Programme

The TOPRA 45th Spring Introductory Course:

Introduction to Pharmaceutical Regulatory Affairs

28-31 March 2023

Coppid Beech Hotel, Bracknell, Berkshire, UK

Day 1

28 March 2023

Chairperson: Morning: Claire Beggs, Jazz Pharma, Afternoon: Zena Smith, Jazz Pharma

Day Co-ordinator: **Dima Al-Hadithi, Minaret Consulting Limited**

****All timings presented are BST**

08:00	**Registration**
08:30	**Welcome & Introduction to the course** Claire Beggs, Jazz Pharma
08:45	**New Product Development, The European Regulatory Environment & the Role of Regulatory Affairs** Steve Brookes, *Biogen*
09:45	**Overview of the MAA** Jenny Lamport, *1st Regulatory Ltd.*
10:45	**Break**
11.00	**Chemical Development/Quality** Brian Corrigan, *MSD*
12:00	**Lunch**
12:45	**Pharmaceutical Development/Quality** *Brian Corrigan, MSD*
13:45	**Module 3. An Agency Perspective** Mirza Ćatibušić*, Health Products Regulatory Authority (HPRA)*
14:45	**Panel Q&A and Closing Remarks** Zena, Smith, *Jazz Pharma*, Claire Beggs, *Chair*
15:00	**Case Study 1 Introduction and break**
15:30	**Case Study 1. Chemistry & Pharmacy** Zena Smith, *Jazz Pharma*
17:00	**End of day 1**
19:00	**Dinner**

Day 2

29 March 2023

Chairperson: Xavier Luria, *DDR Consultancy*

Day Co-ordinator:* Bob Ibbotson, *Shionogi BV

****All timings presented are BST**

08:30	**Understanding the Need for Non-Clinical Safety Studies** Chris Powell, *Cambridge Consulting*
09:30	**The Importance of Pharmacokinetics & Pharmacodynamics in Drug Development** 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, *Consultant*
11:35	**Non-Clinical Panel Discussion and Questions**
12:00	**Clinical Drug Development, Paediatric Investigation Plans & the link with Regulatory Affairs** Steve Pinder, *Envestia Ltd*
13:00	**Lunch**
13:45	**The Regulation of Clinical Trials in Europe – An Agency Perspective** Gunilla Andrew Nielsen, *MPA*
14:40	**The European Clinical Trials Process – Industry Perspective** Shaila Choi, *Seagen Ltd*
15:15	Tea/Coffee Break
15:25	**The MAA – the perspective of an EU Regulatory Authority Clinical Assessor** Jan Span, *Medicines Evaluation Board (MEB)*
16:10	**Clinical Panel Discussion and Questions**
16:30	***Case Study 2. Non-Clinical & Clinical Development*** Ming Ewe*, Smarter Biotech Solutions Limited*
18:30	**End of day 2**
19:00	**Dinner**

Day 3

30 March 2023

Chairperson: Niamh Lawler Turner, *University of Limerick*

Day Co-ordinator:* Ming Ewe, *Smarter Biotech Solutions Limited

****All timings presented are BST**

08:45 **The Centralised Procedure – Practical Industry Experience**
Will James, *Pfizer*

09:45 **The Mutual Recognition Procedure & the Decentralised Procedure – Practical Industry Experience**
Stephen Thompson*, S-Cubed*

10:45 **Break**

11:00 **Generics**
Andrew Modley, *Teva*

12:00 **Lunch**

13:00 **Regulatory Strategy Session Part 1:**

1. Initial considerations for Strategic Thinking
2. Think Global – Key considerations for Worldwide Markets
3. Regulatory/HTA Advice
4. Paediatric Development and PIPs

David Kane, *Vertex /* Neil Roberts*, Gilead*

14:15 **Break**

14:30 **Regulatory Strategy Session Part 2:**

5. Orphan Disease Considerations
6. Accelerating Access (Expedited Pathways)
7. Tradename
8. IP and Exclusivity Considerations

David Kane, *Vertex /* Neil Roberts*, Gilead*

15:45 **Closing remarks of the day**
Niamh Lawler-Turner, *University of Limerick*

16:00 **Case Study 3. Regulatory Strategy**
David Kane, *Vertex*

17:30 **End of day 3**

19:00 **Dinner**

Day 4
31 Mar 2023
Chairperson: Gwenaelle Pemberton, *Syncona Ltd*
Day Co-ordinator: Susanna Dean, *Apothecom Ltd*
****All timings presented are BST**

08:30	**Opening and learning objectives presentation** **Gwenaelle Pemberton,** *Syncona Ltd*
08:40	**Lifecycle Management – Quality** Richard Keane, *Biogen Idec Ltd.*
09.40	**Lifecycle Management – Safety & Efficacy** Kay Martin, *Biogen*
10:40	**Break**
10:55	**Product Information – Regulation of the SmPC, PIL & label** Julia Coombes, *MHRA*
12:10	**Q&A session** Panel: Richard Keane, Kay Martin, Julia Coombes
12:30	**Lunch**
13:15	**Case Study 4: Variations** Jenny Davies, *Haleon*
14:30	**Break**
14:45	**Health Technology Assessment: Why and where does the regulatory professional become involved?** Sara Lopes, *Shionogi BV*
15:15	**An Introduction to Biotechnology & Advanced Therapy Medicinal Products** Paul Smith, *MetisRA Consulting Ltd*
16:15	**The Future ahead in Regulatory Affairs: What to expect next** Laura Liebers, *Vertex Pharmaceuticals*
16:45	**Closing remarks** Gwenaelle Pemberton
17:00	**End of day 4**