The 26th Autumn Introductory Course:
Target the Heart of European Regulatory Affairs

*Preliminary Programme

Online

17th – 20th November 2020

Pre-recorded sessions
3 November – 8 December 2020

**Delegates should listen to these before the course starts
Delegates will have an opportunity to ask questions about the other lectures after the course

Recommended for:	Session
Recommended as pre-read before course start but not mandatory prior to Day 1	**Development of Pharmaceutical Legislations** • The development of regulations, directives and guidelines • Working parties • Opportunities to influence legislation • New legislation
Recommended as pre-read, before Day 4 start but not mandatory	**Life Cycle Management** • Life cycle management – why? • Life of your product • Extending the life of your product • Regulatory strategies • Hot topic – shortage of medicinal product • Commercial strategies
Recommended as pre-read before Day 3 but not mandatory	**Role and structure of EMA** • EMA, its role, responsibilities and structure • EMA and relationships with national agencies • Electronic links between agencies • Transparency
Day 1 of the course	**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
Day 1 of the course	**e-Submissions** • Regulatory guidance leading to eCTD • Prerequisites for proper eCTD usage • Other e-submission initiatives including PIM • EVMPD and IDMP
Day 2 of the course	**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
Day 2 of the course	**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?

Date of release	Session
Day 2 of the course	**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
Day 2 of the course	**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
Day 3 of the course	**Paediatrics** • Paediatric regulation • Paediatric development • Paediatric clinical trials
Day 3 of the course	**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
Day 3 of the course	**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
Day 4 of the course	**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
Day 4 of the course	**Abridged Applications and Generics** • Legal routes of abridged applications • Data exclusivity • Patents • Specifics of generic products

Pre-programme 10 November 2020	
09:30	**Registration online**
10:00	**Opening**
10:15	**Q&A about the course**
10:45	**Break**
11:00	**Networking session**
13:00	**End of the day**

Tuesday 17th November (Day 1)

****All timings presented are GMT.**

08:30	**Registration online**
09:00	**Opening and introduction of day**
09:05	**Welcome, Opening Address & Topra Introduction**
09:15	**Q&A session** On-demand webinars that delegates should listen to: • Common Technical Document Module 1: Administrative Information & Prescribing Information • e-Submissions
09:45	**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
10:45	**Break**
11:00	**Common Technical Document Module 3:** **Quality data from a dossier perspective** • Buildup of Module 3 • Drug Master File and its implications • Drug Product: Excipients and their choice • Stability requirements • Quality Overall Summary: a dossier entrance
12:00	**Lunch**
13:00	**Case study 1 – Chemistry and Pharmacy**
14:30	**Feedback session Case study 1**
15:00	**End of the day**

Wednesday 18th November (Day 2)

****All timings presented are GMT.**

08:30	**Registration online**
08:55	**Opening and introduction of day**
09:00	**Q&A session** On-demand webinars that delegates should listen to: • Clinical (Efficacy) Data from a R&D perspective • What do you need to know as a Regulatory Person about Preclinical? • Common Technical Document Module 5: Clinical (Efficacy) Data • Common Technical Document Module 2: Overviews and Overall Summaries
09:45	**Break**
10:00	**Clinical Trial Authorisations** • Clinical Trial Directive 2001/20/EC • Initial application for authorisation of a clinical trial • EU voluntary harmonised procedure • Methodology studies
11:00	**Break**
11:15	**Clinical Trial Authorisations, continued** • Substantial/Non-substantial amendments • End of trial notification • Pharmacovigilance for Investigational Medicinal Products
12:15	**Lunch**
13:00	**Introduction to Case Study 2**
13:15	**Case Study 2 – Clinical Trial Case Study**
14:45	**Feedback session Case study 2**
15:15	**Close of the day**

Thursday 19th November (Day 3)

****All timings presented are GMT.**

08:30	**Registration online**
08:55	**Opening and introduction of day**
09:00	**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
10:00	**Break**
10:15	**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
11:15	**Choice of Procedure and Introduction to Case study 3** • Options available • Points to consider when choosing the procedure • Strategic considerations
11:30	**Lunch**
12:30	**Case study 3 – Choice of procedure**
14:00	**Feedback session Case study 3**
14:30	**Break**
14:45	**Q&A session** On-demand webinars that delegates should listen to: • Paediatrics • Orphan Designation (OD) • Scientific Advice and Interaction with Authorities
15:30	**Close of the day**

Friday 20th November (Day 4)

****All timings presented are GMT.**

08:30	**Registration online**
08:55	**Introductory comments**
09:00	**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
10:00	**Break**
10:15	**Introduction to Case Study 4**
10:30	**Case Study 4 – Variations**
11:45	**Feedback session Case study 4**
12:15	**Lunch**
13:15	**Q&A session** On-demand webinars that delegates should listen to: • Pharmacovigilance and Risk Management • Abridged Applications and Generics
13.45	**Review of the day and next stage** • Q&A • Feedback • What's next?
14:15	**End of course**

Follow up live Q&A session
Tuesday 1 or 8 December

**Topic areas to be submitted by delegates in advance

09:30	**Registration online**
10:00	**Opening**
10:15	**Panel discussion** On-demand webinars that delegates should listen to: • Development of Pharmaceutical Legislations • Life Cycle Management • Role and structure of EMA
10:45	**Break**
11:00	**Networking session**
13:00	**End of the day**