Programme

The TOPRA 43rd Spring Introductory Course:

Introduction to Pharmaceutical Regulatory Affairs

April 2021

Online

Pre-recorded sessions

Dates: 29 March – 29 April 2021

**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 Regulation of Clinical Trials in Europe – An Agency Perspective** Gunilla Nielson*, Medical Products Agency (MPA)*
Day 2 of the course	**The European Clinical Trials Process – Industry Perspective** Shaila Choi, *KKSC Solutions Ltd*
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	**Accurate, Balanced, Clear? The ABC of Medicines Advertising** Tannyth Cox, *Prescription Medicines Code of Practice Authority*
Day 4 of the course	**Health Technology Assessment: Why and where does the regulatory professional become involved?** Sara Lopes**,** *Shionogi*

Pre-programme

9 April 2021

****All timings presented are GMT**

11:45	**Registration online**
12:00	**Opening and Welcome from TOPRA** Samantha Cooper, *TOPRA*
12:15	**Q&A about the course**
12:45	**Networking session**
14:00	**End of the day**

Day 1

14 April 2021

Chairperson: Jayne Cook, *Abbvie Ltd*

****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*

10:50 **Break**

11:00 **Pharmaceutical Development/Quality**
Brian Corrigan, *MSD*

12:05 **Lunch**

13:00 **Module 3. An Agency Perspective**
Mirza Catibusic*, Health Products Regulatory Authority (HPRA)*

14:00 **Closing remarks of the day**
Jayne Cook, *Abbvie Ltd*

14:15 **Case study Introduction**
Dima Al-Hadithi, *Minaret Consulting Limited*

14:30 **Break**

14:45 **Case Study 1. Chemistry & Pharmacy**

16:45 **End of day 1**

Day 2

15 April 2021

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

10:15 **Non-clinical Panel Q&A**
David Jones, *Medicines and Healthcare products Regulatory Agency* (*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 MAA – the perspective of an EU Regulatory Authority Clinical Assessor**
Jan Span, *Medicines Evaluation Board (MEB)*

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:

- *Gunilla Nielson - The Regulation of Clinical Trials in Europe – An Agency Perspective*
- *Shaila Choi - The European Clinical Trials Process – Industry Perspective*

13:10 **Closing remarks of the day**
Bob Ibbotson, *Lucis Consulting Ltd.*

13:15 **Introduction to Case Study 2. Non-Clinical & Clinical Development**

13:30 **Lunch**

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

16:45 **End of day 2**

Day 3

26 April 2021

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**
Natalie Schmidt, *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**
Natalie Schmidt, *Pfizer*
Pete Embley*, Bionical EMAS*
On-demand sessions that delegates should listen to:
- *Pete Embley - Generic Applications & Biosimilars*

11:30 **Break**

11:40 **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*

12:40 **Lunch**

13:40 **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

27 April 2021

Chairperson: Claire Beggs, *GW Pharmaceuticals*

****All timings presented are GMT**

08:30 **Registration online**

09:00 **Opening and learning objectives presentation**

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

10:35 **Q&A session**
On-demand sessions that delegates should listen to:

- *Lifecycle Management – Quality*
- *Accurate, Balanced, Clear? The ABC of Medicines Advertising*
- *Health Technology Assessment: Why and where does the regulatory professional become involved?*

11:15 **Break**

11:30 **Product Information – Regulation of the SmPC, PIL & label**
Julia Coombes, *MHRA*

12:15 **Lunch**

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

14:15 **Closing remarks**

14:30 **Case Study 4 introduction**

14:45 **Break**

15:00 **Case Study 4. Variations**
Sanna Dean, *Apothecom Ltd*

16:30 **End of day 4**