Module 7: Regulatory Strategy for Established Active Substances

Location: TOPRA Office and online

Module Leader(s): Orlaith Ryan, Eva Kopecna

Date:

Time	Activity	Speaker
14.30 – 14.45	Welcome & Introduction to the Module	Orlaith Ryan Shorla Oncology
REGULATORY PROCEDURES IN THE EU AND DEVISING YOUR STRATEGY		
14.45 – 15.30	Lecture 1: Commercial Importance of Submissions for Established Active Substances	Orlaith Ryan Shorla Oncology
15.30 - 16.15	Lecture 3: Developing a Regulatory Strategy for a Generic Product in the EU	Andrew Modley Teva
16.15 - 17.15	Lecture 4: Legal Perspective on Regulatory Data Protection	Sarah Faircliffe Bird and Bird

Module 7: Regulatory Strategy for Established Active Substances

Date:

Time	Activity	Speaker
09.00 – 09.15	Chairman's Introduction	Eva Kopecna Acino
	REGULATORY PROCEDURES IN THE EU AND DEVISING YOUR STRATEGY	
09.15 – 10.00	Lecture 5: Patent Issues to be Aware of in Planning Regulatory Strategy for Established Active Substances	Chris de Mauny Bird and Bird (Remote)
10.00 - 10.30	**Refreshment Break**	
10.30 – 12.00	Case Study 1: Repurposing Established Active Substances	Isobel Finan Shorla Oncology
12.00 – 13.00	**LUNCH**	
	US STRATEGY FOR ESTABLISHED ACTIVE SUBSTANCES	
13.00 – 14.00	Lecture 6: Submission for Established Active Substances in the USA	Bob Clay Highbury Regulatory Services
14.00 - 14.30	**Refreshment Break**	
14.30 – 15.30	Lecture 7: Patent and Exclusivity Considerations for Abridged Drug and Biologic Applications in the USA?	Sara Koblitz Hyman, Phelps & McNamara, P.C. (Remote)
15.30 - 16.30	Lecture 8: Pricing and Reimbursement Considerations and Strategy for Established Active Substances in US	Howard Tag Tag & Associates (Remote)

09.00 – 09.15	Chairman's Introduction	Orlaith Ryan Shorla Oncology
	EU GENERIC PRODUCTS	
09.15 – 10.00	Lecture 9: Planning your Bioavailability Study – and do you need one?	Anders Fuglsang Fuglsang Pharma (Remote)
10:00 – 10.15	**Refreshment Break**	
10.15 – 11.15	Lecture 10: Developing a Regulatory Strategy for an OTC Product	Dr Eva Kopecna Acino International
11:15 – 12:00	Lecture 11: Bibliographic Applications for Well Established Active Substances	Valerie Policar PPD Part of Thermo Fisher Scientific (Remote)
12:00 – 12.45	**Lunch**	
	EU – WELL ESTABLISHED SUBSTANCES	
12.45 – 14.30	Case Study 2: Strategy for Established Active Substances	Dr Eva Kopecna Acino International
14.30 - 15.00	**Refreshment Break**	
15.00 – 16.00	Lecture 12: Regulatory Strategy for Gaining Approval of Clinical Indications for Existing & New Marketing Authorisation Applications	Muhammad Bashir GSK