



Bulgarian Association For Drug Information (BADI)

PROGRAMME

Foundation Skills in Medical Information 2018

Introduction to Regulatory Affairs, Preclinic, Clinical Trials, Marketing Authorisation Procedures (NP, MPR, DP, NP), Advertisement, Medical Information and Market Access (HTA)

26–28th of September 2018, Sofia

AUDIENCE PROFILE	KNOWLEDGE AND COMPETENCES TARGETED BY THE TRAINING
<p>The course is intended for professionals from the following groups.</p> <ul style="list-style-type: none"> • Beginners in the field of regulatory affairs; • Employees without scientific degree or previous life science experience being responsible for handling medical information inquiries; • Medical advisers; • Administrators and office assistants & working in regulatory environments; • Experts for call centers; • Students in the healthcare universities; <p>This course has been designed to meet the needs of experts working within the field of medical information, as departmental/office administrators, as well as related functions that 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 either English/Bulgarian Language.</p>	<p>General regulatory framework for Drug Safety and Medical Information</p> <ul style="list-style-type: none"> • Ability to understand basic pharmacology terminology and processes; • 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 accurately answer and document medical inquiries; • Ability to handle frequently asked questions (FAQs) by patients and healthcare professionals; • Ability to identify and record adverse events and product technical issues; • Handling simple enquiries including use of the SmPC;



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TRAINING MODULES OUTLINE

26th of September 2018 (wednesday)

MEDICAL INFORMATION RELATED TO THE DRUG DEVELOPMENT PROCESS

9.00 – 9.30 h. Registration

9.30 - 11.15 h.

- What is Medical Information and Terminology?
- Types of Drugs. Classifications & ATC Code
- Understanding of basic Medical/Pharmacological Information Pharmacokinetics fundamentals – absorption, distribution, metabolism, excretion
- Preclinical research - basic principles and terminology
- Clinical research and clinical regulatory affairs – ICH Guideline, GCP

11.15 -11.30 h. Coffee Break

11.30 -12.45 h.

- Approval Process of Clinical trials
- Definitions and Standards for expedited reporting (ICG GCP Tripartite)

12.45 -13.15 h. Lunch Break

13.15 - 15.00 h.

- Handling enquires - what resources should be used?
- Discussion. FAQ by patients and healthcare professionals (exercises)

27th of September 2018 (thursday)

MEDICAL INFORMATION, GENERAL PRINCIPLES AND TERMINOLOGY. PHARMACOLOGY FUNDAMENTALS.

9.00 – 9.30 h. Registration

9.30 – 10.30 h. Competent authorities and Marketing Authorization Procedures (Centralized procedure, MRP, DCP, NP)

10.30 – 10.45 h. Coffee Break

10.45 – 12.00 Market Access

12.00 – 12.30 h. Lunch Break

12.30 – 13.30 Handling of Product quality complaints – identification, categorization, communication to health authorities

13.30 - 14.30 h. Sources of Medical Information. SmPC, PIL

Working in groups – exercises

28th of September 2018 (friday)

PHARMAOVIGILANCE-RELATED MEDICAL INFORMATION AND MARKET ACCESS

9.00 - 9.30 h. Registration

9.30 – 11.00 h.

- What is MEDRA – introduction
- Medical information and Pharmacovigilance and the role they play in Drug Safety
- Post-marketing Safety monitoring overview
- Handling simple enquiries including the SmPC

11.00 – 11.15 h. Coffee Break

11.15 – 13.15 h.

Roles in communication with the Medical Information experts/ Drug Safety Unit

Medical inquiries – identifying and handling of adverse events via phone and/or email, good practices for handling in verbal and written (communication skills)

- Advertisement

13.15 h. -14.00 Lunch Break

14:00 h. -15.00

Competency Quiz & Course Evaluation