

Essentials of Pharmaceutical Regulatory Affairs



Wednesday 10 April 2024

| Time | Presentation | Speaker |
|-------|---|-------------------------------|
| 09:30 | Introduction to TOPRA | TOPRA |
| 09:40 | Introductions – presenters and delegates | All |
| 09:55 | Setting the Scene | Andy Thornley |
| 10:20 | Break (15 minutes) | |
| 10:35 | Overview of Drug Development | Lizzy Heads G&L |
| 11:05 | Regulatory Control of Clinical Trials | David Solomon |
| 11:25 | Break (30 minutes) | |
| 11:55 | The Marketing Authorisation Applications | Rohan Desai G&L |
| 12:15 | Product Information (Labelling) | David Solomon |
| 12:30 | SmPC Game | Andy and David |
| 13:00 | Lunch (40 minutes) | |
| 13:40 | European Marketing Authorisation Procedures | Giannis Tsogkas G&L |
| 14:30 | Marketing Authorisation Strategy | Giannis Tsogkas |
| 14:40 | Break (20 minutes) | |
| 15:00 | Post- Authorisation Activities | Lizzy Heads |
| 15:20 | Post-authorisation activity - Pharmacovigilance | David Solomon |
| 15:30 | Current and Planned Changes in the EU | Andy Thornley |
| 15:35 | Review of learning objectives (with quiz) | All |
| 16:50 | Delegate Feedback and Wrap-up | All |
| 17:00 | Close of Course | All |