CRED Managing Lifecycle and Variations Effectively

Day 1

Time	Activity
10.00	**Registration**
10.30	**Welcome from TOPRA**
10.35	**Chairperson's Introduction**
10.40	**Introduction to Managing Lifecycle** • Post-approval commitments • Variations • Renewals and PSUR • PRAC/CMDh recommendations • Regulatory activities related to change in marketing status
12.00	**Lunch**
13.00	**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: ICH Q12, Brexit etc.
14.15	**Tea/coffee break**
14.30	**Variation Procedures and their impact on strategy and implementation** • Grouping, Work-sharing • Submission strategy, Inc. link to other lifecycle activities • Batch Specific Variations, CCC Scheme • Feedback from usage of the system from a Regulatory Authority perspective. • MRP/DCP considerations • Feedback on Type IA Rejections
16.00	**Panel session**
16.20	**Chair persons conclusion Day 1**
16.30	**Close**

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Day 2

Time	Activity
09.00	**Chairpersons Introduction to Day 2**
09.05	**Introduction to Renewals & Post-Approval Commitments** • Renewal: Legal basis, principles of submission and evaluation • Post- Approval Commitments: Types, submission and evaluations • Experience sharing/ Practical Issues during submission
10.15	**Tea/coffee break**
10.30	**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 • eCTD publishing
12.00	**Lunch**
13.00	**Introduction to Case Studies** (to be run in parallel)
13.10	**Life cycle Case study** *Groups will swap half way* — **Variations Case Study** *Groups will swap half way*
14.40	**Case study feedback and discussions**
15.10	**Panel session**
15.30	**Chair person's conclusion Day 2**
15.35	**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 of the speakers.