Programme

The TOPRA 29th Autumn Introductory Course:

Introduction to Pharmaceutical Regulatory Affairs

4 – 6 November 2025

TOPRA Office

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 4 November 2025
Chairperson: Module Lead

	Time	Topic	Learning Outcomes	
30 mins	08:15	**Registration**		
15 mins	08:45	**Opening and Introduction**		**Module Lead**
30 mins	09:00	**Setting the scene** Regulatory functions Structure of CTD Modules EU Legislation	EU directives and legislation critical awareness of the regulatory environment	**Module Lead**
50 mins (10 mins Q)	09:30	**Lecture 1: Overview of MAA and Legal Basis** Legal basis of applications Module 1 Content Regulatory Operations – eSubmissions (eCTD/ XVMPD/ IDMP/ DADI)	EU directives and legislation critical awareness of the regulatory environment	**Jenny Lamport 1st Regulatory**
30 mins	10:30	**Break**		
50 mins (10 mins Q)	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	***associated documentation*** *for marketing submissions to evaluate current developments critically*	**David Jones Consultant**
45 mins	12:00	**Lunch**		
50 mins (10 mins Q)	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	Approval of clinical trials + *evaluate current developments critically*	**Esther Nougier Boehringer**
45 mins (10 min Q)	14:00	**Lecture 4: Clinical Trial Authorisations** The CTR Process Industry Vs Regulator	Approval of clinical trials	**Jan Ohotski**
15 mins	15:00	**Panel discussion Clinical Trials**		
30 mins	15:15	**Break**		
60 mins	15:45	**Case study – Clinical Trial Authorisations TBD**		**Jan Ohotski**
30 mins	17:15	***Case study feedback***		
	17:45	**End of day 1**		

Day 2

Wednesday 5 November 2025
Chairperson: Module Lead

	Time	Topic	Learning Outcomes	
15 mins	08:45	**Opening**		
50 mins (10 mins Q)	09:00	**Lecture 5: Chemical-Pharmaceutical data from an R&D Perspective** Importance of pharmaceutical development Considerations for different formulations Development: pitfalls and solutions	EU Regulatory aspects of drug development	**Maria Christopoulou Pfizer**
50 mins 10 mins Q)	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	Associated documentation for marketing submissions	**Mirza Catibusic HPRA**
30 mins	11:00	**Break**		
30 mins	11:30	**Dialogue between Industry and RA authority on module 3 and Q + A-**		**Mirza Catibusic**
45 mins	12:00	**Lunch**		
90 mins	12:45	**Case Study 2 CMC**		**Christine Grew/Dima Al-hadithi**
30 mins	14:15	**Case Study 2 CMC feedback**		
50 mins (10 mins Q)	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	Associated documentation for marketing submissions	**Tomáš Radiměřský State Institute for Drug Control, Czechia**
30 mins	15:45	**Break**		
50 mins (10 mins Q)	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	EU regulatory aspects of drug development	**Stewart Cole Jazz Pharma**
	17:15	**End of day 2**		

Day 3

Thursday 6 November 2025
Chairperson: Module Lead

	Time	Topic	Learning Outcomes	
	08:30	**Opening**		
50 mins (10 mins Q)	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	Regulatory marketing authorisation	**Andrew Modley TEVA**
50 mins (10 mins Q)	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	Regulatory marketing authorisation	**Jenny Horwood**
30 mins	10:45	**Break**		
50 mins (10 mins Q)	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		**TBC**
45 mins	12:15	**Lunch**		
15 mins	13:15	**Intro to Case study – choice of procedures**	Regulatory marketing authorisation	**TBC**
90 mins	13:30	**Case study – choice of procedures**		
30 mins	15:00	**Break**		
45 mins	15:30	**Case study feedback**		
15 mins	16:15	**Closing Remarks**		**Module Lead**