to consider after submission and before marketing approval
- What to do after CHMP opinion until EU Commission authorisation
- What is the labelling approval process with the FDA?
- Is harmonisation of EU and US or international labelling possible

MODULE SIX

Examining the legal issues surrounding the European regulations

- Examining legal liability issues
  - 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 leaflet be reviewed?

MODULE SEVEN

Addressing the practical aspects of the Regulations

- The concept of readability of labels and leaflets, and the guidelines for readability testing
- The course leader will examine the quality and readability of some existing product labels and leaflets, and will provide practical criteria to design and write successful, user-focused PILs. It will be your chance to deal with most of the difficulties inherent in the practical implementation of the European and American regulations

MODULE SEVEN

Developing practical steps to implement the readability guidelines

- Providing the right information to fulfill regulatory and best medical practice
  - Communicating with the patient in an effective way
  - Customising the information to meet the needs of physicians and patients
- Giving good quality information
  - What constitutes good quality information? What is readability really and what role does it play?
  - Issues and controversies surrounding information provision
  - Practical insights into user testing of labels and leaflets in different languages since year 2000

MODULE EIGHT

Delegates will examine PLs from several countries and attempt to minimise risk with the best wording

- Practical approach to developing PILs
  - Setting performance standards
  - Developing guidelines for writers and designers
  - Increasing company collaboration with consumers and health professionals
  - Implementing successful quality assurance measures
- Developing a protocol for testing readability of PLs
- Looking at examples of successful and unsuccessful patient information
- Testing the guidelines

WHO IS THIS COURSE FOR?

This course has been specifically designed to address the training needs of Managers and Executives in area such as:

- Regulatory Affairs
- Product Labeling
- Legal Counsel
- Drug Safety
- Medical Affairs
- Marketing
- Medical Information

The course will be beneficial to people new in their role, and more experienced professionals who need clarification on the new requirements.

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For information contact our training consultants

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