Module 7: Regulatory Strategy for Established Active Substances
1st – 3rd April 2025
TOPRA- 6th Floor, 3 Harbour Exchange Square, London E14 9GE

Module Leader(s): **Orlaith Ryan, Eva Kopecna**
Date: Tuesday 1st April 2025

Time	Activity	Speaker
13.00 – 13.15	Welcome & Introduction to the Module	**Orlaith Ryan**
	UNDERSTANDING THE NEED FOR STRATEGY FOR ABRIDGED APPLICATIONS	
13.15 – 14.00	Lecture 1: Commercial Importance of Submissions for Established Active Substances	**Orlaith Ryan** *Shorla Oncology*
	REGULATORY PROCEDURES IN THE EU AND US DEVISING YOUR STRATEGY	
14.00 – 14:45	Lecture 2: Planning Your Strategy: Choice of Procedure, Legal Basis and Achieving Agency Agreement	**Cait Brennan** *Chanelle Pharmaceuticals*
14:45 - 15:30	Lecture 3: Developing a Regulatory Strategy for a Generic Product in the EU	**Adrian Andrews** *Teva*
15:30 - 16:30	Lecture 4: Legal Perspective on Regulatory Data Protection	**Sarah Faircliffe** *Bird and Bird*
16:30 – 17:30	Lecture 5: Submission for Established Active Substances in the USA	**Bob Clay** *Highbury Regulatory Services*

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Date: Wednesday 2nd April 2025

Time	Activity	Speaker
09.00 – 09.15	Chairman's Introduction	**Eva Kopecna** **Acino Confirmed**
REGULATORY PROCEDURES IN THE EU AND DEVISING YOUR STRATEGY		
09.15 – 10.00	Lecture 6: Line extension strategies to enhance market exclusivity	**Ruchika Sharma** *Shorla Oncology*
10.00 - 10.30	**Refreshment Break**	
10.30 – 12.00	Lecture 7: Developing a Regulatory Strategy for an OTC Product	**Dr Eva Kopecna** *Acino International*
12.00 – 13.00	**Lunch**	
PATENT AND EXCLUSIVITY CONSIDERATIONS FOR ESTABLISHED ACTIVE SUBSTANCES		
13.00 – 14.00	Case Study 1: Repurposing Established Active Substances	**Teresa Doyle** *Shorla Oncology*
14.00 – 15:00	Lecture 8: Patent and Exclusivity Considerations for Abridged Drug and Biologic Applications in the USA?	**Sara Koblitz** *Hyman, Phelps & McNamara, P.C.*

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Date: Thursday 3rd April 2025

Time	Activity	Speaker
08:45 – 09:00	Chairman's Introduction	**Orlaith Ryan**
	EU GENERIC PRODUCTS	
09:00– 09:45	Lecture 9: Planning your Bioavailability Study – and do you need one?	**Anders Fuglsang** *Fuglsang Pharma*
09:45 – 10.15	**Refreshment Break**	
10.15 – 11.00	Lecture 10: Bibliographic Applications for Well Established Active Substances	**Valerie Policar** *PPD* *Part of Thermo Fisher Scientific*
11:00-12:00	Lecture 11: Applications for Established Active Ingredients – A Regulatory Agency's Experience'	**Jon Sisson** *Transcrip Group*
12:00 – 13:00	**Lunch**	
	EU – WELL ESTABLISHED SUBSTANCES	
13:00 – 14:30	Case Study 2: Strategy for Established Active Substances	**Dr Eva Kopecna** *Acino International*
14:30 – 15:30	Lecture 12: Patent Issues to be Aware of in Planning Regulatory Strategy for Established Active Substances	**Farida Alayan**