CRED Getting the CMC Dossier Right
Day 1 Programme: Drug Substance
Chair: Vimal Patel, Regulatory CMC Expert

Time	Activity	Presenters
08:45	**Registration online**	
09:00	**Welcome** • Overview of the day	**Vimal Patel** Regulatory CMC Expert
09:15	**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** Freyr Solutions
10:00	**Break**	
10:15	**Control of Drug Substances** • Regulations and Guidelines • Critical Quality Attributes and Specifications • Analytical Methodology and Validation • Reference standards	**Paul Butterworth** AstraZeneca, UK
11:00	**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 ○ Control strategy and Quality by design • Regulatory starting materials • Specifications • Stability • Drug Substance Lifecycle challenges.	**Sophie Nageotte** Regulatory CMC Expert
11:45	**What's so different about Biotech CMC** • Protein characterisation • Comparability – ICH Q5E • Analytical methods	**Paul Jeffreys** Biotech SPIN vice Chairman (Formerly Amgen & Morphotek)
12:15	**Lunch**	
13:15	**Feedback from Regulatory reviews** • Key issues for sponsors to address in Biotech CMC dossiers	**Paul Jeffreys** Biotech SPIN vice Chairman (Formerly Amgen & Morphotek)

Time	Activity	Presenters
13:45	**Case study introduction and set-up**	**Vimal Patel** Regulatory CMC Expert
14:00	**Case study**	
15:00	**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	
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
Chair: Sargon Daniel, Medpace

Time	Activity	Presenters
08:45	**Registration online**	
09:00	**Chairperson's Welcome** • Overview of the day	**Sargon Daniel** Medpace

09:15	**Data Requirements and Practical Guidance for Medicinal Product Development**
	• Issues faced at different phases of development
	  ○ The need to agree the specific product type required
	  ○ Medicinal product production, scale up from development to production batches
	  ○ Process validation requirements for different dosage forms
	  ○ 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

10:00	**Break**	
10:15	**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
11:00	**Break**	
11:15	**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	**Nathalie Vicente** Regulatory CMC Expert

Time	Activity	Presenters
	• Introduction to universal and specific tests/criteria for different dosage forms	
12:00	**Lunch**	

13:00	**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
	  ○ An agency perspective on common findings arising during regulatory review for a range of product formulations
	  ○ Current experience and advice on preparation and presentation of the medicinal product section of the CTD
	• Quality Overall Summary – what reviewers want to see	

14:00	**Introduction and Preparation for the Case Study**	
14:15	**Case Study**	
15:15	**Feedback on Case Study Session**	
16:00	**Chairperson's Review of the Day**	
16:30	**Close**	

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