Programme

The TOPRA 42nd Spring Introductory Course:

Introduction to Pharmaceutical Regulatory Affairs

31 Mar – 3 April 2020

Online

Tuesday 31 Mar 2020

Chairperson: Jayne Cook, *Abbvie Ltd*

08:30	**Registration online**
09:00	**Welcome & Introduction to the course** Claire Beggs, GW Pharma & Samantha Alsbury, *TOPRA*
09:15	**New Product Development, The European Regulatory Environment & the Role of Regulatory Affairs** Steve Brookes, *Biogen*
10:20	**Break**
10:35	**Overview of the MAA** Jenny Lamport*, 1st Regulatory Ltd.*
11:35	**Chemical Development/Quality** Brian Corrigan, *MSD*
12:40	**Lunch**
13:25	**Pharmaceutical Development/Quality** Brian Corrigan, *MSD*
14:30	**Module 3. An Agency Perspective** Mirza Catibusic*, Health Products Regulatory Authority (HPRA)*
15:35	**Break**
15:50	**Case Study 1. Chemistry & Pharmacy** Sally Steeden, *Biogen*
16:10	**Closing remarks of the day** Jayne Cook, *Abbvie Ltd*

Wednesday 1 April 2020

Chairperson: Bob Ibbotson, *Lucis Consulting Ltd.*

08:30 **Registration online**

08:55 **Opening and learning objectives presentation**
Bob Ibbotson, *Lucis Consulting Ltd.*

09:00 **Understanding the Need for Non Clinical Safety Studies**
Chris Powell**,** *GlaxoSmithKline*

10:10 **The Importance of Pharmacokinetics & Pharmacodynamics in Drug Development**
Helen Walker, *HW ClinPharm Ltd*

11:15 **Break**

11:30 **The Components of the Non-Clinical Section of a Marketing Authorisation Application**
David Jones, *Medicines and Healthcare products Regulatory Agency* (*MHRA)*

12:40 **Lunch**

13:30 **Clinical Drug Development, Paediatric Investigation Plans & the link with Regulatory Affairs**
Steve Pinder, *Envestia Ltd*

14:45 **Break**

14:50 **The Regulation of Clinical Trials in Europe – An Agency Perspective**
Gunilla Nielson*, Medical Products Agency (MPA)*

15:45 **The European Clinical Trials Process – Industry Perspective**
Shaila Choi, *KKSC Solutions Ltd*

16:25 **Break**

16:30 **The MAA – the perspective of an EU Regulatory Authority Clinical Assessor**
Jan Span, *Medicines Evaluation Board (MEB)*

17:30 **Case Study 2. Non-Clinical & Clinical Development**
Ming Ewe, *Freeline*

17:45 **Closing remarks of the day**
Bob Ibbotson, *Lucis Consulting Ltd.*

Thursday 2 Apr 2020

Chairperson: Niamh Lawler-Turner, *PharmaFind Ltd*

08:30 **Registration online**

09:00 **Opening and learning objectives presentation**
Niamh Lawler-Turner**,** *PharmaFind Ltd*

09:05 **The Centralised Procedure - Practical Industry Experience**
Jenny Horwood, *Pfizer*

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

11:15 **Break**

11:30 **EU Procedures and the Factors for Success – My Experience as a Pharmaceutical Assessor and Unit Manager**
Sue Harris, *ex-MHRA*

12:35 **Generic Applications & Biosimilars**
Pete Embley*, Bionical EMAS*

13:40 **Lunch**

14:30 **Regulatory Strategy Session Part 1:**

1. **Initial considerations – bigger picture & strategic thinking**
2. **Information protection**
3. **Think global**
4. **Regulatory/HTA advice**

David Kane, *Vertex Pharmaceuticals (Europe) Ltd*

15:30 **Break**

15:45 **Regulatory Strategy Session Part 2:**

1. **Paediatric development & PIPs**
2. **Orphans**
3. **Early access**
4. **Tradenames**

David Kane, *Vertex Pharmaceuticals (Europe) Ltd*

17:15 **Case Study 3. Regulatory Strategy**
David Kane, *Vertex Pharmaceuticals (Europe) Ltd*

17:30 **Closing remarks of the day**
Niamh Lawler-Turner**,** *PharmaFind Ltd*

Friday 3 Apr 2020

Chairperson: Luis Casanova, *Shionogi*

08:30	**Registration online**
09:00	**Opening and learning objectives presentation** Luis Casanova**,** *Shionogi*
09:05	**Lifecycle Management – Quality** Isabel Zwart, *Biogen*
10:10	**Lifecycle Management - Safety & Efficacy** Avni Pandhi, *Biogen*
11:15	**Break**
11:30	**Product Information – Regulation of the SmPC, PIL & label** Julia Coombes, *MHRA*
12:50	**Accurate, Balanced, Clear? The ABC of Medicines Advertising** Tannyth Cox, *Prescription Medicines Code of Practice Authority*
13:30	**Lunch**
14:15	**Health Technology Assessment: Why and where does the regulatory professional become involved?** Sara Lopes**,** *Shionogi*
15:05	**An Introduction to Biotechnology & Advanced Therapy Medicinal Products** Paul Smith, *MetisRA Consulting Ltd*
16:10	**Break**
16:15	**Case Study 4. Variations** Sanna Dean, *Abbvie Ltd*
16:30	**Questions and closing remarks** Luis Casanova**,** *Shionogi*