Innovative Approaches to Excellence in Regulatory Sciences

A collaboration between the Malta Medicines Authority and TOPRA
the Organisation for Professionals in Regulatory Affairs

Venue: Malta Life Sciences Park, San Ġwann

12 March 2018	1-day course: Essentials of EU Regulatory Affairs
13-14 March 2018	2-day course: Introduction to EU Regulatory Procedures for Medicines

12 March 2018

Essentials of EU Pharmaceutical Regulatory Affairs

A one-day course designed to provide awareness of the regulatory environment and an appreciation of some of the main regulatory processes and issues in the EU.

This course is suitable for new recruits, people considering a career in regulatory affairs, personal assistants, administrators, support staff and professionals in other related areas such as medical, manufacturing, marketing and project management in both government agencies and industry.

13-14 March 2018

Introduction to EU Regulatory Procedures

This introductory course is the most wide-ranging, authoritative and practical course of its type in Europe, developed by TOPRA experts to provide regulatory professionals with a solid foundation in the key aspects of Regulatory Affairs and the role it plays.

Objectives of the Programme

- To set the scene for the course. A basic overview of the course itself, with an understanding of drug development, the regulatory environment and the role of regulatory affairs within the pharmaceutical industry.
- To gain a detailed knowledge of chemical and pharmaceutical development. To become familiar with the content of a marketing authorisation application (MAA), in particular, Module 3 plus biotechnology and advanced therapy medicinal products.
- To gain an understanding of the pharmacological and toxicological background to drug development.
- To become familiar with the non-clinical and clinical sections of the European MAA. To provide an overview of clinical research and the regulatory control of clinical trials.
- To gain an in-depth understanding of European Procedures (Mutual Recognition, Decentralised and Centralised), with factors for success from a theoretical and practical perspective, from the viewpoint of the regulators and industry.
- To provide advice on filing generic applications.
- To provide an overview on the post-approval aspects of regulatory affairs including pharmacovigilance and variations.
- To introduce, product information (SmPC, labels & leaflets).
- To establish an understanding of medicines advertising in Malta.
- To introduce the strategic thinking behind defining regulatory strategy including the following topics:
  - Global Strategies;
  - Regulatory Advice;
  - Paediatric Development;
  - Information Protection;
  - Tradenames;
  - Orphans;
  - Early Access.

The objectives of each day are achieved by use of lectures, interactive sessions and case studies. More detailed learning objectives are presented in the lecture notes at the beginning of each day.