The TOPRA 47th Spring Introductory Course:

Introduction to Pharmaceutical Regulatory Affairs

15-17 April 2025

Lincoln Plaza Hotel

2 Lincoln Plaza

London E14 9BN

Programme

Learning Outcome:

Extract from the Module Learning Outcomes Module 0 | TOPRA MSc Regulatory Affairs programme

Knowledge Requirements

- Demonstrate a conceptual understanding of the regulatory requirements:
    - EU directives and legislation;
    - Regulatory authorisation and **associated documentation** for marketing submissions to evaluate current developments critically
- Display a comprehensive understanding of the EU regulatory aspects of drug development
- Possess a systematic understanding of knowledge in and a critical awareness of the regulatory environment and procedures governing regulatory approval of **clinical trials** in the EU and regulatory marketing authorisation in the context of drug development.

Skills and attributes

Successful students will typically:

- Demonstrate the ability to **critically analyse the legal documentation and guideline considerations** of EU regulatory affairs
- Deal with complex issues both systematically and creatively, make sound judgments in the absence of complete data, and communicate their conclusions clearly to specialist and non-specialist audiences in relation to obtaining regulatory authorisation
- Critically appraise and evaluate communications from regulatory bodies and research publications.

This suggests the following lecture topics MUST cover EU only for

1. Legislative framework
2. The MAA procedures
3. The CTD modules
4. Clinical Trials process
5. Reg Strategy Development Reg Tools

Case Studies should allow practical application to develop skills and attributes including the interpretation of legislation and critical appraisal of data presented

Day 1 Tuesday 15th April

Time	Topic	Speaker
08:30	**Registration**	
08:45	**Opening Introduction and Setting the scene** Regulatory functions Structure of CTD Modules EU Legislation	**Module Lead**
09:15	**Lecture 1: Overview of MAA and Legal Basis** Legal basis of applications Module 1 Content Regulatory Operations – eSubmissions (eCTD/ XVMPD/ IDMP/ DADI / SPOR	**Jenny Lamport** **1st Regulatory** **&** **Grzegorz Kojro**
10:30	**Break**	
11:00	**Lecture 2: Common Technical Document Module 4 Non Clinical** First Necessary first trial of man Further preclinical data for the MAA and the link to the SmPC	**David Jones** **Consultant**
12:00	**Lunch**	
13:00	**Lecture 3: Module 5 Clinical Development** Overview of clinical development Phase I, II, III trials Clinical Regulatory strategy and impact of HTA Clinical pharmacology data (PD & PK) Clinical efficacy and safety data	**Steve Pinder** **Envestia Ltd**
14:00	**Lecture 4: Clinical Trial Authorisations** The CTR Process Industry Vs Regulator	**Gunilla Nielsen** **Swedish Medical Products Agency**
15:00	**Dialogue between Industry and RA authority on Clinical Trials and Q + A-**	**Steve Pinder/Gunilla Nielsen**
15:15	**Break**	
15:45	**Case study – Clinical Trial Authorisations TBD**	**Shaila Choi** **Azafaros AG**
17:15	***Case study feedback***	
17:45	**End of day 1**	

Day 2 Wednesday 16th April

Time	Topic	Speaker
08:45	**Opening**	
09:00	**Lecture 5: Chemical-Pharmaceutical data from an R&D Perspective** Importance of pharmaceutical development Considerations for different formulations Development: pitfalls and solutions	***TBC***
10:00	**Lecture 6: Common Technical Documentation Module 3** Build-up of Module 3 Drug Master File and its implications Module 3 deficiencies Stability requirements	**Mirza Catibusic** **Health Products Regulatory Authority Ireland**
11:00	**Break**	
11:30	**Dialogue between Industry and RA authority on module 3 and Q + A-**	**Mirza Catibusic**
12:00	**Lunch**	
12:45	**Case Study 2 CMC**	**Christine Grew** **Canopy Life Sciences** **Dima Al-hadithi** **Minaret Consulting**
14:15	**Case Study 2 CMC feedback**	
14:45	**Lecture 7: Common Technical Document Module 2** Structure and purpose of Module 2 Content and presentation of quality, non-clinical and clinical and clinical overview and summaries Consistency and links between documents	**Tomáš Radiměřský** **State Institute for Drug Control, Czechia**
15:45	**Break**	
16:15	**Lecture 8: Regulatory Strategy** Global Strategic Considerations for development with EU focus Health authority interactions (including Scientific/HTA Advice) - when to use and practical advice Paediatric Development and PIPs Risk benefit analysis The link to the SPC Orphans- optional	**Jens van Wijngaarden & Frank de Vries** **Propharma Group**
17:15	**End of day 2**	

Day 3 Thursday 17th April

Time	Topic	Speaker
08:30	**Opening**	
08:45	**Lecture 9: The Mutual Recognition Procedure and the Decentralised Procedure** A short overview – when to use the procedure Overview of MR and DC procedures CMDh referral process Duplicate licences Impact on Prescription Status	**Stephen Thomson** **S-Cubed**
09:45	**Lecture 10: Centralised Procedure** When to use the procedure How to manage the procedure: internally and externally Practical experience to date including orphan drugs Implications of using the procedure – public assessment reports & binding decisions Accelerated pathways	**Jenny Horwood** **Pfizer**
10:45	**Break**	
11:15	**Lecture 11: Post approval – Variations and Renewals** Variation Regulation Categorization (Type IA, IA (in), IB, I) New application Vs variation Grouping and work-sharing New legislation on renewals and updates to the variation Reg Requirements and documents to be provided Timelines for submission and assessment	**Richard Keane** **Kay Martin** **Biogen**
12:15	**Lunch**	
13:15	**Intro to Case study – choice of procedures**	**Jens van Wijngaarden & Frank de Vries** **Propharma Group**
13:30	**Case study – choice of procedures**	**Jens van Wijngaarden & Frank de Vries** **Propharma Group**
15:00	**Case study feedback**	
15:30	**Closing Remarks**	**Module Lead**