# Day 1 Programme: Drug Substance

**Time (BST)** | **Activity** | **Presenters**
--- | --- | ---
09:00 | Registration/Registration online |
09:15 | Welcome from TOPRA |
09:20 | Welcome | Vimal Patel, Regulatory CMC Expert
- Overview of the day
09:30 | Introduction to Preparing the Perfect Common Technical Document (CTD) Module 3 Part ’S’ | Chris Carr, Bio Products Laboratory Ltd
- 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

10:15 | Break |
10:45 | Control of Drug Substances | Bethany Jackson, AstraZeneca, UK
- Regulations and Guidelines
- Critical Quality Attributes and Specifications
- Analytical Methodology and Validation
- Reference standards

11:30 | Data Requirements and Practical Guidance for Drug Substance Development | Olivier Dirat, Pfizer
- 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.

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) | Bassel Odeh, Medicines and Healthcare products Regulatory Agency
- Potential pitfalls and practical issues experienced with
<table>
<thead>
<tr>
<th>Time (BST)</th>
<th>Activity</th>
<th>Presenters</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>the active drug substance section of an MAA</td>
<td>(MHRA)</td>
</tr>
<tr>
<td></td>
<td>• An agency perspective on common findings arising during regulatory review</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Current experience and advice on preparation of the drug substance section of the CTD</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Quality Overall Summary – what reviewers want to see</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Falsified Medicines Legislation</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Inspection issues for drug substance manufacturers</td>
<td></td>
</tr>
</tbody>
</table>

| 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.*
# Drug Product

## 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 | Nynke Brouwer  
Medicines Evaluation Board (MEB)
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
<table>
<thead>
<tr>
<th>Time (BST)</th>
<th>Activity</th>
<th>Presenters</th>
</tr>
</thead>
<tbody>
<tr>
<td>12:45</td>
<td>Lunch</td>
<td></td>
</tr>
<tr>
<td>13:45</td>
<td><strong>Regulatory Agency’s Perspective</strong></td>
<td>Alejandro Montón Silva Medies Evaluation Board (MEB)</td>
</tr>
<tr>
<td>13:45</td>
<td>• Potential pitfalls and practical issues experienced with the medicinal product section of an MAA</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o An agency perspective on common findings arising during regulatory review for a range of product formulations</td>
<td></td>
</tr>
<tr>
<td></td>
<td>o Current experience and advice on preparation and presentation of the medicinal product section of the CTD</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Quality Overall Summary – what reviewers want to see</td>
<td></td>
</tr>
<tr>
<td>14:30</td>
<td><strong>Introduction and Preparation for the Case Study</strong></td>
<td>Vim Patel Medies Evaluation Board (MEB)</td>
</tr>
<tr>
<td>14:45</td>
<td><strong>Case Study</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Tea/coffee to be taken in case study groups</em></td>
<td></td>
</tr>
<tr>
<td>15:45</td>
<td><strong>Feedback on Case Study Session</strong></td>
<td></td>
</tr>
<tr>
<td>16:15</td>
<td><strong>Chairperson’s Review of the Day</strong></td>
<td>Sargon Daniel Aimmune Therapeutics</td>
</tr>
<tr>
<td>16:45</td>
<td><strong>Close</strong></td>
<td></td>
</tr>
</tbody>
</table>

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