



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

Time	Activity	Presenters
09:00	Registration/Registration online	
09:15	Welcome <ul style="list-style-type: none"> • Overview of the day 	Vimal Patel (<i>in person</i>) Regulatory CMC Expert
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 • Overview of variations in the EU • Due Diligence Tips 	Chris Carr (<i>remotely</i>) BPL
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 	Peter Hamilton (<i>remotely</i>) 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 <ul style="list-style-type: none"> ◦ Control strategy and Quality by design • Regulatory starting materials • Specifications • Stability • Drug Substance Lifecycle challenges. 	Sophie Nageotte (<i>remotely</i>) Regulatory CMC Expert
12:15	Lunch	
13:15	Case study introduction and set-up	Vimal Patel (<i>in person</i>) Regulatory CMC Expert
13:30	Case study <i>Tea/coffee to be taken in case study groups</i>	<i>Hybrid delivery</i>
14:30	Feedback on Case Study Session	



Time	Activity	Presenters
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 (<i>in person</i>) 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
Day 2 Programme: Drug Product
Chair: Sargon Daniel, Aimmune Therapeutics

Time	Activity	Presenters
09:00	Registration/Registration online	
09:30	Chairperson's Welcome <ul style="list-style-type: none"> • Overview of the day 	Sargon Daniel (<i>remotely</i>) Aimmune Therapeutics
09:45	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. <p>Specific data requirements for and issues associated with different dosage forms ICH Q8 and QBD</p>	Graham Powell (<i>in person</i>) Mylan
10:30	Break	
11:00	Introduction to Preparing the Perfect Common Technical Document (CTD) Module 3 Part 'P' <ul style="list-style-type: none"> • 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 (<i>remotely</i>) Salutas Pharma
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 • Roles of competent authorities and pharmacopoeias in controlling the quality of medicinal product 	Christian Monnerjahn (<i>remotely</i>) Salutas Pharma



Time	Activity	Presenters
	<ul style="list-style-type: none">• 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">• An interactive session	<i>Hybrid delivery</i>
14:30	Introduction and Preparation for the Case Study	Sargon Daniel (<i>remotely</i>) Aimmune Therapeutics
14:45	Case Study <i>Tea/coffee to be taken in case study groups</i>	<i>Hybrid delivery</i>
15:45	Feedback on Case Study Session	
16:15	Chairperson's Review of the Day	Sargon Daniel (<i>remotely</i>) Aimmune Therapeutics
16:45	Close	

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