Module 3: Regulatory Requirements for a New Active Substance: Quality
10th Feb 2026 – 12th Feb 2026,

Nhow Hotel in Frankfurt, Brüsseler Str. 1-3, 60327 Frankfurt am Main

Module Leader(s): **Christian Maasch**

Date: Tuesday 10th Feb

Time	Activity	Speaker
13.00	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	**Ruxandra Ionescu** **ProPharma Group**
14.30 - 15.00	Refreshment Break	
15.00 – 16.00	Lecture 2: API Manufacture and In-Process Controls	**Ruxandra Ionescu** **ProPharma Group**
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: Wednesday 11th Feb

Time	Activity	Speaker
09.00 – 10.00	Lecture 5: Analytical Methods and Validation	**In-person or remote** **Eurofins**
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,** **Torsten Kneuss ,** **other Speakers**
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 Feb

09.00 – 10.00	Lecture 8: Pharmaceutical Packaging	**Torsten Kneuss Bayer**
10.00 – 10.30	Refreshment break	
10.30 – 12.00	Case Study 2 (Packaging)	**Torsten Kneuss & Christian Maasch**
12.00 – 13.00	Lecture 9: Good Manufacturing Practice – Clinical Supply and Regulatory Considerations	**Simona Riedel, VfA, German Association of Research-Based Pharmaceutical Companies.**
13.00 – 13.30	**LUNCH**	
13.30 – 14.30	Lecture 10: How AI and digitalization are reshaping Regulatory CMC Managers' work — an industry and regulator viewpoint Regulatory	**David Boutellier REMATIQ**
14.30-15.00	Lecture 11: Agency Perspective and Closing	**Christian Maasch, all**

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