BPCI CMC Regulatory Affairs Training 15th to 16th September 2022

AGENDA

Day 1 Preapproval Regulatory Affairs

Topic	Time	Speaker
Introduction	08:30 to 08:45	Siobhán Dean Biopharmachem Ireland
EU Pharmaceutical Legislation & EU Regulatory Systems (Centralised Procedure, MR & National	08:50 to 09:50	Anne Marie Mannion A.M Consultancy
Registration of APIs (including CEPs)	09:55 to 10:55	Dr. Colette Rohan Director of Regulatory Affairs, McKesson Northstar, Cork
Coffee	11:00 to 11:15	
CTD: Drug Substance Small Molecule	11:15 to 11:45	Maria McCarra, Regulatory Affairs Scientist Eli Lilly Ltd.
CTD: Drug Substance Large Molecule	11:50 to 12:15	TBC
Advanced Therapies Special Consideration	12:20 to 13:00	Meg Leahey Senior Director Global CMC Biologics Sanofi
Lunch	13:00 to 13:30	
CTD: Drug Product	**13:30 to 14:30**	Meg McCarthy, PRSI Ltd
FAQ	14:35 to 17:00	All

Day 2, .Post Approval Regulatory Affairs

Topic	Time	Speaker
Introduction	08:30 to 08:45	Siobhán Dean BioPharmaChem Ireland
Common Deficiencies in CMC part of Application	**08:50- 09:50**	**Mirza Catibusic, The HPRA**
EU Variations and Industry Experience with Variations	09:55 – 10:55	Helen Crowley Regulatory & PPV Manager, Eamonn McGowran Strategic Regulatory and Quality Advisor Kora Healthcare
Coffee	11:00 to 11: 15	
Common Issues with Variations and Batch Specific Requests	**11:15 to 12:45**	**Mirza Catibusic, The HPRA**
Lunch	12:45 to 13:30	
US Pharmaceutical Legislation & Submissions	13:30 to 14:00	Meg McCarthy, PRSI Ltd
US Post Approval Changes	14:05 to 14:35	TBC Meg Leahey Senior Director Global CMC Biologics Sanofi
FAQ	**14:40 to 15:30**	**All**