CRED Navigating European Regulatory Procedures

Day One

Time	Session
09.30	**Registration and coffee**
10.00	**Welcome from TOPRA**
10.05	**Chairman's Introduction**
10.10	**Case study introduction** • Delegates will be divided into groups for afternoon case study and provided with material.
10.15	**Overview of the European Regulations** • A brief outline of the Centralised and Mutual Recognition/Decentralised procedures • The role of the regulatory bodies, i.e. EMA, CHMP, COMP, PDCO, SAGs, EU Commission, CMDh, National Authorities, ATMP, PRAC, EMA re-structure • Orphan Drug Regulations • Paediatric Regulations • PRIME and similar initiatives • Considerations for SMEs • The role of patients
11.05	**Developing your Global Filing Strategy** • Influencing factors, e.g. product type, strength of data, internal & external initiatives (include in learning objectives) • Scientific advice – where and how to obtain it • Utilising internal and external expertise • Integrating filing strategy with commercial objectives • Choosing a procedure – key factors (default procedure unless otherwise indicated/company preference?) • Orphan Drug Considerations • Paediatric Study Requirements • Accelerated approval programs • Briefly mention pharmacoeconomics and HTA requirements • Other initiatives (e.g. PRIME)
11.55	**Tea/ Coffee break**
12.20	**Developing Strategy for Filing Non-NCEs** • Bibliographic/ established use • Abridged • Line extensions/generics/hybrids • Biosimilars • Borderline and combination products • Herbals

Time	Session
13.20	**Decentralised and Mutual Recognition Procedures** • Background to mutual recognition concept • Key features and differences of MRP/DCP • Role of the Reference Member State and booking your RMS slot • DCP procedure timetable • Organising your company • Interacting with the Authorities during the procedure • Common problems and pitfalls in DCP • Repeat-use MRP • The role of CMDh • Appealing a negative decision - referral and arbitration • Common problems and pitfalls in MRP
14.20	**Lunch**
15.20	**Finalising your European Regulatory Strategy** • Scheduling the submission • Access to procedures • Commercial considerations • Tradename issues • Pre-submission meetings • Timelines • Conditional approvals/exceptional circumstance
16.20	**Case Study** (*Coffee/tea to be taken in case study groups)*
17.05	**Case Study Feedback** Presentation of results and discussion
17.35	**Review of the day**
18.05	**Close of Day One**

Day Two

Time	Presenter
08.30	**Introduction** • Review of day 1 • Objectives for day 2
08.40	**Key EU Regional Considerations** • Electronic dossier format (eCTD) • Labelling and leaflets including readability testing • Translations • Pharmacovigilance Site Master File and Risk Management Plan • Environmental Risk Assessment • Paediatric Investigational Plans • Manufacturing aspects – site inspections, QC testing and QP release
09.40	**Centralised Procedure - The Details** • Preparing for a CP (including eCTD compilation) • Managing the procedure • Interacting with the EMEA/(co-)rapporteur/PRAC • The role of the CHMP • The Commission decision making process • Re-examination of an Opinion • Organising your company • Common problems and pitfalls
10.10	**Tea/ coffee break**

10.30	**New MAAs in the Centralised Procedure – Theory versus Reality**
	• Understanding the potential for deviating from the rule book
	  • Impact of PRAC
	  • Impact of CAT
	  • Impact of ODD
	  • What are the potential outcomes at D181?
	• Thinking strategically
	• Learning to manage internal expectations

11.10	**Working Effectively with Regulators – Regulators Perspective** • Pre-submission meetings • Knowing your regulators • Key milestones in a procedure • Preparing a response strategy • Scientific Advice
12.10	**Lunch**

Time	Presenter
13.10	**Case Study** *(Tea/coffee during group session from 14:30)*
14.55	**Case Study Feedback** Presentation of results and discussion
15.25	**Agency perspective on strategic and practical considerations** • Developing and optimising your strategic plan – how to maximise the chances of an early approval • Scientific advice and its impact on a successful application • Validation, responses to questions and end of procedure – best practice advice • Typical dossier deficiencies and how to avoid them (no. of dossiers that go through first time and if not, why not) • Common pitfalls (both practical and strategic) • Real-life procedure timings – where time can be lost in a procedure • Talking to regulatory agencies • Optimising appeals and hearings
16.25	**Review of the day**
17.25	**Close of Meeting**

Delegates will be encouraged to ask questions throughout the day so as to ensure the meeting is as interactive as possible. There will be an interactive session with each speaker, at the end of each talk to consolidate the key points of each talk, and to allow the delegate to interact with all of the speakers.