CRED Getting the CMC Dossier Right
Day 1 Programme: Drug Substance
11-12 September 2019
Programme subject to change

Time	Activity	
09:00	**Registration**	
09:15	**Welcome** • Overview of the day	**Vimal Patel** NVP Healthcare Consulting
09:30	**Introduction to Preparing the Perfect Common Technical Document (CTD) Module 3 Part 'S'** • Origin of the Common Technical Document • Overview of CTD structure - where drug substance data fits (Module 3.2.S) • Different routes to incorporate drug substance data into 3.2.S: originator data, DMF or CEP • Overview of variations in the EU • Due Diligence Tips	**Chris Carr** ERA Consulting UK LTD
10:15	**Tea, coffee break**	
10:30	**Control of Drug Substances** • Regulations and Guidelines • Critical Quality Attributes and Specifications • Analytical Methodology and Validation • Reference standards	**Paul Butterworth** AstraZeneca, UK
11:15	**Data Requirements and Practical Guidance for Drug Substance Development** • Challenges of drug development and the role of the regulatory team member • Drug development – the objective and supporting guidelines o Control strategy and Quality by design • Regulatory starting materials • Specifications • Stability • Drug Substance Lifecycle challenges.	**Kate Arnot** AstraZeneca, UK
12:00	**What's so different about Biotech CMC** • Protein characterisation • Comparability – ICH Q5E • Analytical methods	**Paul Jeffreys** Biotch SPIN vice Chairman (Formerly Amgen & Morphotek)
12:30	**Lunch**	
13:30	**Feedback from Regulatory reviews** • Key issues for sponsors to address in Biotech CMC dossiers	**Paul Jeffreys** Biotch SPIN vice Chairman (Formerly Amgen & Morphotek)

Time	Activity	
14:00	**Case study** *Tea/coffee* to *be taken in case study groups* **Feedback on Case Study Session**	
15:30	**Regulatory Agency's Perspective on the Drug Substance Section of Marketing Authorisation Applications (MAAs)** • Potential pitfalls and practical issues experienced with the active drug substance section of an MAA • An agency perspective on common findings arising during regulatory review • Current experience and advice on preparation of the drug substance section of the CTD • Quality Overall Summary –what reviewers want to see • Falsified Medicines Legislation • Inspection issues for drug substance manufacturers	**Karin Boon** MHRA
16:30	**Q&A**	
17:00	**Chairman's Review of the Day**	
17:30	**Close**	

Delegates will be encouraged to ask questions throughout the day so as to ensure the meeting is as interactive as possible.

CRED Getting the CMC Dossier Right
Day 2 Programme: Drug Product

Time	Activity	
09:30	**Chairperson's Welcome** • Overview of the day	

09:45	**Data Requirements and Practical Guidance for Medicinal Product Development**
	• Issues faced at different phases of development
	  o The need to agree the specific product type required
	  o Medicinal product production, scale up from development to production batches
	  o Process validation requirements for different dosage forms
	  o Stability programmes and data requirements
	• When/how to deal with changes during development to ensure this does not invalidate any of the clinical/other data already generated.
	Specific data requirements for and issues associated with different dosage forms ICH Q8 and QBD
		Graham Powell
		Mylan

10:30	**Introduction to Preparing the Perfect Common Technical Document (CTD) Module 3 Part 'P'** • Legal framework • An outline of the different sections within Module 3.2.P and an overview as to content within each section. • Key Sources of reference information concerning the CTD and data requirements for the medicinal product • Due diligence tips • Variations	**Christian Monnerjahn** Salutas Pharma
11:15	**Tea, coffee break**	
11:30	**Control of Medicinal Product** • How specifications for finished product are set and maintained • Review and development of specifications • Analytical Procedures/Validation of analytical procedures and justification of specifications • Application of ICH General Concepts in setting and reviewing of specification • Roles of competent authorities and pharmacopoeias in controlling the quality of medicinal product • Introduction to universal and specific tests/criteria for different dosage forms	**Graham Powell** Mylan

Time	Activity	
12:15	**Lunch**	
13:15	**Regulatory Agency's Perspective on the Medicinal Product Section of Marketing Authorisation Applications (MAAs)** • Potential pitfalls and practical issues experienced with the medicinal product section of an MAA o An agency perspective on common findings arising during regulatory review for a range of product formulations o Current experience and advice on preparation and presentation of the medicinal product section of the CTD • Quality Overall Summary – what reviewers want to see	**Melanie Pires** MHRA
14:15	**Introduction and Preparation for the Case Study** **Case Study** *Tea/coffee* to *be taken in case study groups* **Feedback on Case Study Session**	
15:45	**Chairperson's Review of the Day**	
16:15	**Close**	

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