The 28th Autumn Introductory Course:

Ramada Hotel, Lisbon, Portugal

12 – 15 November 2024

	Day 1 **Tuesday 12th November 2024** **Chair: Course Lead**	
08:25	Opening and Introduction	Course Lead
08:30	Lecture 1: Common Technical Document Module 1: • Introduction to CTD • Overview of Module 1 • Product information • PIL user testing	Marloes van der Geer Qdossier
09:45	Lecture 2:Clinical Trial Authorisations	Jan Ohotski Medpace
10:45	Break	
11:15	Case study 1 – Clinical Trials	Jan Ohotski
13:00	Lunch	
13:45	Lecture 3: e-Submissions • Regulatory guidance leading to eCTD • Prerequisites for proper eCTD usage • Other e-submissions initiatives including EVMPD, IDMP and DADI	Marloes van der Geer Qdossier Hans van Bruggen
14:45	Lecture 4: Clinical Data from a R&D Perspective & Common Technical Document Module 5 • Overview of clinical development • Phase I, II, III trials • Regulatory strategy re clinical development including Health Technology Assessment • Clinical pharmacology data (PD & PK) • Clinical efficacy and safety data • Risk benefit analysis • The link to the SPC	Esther Nougier Boehringer-Ingelheim
15:45	Break	
16:15	Lecture 5: What do you need to know as a Regulatory Person and Preclinical • Value of regulatory • First necessary first trial of man • Further preclinical data for the MAA and the link to the SmPC • Environmental risk assessment?	Elizabeth Soames ProPharma Group
17:15	Close of day	Course Lead

	Day 2 **Wednesday 13th November 2024** **Chair: Course Lead**	
09:00	Opening and Introduction	Course Lead
09:05	Lecture 6: Chemical-Pharmaceutical data from an R&D Perspective • Importance of pharmaceutical development • Clinical trial formulation • Dosage forms and development • Development: pitfalls and solutions • Good Manufacturing Practice	Stefan Hirsch Novartis
09:50	Lecture 7: Common Technical Documentation Module 3 • Build-up of Module 3 • Drug Master File and its implications • Drug Product: Excipients and their choice • Stability requirements • Quality Overall Summary: a dossier entrance:	Stephane Vranckx GSK
10:30	Break	
11:00	Case study 2 Quality	Sacha Lynch
13:00	Lunch	
13:45	Case study feedback	
14:30	Break	
15:00	Lecture 8: Scientific Advice and Interaction with Authorities • The importance of seeking scientific advice • When to seek advice • Practical advice for interactions with agencies • Interactions with PRAC • Health Technology Assessment – interaction • Oral hearing	Stewart Cole Jazz Pharmaceuticals
16:00	Panel Discussion	
17:00	Close	

Day 3
Thursday 14th November 2024
Chair: Course Lead supported by Vicy Abbott

08:00	Registration welcome and Introductions	Course Lead
08:30	Lecture 9: The European Medicines Agency • Structure of EMA and their role • Interactions with the rapporteur and co-rapporteur • Interacting with Industry • Management with other countries	Patricia Almeida EMA
09:15	Lecture 10: The Mutual Recognition Procedure and the Decentralise Procedure • A short overview – when to use the procedure • Overview of MR and DC procedures • CMDh referral process • Duplicate licenses • Impact on Prescription Status	Kora Doorduyn-van der StoepMedicines Evaluation Board in The Netherlands, Vice chair of CMDh
10:15	Break	
10:45	Lecture 11: An Introduction to the 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	Ricky Radia Gilead
11:45	Lecture 12: Abridged Applications and Generics • Legal routes of abridged applications • Data exclusivity • Patents • Specifics of generic products	Andrew Modley TEVA
12:45	Lunch	
13:30	Intro to Case Study Choice of Procedures	Vicky Abbott
14:00	Case Study 3 Choice of Procedure	Vicky Abbott supported by Course Lead
15:30	Break	
16:30	Feedback Case study 3	Vicky Abbott
17:30	Close	Course Lead

Day 4
Friday 15th November
Chair Course Lead

09:00	Opening and Introduction of day 4	Course Lead
09:05	Lecture 13: Variations and Renewals • Variation Regulation • Categorization (Type IA, IA(in), IB, II) • 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	Marta Viras PPD
10:00	Break	
10:30	Case Study 4 -Variations	Marta Viras
12:30	Lunch	
13:15	Lecture 14: Pharmacovigilance and Risk Management • Legal requirements – new PhVig legislation • Definitions and conventions • Good drug safety labelling practice • Regulatory action with regards to drug safety • Safety Risk Management and why • Risk Management – regulatory status, programmes, examples and its value; educational materials	Tom Nicols Drive Phase PV
14:15	Lecture 15: Common Technical Document Module 2: • Structure and purpose of module 2 • Content and presentation of quality, non-clinical and clinical overview and summaries • Consistency and links between documents	Andreia Mendes Infarmed
15:15	Closing remarks	Course Lead