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

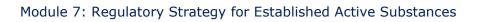
14.45 - 15.30	Lecture 1: Commercial Importance of Submissions for Established Active Substances	Orlaith Ryan Shorla Oncology
15.30 - 16.15	Lecture 3: Developing a Regulatory Strategy for a Generic Product in the EU	Andrew Modley Teva
16.15 - 17.15	Lecture 4: Legal Perspective on Regulatory Data Protection	Sarah Faircliffe Bird and Bird



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)		

Date: Friday 14th October 2022





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				
	EU GENERIC PRODUCTS Lecture 9: Planning your Bioavailability Study – and do you need one? Refreshment Break Lecture 10: Developing a Regulatory Strategy for an OTC Product Lecture 11: Bibliographic Applications for Well Established Active Substances Lunch WELL ESTABLISHED SUBSTAI Case Study 2: Strategy for Established Active Substances Refreshment Break Lecture 12: Regulatory Strategy for Gaining Approval of Clinical Indications for Existing & New Marketing				