Programme

The TOPRA 41st Spring Introductory Course:

Introduction to Pharmaceutical Regulatory Affairs

20 – 23 May 2019

De Vere Selsdon Estate, 126 Addington Rd, South Croydon CR2 8YA

Monday 20 May 2019

Chairperson: Mike Robertson, Pharmaceutical Quality Matters
Day Coordinator: Jayne Cook, Abbvie Ltd

8:30	**Registration & Tea/coffee**
09:00	**Welcome & Introduction to the course** Steve Brookes, *Biogen &* Samantha Alsbury, *TOPRA*
09:15	**New Product Development, The European Regulatory Environment & the Role of Regulatory Affairs** Steve Brookes, *Biogen*
10:20	**Overview of the MAA** Ruth Flynn, *AbbVie Ltd*
11:15	**Tea/ coffee break**
11:30	**Chemical Development/Quality** Brian Corrigan, *MSD*
12:30	**Lunch**
13:30	**Pharmaceutical Development/Quality** Brian Corrigan, *MSD*
14:30	**Module 3. An Agency Perspective** Mirza Catibusic, Health Products Regulatory Authority (*HPRA)*
15:30	**Tea/ coffee break**
15:45	**Case Study 1. Chemistry & Pharmacy** Sally Steeden, *BioPharm Solutions Ltd*
18:00	**Close**
20:00	**Dinner in the restaurant**

Tuesday 21 May 2019

Chairperson: Xavier Luriat, *Consultancy*
Day Coordinator: Bob Ibbotson, *Lucis Consulting Ltd.*

08:30	**Understanding the Need for Non-Clinical Safety Studies** Chris Powell, *GlaxoSmithKline*
09:30	**The Importance of Pharmacokinetics & Pharmacodynamics in Drug Development & Registration** Helen Walker, *HW ClinPharm Ltd*
10:30	**Tea / coffee break**
10:45	**The Components of the Non-Clinical Section of a Marketing Authorisation Application** David Jones, *Medicines and Healthcare products Regulatory Agency* (*MHRA)*
11:45	**Questions**
12:00	**Lunch**
13:00	**Clinical Drug Development, Paediatric Investigation Plans & the link with Regulatory Affairs** Ian Dews, *Envestia Ltd*
14:00	**The Regulation of Clinical Trials in Europe – An Agency Perspective** Graham McNaughton, *MHRA*
14:55	**Tea / coffee break**
15:10	**The European Clinical Trials Process – Industry Perspective** Shaila Choi, *KKSC Solutions LTD*
15:40	**The Components of the Clinical Section of a Marketing Authorisation Application** Jan Span, *Medicines Evaluation Board (MEB)*
16:25	**Questions**
16:30	**Case Study 2: Non-Clinical & Clinical Development** Claire Beggs, *AbbVie Ltd*
20:00	**Dinner in the Phoenix Lounge & Team quiz**

Wednesday 22 May 2019

Chairperson: Sue Harris, ex-MHRA
Day Coordinator: Niamh Lawler-Turner, *PharmaFind Ltd*

08:30 **EU Procedures and the Factors for Success – My Experience as a Pharmaceutical Assessor and Unit Manager**
Sue Harris*, ex-MHRA*

09:30 **The Centralised Procedure - Practical Industry Experience**
Natalie Schmidt, *Pfizer*

10:30 **Tea / coffee break**

10:45 **The Mutual Recognition Procedure & the Decentralised Procedure – Practical Industry Experience**
Pete Embley*, Bionical EMAS*

11:45 **Generic Applications & Biosimilars**
Pete Embley*, Bionical EMAS*

12:30 **Questions**

12:45 **Lunch**

13:45 **Regulatory Strategy Session Part 1:**
1. **Initial considerations – bigger picture & strategic thinking**
2. **Information protection**
3. **Think global**
4. **Regulatory / HTA advice**

Neil Roberts, *Gilead Sciences International* & David Kane, *Vertex Pharmaceuticals (Europe) Ltd*

14:45 **Tea / coffee break**

15:00 **Regulatory Strategy Session Part 2:**
1. **Paediatric development & PIPs**
2. **Orphans**
3. **Early access**
4. **Tradenames**

Neil Roberts, *Gilead Sciences International* & David Kane, *Vertex Pharmaceuticals (Europe) Ltd*

16:30 ***Case Study 3.*** **Regulatory Strategy**
David Kane, *Vertex Pharmaceuticals (Europe) Ltd*

19:00 **Drinks reception in the Orangery**

19:30 **Dinner / dance in the Sanderson**

Thursday 23 May 2019

Chairperson: Susannah Clements, GSK
Day Coordinator: Emma Holmes, *Medeor Consulting Ltd*

08:30	**Lifecycle Management – Quality** Isabel Zwart, *Biogen*
09:30	**Lifecycle Management - Safety & Efficacy** Avni Pandhi, *Biogen*
10:45	**Tea / coffee break**
11:00	**Product Information – Regulation of the SmPC, PIL & label** Julia Coombes, *MHRA*
12:15	**Accurate, Balanced, Clear? The ABC of Medicines Advertising** Tannyth Cox, *Prescription Medicines Code of Practice Authority*
12:45	**Lunch**
13:45	***Case Study 3.* Variations** Ming Ewe, *Freeline Therapeutics*
15:00	**Tea / coffee break**
15:15	**Health Technology Assessment: Why and where does the regulatory professional become involved?** Sharon Gorman, *Pfizer*
16:00	**An Introduction to Biotechnology & Advanced Therapy Medicinal Products** Paul Smith, *MetisRA Consulting Ltd*
17:00	**Questions and closing remarks** Susannah Clements, *GlaxoSmithKline*