**CRED Getting the CMC Dossier Right, 12 September 2023**
**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**<br>• Overview of the day | **Vimal Patel**<br>Regulatory CMC Expert |
| **09:30** | **Introduction to Preparing the Perfect Common Technical Document (CTD) Module 3 Part 'S'**<br>• Origin of the Common Technical Document<br>• Overview of CTD structure - where drug substance data fits (Module 3.2.S)<br>• Different routes to incorporate drug substance data into 3.2.S: originator data, DMF or CEP<br>• Due Diligence Tips | **Chris Carr**<br>Bio Products Laboratory Ltd |
| **10:15** | **Break** | |
| **10:45** | **Control of Drug Substances**<br>• Regulations and Guidelines<br>• Critical Quality Attributes and Specifications<br>• Analytical Methodology and Validation<br>• Reference standards | **Bethany Jackson**<br>AstraZeneca, UK |
| **11:30** | **Data Requirements and Practical Guidance for Drug Substance Development**<br>• Challenges of drug development and the role of the regulatory team member<br>• Drug development – the objective and supporting guidelines<br>  ○ Control strategy and Quality by design<br>• Regulatory starting materials<br>• Specifications<br>• Stability<br>• Drug Substance Lifecycle challenges. | **Olivier Dirat**<br>Pfizer |
| **12:15** | **Lunch** | |
| **13:15** | **Case study introduction and set-up** | **Vimal Patel**<br>Regulatory CMC Expert |
| **13:30** | **Case study**<br>*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)**<br>• Potential pitfalls and practical issues experienced with | **Bassel Odeh**<br>Medicines and Healthcare products Regulatory Agency |

| Time (BST) | Activity | Presenters |
|---|---|---|
| | the active drug substance section of an MAA<br>• An agency perspective on common findings arising during regulatory review<br>• Current experience and advice on preparation of the drug substance section of the CTD<br>• Quality Overall Summary –what reviewers want to see<br>• Falsified Medicines Legislation<br>• Inspection issues for drug substance manufacturers | (MHRA) |
| **16:00** | **Q&A** | |
| **17:00** | **Chairman's Review of the Day** | **Vimal Patel**<br>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, 13 September 2023**
**Day 2 Programme: Drug Product**
Chair: Sargon Daniel, Aimmune Therapeutics

| Time (BST) | Activity | Presenters |
|---|---|---|
| **09:00** | **Registration/Registration online** | |
| **09:30** | **Chairperson's Welcome**<br>• Overview of the day | **Sargon Daniel**<br>Aimmune Therapeutics |
| **09:45** | **Introduction to Preparing the Perfect Common Technical Document (CTD) Module 3 Part 'P'**<br>• Overview of Module 3.2.P CTD structure and key guidelines for content<br>• Considerations for data presentation in the sections of 3.2.P<br>• Due diligence tips<br>• Approaching the Quality Overall Summary | **Christian Monnerjahn**<br>Eckert & Ziegler Radiopharma GmbH |
| **10:30** | **Break** | |
| **11:00** | **Data Requirements and Practical Guidance for Medicinal Product Development**<br>• Issues faced at different phases of development<br>  ○ The need to agree the specific product type required<br>  ○ Medicinal product production, scale up from development to production batches<br>  ○ Process validation requirements for different dosage forms<br>  ○ Stability programmes and data requirements<br>• When/how to deal with changes during development to ensure this does not invalidate any of the clinical/other data already generated.<br>• Specific data requirements for and issues associated with different dosage forms ICH Q8 and QBD | **Nynke Brouwer**<br>Medicines Evaluation Board (MEB) |
| **11:45** | **Control of Medicinal Product**<br>• How specifications for finished product are set and maintained<br>• Review and development of specifications<br>• Analytical Procedures/Validation of analytical procedures and justification of specifications<br>• Application of ICH General Concepts in setting and reviewing of specification<br>• Roles of competent authorities and pharmacopoeias in controlling the quality of medicinal product<br>• Introduction to universal and specific tests/criteria for | **Paul Marshall**<br>Jazz Pharmaceuticals |

| Time (BST) | Activity | Presenters |
|---|---|---|
| | different dosage forms | |
| **12:45** | **Lunch** | |
| **13:45** | **Regulatory Agency's Perspective**<br>• Potential pitfalls and practical issues experienced with the medicinal product section of an MAA<br>  ○ An agency perspective on common findings arising during regulatory review for a range of product formulations<br>  ○ Current experience and advice on preparation and presentation of the medicinal product section of the CTD<br>• Quality Overall Summary – what reviewers want to see | **Alejandro Montón Silva**<br>Medicines Evaluation Board (MEB) |
| **14:30** | **Introduction and Preparation for the Case Study** | **Vim Patel**<br>PTC Therapeutics, Inc |
| **14:45** | **Case Study**<br>*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**<br>Aimmune Therapeutics |
| **16:45** | **Close** | |

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