Module 7: Regulatory Strategy for Established Active Substances

Location: London, UK and online

Module Leader(s): Orlaith Ryan, Eva Kopecna

Date: Tuesday 1 April 2025

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

Module 7: Regulatory Strategy for Established Active Substances

Date: Wednesday 2 April 2025

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

Date: Thursday 3 April 2025

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