Programme

The TOPRA 46th Spring Introductory Course:

Introduction to Pharmaceutical Regulatory Affairs

16 – 19 April 2024

ETC Venues

86 Edgware Road

London W2 2EA

Day 1

16 April 2024
Chairperson:
Dima Al-Hadithi, Minaret Consulting Limited
****All timings presented are BST**

08:00	**Registration**
08:30	**Welcome & Introduction to the course** TBC
08:45	**Lecture 1: New Product Development, The European Regulatory Environment & the Role of Regulatory Affairs** **Ming Ewe**
09:45	**Lecture 2: Overview of the MAA** Jenny Lamport, *1st Regulatory Ltd.*
10:45	**Break**
11.00	**Lecture 3: Chemical Development/Quality** Helene Syrett *MSD*
12:00	**Lunch**
12:45	**Lecture 4: Pharmaceutical Development/Quality** Helene Syrett *MSD*
13:45	**Lecture 5: Module 3. An Agency Perspective** Mirza Ćatibušić*, Health Products Regulatory Authority (HPRA)*
14:45	**Panel Q&A and Closing Remarks** All speakers
15:00	**Case Study 1 Introduction and break** Zena Smith, *Jazz Pharma*
15:30	**Case Study 1. Chemistry & Pharmacy**
17:00	**End of day 1**

Day 2

17 April 2024

Chairperson: Bob Ibbotson

Day Co-ordinator: **Shaila Choi**

Seagen International Gmbh

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08:30	**Lecture 6: Understanding the Need for Non-Clinical Safety Studies** Chris Powell, *Cambridge Consulting*
09:30	**Lecture 7: The Importance of Pharmacokinetics & Pharmacodynamics in Drug Development** Helen Walker, *HW ClinPharm Ltd*
10:30	**Tea/ coffee break**
10:45	**Lecture 8: 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	**Lecture 9: Clinical Drug Development, Paediatric Investigation Plans & the link with Regulatory Affairs** Steve Pinder, *Envestia Ltd*
13:00	**Lunch**
13:45	**Lecture 10: The Regulation of Clinical Trials in Europe – An Agency Perspective** Gunilla Andrew Nielson, *MPA*
14:40	**Lecture 11: The European Clinical Trials Process – Industry Perspective** Shaila Choi, *Seagen International Gmbh*
15:15	Tea/Coffee Break
15:25	**Lecture 12: 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*** Shaila Choi, *Seagen International Gmbh*
18:30	**End of day 2**

Day 3

18 April 2024

Chairperson: Niamh Lawler Turner, *University of Limerick*

****All timings presented are BST**

08:45 **Lecture 13: The Centralised Procedure – Practical Industry Experience**
Jenny Horwood, *Pfizer*/Will James, *Pfizer*

09:45 **Lecture 14: The Mutual Recognition Procedure & the Decentralised Procedure – Practical Industry Experience**
Stephen Thompson*, S-Cubed*

10:45 **Break**

11:00 **Lecture 15: Generics**
Andrew Modley, *Teva*

12:00 **Lunch**

13:00 **Lecture 16: Regulatory Strategy Session Part 1:**
Jens va Wijngaarden and Frank de Fries, *ProPharma Group*

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

14:15 **Break**

14:30 **Lecture 17: Regulatory Strategy Session Part 2:**
Jens va Wijngaarden and Frank de Fries, *ProPharma Group*

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

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

16:00 **Case Study 3. Regulatory Strategy**
Jens va Wijngaarden and Frank de Fries, *ProPharma Group*

17:30 **End of day 3**

Day 4
19 April 2024
Chairpersons: Christine Grew
Gabriela Fok, Ipsen
****All timings presented are BST**

08:30 **Opening and learning objectives presentation**
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08:40 **Lecture 18: Lifecycle Management – Quality**
Richard Keane, *Biogen Idec Ltd.*

09.40 **Lecture 19: Lifecycle Management – Safety & Efficacy**
Kay Martin, *Biogen*

10:40 **Break**

10:55 **Lecture 20: 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 **Lecture 21: Health Technology Assessment: Why and where does the regulatory professional become involved?**
Sara Lopes, *Shionogi BV*

15:30 **Lecture 22: An Introduction to Biotechnology & Advanced Therapy Medicinal Products**
Ming Ewe

16:30 **Lecture 23: The Future ahead in Regulatory Affairs: What to expect next**
Laura Liebers, *Vertex Pharmaceuticals*

17:00 **Closing remarks**
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17:15 **End of day 4**