MALTA MEDICINES AUTHORITY - TOPRA TRAINING PROGRAMME 13th and 14th March

Introduction to EU Regulatory Procedures

To provide an informative and interactive programme of information covering regulatory affairs activities from start to end of medicinal product lifecycle

Day ONE

Time	Topic
0830-0900	Registration
0900-0915	Introduction and aims of the training
0915-0945	The EU regulatory environment and the role of regulatory affairs
0945-1030	Drug development and life-cycle pathways • Strategy / scientific advice • Nonclinical development • Clinical programme support • Manufacturing / process development • Preparation and management of the RA submission • Life cycle support
1030	Coffee
1045-1200	The importance of nonclinical safety studies and how the data are used in regulatory submissions
1200-1300	Drug substance, drug product and manufacturing data
1300	Lunch
1345-1430	Clinical data requirements for different types of products
1430-1600	Supporting clinical trials The links between the studies, the IMPD and the CTD
1600-1630	Summary session
1630-1800	Case Study 1: Early development support – nonclinical and clinical
1800	Reception and Team Quiz

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Day TWO

Time	Topic
0900-0915	Overview of Day 1 and aims for Day 2
0915-1000	Malta Medicines Authority's view of EU Procedures and factors for success
1000-1030	EU submissions procedures
1030	Coffee
1045-1100	EU submissions procedures team task
1100-1130	The centralised procedure: common challenges
1130-1200	DCP and MRP: common challenges
1200-1230	Generic products and biosimilars
1230-1300	Feedback session
1300	Lunch
1345-1430	Lifecycle management (I): Regulatory Compliance • The MA Holders obligations and some nightmare examples of how not to do this • When is a variation not a variation?
1430-1515	Workshop – Variations
1515-1615	Safe use of medicines by the patient: • The importance of the SPC / PIL / Label • How this links with claims
1615-1715	Workshop: Regulatory Strategies
1715-1745	Questions / Training review
1745-1800	Closing