CRED Managing Variations and other Lifecycle Processes Effectively

Chair: Priti Darjee, *Advanz Pharma*

Day 1:

Time	Activity	Speaker
9.00	**Registration online**	
9.15	**Welcome from TOPRA**	
9.20	**Chairperson's Introduction** • Overview of the programme	**Priti Darjee** *Advanz Pharma*
9.45	**Introduction to Variations** • 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 • Future considerations	**Richard Keane,** *Biogen*
11.15	**Break**	
11.30	**Variation Procedures and their impact on strategy and implementation –** • Grouping, Work-sharing • Submission strategy, Inc. link to other lifecycle activities • Batch Specific Variations • Feedback from usage of the system from a Regulatory Authority perspective. • MRP/DCP considerations • Feedback on Type IA Rejections	**Nicole Kavanagh** *HPRA*
13.00	**Lunch**	
14.00	**Variation Procedures – Industry perspective** • Cross Functional Planning (before, during and after approval) • Regulatory Submission Strategy & Timelines • Mitigating Risk to Supply • Communication with agencies • Challenges (e.g. labelling implementation)	**Sanyam Gandhi** *Takeda*
15.30	**Panel discussion**	
16.00	**Case study - introduction**	
16.15	**Chairperson's conclusion Day 1**	
16.30	**Close**	

CRED Managing Lifecycle and Variations Effectively

Chair: Marie Claire Aquilina, *Gilead*

Day 2:

Time	Activity	Speaker
9.00	**Registration online**	
9.15	**Chairperson's Introduction to Day 2**	**Marie Claire Aquilina** *Gilead*
9.30	**Introduction to Managing Lifecycle, Renewals & Post-Approval Commitments** • Renewal: Legal basis, principles of submission and evaluation • Post- Approval Commitments: Types, submission and evaluations • Regulatory activities related to change in marketing status	**Thibault Patrier** *PPD*
10.45	**Break**	
11.00	**Variations – CMC aspects** 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	**Giannis Tsogkas** *G&L Scientific*
12.15	**Lunch**	
13.15	**Examples of Lifecycle Planning and Strategy** • Examples/case studies & challenges/considerations for impact assessment, planning and strategy • Management of national text and artwork • Post-approval commitments • Renewals, PSURs • Change of RMS, MAH transfers • Sunset clause, market cessation, launch, relaunch, cancellation	**Adan Hawley** *G&L Scientific*
14.30	**Break**	
14.45	**Case study**	
16.15	**Case study feedback and discussions**	
16.45	**Chairperson's conclusion Day 2**	
17.00	**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.