



CRED Managing Variations and other Lifecycle Processes Effectively

12 – 13 May 2026

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
<p>Introduction to Variations</p> <ul style="list-style-type: none"> • Overview of the key principles of Regulations (712/2012 amending 1234/2008) and variation guideline • Variation Types, data requirements • Experience sharing/Practical issues for submissions with focus on centralised procedure <p style="text-align: center;">Future considerations</p>	<p>Thibault Patrier <i>PPD</i></p>

Day 1

Time	Activity	Speaker
9:00	Registration	
9:15	Welcome from TOPRA	
9:20	<p>Chairperson’s Introduction</p> <ul style="list-style-type: none"> • Overview of the programme • Initial Q&A 	<p>Joana Meireles <i>Leyden Labs</i></p>
9:40	<p>Variation Procedures – Industry perspective</p> <ul style="list-style-type: none"> • Cross Functional Planning (before, during and after approval) • Regulatory Submission Strategy & Timelines • Mitigating Risk to Supply • Grouping, Work-sharing • Submission strategy, Inc. link to other lifecycle activities • Communication with agencies • Challenges (e.g., labelling implementation) 	<p>Marta Viras <i>PPD</i></p>
11:20	Break	
11:35	<p>Variation Procedures – Authority perspective</p> <ul style="list-style-type: none"> • Batch Specific Variations • Feedback from usage of the system from a Regulatory Authority perspective. • MRP/DCP considerations • Feedback on Type IA Rejections 	<p>Matthew Camilleri <i>Malta Medicines Authority</i></p>
13:00	Lunch	



Time	Activity	Speaker
14:00	Variations – CMC aspects <ul style="list-style-type: none">• Introduction to most common CMC variations• Changes to Container closure, manufacturing site transfers, batch size, excipients, and manufacturing process• CMC RA functions in companies and their role• Challenges: CMC variations and knock-on effect on product information for example shelf life; storage conditions, batch release site, excipients	Antonio Imparato <i>Merck</i>
15:00	Panel discussion	
15:30	Case study – introduction	
16:30	Chairperson’s conclusion Day 1 (shave 15 min off)	
17:00	Close	



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Day 2

Time	Activity	Speaker
9:00	Registration	
9:15	Chairperson's Introduction to Day 2	Thibault Patrier <i>PPD</i>
9:30	Introduction to Managing Lifecycle, Renewals & Post-Approval Commitments <ul style="list-style-type: none"> • Renewal: Legal basis, principles of submission and evaluation • Add Intro to PSURs • Post- Approval Commitments: Types, submission, and evaluations • Regulatory activities related to change in marketing status (Sunset clause, market cessation, launch, relaunch, cancellation) • Change of RMS, MAH transfers 	Thibault Patrier <i>PPD</i>
11:15	Break	
11:30	Examples of Lifecycle Planning and Strategy <ul style="list-style-type: none"> • Examples/case studies & challenges/considerations for impact assessment, planning and strategy • Management of national text and artwork • Renewals, PSURs 	Joana Meireles <i>Leyden Labs</i>
13:00	Lunch	
14:00	Case study	Thibault Patrier <i>PPD</i>
14:45	Case study feedback and discussions	
16:00	Chairperson's conclusion Day 2	Thibault Patrier <i>PPD</i>
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.