

# Essentials of Pharmaceutical Regulatory Affairs

**15 October 2026**

| Time  | Presentation                                    | Speaker                    |
|-------|-------------------------------------------------|----------------------------|
| 09:00 | Introduction to TOPRA                           | TOPRA                      |
| 09:15 | Introductions – Presenters and Delegates        | Andrew (Andy) Thornley     |
| 09:40 | Setting the Scene                               | Victor Goncharuk with Andy |
| 10:30 | Overview of Drug Development                    | Victor Goncharuk           |
| 11:05 | Break (20 minutes)                              |                            |
| 11:25 | Regulatory Control of Clinical Trials           | David Solomon              |
| 11:50 | The Marketing Authorisation Application Dossier | Andy Thornley              |
| 12:15 | Product Information (Labelling)                 | Andy Thornley              |
| 12:30 | SmPC Game                                       | Andy and David             |
| 13:00 | Break (40 minutes)                              |                            |
| 13:40 | European Marketing Authorisation Procedures     | David Solomon              |
| 14:20 | Marketing Authorisation Strategy                | David and Andy             |
| 14:30 | Break (20 minutes)                              |                            |
| 14:50 | Post- Authorisation Activities                  |                            |
| 15:15 | Product Safety (Pharmacovigilance)              | David Solomon              |
| 15:30 | Current and Planned Changes in the EU           | Victor Goncharuk           |
| 15:40 | Review of Learning Objectives and Quiz          | All Presenters             |
| 16:00 | Delegate Feedback and Wrap-up                   | All Presenters/ TOPRA      |