MALTA MEDICINES AUTHORITY - TOPRA TRAINING PROGRAMME 12th March

Essentials of EU Regulatory Affairs

To provide awareness of the regulatory environment and an appreciation of the main regulatory processes and issues in the EU

Time	Topic
09:00	Introduction and Aims
09:15	How and why regulations arose (EU and US examples)
09:30	Roles of Regulatory Affairs staff
09:45	The regulatory framework for the EU
10:00	Overview of medical product development process
10:30	Clinical development
11:00	The EU MAA Dossier
12:00	Product Information/ Labelling
12:45	Lunch
13:30	How drugs are registered – EU marketing application procedures
14:45	Submitting a decentralized procedure (DCP) application with Malta as Reference Member State
15:15	Break
15:30	How marketing approval is maintained
16:00	Medical product safety surveillance
16:15	Overview and consolidation
17:00	Close