bbb biotechnologieverbund berlin-brandenburg e.V.

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XENDO SOLUTIONS FOR LIFE SCIENCES

XENDO DEUTSCHLAND GMBH
Siemensdamm 62, 13627 Berlin

Biotech-BBQ – what's hot?

Date:	26.09.2018 | 8:00 - 16:15
Venue:	CQ Beratung + Bildung, Strelitzer Straße 60, 10115 Berlin
Organizer:	bbb Biotechnologieverbund Berlin-Brandenburg Akademie UG (haftungsbeschränkt)
Costs/fee:	90,- € (75,- € bei Anmeldung bis zum 31. Juli 2018)

Introduction:

It is an exciting time for companies developing new and complex biopharmaceuticals. As we gain more experience in the application of highly advanced technologies, as well as in new production processes for biopharmaceuticals, the regulatory landscape and recent strategies for the development of these products are rapidly evolving. It is not an easy task to keep track of best development practices and regulatory requirements.

This interactive workshop will support you in your efforts to better understand these relevant topics based on the vast experience of our speakers who will present case studies in their respective fields. As a highlight of this workshop a panel discussion will take place to address and discuss questions and issues that you are facing in your daily business.

Outcomes of this workshop: gaining insights into improving your product development regarding timelines, costs and risk management.

Who should attend: Professionals and Managers in regulatory and development functions and Financial Investors. Presentations will be in English; the detailed agenda can be found here/below.

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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**