



CRED Navigating European Regulatory Procedures 15-16 March 2022

Day One – 15 March 2022

Time	Session	Presenter
09.30	Registration and coffee	
09.45	Chairman's Introduction	Robert Clay Highbury Regulatory Science Limited
09.50	Case study introduction <ul style="list-style-type: none"> Delegates will be divided into groups for afternoon case study and provided with material. 	Matthew Sardo Sardo Trading Limited
09.55	Overview of the European Regulations <ul style="list-style-type: none"> 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 	Kora Doorduyn-van der Stoep Medicines Evaluation Board (MEB)
11.05	Developing your Global Filing Strategy <ul style="list-style-type: none"> 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) 	Robert Clay Highbury Regulatory Science Limited
11.55	Tea/ Coffee break	
12.20	Developing Strategy for Filing Non-NCEs <ul style="list-style-type: none"> Bibliographic/ established use Abridged <ul style="list-style-type: none"> Line extensions/generics/hybrids 	

Time	Session	Presenter
	<ul style="list-style-type: none"> Biosimilars Borderline and combination products Herbals 	
13.20	Decentralised and Mutual Recognition Procedures	Stephen Smith
	<ul style="list-style-type: none"> 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 	GSK
14.20	Lunch	
15.20	Finalising your European Regulatory Strategy	Peter Embley
	<ul style="list-style-type: none"> Scheduling the submission Access to procedures Commercial considerations Tradename issues Pre-submission meetings Timelines Conditional approvals/exceptional circumstance 	Bionical Emass
16.20	Case Study (<i>Coffee/tea to be taken in case study groups</i>)	Matthew Sardo
17.05	Case Study Feedback	
	Presentation of results and discussion	
17.35	Review of the day	Robert Clay
		Highbury Regulatory Science Limited
18.05	Close of Day One	

Day Two – 16 March 2022

Time	Session	Presenter
08.30	Introduction <ul style="list-style-type: none"> Review of day 1 Objectives for day 2 	Robert Clay Highbury Regulatory Science Limited
08.40	Key EU Regional Considerations <ul style="list-style-type: none"> 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 	Philip Senior Pfizer Limited
09.40	Centralised Procedure - The Details <ul style="list-style-type: none"> 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 	Claire Levee Regulatory Consultant
10.10	Tea/ coffee break	
10.30	Agency perspective on strategic and practical considerations – how to work effectively <ul style="list-style-type: none"> 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 Scientific Advice 	Kora Doorduyn-van der Stoep Medicines Evaluation Board (MEB)



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11.30	New MAAs in the Centralised Procedure – Theory versus Reality <ul style="list-style-type: none"> • Understanding the potential for deviating from the rule book <ul style="list-style-type: none"> • Impact of PRAC • Impact of CAT • Impact of ODD • What are the potential outcomes at D181? • Thinking strategically <p>Learning to manage internal expectations</p>	Paul Nitschmann Intercept Pharmaceuticals
12.30	Lunch	
13.30	Case Study (<i>Tea/coffee during group session from 14:30</i>)	Matthew Sardo Sardo Trading Limited
15.15	Case Study Feedback Presentation of results and discussion	
15.45	Review of the day	Robert Clay Highbury Regulatory Science Limited
16.15	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.