The 27th Autumn Introductory Course:
Target the Heart of European Regulatory Affairs

*Preliminary Programme

Online

2nd – 5th November 2021

Pre-recorded sessions
11 October – 1 November 2021

**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	**Andrew Willis** A. Willis Consulting
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	**EMA speaker**
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	**Marloes van der Geer** Qdossier
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	**Hans van Bruggen** Qdossier
Day 1 of the course	**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
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	**Esther Nougier** Gilead

Date of release	Session	
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?	**Elizabeth Soames** DLRC
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	**Natalie Anne Schmidt** Pfizer
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	**Tomas Radimersky** State Institute for Drug Control
Day 3 of the course	**Paediatrics** • Paediatric regulation • Paediatric development • Paediatric clinical trials	**Azzurra Ravizza** Pfizer
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	**Arthur Merlin d'Estreux,** Jazz Pharmaceuticals
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	**Arthur Merlin d'Estreux,** Jazz Pharmaceuticals
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	**Pauline Gerritsen** Gerritsen Pharmacovigilance Consulting
Day 4 of the course	**Abridged Applications and Generics** • Legal routes of abridged applications • Data exclusivity • Patents • Specifics of generic products	**Andrew Modley** TEVA

Pre-programme 26th October 2021	
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 2nd November (Day 1)

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

Chair: Vicky Abbott/Mathias Finkler

08:30	**Registration online**	
09:00	**Welcome, Opening Address from the Working Party**	
09:05	**Opening and introduction of day**	
09:10	**Q&A session** On-demand webinars that delegates should listen to: • Common Technical Document Module 1: Administrative Information & Prescribing Information • e-Submissions • Chemical-Pharmaceutical data from a R&D Perspective	**Marloes van der Geer** Qdossier **Hans van Bruggen** Qdossier
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	**Stefan Hirsch** Novartis Pharma AG
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	**Sandrine Lemaire** GlaxoSmithKline
12:00	**Lunch**	
13:00	**Case study 1 – Chemistry and Pharmacy**	**Sandrine Lemaire** GlaxoSmithKline
14:30	**Feedback session Case study 1**	
15:00	**End of the day**	

Wednesday 3rd November (Day 2)

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

Chair: Azzurra Ravizza/Anne Lenihan

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	**Elizabeth Soames** DLRC **Esther Nougier** Gilead **Natalie Anne Schmidt** Pfizer **Tomas Radimersky** State Institute for Drug Control
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	**Ann Scott** OA Regulatory Limited
11:00	**Break**	
11:15	**Clinical Trial Authorisations, continued** • Substantial/Non-substantial amendments • End of trial notification • Pharmacovigilance for Investigational Medicinal Products	**Anne Lenihan** Pfizer Ltd
12:15	**Lunch**	
13:00	**Introduction to Case Study 2**	**Anne Lenihan** Pfizer Ltd
13:15	**Case Study 2 – Clinical Trial Case Study**	
14:45	**Feedback session Case study 2**	
15:15	**Close of the day**	

Thursday 4th November (Day 3)

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

Chair: Katie Pye/ Arthur Merlin d'Estreux

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	**Kora Doorduyn-van der Stoep** Medicines Evaluation Board in The Netherlands, Vice chair of CMDh
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	**Natalie Anne Schmidt** Pfizer
11:15	**Break**	
11:30	**Q&A session** On-demand webinars that delegates should listen to: • Paediatrics • Orphan Designation (OD) Scientific Advice and Interaction with Authorities	**Arthur Merlin d'Estreux,** Jazz Pharmaceuticals **Azzurra Ravizza** Pfizer
12:00	**Lunch**	
13:00	**Case study 3 – Choice of procedure**	**Vicky Abbott** Sapientia Regulatory Services Ltd
14:30	**Feedback session Case study 3**	
15:00	**Close of the day**	

Friday 5th November (Day 4)

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

Chair: Marion Kreitz/Ronald de Meijer

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	**Christine Forster** TEVA
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	**Pauline Gerritsen** Gerritsen Pharmacovigilance Consulting **Andrew Modley** TEVA
13:45	**Review of the day and next stage** • Q&A • Feedback • What's next?	
14:00	**End of course**	

Post-programme session
Monday, 8th November 2021

**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**