BPCI CMC Regulatory Affairs Training Programme

Tuesday 2nd and Wednesday 3rd October

Clayton Hotel Silver Springs, Tivoli, Co. Cork
(Google Maps location)

This is the 11th CMC Regulatory Affairs training course that BPCI have run. We are indebted to the HPRA as well as our industry speakers for the significant time and input they have provided in the design of the programme. It will address some common mistakes that are made with change variations and give some valuable industry insights from people who are working on these submissions first hand. The key EU/US legislation and regulatory systems for drug/biologic approval and change submission is also covered, along with some more advanced topics. This course is aimed for people who would like to update their regulatory affairs knowledge and for those who are interested in moving into the space.

Day 1: 02nd Oct. Pre-Approval Regulatory Affairs

Topic	Time	Speaker
Registration	08:45 to 09 30	All
Introduction	09:30 to 09:45	Enda Dempsey, BPCI
EU Pharmaceutical Legislation & EU Regulatory Systems (Centralised Procedure, MR & National	09:45 to 10:30	Anne Marie Mannion A.M Consultancy
Registration of APIs (including CEPs)	10:30 to 11:30	Meg McCarthy, Pharma QA Services Ltd.
Coffee	11:30 to 12:00	All
CTD: Drug Substance Small Molecule	12:00 to 13:00	Maria McCarra, Regulatory Affairs Manager, Recordati Ireland Ltd.
CTD: Drug Substance Large Molecule	13:00 to 14:00	Brian Corrigan, MSD
Lunch	14:00 to 14:30	
CTD: Drug Product	14:30 to 15:30	Mirza Catibusic, HPRA
Workshop: Choosing an Application Route	15:30 to 16:30	All
Q&A	16:30 to 17:00	All
Evening Meal	19:30 to 12:00	All

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Day 2: 03rd Oct. Post-Approval Regulatory Affairs

Topic	Time	Speaker
Common Deficiencies in CMC part of Application	08:30 - 09:30	Mirza Catibusic, HPRA
EU Variations and Industry Experience with Variations	09:30 – 10:30	Fionnuala Newton, Site Change Co-Ordinator, Novartis & Meg McCarthy, Pharma QA Services Ltd.
Coffee	10:30 to 11:00	All
Common Issues with Variations	11:00 to 12:00	Mirza Catibusic, HPRA
Brexit	12:00 to 13:00	Victor Cowper and Jon Jeffery, Pharmalex
Lunch	13.00 to 13:30	All
US Pharmaceutical Legislation & Submissions	13:30 to 14:30	Meg McCarthy, Pharma QA Services Ltd.
US Post Approval Changes	14:30 to 15:30	Orlaith O'Brien, Senior Consultant, Shorla Consulting
FAQ	15:30 to 16:00	All

Day 2: Post Approval Regulatory Affairs