Module 7: Regulatory Strategy for Established Active Substances
12th - 14th October 2022

Location: TOPRA Office, 6th Floor, 3 Harbour Exchange, London, E14 8GE and online

Module Leader(s): Orlaith Ryan, Eva Kopecna

Date: Wednesday 12th October 2022

Time	Activity	Speaker
13.00 – 13.15	Welcome & Introduction to the Module	Orlaith Ryan
REGULATORY PROCEDURES IN THE EU AND DEVISING YOUR STRATEGY		
13.15 – 14.15	Lecture 1: Commercial Importance of Submissions for Established Active Substances	Orlaith Ryan Shorla Pharma
14.15 – 14.45	**Refreshment Break**	
UNDERSTANDING THE NEED FOR STRATEGY FOR ABRIDGED APPLICATIONS		
14.45 – 15.30	Lecture 2: Planning Your Strategy: Choice of Procedure, Legal Basis and Achieving Agency Agreement	Cait Brennan Chanelle Pharmaceuticals
15.30 - 16.15	Lecture 3: Patent and Exclusivity Considerations for Abridged Drug and Biologic Applications in the USA?	Kurt Karst Hyman, Phelps & McNamara, P.C.
16.15 - 17.15	Lecture 4: Legal Perspective on Regulatory Data Protection	Sarah Faircliffe Bird and Bird

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Date: Thursday 13th October 2022

Time	Activity	Speaker
09.00 – 09.15	Chairman's Introduction	Eva Kopecna
	REGULATORY PROCEDURES IN THE EU AND DEVISING YOUR STRATEGY	
09.15 – 10.00	Lecture 5: Patent Issues to be Award of in Planning Regulatory Strategy for Established Active Substances	William Smith Bird and Bird
10.00 - 10.30	**Refreshment Break**	
10.30 – 12.00	Case Study 1: Determination of the Legal Basis for Abridged Applications	Maria McCarra Eli Lily
12.00 – 13.00	**LUNCH**	
	EU and US – GENERIC PRODUCTS	
13.00 – 14.00	Lecture 6: Developing a Regulatory Strategy for a Generic Product in the EU	Andrew Modley Teva
14.00 - 15.00	**Refreshment Break**	
15.00 – 16.00	Lecture 7: Submission for Established Active Substances in the USA	Bob Clay Highbury Regulatory Services
16.00 - 16.45	Lecture 8: Planning your Bioavailability Study – and do you need one?	Anders Fuglsang Fuglsang Pharma

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Date: Friday 14th October 20223

09.00 – 09.15	Chairman's Introduction	Orlaith Ryan
	EU Generic Products	
09.15 – 10.00	Lecture 8: Planning your Bioavailability Study – and do you need one?	Anders Fuglsang Fuglsang Pharma
10:00 – 10.30	**Refreshment Break**	
10.30 – 11.15	Lecture 9: Developing a Regulatory Strategy for an OTC Product	Dr Eva Kopecna Acino International
10.45 – 11.45	Lecture 10: Bibliographic Applications for Well Established Active Substances	James McCormick PPDI
11.45 – 12.45	**Lunch**	
	EU – WELL ESTABLISHED SUBSTANCES	
12.45 – 14.30	Case Study 2: Strategy for Established Active Substances Part 1	Dr Eva Kopecna Acino International
14.30 - 15.30	**Refreshment Break**	
15.30 – 16.30	Lecture 11: Applications for Established Active Ingredients – A Regulatory Agency's Experience'	Jonathan Sissons MHRA