



## CRED An Overview of Regulatory Product Information

02 September 2026

**Course Chair:** Petrina Pearce, Advanz Pharma

| Time  | Session   | Presenter   |
|-------|---|---|
| 08:45 | <b>Registration and Coffee</b>  |   |
| 09:00 | <b>Welcome from TOPRA</b>   |   |
| 09:05 | <b>Welcome from Chairman</b> <ul style="list-style-type: none"> <li>• Overview of the day</li> </ul>  | <b>Petrina Pearce</b><br>Advanz Pharma  |
| 09:10 | <b>The Company Core Data Sheet</b> <ul style="list-style-type: none"> <li>• Origins of the CCDS and its purpose</li> <li>• Preparation and implementation of the CCDS</li> <li>• Implications of regional differences for the CCDS and global labelling management</li> </ul>   | <b>Gabriela Fok</b><br>Ipsen  |
| 09:50 | <b>SmPC: Regulator's perspective</b> <ul style="list-style-type: none"> <li>• The role of the SmPC</li> <li>• Overview of SmPC legislation/guidelines and template</li> <li>• Current SmPC issues and developments</li> </ul>   | <b>TBC</b>  |
| 10:50 | <b>Break</b>  |   |
| 11:05 | <b>Strategy for the Development of the Optimal SmPC</b> <ul style="list-style-type: none"> <li>• Definition of an optimal SmPC</li> <li>• Contributing factors to an optimal SmPC</li> <li>• Key Stakeholders in an optimal SmPC</li> <li>• Common Pitfalls in the development of an optimal SmPC</li> <li>• Influence of the optimal SmPC on the development programme</li> <li>• Competitor analysis</li> </ul> | <b>Natalie Clark</b><br>GSK   |
| 12:05 | <b>Case Study and feedback - SmPCs</b>  | <b>Emily Meegan</b><br><b>Crystal Nkafu</b><br><b>Junias Adu – Gyamfi</b><br><b>Gabriela Fok</b><br>Ipsen |
| 12:45 | <b>Panel Discussion</b>   |   |
| 13:00 | <b>Lunch</b>  |   |
| 13:45 | <b>Labels and Leaflets: Regulator's perspective</b> <ul style="list-style-type: none"> <li>• Current legislation including recent changes</li> <li>• Label and leaflet requirements, including guidelines</li> <li>• Packaging with patient safety in mind</li> <li>• Good quality patient information &amp; user testing</li> <li>• Future focus for patient information</li> </ul>                              | <b>TBC</b>  |



| <b>Time</b>  | <b>Session</b>   | <b>Presenter</b>  |
|--------------|--|---|
| <b>14:45</b> | <b>Preparation of the Label and Leaflet: Industry perspective</b><br>Practical issues encountered when preparing proposed label and leaflet text for an MAA, including: <ul style="list-style-type: none"> <li>• Specific requirements for Mutual Recognition,</li> <li>• Decentralised and Centralised procedures</li> <li>• Readability</li> <li>• Translations</li> <li>• Timings</li> </ul>      | <b>Ronnie Mundair</b><br>Pfizer   |
| <b>15:15</b> | <b>Break</b>   |   |
| <b>15:30</b> | <b>Implementation of Labels and Leaflets: Industry perspective</b><br>Practical issues encountered when implementing MA approved text into the marketplace, including: <ul style="list-style-type: none"> <li>• Cross functional collaboration with stake holders</li> <li>• Safety issues</li> <li>• Commercial aspects</li> <li>• Production and logistical issues</li> <li>• Timelines</li> </ul> | <b>Betti Mozes-Stoddart</b><br>Jazz<br>Pharmaceuticals  |
| <b>16:15</b> | <b>Case Study – Labels and Leaflets</b>  | <b>Emily Meegan</b><br><b>Crystal Nkafu</b><br><b>Junias Adu – Gyamfi</b><br><b>Gabriela Fok</b><br>Ipsen |
| <b>16:55</b> | <b>Chairman’s Review of the Day &amp; Final Discussion Session</b>   | <b>Petrina Pearce</b><br>Advanz Pharma  |
| <b>17:10</b> | <b>Close of Workshop</b>   |   |

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