Module: Overview of EU Regulatory Affairs
Date: 03/11/2026 - 05/11/2026

Location: Hilton Vienna Plaza
Schottenring 11, 01. Innere Stadt, 1010 Vienna, Austria
Module Leaders: Sacha Lynch, Grzegorz Kojro
Day 1: 03/11/2026

Time	Activity	Speaker
08:15 – 09:00	**Welcome & Introduction to the Module**	**Sacha Lynch Grzegorz Kojro**
09:00 – 10:00	**Lecture 1: Overview of MAA and Legal Basis** • Recap on Structure of CTD Modules • Brief recap on EU and UK Legislation • Legal basis of applications • Content of M1	**Sacha Lynch**
10:00 – 10:15	**Refreshment Break**	
10:15 – 11:15	**Lecture 2: 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**
11:15 – 11:30	**Break**	
11:30 – 12:30	**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	**Esther Nougier Boehringer**
12:30 – 13:30	**Lunch**	
13:30 – 14:30	**Lecture 4: EU Clinical Trial Authorisations** • The Clinical Trial Regulation • Clinical Trials Information System • The application process • Clinical Trial Publication requirements • Modifications and Notifications	**Jan Ohotski Boyds Consultants**
14:30 – 15:30	**Lecture 5: UK Clinical Trials Landscape** • Overview of the differences from the EU CTR process • The UK CTR process • Route A and Route B modifications • UK Transparency considerations	**Dmitry Obolskiy QbD Group**
15:30 – 16:00	**Break**	
16:00 – 16:30	**Quiz**	**Module Lead**
16:30 – 17:00	**End of day 1 wrap up and final questions**	**Module Lead**

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Day 2: 04/11/2026

Time	Activity	Speaker
08:45 – 09.00	**Introduction to Day 2 and review of Day 1**	
09:00 – 10:00	**Lecture 6: Chemical-Pharmaceutical data from an R&D Perspective** • Importance of pharmaceutical development • Considerations for different formulations • Development: pitfalls and solutions	**Ouannassa Rached Pfizer**
10:00– 10:15	**Refreshment Break**	
10:15 – 11:15	**Lecture 7: Common Technical Documentation Module 3** • Build-up of Module 3 • Drug Master File and its implications • Module 3 deficiencies • Stability requirements	**Stephane Vranckx GSK**
11:15 – 11:30	**Break**	
11:30 – 12:00	**Lecture 8: Regulatory Operations** • OMS, PMS, SPOR, web-based eAF, ectd, 4.0, RIMs system etc	**Grzegorz Kojro**
12:00 – 13:00	**Lunch**	
13:00 – 14:00	**Lecture 9: 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**
14:00 – 15:00	**Case Study CMC**	**Stephane Vranckx GSK**
15:00 – 15:30	**Break**	
16:00 – 17:00	**Lecture 10: 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 • Orphans	**Stewart Cole Jazz Pharma**
17:00 – 17:15	**End of day 1 wrap up and final questions**	

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Day 3: 05/11/2026

Time	Activity	Speaker
08:45 –09:00	**Introduction to Day 3 and Review of Day 2**	
09:00 – 10:00	**Lecture 11: 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	**Malcolm Tait TEVA**
10:00 – 11:00	**Lecture 12: 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 Consultant**
11:00 – 11:20	**Break**	
11:20 – 12:15	**Lecture 13: UK Procedures** • UK ILAP and Early Access Scheme • Overview of International Procedures • Overview of National MAA Requirements	**Sacha Lynch**
12:15 – 13:15	**Lunch**	
13:15 – 14:15	**Case study – choice of procedure**	**Sacha Lynch**
14:15 – 14:45	**Case study feedback**	
14:45 – 15:15	**Break**	
15:15 – 16:15	**Lecture 14: Post Approvals – 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	**Suzanne De Montlebert EMA**
16:15 – 16:30	**Closing remarks**	**Module Lead**