Module 3: Regulatory Requirements for a New Active Substance: Quality
2 - 4 February 2022

TOPRA Office, 6th Floor, 3 Harbour Exchange, London, E 14 9GE, UK

Module Leader(s): **Karen Foster**

Date: Wednesday 2nd February

Time	Activity	Speaker
13.00	Registration	
13.15 – 13.30	Welcome & Introduction to Module 3	Karen Foster Module Leader
	Management in Regulatory Affairs	
13.30 – 14.30	Lecture 1: CMC in the Drug Development Programme	Mike James Cambridge Regulatory
14.30 - 15.00	Refreshment Break	
15.00 – 16.00	Lecture 2: API Manufacture and In-Process Controls	Mike James Cambridge Regulatory
16.00 – 17.00	Lecture 3: Nomenclature and Characterisation of the Active Ingredient	Christian Maasch Takeda
17.00 – 18.00	Lecture 4: CMC Project Management	Christian Maasch Takeda

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Date: Thursday 3rd February

Time	Activity	Speaker
09.00 – 10.00	Lecture 5: Analytical Methods and Validation	George Vine P&G Personal Health
10.00 – 10.30	Refreshment Break	
10.30 – 11.30	Lecture 6: Developing Specifications for the Active Ingredient	Karen Foster P&G Personal Health
11.30 – 12.30	Lecture 7: Pharmaceutical Development and Manufacture of the Drug Product	Tahir Nazir AstraZeneca
12.30 – 13.30	**LUNCH**	
13.30 – 15.00	Case Study 1 with discussions and presentations	
15.30 – 16.00	Refreshment Break	
16.00 – 17.00	Lecture 8: Stability of the Drug product	Tahir Nazir AstraZeneca

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09.00 – 10.00	Lecture 9: Good Manufacturing Practice – Clinical Supply	Anne Radmall AstraZeneca
10.00 – 10.30	Refreshment break	
10.30 – 11.30	Lecture 10: Pharmaceutical Packaging	Torsten Kneuss Bayer
11.30 – 13.00	Case Study 2	
13.00 – 13.30	**LUNCH**	
13.30 – 14.30	Lecture 11: Regulatory Agency Perspective	Elspeth Gray MHRA
14.30 -15.00	Closing	