The 25th Autumn Introductory Course:
Target the Heart of European Regulatory Affairs

*Preliminary Programme

Berlin

IntercityHotel Hauptbahnhof Berlin

5th -8th November 2019

*Please note, the preliminary programme is subject to change.

Tuesday 5th November (Day 1)

Chair: Marion Kreitz, Bencard Allergie GmbH

08:30	**Arrival and Registration**	
09:00	**Opening and introduction of day**	**Marion Kreitz**
09:05	**Welcome, Opening Address & Topra Introduction**	**Ronald de Meijer** Astellas Pharma B.V. **Samantha Alsbury** TOPRA
09:35	**Common Technical Document Module 1: Administrative Information & Prescribing Information** • Introduction to CTD • Overview of Module 1 • Type of application (including abridged applications) • Summary of Product Characteristics (SmPC) • Application form including appendices • PIL user testing • EU regional requirements	**Hans van Bruggen** eCTDconsultancy
10:35	**Break**	
11:00	**e-Submissions** • Regulatory guidance leading to eCTD • Prerequisites for proper eCTD usage • Other e-submission initiatives including PIM • EVMPD and IDMP	**Hans van Bruggen** eCTDconsultancy
12:00	**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
12:45	**Lunch**	
13:45	**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	**Sandrine Lemaire** GlaxoSmithKline
14:45	**Introduction to Case study 1**	**Sandrine Lemaire**
15:00	**Break**	
15:15	**Case study 1 – Chemistry and Pharmacy**	**Sandrine Lemaire** **Hans van Bruggen**
17:00	**Feedback session Case study 1**	**Sandrine Lemaire** **Hans van Bruggen**
17:45	**Welcome Reception**	
18:15	**Dinner**	

Wednesday 6th November (Day 2)

Chair: Azzurra Ravizza, Pfizer Ltd

08:30	**Opening and introduction of day**	**Azzurra Ravizza**
08:35	**Clinical (Efficacy) Data from a R&D perspective** • 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	**Lynda Troy** AstraZeneca
09:20	**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** DLRC Ltd.
10:00	**Break**	
10:30	**Clinical Trial Authorisations** • Clinical Trial Directive 2001/20/EC • Initial application for authorisation of a clinical trial • EU voluntary harmonised procedure • Methodology studies	**Ann Scott** OA Regulatory Limited
11:15	**Clinical Trial Authorisations, continued** • Substantial/Non-substantial amendments • End of trial notification • Pharmacovigilance for Investigational Medicinal Products	**Anne Lenihan** Pfizer Ltd
12:00	**Introduction to Case Study 2**	**Anne Lenihan** **Ann Scott**
12:15	**Lunch**	
13:15	**Case Study 2 – Clinical Trial Case Study**	**Anne Lenihan** **Ann Scott**
15:15	**Break**	
15:45	**Common Technical Document Module 5: Clinical (Efficacy) Data** • Clinical pharmacology data (PD & PK) • Clinical efficacy and safety data • Risk benefit analysis • The link to the SPC	**Lynda Troy** AstraZeneca
16:30	**Common Technical Document Module 2: Overviews and Overall Summaries** • Structure and purpose of Module 2 • Content and presentation of quality, non-clinical and clinical overviews and summaries • Consistency and links between documents	**Tomáš Radimersky** State Institute for Drug Control
17:15	**Close of the day**	
18:30	**Dinner in city**	

Thursday 7th November (Day 3)

Chair: Arthur Merlin d'Estreux, TEVA

09:00	**Opening and introduction of day**	**Arthur Merlin d'Estreux**
09.05	**Paediatrics** • Paediatric regulation • Paediatric development • Paediatric clinical trials	**Azzurra Ravizza** Pfizer
09:45	**Orphan Designation (OD)** • Regulation on Orphan Medicinal Products • Applying for Rare Disease (Orphan) Designation • Notion of Orphan Similarity and evaluation of orphan Superiority • The reality: OD Case Studies	**Arthur Merlin d'Estreux** TEVA
10.15	**Break**	
10:45	**Scientific Advice and Interaction with Authorities** • The importance of seeking scientific advice • When to seek advice • EMA vs. national advice: differences and how do we decide which route to take • Practical advice for interactions with agencies • Interactions with PRAC • Health Technology Assessment – interaction • Oral hearing	**Arthur Merlin d'Estreux** TEVA
11:45	**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
12:45	**Lunch**	
13:45	**An Introduction to the Centralised Procedure** • An overview • Interactions with the rapporteur and co-rapporteur • 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	**Claire Onody** UCB
14.45	**Choice of Procedure and Introduction to Case study 3** • Options available • Points to consider when choosing the procedure • Strategic considerations	**Vicky Jones** Sapientia Regulatory Services Ltd
15.15	**Break**	
15.30	**Case study 3 – Choice of procedure**	**Vicky Jones**
17:15	**Close of the day**	
18:00	**Dinner**	

Friday 8th November (Day 4)

Chair: Ronald de Meijer, Astellas Pharma B.V.

08:30	**Opening and introduction of day**	**Ronald de Meijer** Astellas Pharma B.V.
08:35	**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
09:35	**Variations and Renewals** • Variation Regulation • Categorization (Type IA, IA(in), IB, II) • New application vs variation • Grouping and worksharing • New legislation on renewals • Requirements and documents to be provided • Timelines for submission and assessment	**Bimal Patel** Consultant
10:15	**Break**	
10:45	**Introduction to Case Study 4** **Case Study 4 – Variations**	**Bimal Patel** **Ronald de Meijer**
12:45	**Lunch**	
13:45	**Abridged Applications and Generics** • Legal routes of abridged applications • Data exclusivity • Patents • Specifics of generic products	**Andrew Modley** TEVA
14:45	**Chairperson's Closing Remarks**	**Ronald de Meijer**
15:00	**End of course**	