Module 3: Regulatory Requirements for a New Active Substance: Quality

10/02/2026-12/02/2026

Location: NHOW FRANKFURT, BRÜSSELER STRAßE 1-3, D-60327 FRANKFURT AM MAIN
Module Leader: Christian Maasch
Date: Tuesday 10th

Time	Activity	Speaker
13.00 - 13.15	Registration	
13.15 – 13.30	Welcome & Introduction to Module 3	**Christian Maasch** Takeda
	Management in Regulatory Affairs	
13.30 – 14.30	Lecture 1: CMC in the Drug Development Programme	**TBC** The Force CT
14.30 - 15.00	**Refreshment Break**	
15.00 – 16.00	Lecture 2: API Manufacture and In-Process Controls	**TBC** The Force CT
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
18.00	**Close**	

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Date: Wednesday 11th

Time	Activity	Speaker
09.00 – 10.00	Lecture 5: Analytical Methods and Validation	**TBC** BioNTech
10.00 – 10.30	**Refreshment Break**	
10.30 – 11.30	Lecture 6: Developing Specifications for the Active Ingredient	**Christian Maasch** Takeda
11.30 – 12.30	Lecture 7: Pharmaceutical Development and Manufacture of the Drug Product	**Torsten Kneuss** Bayer
12.30 – 13.30	**LUNCH**	
13.30 – 15.30	Case Study 1 with discussions and presentations	**Christian Maasch** Takeda
15.30 – 16.00	**Refreshment Break**	
16.00 – 17.00	Lecture 8: Stability of the Drug product	**Torsten Kneuss** Bayer

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Date: Thursday 12th

Time	Activity	Speaker
09.00 – 10.00	Lecture 9: Pharmaceutical Packaging	**Torsten Kneuss** Bayer
10.00 – 10.30	**Refreshment break**	
10.30 – 12.00	Case Study 2 (Packaging)	**Torsten Kneuss** Bayer
12.00 – 13.00	Lecture 10: Good Manufacturing Practice – Clinical Supply and Regulatory Considerations	**Robert Schultz-Heienbrok** Charité CRO
13.00 – 13.30	**LUNCH**	
13.30 – 14.30	Lecture 11: Regulatory Agency Perspective	**TBC**
14.30 -15.00	**Closing**	