Essentials of Pharmaceutical Regulatory Affairs (Online)

Programme 2021

Day 1: 14 June 2021

Presenter: Carlos Langezaal - Senior Director, Regulatory Affairs, Bristol-Myers Squibb

Please note all times are in US EST (BST +5h/ CEST + 6h/ US PST -3)

Time	Topic
11:00	Welcome and Introduction to Course
11:10	Overview of European Union (EU) • Facts of the EU • Key players and systems in the EU • EU Law • European Agencies
12:10	Break
12:20	Regulation of Clinical Research in Europe • Current Process (Clinical Trial Directive) • New Process (Clinical Trial Regulation) • CTA application • CTA amendments • End-of-Trial Notifications and reports • Voluntary Harmonised Procedure (VHP)
13:30	Break
13:45	European Marketing Authorisation Procedures • European Regulatory Landscape • Overview Application Procedures • Centralised Procedure
15:00	Q & A Day 1 and wrap up
15:30	End of Day one

Day 2: 15 June 2021

Presenter: Carlos Langezaal - Senior Director, Regulatory Affairs, Bristol-Myers Squibb

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Time	Topic
11:00	Welcome and Recap Day 1
11:10	Mutual Recognition and Decentralised Procedure • Common features and Eligibility • Decentralised Procedure • Mutual Recognition Procedure
12:00	Legal Classification, Labels, Leaflets, SMPCs, Advertising
12:50	Break
13:00	Post-Authorisation Activities • Post-licensing commitments • Amendments to Mas • Renewals
13:30	EU-Specific Challenges • CTD • Pharmacovigilance Legislation • Product Information Requirements • Paediatric development • EU SME office
14:25	Break
14:30	Q &A and Exercise
15:00	Close