



CRED Managing Variations and other Lifecycle Processes Effectively

29 – 30 May 2024

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>Richard Keane Biogen</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>Thibault Patrier PPD</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 PPD</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 Malta Medicines Authority</p>
13:00	Lunch	
14:00	<p>Variations – CMC aspects</p> <ul style="list-style-type: none"> • Introduction to most common CMC variations 	<p>Giannis Tsoqkas</p>

All times are in CEST.



Time	Activity	Speaker
	<ul style="list-style-type: none">• 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	G&L Health Advisor
15:00	Panel discussion	
15:30	Case study – introduction	
16:30	Chairperson’s conclusion Day 1	
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 PPD
9:30	<p>Introduction to Managing Lifecycle, Renewals & Post-Approval Commitments</p> <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 PPD
11:15	Break	
11:30	<p>Examples of Lifecycle Planning and Strategy</p> <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 	Rachel Harte 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.