**CRED Managing Variations and other Lifecycle Processes Effectively**

**27 – 28 May 2025**

## Pre-recorded sessions

Delegates should listen to these before the course starts. There will be an opportunity to ask questions during the course.

| Session details | Presenter |
|---|---|
| **Introduction to Variations**<br>• Overview of the key principles of Regulations (712/2012 amending 1234/2008) and variation guideline<br>• Variation Types, data requirements<br>• Experience sharing/Practical issues for submissions with focus on centralised procedure<br>Future considerations | **Richard Keane**<br>Biogen |

## Day 1

| Time | Activity | Speaker |
|---|---|---|
| **9:00** | **Registration** | |
| **9:15** | **Welcome from TOPRA** | |
| **9:20** | **Chairperson's Introduction**<br>• Overview of the programme<br>• Initial Q&A | **Sheetal Vaidya**<br>G&L Health |
| **9:40** | **Variation Procedures – Industry perspective**<br>• Cross Functional Planning (before, during and after approval)<br>• Regulatory Submission Strategy & Timelines<br>• Mitigating Risk to Supply<br>• Grouping, Work-sharing<br>• Submission strategy, Inc. link to other lifecycle activities<br>• Communication with agencies<br>• Challenges (e.g., labelling implementation) | **Marta Viras**<br>PPD |
| **11:20** | **Break** | |
| **11:35** | **Variation Procedures – Authority perspective**<br>• Batch Specific Variations<br>• Feedback from usage of the system from a Regulatory Authority perspective.<br>• MRP/DCP considerations<br>• Feedback on Type IA Rejections | **Matthew Camilleri**<br>Malta Medicines Authority |
| **13:00** | **Lunch** | |

*All times are in CEST.*

| Time | Activity | Speaker |
|---|---|---|
| **14:00** | **Variations – CMC aspects**<br>• Introduction to most common CMC variations<br>• Changes to Container closure, manufacturing site transfers, batch size, excipients, and manufacturing process<br>• CMC RA functions in companies and their role<br>• Challenges: CMC variations and knock-on effect on product information for example shelf life; storage conditions, batch release site, excipients | **Yevheniia Prysiazhna**<br>G&L Health Advisor |
| **15:00** | **Panel discussion** | |
| **15:30** | **Case study – introduction** | |
| **16:30** | **Chairperson's conclusion Day 1** | |
| **17:00** | **Close** | |

*All times are in CEST.*

## CRED Managing Variations and other Lifecycle Processes Effectively

**Day 2**

| Time | Activity | Speaker |
|---|---|---|
| **9:00** | **Registration** | |
| **9:15** | **Chairperson's Introduction to Day 2** | **Thibault Patrier**<br>PPD |
| **9:30** | **Introduction to Managing Lifecycle, Renewals & Post-Approval Commitments**<br>• Renewal: Legal basis, principles of submission and evaluation<br>• Add Intro to PSURs<br>• Post- Approval Commitments: Types, submission, and evaluations<br>• Regulatory activities related to change in marketing status (Sunset clause, market cessation, launch, relaunch, cancellation)<br>• Change of RMS, MAH transfers | **Thibault Patrier**<br>PPD |
| **11:15** | **Break** | |
| **11:30** | **Examples of Lifecycle Planning and Strategy**<br>• Examples/case studies & challenges/considerations for impact assessment, planning and strategy<br>• Management of national text and artwork<br>• Renewals, PSURs | **Rachel Harte**<br>CAI UK |
| **13:00** | **Lunch** | |
| **14:00** | **Case study** | |
| **14:45** | **Case study feedback and discussions** | |
| **16:00** | **Chairperson's conclusion Day 2** | |
| **16:30** | **Close** | |

*Delegates will be encouraged to ask questions throughout the day so as to ensure the meeting is as interactive as possible. There will be an interactive session with each speaker, at the end of each talk to consolidate the key points of each talk, and to allow the delegate to interact with all the speakers.*

*All times are in CEST.*