



## CRED Getting the CMC Dossier Right, 4 September 2024

### Day 1 Programme: Drug Substance

Chair: Vimal Patel, Regulatory CMC Expert

Time (BST)	Activity	Presenters
09:00	<b>Registration/Registration online</b>	
09:15	<b>Welcome from TOPRA</b>	<b>Vimal Patel</b> Regulatory CMC Expert
09:20	<b>Welcome</b> <ul style="list-style-type: none"><li>• Overview of the day</li></ul>	
09:30	<b>Introduction to Preparing the Perfect Common Technical Document (CTD) Module 3 Part 'S'</b> <ul style="list-style-type: none"><li>• Origin of the Common Technical Document</li><li>• Overview of CTD structure - where drug substance data fits (Module 3.2.S)</li><li>• Different routes to incorporate drug substance data into 3.2.S: originator data, DMF or CEP</li><li>• Due Diligence Tips</li></ul>	<b>Chris Carr</b> Bio Products Laboratory Ltd.
10:15	<b>Break</b>	
10:45	<b>Control of Drug Substances</b> <ul style="list-style-type: none"><li>• Regulations and Guidelines</li><li>• Critical Quality Attributes and Specifications</li><li>• Analytical Methodology and Validation</li><li>• Reference standards</li></ul>	<b>Bethany Jackson</b> AstraZeneca, UK
11:30	<b>Data Requirements and Practical Guidance for Drug Substance Development</b> <ul style="list-style-type: none"><li>• Challenges of drug development and the role of the regulatory team member</li><li>• Drug development - the objective and supporting guidelines; Control strategy and Quality by design</li><li>• Regulatory starting materials</li><li>• Specifications</li><li>• Stability</li><li>• Drug Substance Lifecycle challenges.</li></ul>	<b>Olivier Dirat</b> Pfizer
12:15	<b>Lunch</b>	
13:15	<b>Case study introduction and set-up</b>	<b>Vimal Patel</b> Regulatory CMC Expert



Time (BST)	Activity	Presenters
13:30	<b>Case study</b> <i>Tea/coffee to be taken in case study groups</i>	
14:30	<b>Feedback on Case Study Session</b>	
15:00	<b>Regulatory Agency's Perspective on the Drug Substance Section of Marketing Authorisation Applications (MAAs)</b> <ul style="list-style-type: none"> <li>• Potential pitfalls and practical issues experienced with the active drug substance section of an MAA</li> <li>• An agency perspective on common findings arising during regulatory review</li> <li>• Current experience and advice on preparation of the drug substance section of the CTD</li> <li>• Quality Overall Summary –what reviewers want to see</li> <li>• Falsified Medicines Legislation</li> <li>• Inspection issues for drug substance manufacturers</li> </ul>	<b>Bassel Odeh</b> Medicines and Healthcare products Regulatory Agency (MHRA)
16:00	<b>Q&amp;A</b>	
17:00	<b>Chairman's Review of the Day</b>	<b>Vimal Patel</b> Regulatory CMC Expert
17:30	<b>Close</b>	

***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, 5 September 2024

### Day 2 Programme: Drug Product

Chair: Sargon Daniel, Regulatory Affairs Director, VIR Biotechnology, Inc

Time (BST)	Activity	Presenters
<b>09:00</b>	<b>Registration/Registration online</b>	
<b>09:30</b>	<b>Chairperson's Welcome</b> <ul style="list-style-type: none"> <li>• Overview of the day</li> </ul>	<b>Sargon Daniel</b> VIR Biotechnology, Inc
<b>09:45</b>	<b>Introduction to Preparing the Perfect Common Technical Document (CTD) Module 3 Part 'P'</b> <ul style="list-style-type: none"> <li>• Overview of Module 3.2.P CTD structure and key guidelines for content</li> <li>• Considerations for data presentation in the sections of 3.2.P</li> <li>• Due diligence tips</li> <li>• Approaching the Quality Overall Summary</li> </ul>	<b>Christian Monnerjahn</b> Eckert & Ziegler Radiopharma GmbH
<b>10:30</b>	<b>Break</b>	
<b>11:00</b>	<b>Data Requirements and Practical Guidance for Medicinal Product Development</b> <ul style="list-style-type: none"> <li>• Issues faced at different phases of development               <ul style="list-style-type: none"> <li>○ The need to agree the specific product type required</li> <li>○ Medicinal product production, scale up from development to production batches</li> <li>○ Process validation requirements for different dosage forms</li> <li>○ Stability programmes and data requirements</li> </ul> </li> <li>• When/how to deal with changes during development to ensure this does not invalidate any of the clinical/other data already generated.</li> <li>• Specific data requirements for and issues associated with different dosage forms ICH Q8 and QBD</li> </ul>	<b>Sharon Page</b> Pfizer
<b>11:45</b>	<b>Control of Medicinal Product</b> <ul style="list-style-type: none"> <li>• How specifications for finished product are set and maintained</li> <li>• Review and development of specifications</li> <li>• Analytical Procedures/Validation of analytical procedures and justification of specifications</li> </ul>	<b>Paul Marshall</b> Jazz Pharmaceuticals

Time (BST)	Activity	Presenters
	<ul style="list-style-type: none"> <li>• Application of ICH General Concepts in setting and reviewing of specification</li> <li>• Roles of competent authorities and pharmacopoeias in controlling the quality of medicinal product</li> <li>• Introduction to universal and specific tests/criteria for different dosage forms</li> </ul>	
<b>12:45</b>	<b>Lunch</b>	
<b>13:45</b>	<b>Regulatory Agency's Perspective</b>	<b>Alejandro Montón Silva</b>
	<ul style="list-style-type: none"> <li>• Potential pitfalls and practical issues experienced with the medicinal product section of an MAA <ul style="list-style-type: none"> <li>◦ An agency perspective on common findings arising during regulatory review for a range of product formulations</li> <li>◦ Current experience and advice on preparation and presentation of the medicinal product section of the CTD</li> </ul> </li> <li>• Quality Overall Summary – what reviewers want to see</li> </ul>	Medicines Evaluation Board (MEB)
<b>14:30</b>	<b>Introduction and Preparation for the Case Study</b>	<b>Sargon Daniel</b>
		VIR Biotechnology, Inc
		<b>Christian Monnerjahn</b>
		Eckert & Ziegler Radiopharma GmbH
<b>14:45</b>	<b>Case Study</b>	
	<i>Tea/coffee to be taken in case study groups</i>	
<b>15:45</b>	<b>Feedback on Case Study Session</b>	
<b>16:15</b>	<b>Chairperson's Review of the Day</b>	<b>Sargon Daniel</b>
		VIR Biotechnology, Inc
<b>16:45</b>	<b>Close</b>	

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