Module 7: Regulatory Strategy for Established Active Substances
1st – 3rd April 2025

Location: Lincoln Plaza Hotel, Lincoln Place, London E14 9NN, UK

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	Lecture 8: Patent Issues to be Aware of in Planning Regulatory Strategy for Established Active Substances	TBC
14.00 – 15:00	Lecture 9: Patent and Exclusivity Considerations for Abridged Drug and Biologic Applications in the USA?	Sara Koblitz Hyman, Phelps & McNamara, P.C.
15:00 – 15.30	**Refreshment Break**	
15.30 - 16.30	Case Study 1: Repurposing Established Active Substances	Teresa Doyle Shorla Oncology

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Date: Thursday 3rd April 2025

08:45 – 09:00	Chairman's Introduction	Orlaith Ryan
	EU GENERIC PRODUCTS	
09:00– 09:45	Lecture 10: Planning your Bioavailability Study – and do you need one?	Anders Fuglsang Fuglsang Pharma
09:45 – 10.15	**Refreshment Break**	
10.15 – 11.00	Lecture 11: Bibliographic Applications for Well Established Active Substances	Valerie Policar PPD Part of Thermo Fisher Scientific
11:00-12:00	Lecture 12: 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 – 13:45	Case Study 2: Strategy for Established Active Substances Part 1	Dr Eva Kopecna Acino International
13:45 - 14:00	**Module Close**	