Module 7: Regulatory Strategy for Established Active Substances
23rd – 25th September 2020

Location: Online

Module Leader(s): Orlaith Ryan, Eva Kopecna

Date: Wednesday 23rd September 2020

Time	Activity	Speaker
16.00	Registration	
16.30	Welcome & Introduction to the Module	Orlaith Ryan
	UNDERSTANDING THE NEED FOR STRATEGY FOR ABRIDGED APPLICATIONS	
16.30 – 17.15	Lecture 1: Commercial Importance of Submissions for Established Active Substances	Cait Brennan Chanelle Pharmaceuticals
	REGULATORY PROCEDURES IN THE EU AND DEVISING YOUR STRATEGY	
17.15 – 18.00	Lecture 2: Planning Your Strategy: Choice of Procedure, Legal Basis and Achieving Agency Agreement	Orlaith Ryan Shorla Pharma

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Date: Thursday 24th September 202-

Time	Activity	Speaker
08.30 – 08.45	Chairman's Introduction	Orlaith Ryan
	REGULATORY PROCEDURES IN THE EU AND DEVISING YOUR STRATEGY	
08.45– 09.30	Lecture 3: Harmonisation of the Product Information	Paul Marshall DLRC
09.30 – 10.30	Lecture 4: Legal Perspective on Regulatory Data Protection	Sarah Faircliffe Bird and Bird
10.30 – 11.00	**Refreshment Break**	
11.00 – 11.45	Lecture 5: Options for Abridged Applications: Line Extension, Hybrid Application or Variation	To be announced
11.45 – 12.30	Lecture 6: Patent Issues to be Aware of in Planning Regulatory Strategy for Established Active Substances	William Smith Bird and Bird
12.30 – 13.30	**LUNCH**	
13.30 – 16.00	Case Study 1: Determination of the Legal Basis for Abridged Applications	Meg McCarthy
16.00 – 16.30	**Refreshment Break**	
	EU and US – GENERIC PRODUCTS	
16.30 – 17.15	Lecture 7: Developing a Regulatory Strategy for a Generic Product in the EU	Andrew Modley Teva
17.15 – 18.00	Lecture 8: Submission for Established Active Substances in the USA	To be announced

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Date: Friday 25th September 2020

08.30 – 08.45	Chairman's Introduction	Orlaith Ryan
	EU Generic Products	
08.45 – 09.30	Lecture 9: Planning your Bioavailability Study – and do you need one?	Dejan Krajcar LEK
09.30 – 10.15	Lecture 10: Developing a Regulatory Strategy for an OTC Product	Dr Eva Kopecna Acino International
10:15 – 10.45	Refreshment Break and Check Out	
10.45 – 11.45	Lecture 11: Bibliographic Applications for Well Established Active Substances	James McCormick PPDI
	EU – WELL ESTABLISHED SUBSTANCES	
11.45 – 12.30 **Lecture 10**	Lecture 12: Applications for Established Active Ingredients – A Regulatory Agency's Experience'	To be announced
12.30 – 13.30	Lunch	
13.30 – 16.00	Case Study 2: Strategy for Established Active Substances	Dr Eva Kopecna Acino International
16.00	Close of Module	