Programme

The TOPRA 44th Spring Introductory Course:

Introduction to Pharmaceutical Regulatory Affairs

28-29 March and 4-5 April 2022

Online

Pre-recorded sessions

Dates: 14 March – 6 May 2022

**Delegates should listen to these before the course starts

Delegates will have an opportunity to ask questions during the course

Recommended for:	Session
Day 1 of the course	**Overview of the MAA** Jenny Lamport*, 1st Regulatory Ltd.*
Day 1 of the course	**Chemical Development/Quality** Brian Corrigan, *MSD*
Day 2 of the course	**Understanding the Need for Non Clinical Safety Studies** Chris Powell**,** *Consultant*
Day 2 of the course	**The Importance of Pharmacokinetics & Pharmacodynamics in Drug Development** Helen Walker, *HW ClinPharm Ltd*
Day 2 of the course	**The European Clinical Trials Process – Industry Perspective** Shaila Choi, *KKSC Solutions Ltd*
Day 2 of the course	**The MAA – the perspective of an EU Regulatory Authority Clinical Assessor** Jan Span, *Medicines Evaluation Board (MEB)*
Day 3 of the course	**Generic Applications & Biosimilars** Pete Embley*, Bionical EMAS*
Day 4 of the course	**Lifecycle Management – Quality** Richard Keane, *Biogen*
Day 4 of the course	**Health Technology Assessment: Why and where does the regulatory professional become involved?** Sara Lopes**,** *Shionogi*

Pre-programme

25 March 2022

****All timings presented are GMT**

9:30	**Registration online**
10:00	**Opening and Welcome from TOPRA**
10:15	**Q&A about the course**
10:45	**Networking session**
12:00	**End of the day**

Day 1

28 March 2022

Chairperson: Claire Beggs, *GW Pharma*

****All timings presented are GMT**

08:30 **Registration online**

09:00 **Welcome & Introduction to the course**
Claire Beggs, GW Pharma

09:15 **New Product Development, The European Regulatory Environment & the Role of Regulatory Affairs**
Steve Brookes, *Biogen*

10:20 **Panel Q&A**
Jenny Lamport, *1st Regulatory Ltd.*
Brian Corrigan, *MSD*
On-demand sessions that delegates should listen to:
- *Jenny Lamport - Overview of the MAA*
- *Brian Corrigan - Chemical Development/Quality*

11:00 **Break**

11:15 **Pharmaceutical Development/Quality**
Brian Corrigan, *MSD*

12:20 **Lunch**

13:15 **Module 3. An Agency Perspective**
Mirza Catibusic*, Health Products Regulatory Authority (HPRA)*

14:15 **Closing remarks of the day**
Claire Beggs, *GW Pharma*

14:30 **Break**

14:45 **Case Study 1. Chemistry & Pharmacy**
Dima Al-Hadithi, *Minaret Consulting Limited*

16:45 **End of day 1**

Day 2

29 March 2022

Chairperson: Bob Ibbotson, *Lucis Consulting Ltd.*

****All timings presented are GMT**

08:30 **Registration online**

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

09:00 **The Non-Clinical MAA and CTA Dossier – Advice from a former Assessor**
David Jones, *Consultant, ex-MHRA*

10:00 **Non-clinical Panel Q&A**
David Jones, *Consultant, ex-MHRA*
Chris Powell, *Consultant*
Helen Walker, *HW ClinPharm Ltd*
On-demand sessions that delegates should listen to:

- *Chris Powell - Understanding the Need for Non-Clinical Safety Studies*
- *Helen Walker - The Importance of Pharmacokinetics & Pharmacodynamics in Drug Development*

10:45 **Break**

11:00 **Clinical Drug Development, Paediatric Investigation Plans & the link with Regulatory Affairs**
Steve Pinder, *Envestia Ltd*

12:00 **The Regulation of Clinical Trials in Europe – An Agency Perspective**
Gunilla Nielson, *Medical Products Agency (MPA)*

12:45 **Clinical Panel Q&A**
Shaila Choi, *Seagen Ltd*
Gunilla Nielson*, Medical Products Agency (MPA)*
Steve Pinder, *Envestia Ltd*
Jan Span, *Medicines Evaluation Board (MEB)*
On-demand sessions that delegates should listen to:

- *Jan Span - The MAA – the perspective of an EU Regulatory Authority Clinical Assessor*
- *Shaila Choi - The European Clinical Trials Process – Industry Perspective*

13:25 **Closing remarks of the day**
Bob Ibbotson, *Lucis Consulting Ltd.*

13:30 **Lunch**

14:30 **Case Study 2. Non-Clinical & Clinical Development**
Ming Ewe, *Regulatory Consultant*

16:30 **End of day 2**

Day 3

4 April 2022

Chairperson: Jane Nicholson

****All timings presented are GMT**

08:30 **Registration online**

08:55 **Opening and learning objectives presentation**
Jane Nicholson

09:00 **The Centralised Procedure – Practical Industry Experience**
Jenny Horwood, *Pfizer*

10:00 **Break**

10:15 **The Mutual Recognition Procedure & the Decentralised Procedure – Practical Industry Experience**
Pete Embley*, Bionical EMAS*

11:15 **Panel Q&A**
Jenny Horwood, *Pfizer*
Pete Embley*, Bionical EMAS*
On-demand sessions that delegates should listen to:
- *Pete Embley - Generic Applications & Biosimilars*

11:45 **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 /* Neil Roberts*, Gilead*

12:45 **Lunch**

13:45 **Regulatory Strategy Session Part 2:**
1. **Paediatric development & PIPs**
2. **Orphans**
3. **Early access**
4. **Tradenames**

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

15:00 **Closing remarks of the day**
Jane Nicholson

15:15 **Break**

15:30 **Case Study 3. Regulatory Strategy**
David Kane, *Vertex*

16:30 **End of day 3**

Day 4

5 April 2022

Chairperson: Sanna Dean, *Apothecom Ltd*

****All timings presented are GMT**

08:30 **Registration online**

08:45 **Opening and learning objectives presentation**
Susanna Dean, *Apothecom Ltd*

08.50 **Lifecycle Management – Safety & Efficacy**
Kay Martin, *Biogen*

10:20 **Q&A session**
On-demand sessions that delegates should listen to:

- Richard Keane - *Lifecycle Management – Quality*
- Sara Lopes - *Health Technology Assessment: Why and where does the regulatory professional become involved?*

11:00 **Break**

11:15 **Product Information – Regulation of the SmPC, PIL & label**
Julia Coombes, *MHRA*

12:30 **Lunch**

13:15 **An Introduction to Biotechnology & Advanced Therapy Medicinal Products**
Paul Smith, *MetisRA Consulting Ltd*

14:15 **Future of the Pharmaceutical Industry/Regulatory**
Laura Liebers, *Vertex Pharmaceuticals*

14:45 **Inspections**
Robert Ibbotson, *Lucis Consulting*

15:15 **Break**

15:30 **Case Study 4 introduction**
Jenny Davies, *Jenny Davies Regulatory Services Ltd*

15:45 **Case Study 4. Variations**

17:15 **Closing remarks**
Susanna Dean, *Apothecom Ltd*

17:30 **End of day 4 and the course**