CRED Getting the CMC Dossier Right, 5 October 2022
Day 1 Programme: Drug Substance
Chair: Vimal Patel, Regulatory CMC Expert

Time (BST)	Activity	Presenters
09:00	**Registration/Registration online**	
09:15	**Welcome from TOPRA**	
09:20	**Welcome** • Overview of the day	**Vimal Patel** Regulatory CMC Expert
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 • Due Diligence Tips	**Chris Carr** Bio Products Laboratory Ltd
10:15	**Break**	
10:45	**Control of Drug Substances** • Regulations and Guidelines • Critical Quality Attributes and Specifications • Analytical Methodology and Validation • Reference standards	**Peter Hamilton** AstraZeneca, UK
11:30	**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.	**Olivier Dirat** Pfizer
12:15	**Lunch**	
13:15	**Case study introduction and set-up**	**Vimal Patel** Regulatory CMC Expert
13:30	**Case study** *Tea/coffee to be taken in case study groups*	
14:30	**Feedback on Case Study Session**	
15:00	**Regulatory Agency's Perspective on the Drug Substance Section of Marketing Authorisation Applications (MAAs)** • Potential pitfalls and practical issues experienced with	**Karin Boon** Medicines and Healthcare products Regulatory Agency

Time (BST)	Activity	Presenters
	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	(MHRA)
16:00	**Q&A**	
17:00	**Chairman's Review of the Day**	**Vimal Patel** Regulatory CMC Expert
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, 6 October 2022
Day 2 Programme: Drug Product
Chair: Sargon Daniel, Aimmune Therapeutics

Time (BST)	Activity	Presenters
09:00	**Registration/Registration online**	
09:30	**Chairperson's Welcome** • Overview of the day	**Sargon Daniel** Aimmune Therapeutics
09:45	**Introduction to Preparing the Perfect Common Technical Document (CTD) Module 3 Part 'P'** • Overview of Module 3.2.P CTD structure and key guidelines for content • Considerations for data presentation in the sections of 3.2.P • Due diligence tips • Approaching the Quality Overall Summary	**Christian Monnerjahn** Eckert & Ziegler Radiopharma GmbH
10:30	**Break**	

11:00	**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

11:45	**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	**Paul Marshall** Jazz Pharmaceuticals

Time (BST)	Activity	Presenters
	different dosage forms	
12:45	**Lunch**	

13:45	**Regulatory Agency's Perspective**
	• 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
		Alejandro Montón Silva
		Medicines Evaluation Board (MEB)

14:30	**Introduction and Preparation for the Case Study**	**Francesca Buttigieg** PTC Therapeutics, Inc
14:45	**Case Study** *Tea/coffee* to *be taken in case study groups*	
15:45	**Feedback on Case Study Session**	
16:15	**Chairperson's Review of the Day**	**Sargon Daniel** Aimmune Therapeutics
16:45	**Close**	

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