The 28th Autumn Introductory Course:
Target the Heart of European Regulatory Affairs

Vienna House Diplomat Prague
14 - 17 November 2023

Tuesday 14th November (Day 1)
Chair: Nick Sykes
Bencard Allergie GmbH

08:00	**Arrival and Registration**	
08:15	**Welcome and TOPRA Introduction**	**Video**
08:20	**Course Opening Address & Introduction to Day 1**	**Arthur Merlin d'Estreux** Jazz Pharmaceuticals **Nick Sykes** Pfizer
08:30	**Lecture 1: Common Technical Document Module 1: Administrative Information & Prescribing Information** • Introduction to CTD • Overview of Module 1 • Product information • PIL user testing • Type of application	**Marloes van der Geer** Qdossier, a Celegence company
09:15	**Lecture 2: e-Submissions** • Regulatory guidance leading to eCTD • Prerequisites for proper eCTD usage • Other e-submission initiatives including EVMPD, IDMP and DADI	**Hans van Bruggen** Qdossier, a Celegence company
10:15	**Break**	
10:30	**Lecture 3: Chemical-Pharmaceutical data from a R&D Perspective** • Importance of pharmaceutical development • Clinical trial formulation • Dosage forms and development • Development: pitfalls and solutions • Good Manufacturing Practice	**Stefan Hirsch** Novartis Pharma AG
11:30	**Lecture 4: Common Technical Document Module 3: Quality data from a dossier perspective** • 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	**Stéphane Vranckx** GlaxoSmithKline
12:30	**Lunch**	
13:30	**Introduction to Case study 1**	**Nicholas Sweeney** Jazz Pharmaceuticals
13:45	**Case study 1 – Chemistry and Pharmacy**	**Nicholas Sweeney**
16:00	**Break**	
16:30	**Feedback session Case study 1**	**Nicholas Sweeney**
18:00	**Close of the day**	
18:30	**Dinner**	

Wednesday 15th November (Day 2)
Chair: Azzurra Ravizza
Pfizer

08:30	**Opening and Introduction of day 2**	**Azzurra Ravizza** Pfizer
08:35	**Lecture 5: Clinical Data from a R&D perspective & Common Technical Document Module 5 (Efficacy)** • Overview of clinical development • Phase I, II, III trials • Setting up a study • Regulatory strategy re clinical development including Health Technology Assessment • Role of a Regulatory Professional • Clinical pharmacology data (PD & PK) • Clinical efficacy and safety data • Risk benefit analysis • The link to the SPC	**Esther Nougier** Boehringer-Ingelheim
09:35	**Lecture 6: What do you need to know as a Regulatory Person about Preclinical?** • Value of regulatory • First necessary first trial of man • Further preclinical data for the MAA • Environmental risk assessment?	**Elizabeth Soames** Scendea
10:35	**Break**	
11:00	**Lecture 7: Clinical Trial Authorisations**	**Jan Ohotski** Medpace
12:00	**Lunch**	
13:00	**Introduction to Case Study 2**	**Jan Ohotski** **Kate Smoter**
13:15	**Case Study 2 – Clinical Trial Case Study**	**Jan Ohotski** **Kate Smoter**
15:15	**Break**	
15:45	**Lecture 8: Common Technical Document Module 2: Overviews and Overall Summaries** • Structure and purpose of Module 2 • Content and presentation of quality, non-clinical and clinical overview and summaries • Consistency and links between documents	**Tomáš Radiměřský** **State Institute for Drug Control**
16:30	**Close of the day**	
18:00	**Dinner**	

Thursday 16th November (Day 3)
Chair: Vicky Abbott
Sapientia Regulatory Services Ltd

09:00	**Opening and Introduction of day 3**	**Vicky Abbott** Sapientia Regulatory Services Ltd
09:05	**Lecture 9: 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	**Arthur Merlin d'Estreux** Jazz Pharmaceuticals
09:50	**Lecture 10: The Mutual Recognition Procedure & the Decentralised Procedure** • A short overview • Overview of MR and DC procedures • CMDh referral process • Duplicate licenses • Impact of prescription status	**Kora Doorduyn-van der Stoep** Medicines Evaluation Board in The Netherlands, Vice chair of CMDh
10:50	**Break**	
11:20	**Lecture 11: The European Medicines Association** • Structure of EMA and their role • Interactions with the rapporteur and co-rapporteur • Interacting with Industry • Management with other countries	**Ana-Maria Vladulescu** EMA
11:50	**Lecture 12: An Introduction to the Centralised 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	
12:30	**Lunch**	
13:30	**Lecture 13: Choice of Procedure and Introduction to Case study 3** • Options available • Points to consider when choosing the procedure Strategic considerations	**Vicky Abbott** Sapientia Regulatory Services Ltd
14:00	**Case study 3 – Choice of procedure**	**Vicky Abbott** Sapientia Regulatory Services Ltd
15:00	**Break**	
15:30	**Case study 3 cont. – Choice of procedure**	**Vicky Abbott**
16:15	**Panel discussion and Q&A**	**Arthur Merlin d'Estreux** **Vicky Abbott** **Azzurra Ravizza** **Ana-Maria Vladulescu**
18:00	**Dinner**	

Friday 17th November (Day 4)
Chair: Ronald de Meijer
Astellas Pharma B.V.

08:30	**Opening and Introduction of day 4**	**Ronald de Meijer** Astellas Pharma B.V.
08:35	**Lecture 14: Abridged Applications and Generics** • Legal routes of abridged applications • Data exclusivity • Patents Specifics of generic products	**Andrew Modley** TEVA
09:35	**Lecture 15: Variations and Renewals** • Variation Regulation • Categorization (Type IA, IA(in), IB, II) • New application vs variation • Grouping and work-sharing • New legislation on renewals • Requirements and documents to be provided • Timelines for submission and assessment • **Introduction to Case Study 4 - Variations**	**Marta Viras** PPD
10:40	**Break (Refreshments to be taken into Case Study rooms)**	
10:50	**Case Study 4 – Variations**	**Marta Viras** PPD
12:45	**Lunch**	
13:45	**Lecture 16: Pharmacovigilance and Risk Management** • Legal requirements – new PhVig legislation • Definitions and conventions • Good drug safety labelling practice • Regulatory action with regards to drug safety • Electronic submissions • Safety Risk Management and why Risk Management – regulatory status, programmes, examples and its value; educational materials	**Pauline Gerritsen** Gerritsen Pharmacovigilance Consulting
14:45	**Chairperson's Closing Remarks**	
15:00	**End of course**	