

CRED Getting the CMC Dossier Right

2 September 2025

Day 1 Programme: Drug Substance

Chair: Christian Monnerjahn, Eckert & Ziegler Radiopharma GmbH

Time (BST)	Activity	Presenters
09:00	Registration/Registration online	
09:15	Welcome from TOPRA	
09:20	Welcome <ul style="list-style-type: none"> Overview of the day 	Christian Monnerjahn
09:30	Introduction to Preparing the Perfect Common Technical Document (CTD) Module 3 Part 'S' <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> Regulations and Guidelines Critical Quality Attributes and Specifications Analytical Methodology and Validation Reference standards 	Bethany Jackson AstraZeneca, UK
11:30	Data Requirements and Practical Guidance for Drug Substance Development <ul style="list-style-type: none"> 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. 	Giovanni Giuliano Arcinova
12:15	Lunch	

Time (BST)	Activity	Presenters
13:15	Case study introduction and set-up	Christian Monnerjahn
13:30	Case study <i>Tea/coffee to be taken in case study groups</i>	
14:30	Feedback on Case Study Session	
15:00	Regulatory Agency's Perspective on the Drug Substance Section of Marketing Authorisation Applications (MAAs) <ul style="list-style-type: none"> • 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 Medicines and Healthcare products Regulatory Agency (MHRA)
16:00	Q&A	
17:00	Chairman's Review of the Day	Christian Monnerjahn
17:30	Close	

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

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3 September 2025

Day 2 Programme: Drug Product

Chair: Sargon Daniel, VIR Biotechnology, Inc

Time (BST)	Activity	Presenters
09:00	Registration/Registration online	
09:30	Chairperson's Welcome <ul style="list-style-type: none"> Overview of the day 	Sargon Daniel VIR Biotechnology, Inc
09:45	Introduction to Preparing the Perfect Common Technical Document (CTD) Module 3 Part 'P' <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> Issues faced at different phases of development <ul style="list-style-type: none"> 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 	Lisa Allan CMC Regulatory Solutions
11:45	Control of Medicinal Product <ul style="list-style-type: none"> 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 	Paul Marshall Jazz Pharmaceuticals

Time (BST)	Activity	Presenters
	<ul style="list-style-type: none"> • Roles of competent authorities and pharmacopoeias in controlling the quality of medicinal product • Introduction to universal and specific tests/criteria for different dosage forms 	
12:45	Lunch	
13:45	Regulatory Agency's Perspective <ul style="list-style-type: none"> • Potential pitfalls and practical issues experienced with the medicinal product section of an MAA <ul style="list-style-type: none"> ○ 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 	Deeksha Ganga Medicines Evaluation Board (MEB)
14:30	Introduction and Preparation for the Case Study	Sargon Daniel VIR Biotechnology, Inc Christian Monnerjahn Eckert & Ziegler Radiopharma GmbH
14:45	Case Study <i>Tea/coffee to be taken in case study groups</i>	Micheal Paul Sargon Daniel
15:45	Feedback on Case Study Session	
16:15	Chairperson's Review of the Day	Sargon Daniel VIR Biotechnology, Inc
16:45	Close	

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