CRED Navigating European Regulatory Procedures
22-23 March 2018, Utrecht

Course Chairman: Bob Clay, Highbury Regulatory Science

Day One

Time	Session	Presenter
09.30	**Registration and coffee**	
10.00	**Welcome from TOPRA**	**TOPRA**
10.05	**Chairman's Introduction**	**Bob Clay**
10.10	**Case study introduction** • Delegates will be divided into groups for afternoon case study and provided with material.	**Matthew Sardo** Sardo Trading Limited
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	**Priscilla Schoondermark** - MEB
10.55	**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)	**Bob Clay** Highbury Regulatory Science Limited
11.55	**Tea/ Coffee break**	
12.20	**Developing Strategy for Filing Non-NCEs** • Bibliographic/ established use • Abridged	**Peter Embley** VCLS

Time	Session	Presenter
	• Line extensions/generics/hybrids • Biosimilars • Borderline and combination products • Herbals	
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	**Steve Smith** Mundipharma Research Ltd
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	**Jackie Mitchell** Shield Therapeutics
16.20	**Case Study** (*Coffee/tea to be taken in case study groups)*	
17.05	**Case Study Feedback** Presentation of results and discussion	**Matthew Sardo** Sardo Trading Limited
17.35	**Review of the day**	
18.05	**Close of Day One**	

Day Two

Time	Presenter	Speaker
08.30	**Introduction** • Review of day 1 • Objectives for day 2	**Bob Clay** Highbury Regulatory Science Limited
08.40	**Key EU Regional Considerations** • Electronic dossier format (eCTD/NeeS) • 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	**Philip Senior** Pfizer
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	**Dave Gilbert** Dave Gilbert Consulting
10.10	**Tea/ coffee break**	

10.30	**New MMAs 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
		Dave Gilbert
		Dave Gilbert Consulting

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	**Kora Doorduyn-van der Stoep** MEB

Time	Presenter	Speaker
12.10	**Lunch**	
13.10	**Case Study** *(Tea/coffee during group session from 14:30)*	
14.55	**Case Study Feedback** Presentation of results and discussion	**Matthew Sardo** Sardo Trading Limited
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	**Kora Doorduyn-van der Stoep** **&** **Priscilla Schoondermark** MEB
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.