

AGENDA

8:00 – 8:30	Registration
8:30 – 8:45	Welcome by BBB Speaker from BBB
8:45 – 9:00	Introduction to the Workshop Dr. Eugene O’Keefe, Xendo Deutschland GmbH
9:00 – 9:30	The Landscape of Biopharmaceuticals – Trends and Markets Christian Maasch, Xendo Deutschland GmbH
9:30 – 9:45	Innovative Approaches in Product Development Jacinta Lodge, Xendo Deutschland GmbH
9:45 – 10:15	Coffee break
10:15 – 11:00	Project Management, Strategic Planning and Regulatory Landscape for the Development of Complex Biopharmaceuticals Christian Maasch, Xendo Deutschland GmbH
11:00 – 11:45	Quality by Design in Product Development: Quality Target Product Profile & Critical Quality Attributes Frank Hermens, Xendo B.V.
11:45 – 12:30	Lunch break
12:30 – 13:15	The Importance of Immunogenicity Investigations in the Clinical Development of Antibody Treatments Anke Domdey, Ando Bioanalytical Outsourcing
13:15 – 14:00	The Transition of Late-phase Development to the Market: RA CMC Challenges for a Biopharmaceutical Rika Sperling, RA CMC Manager, Regulatory CMC Biotech Berlin, Bayer AG
14:00 – 14:15	Coffee Break
14:15 – 15:00	Pricing and Reimbursement of Biopharmaceuticals A Speaker of Sofus Regulatory Affairs AB (part of Xendo)
15:00 – 15:30	Brexit: Consequences and Preparation Tips for Biotech & Pharma Xenia v Maltzan, Xendo Deutschland GmbH
15:30 – 16:00	Paneldiscussion
16:00 – 16:15	Wrap Up and Closing Remarks