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

## *Preliminary Programme

**Prague**

**Vienna House Diplomat Prague**
**15 - 18 November 2022**

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

**Tuesday 15 November (Day 1)**
**Chair: Marion Kreitz**
Bencard Allergie GmbH

| | | |
|---|---|---|
| **08:30** | **Arrival and Registration** | |
| **09:00** | **Opening and introduction of day** | **Arthur Merlin d'Estreux**<br>Jazz Pharmaceuticals |
| **09:05** | **Welcome, Opening Address & TOPRA Introduction** | **TOPRA** |
| **09:35** | **Common Technical Document Module 1: Administrative Information & Prescribing Information**<br>• Introduction to CTD<br>• Overview of Module 1<br>• Product information<br>• PIL user testing<br>• Type of application | **Marloes van der Geer**<br>Qdossier |
| **10:05** | **e-Submissions**<br>• Regulatory guidance leading to eCTD<br>• Prerequisites for proper eCTD usage<br>• Other e-submission initiatives including PIM<br>• EVMPD and IDMP | **Hans van Bruggen**<br>Qdossier |
| **11:05** | **Break** | |
| **11:30** | **Chemical-Pharmaceutical data from a R&D Perspective**<br>• Importance of pharmaceutical development<br>• Clinical trial formulation<br>• Dosage forms and development<br>• Development: pitfalls and solutions<br>• Good Manufacturing Practice | **Stefan Hirsch**<br>Novartis Pharma AG |
| **12:15** | **Lunch** | |
| **12:10** | **Common Technical Document Module 3: Quality data from a dossier perspective**<br>• Build-up of Module 3<br>• Drug Master File and its implications<br>• Drug Product: Excipients and their choice<br>• Stability requirements<br>• Quality Overall Summary: a dossier entrance | **Sandrine Lemaire**<br>GlaxoSmithKline |
| **13:10** | **Introduction to Case study 1** | **Sandrine Lemaire**<br>GlaxoSmithKline<br><br>**Nicholas Sweeney**<br>Jazz Pharmaceuticals |
| **13:25** | **Break** | |
| **13:40** | **Case study 1 – Chemistry and Pharmacy** | **Sandrine Lemaire**<br>**Nicholas Sweeney** |
| **15:25** | **Feedback session Case study 1** | **Sandrine Lemaire**<br>**Nicholas Sweeney** |
| **17:30** | **Close of the day** | |
| **18:00** | **Dinner** | |

| | Wednesday 16th November (Day 2)<br>Chair: Azzurra Ravizza<br>Pfizer | |
|---|---|---|
| **08:30** | **Opening and introduction of day** | **Azzurra Ravizza**<br>Pfizer |
| **08:35** | **Clinical Data from a R&D perspective & Common Technical Document Module 5 (Efficacy)**<br>• Overview of clinical development<br>• Phase I, II, III trials<br>• Setting up a study<br>• Regulatory strategy re clinical development including Health Technology Assessment<br>• Role of a Regulatory Professional<br>• Clinical pharmacology data (PD & PK)<br>• Clinical efficacy and safety data<br>• Risk benefit analysis<br>• The link to the SPC | **Speaker to be confirmed** |
| **09:35** | **What do you need to know as a Regulatory Person about Preclinical?**<br>• Value of regulatory<br>• First necessary first trial of man<br>• Further preclinical data for the MAA<br>• Environmental risk assessment? | **Elizabeth Soames**<br>DLRC Ltd. |
| **10:35** | **Break** | |
| **11:05** | **Clinical Trial Authorisations** | **Ann Scott**<br>OA Regulatory Limited<br><br>**Jan Ohotski**<br>Medpace |
| **12:00** | **Lunch** | |
| **13:00** | **Clinical Trial Authorisations, continued** | **Karina Griffiths**<br>Pfizer |
| **13:55** | **Introduction to Case Study 2** | **Ann Scott**<br>**Jan Ohotski**<br>**Karina Griffiths** |
| **14:10** | **Case Study 2 – Clinical Trial Case Study** | **Ann Scott**<br>**Jan Ohotski**<br>**Karina Griffiths** |
| **16:15** | **Break** | |
| **16:15** | **Common Technical Document Module 2: Overviews and Overall Summaries**<br>• Structure and purpose of Module 2<br>• Content and presentation of quality, non-clinical and clinical overview and summaries<br>• Consistency and links between documents | **Iva Gottsteinová**<br>State Institute for Drug Control |
| **17:00** | **Close of the day** | |
| **18:00** | **Dinner** | |

**Thursday 17th November (Day 3)**
**Chair: Vicky Abbott**
Sapientia Regulatory Services Ltd

| | | |
|---|---|---|
| **09:00** | **Opening and introduction of day** | |
| **09:05** | **Scientific Advice and Interaction with Authorities**<br>• The importance of seeking scientific advice<br>• When to seek advice<br>• Practical advice for interactions with agencies<br>• Interactions with PRAC<br>• Health Technology Assessment – interaction<br>• Oral hearing | **Arthur Merlin d'Estreux**<br>Jazz Pharmaceuticals |
| **09:50** | **The Mutual Recognition Procedure & the Decentralised Procedure**<br>• A short overview<br>• Overview of MR and DC procedures<br>• CMDh referral process<br>• Duplicate licenses<br>• Impact of prescription status | **Kora Doorduyn-van der Stoep**<br>Medicines Evaluation Board in The Netherlands, Vice chair of CMDh |
| **10:50** | **Break** | |
| **11:20** | **An Introduction to the Centralised Procedure**<br>• An overview<br>• Role and structure of EMA<br>• Interactions with the rapporteur and co-rapporteur<br>• How to manage the procedure: internally and externally<br>• Practical experience to date including orphan drugs<br>• Implications of using the procedure – public assessment reports & binding decisions<br>• Accelerated pathways | **Natalie Schmidt**<br>Pfizer |
| **12:30** | **Lunch** | |
| **13:30** | **Choice of Procedure and Introduction to Case study 3**<br>• Options available<br>• Points to consider when choosing the procedure<br>Strategic considerations | **Vicky Abbott**<br>Sapientia Regulatory Services Ltd |
| **14:00** | **Break** | |
| **14:30** | **Case study 3 – Choice of procedure** | **Vicky Abbott** |
| **16:15** | **Close of the day** | |
| **18:00** | **Dinner** | |

**Friday 18th November (Day 4)**
**Chair: Ronald de Meijer**
Astellas Pharma B.V.

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