Foundation Skills in Medical Information

Training of the Bulgarian Association for Drug Information

26 - 28 of September 2017

Audience Profile

Beginners in the field of regulatory affairs, Employees without scientific degree or previous life sciences experience tasked with handling medical information inquiries, medical advisers, administrators who works in regulatory environments, experts for call centers, students in the health universities.

This course has been designed to meet the needs of experts working within medical information, as departmental administrators, and those working in related functions who would benefit from foundational knowledge of medical Information practices. It provides the opportunity to consolidate existing knowledge and get a complete overview of medical Information.

The course will be in Bulgarian language, but the presentations will be in English/Bulgarian Language

Knowledge and competences targeted by the training 26- 28 of September 2017

- General regulatory framework for Drug Safety and Medical Information
- Ability to understand basic pharmacology terminology
- Possess overall understanding of drug development process
- Possess overall understanding of medical Information concepts and processes
- Possess general awareness of medical information regulatory framework and key requirements
- Ability to answer and document medical inquiries accurately and
- FAQ by patients and health care professionals
- Ability to identify and record adverse events and product issues
- Handling simple enquiries including use of the SmPC

Training Modules Outline

Medical Information, general princiles and terminology
Pharmacology fundamentals 26th of September
9:00 Registration, Arrival refreshments
9:30 Wecome & Introduction
9.40 What is Medical Information and Terminology,
10.15 -10.30 Coffee Break
10.30 Types of Drugs: Classifications & ATC CODE,

11.00 Understanding of basic Medical/Pharmacological Information Pharmacokinetics fundamentals – the Absorption, Distribution, Metabolism, Excretion)
12.00 Competent authorities and Marketing Authorization Procedures _(MRP, DP, CP)
13 .15- 13.45 Lunch Time
13.45 - 14.30 Sources of Medical Information: SmPC, PIL,
Working in Groups - exercises

Medical Information related to the drug development process – 27 th of September 2017

9:00 Registration, Arrival refreshments
9:30 Preclinical research- basic principles and terminology
10.00 Clinical research and clinical regulatory affairs - ICH, GCP
10.30 -45 Coffee Break
10.45 -11.15 Approval Process of Clinical trials

11.15 What is MEDRA - Introduction
11.45 Definitions and Standards for expedited reporting (ICG GCP Tripartite)
12.30 - 13.00 Lunch Break
13.00 Handling enquires - What resources should be used
13.30 Discussion and FAQ by patients and health care professionals
(exercises)

Medical Information related to the pharmacovigilance - 28 th of September 2017
9:00 Registration, Arrival refreshments
9.30 Medical information and Pharmacovigilance and the role they play in Drug Safety10. 00 Post Marketing Safety Monitoring overview
10.30 -10. 45 Coffee Break
10.45 Handling simple enquiries including the SmPC
11.15. Roles in the Medical Information process communication with the MI experts/ Drug Safety Unit
11.45. Medical inquiries handling – identifying and handling of adverse events via telephone and email (communication skills)
12.15. Good practices for medical information inquires handling verbal and written)
12.45 - 13.15 Lunch Break

- 13.15 Product quality complaints handling -

13.45 Competency Quiz & Course Evaluation