



CRED Managing Lifecycle and Variations Effectively

Programme subject to change

Chair: Shilpa Jain, Teva Pharmaceuticals

DAY 1: 12 June 2019

| Time | Activity | |
|-------|---|--|
| 10.00 | Registration | |
| 10.30 | Welcome from TOPRA | |
| 10.35 | Chairperson's Introduction | |
| | Introduction to Managing Lifecycle | |
| 10.40 | <ul style="list-style-type: none"> • Post-approval commitments • Variations • Renewals and PSUR • PRAC/CMDh recommendations • Regulatory activities related to change in marketing status | <p>Shilpa Jain Teva Pharmaceuticals</p> |
| 12.00 | Lunch | |
| | Introduction to Variations | |
| 13.00 | <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 • Future considerations: ICH Q12, Brexit etc. | <p>Isabel Zwart Biogen</p> |
| 14.15 | Tea/coffee break | |
| | Variation Procedures and their impact on strategy and implementation | |
| 14.30 | <ul style="list-style-type: none"> • 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 | <p>Krystyna Fielden MHRA</p> <p>Elena Razzano MHRA</p> |
| 16.00 | Panel session | |
| 16.20 | Chair persons conclusion Day 1 | |
| 16.30 | Close | |



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Chair: Priti Darjee, Concordia International Rx (UK) Limited

DAY 2: 13 June 2019

| Time | Activity | |
|-------|---|---|
| 09.00 | Chairpersons Introduction to Day 2 | |
| | Introduction to Renewals & Post-Approval Commitments | Rina Joshi |
| | <ul style="list-style-type: none"> • Renewal: Legal basis, principles of submission and evaluation | Teva |
| 09.05 | <ul style="list-style-type: none"> • Post- Approval Commitments: Types, submission and evaluations • Experience sharing/ Practical Issues during submission | Pharmaceuticals |
| 10.15 | Tea/coffee break | |
| | Examples of Lifecycle Planning and Strategy | Marina Drosopoulou |
| | <ul style="list-style-type: none"> • 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 | Perrigo Company plc |
| 10.30 | | |
| 12.00 | Lunch | |
| 13.00 | Introduction to Case Studies (to be run in parallel) | |
| | Life cycle Case study | Variations Case Study |
| | <i>Groups will swap half way</i> | <i>Groups will swap half way</i> |
| 13.10 | | Priti Darjee |
| | | Concordia International Rx (UK) Limited |
| 14.40 | Case study feedback and discussions | |
| 15.10 | Panel session | |
| 15.30 | Chair person's conclusion Day 2 | |
| 15.35 | Close | |