Module 3: Regulatory Requirements for a New Active Substance: Quality
4th – 6th December 2019

De Vere Latimer Estate, Church Lane, HP5 1UG Chesham, UK

Module Leader(s): **Per Niklasson**

Date: Wednesday 4th December

Time	Activity	Speaker
16.15	Registration	
16.30 – 16.45	Welcome & Introduction to Module 3	Per Niklasson, Per AstraZeneca
	Management in Regulatory Affairs	
16.45 – 17.45	Lecture 1: CMC in the Drug Development Programme	Mike James Cambridge Regulatory
17.45 – 18.45	Lecture 2: API Manufacture and In-Process Controls	Mike James Cambridge Regulatory
18.45	New Student Tutorial	Dr Laura Brown Course Director
19.30	**Dinner**	

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Date: Thursday 5th December

Time	Activity	Speaker
09.00 – 10.00	Lecture 3: Nomenclature and Characterisation of the Active Ingredient	Christian Maasch Takeda
10.00 – 10.30	Refreshment Break	
10.30 – 11.30	Lecture 4: Analytical Methods and Validation	Craig Donnelly ICON
11.30 – 12.30	Lecture 5: Developing Specifications for the Active Ingredient	Craig Donnelly ICON
12.30 – 13.30	**LUNCH**	
13.30 – 14.30	Lecture 6: CMC Project Management	Christian Maasch Takeda
14.30 – 16.30	Case Study 1 with discussions and presentations with refreshment break	Per Niklasson AstraZeneca
16.30 – 17.30	Lecture 7: Pharmaceutical Development and Manufacture of the Drug Product	Tahir Nazir AstraZeneca
17.30 – 1815	Lecture 8: Stability of the Drug product	Tahir Nazir AstraZeneca
19.00	Dinner	

Date: Friday 6th December

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	Per Niklasson AstraZeneca
13.00 – 13.30	**LUNCH**	
13.30 – 14.30	Lecture 11: Regulatory Agency Perspective	TBC
14.30 -15.00	Closing remarks and departure	Per Niklasson AstraZeneca