Webcast series

FORUM

PharmaFORUM Webcast Biologics

Development, Quality and Regulatory Affairs

The upcoming webcasts at a glance

- Early and late-stage biotherapeutic development
- Quality documentation for biotech IMPs
- Cell line development and virus safety
- Upstream and downstream development
- Formulation, analytics and bioassay setups
- Stability concept – pre and post launch
- Comparability – similarity assessment
- ICH Q12: CMC lifecycle management

Please try us out: A free demo is online available!

Your benefits

- One live webcast with international experts every month
- Consolidated information in a short period of time at your work place
- Possibility to directly interact with the speaker via chat

www.forum-institut.com/pharma-webcast-biologics

PharmaFORUM Webcast Biologics

Concept

Do you work with biologics? Then, we would like to invite you to join our live webcast series.

Our experts will provide you with the latest information on the current challenges in analytics, development, quality and regulatory affairs (pre- and post-authorisation phases) of biologics every month. Most webcasts are specifically focused on CMC while addressing topics at the interface quality and regulatory affairs.

You will meet our experts in a virtual conference room and share your experiences live. Each meeting will be held as a 1.5 to 2-hour webcast, presenting the latest news with supporting presentation slides. To be best prepared, you will be able to download the complete presentation documents prior to each webcast.

Your benefits

- Twelve live webcasts with international experts per year.
- Recorded webcasts at our learning centre to review as often as you like.
- Documentation for your download.
- Multiple choice test after each webcast to obtain a personal certificate.

Additional useful information

Are you unable to attend one of the webcasts? No problem! Following each live meeting, you will be able to retrieve the recorded webcast from our learning centre using your personal password. This allows you to review each webcast at any time and as often as you like. An optional multiple choice test finalizes each webcast, giving you the possibility to receive a personal certificate.

Get a first impression at
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Technical requirements

In order to join in our live webcast, you will need a standard PC with a current browser, a soundcard, speakers or a headset, and a reliable Internet connection. You may choose between calling via telephone and calling via computer (VoIP) for audio connectivity.

Programme, dates and experts

Starts at 14:00 CET

Your Programme	Date	Your Expert
Interaction with Agencies ▌ National “versus” EMA Scientific Advice ▌ Strategically plan interaction with authorities ▌ What to expect from the interaction	26 October 2018	Dr Christian Schneider
QbD elements in early and late stage biotherapeutic development (from research to first in human until commercial) Implementation of QbD elements: ▌ Quality attributes/critical quality attributes ▌ quality target product profile (QTPP) ▌ Comparability studies	27 November 2018	Dr Dorothee Ambrosius
Quality of biotech IMPs – the current challenges ▌ Impact of the current voluntary harmonisation procedure (VHP) and the new clinical trial regulation on pharmaceutical quality ▌ Current and future regulatory scientific requirements and challenges with regards to quality and its documentation	11 December 2018	Dr Jörg Engelbergs
Analytical development concepts to guide CMC development ▌ Current analytical methods ▌ Specification and validation ▌ Developmental vs. CMC data	22 January 2019	Dr René Thürmer -requested-
Cell line development ▌ Host cells ▌ State-of-the-art cell line generation process ▌ Importance of monoclonality assurance ▌ Bioreactor assessment, clone characterization, expression vector design ▌ Phenotypic & genotypic stability	13 February 2019	Dr Barbara Enenkel and Dr Simon Fischer
Virus safety ▌ Potential sources of virus contamination ▌ Cell line qualification: testing for viruses ▌ Testing for viruses in unprocessed bulk ▌ Virus validation studies	13 March 2019	Dr Barbara Enenkel and Dr Sabine Häcker

Programme, dates and experts

Starts at 14:00 CET

Your Programme	Date	Your Expert
Upstream development (early and late stage) ▌ Process characterisation ▌ Fermentation development ▌ Scale-up and scale-down approaches	9 April 2019	Dr Markus M. Müller
Downstream development (late stage) ▌ Late stage development ▌ Stage I validation	14 May 2019	Jessica Stolzenberger
Pharmaceutical development of biologics drug products: the interface of formulation, primary packaging and application	4 June 2019	Dr Susanne Jörg
Bioassays ▌ Why are they needed? ▌ Advantages/disadvantages of bioassay setups ▌ Replacement of bioassays	2 July 2019	Dr Katrin Buss -requested-
Stability concept: pre- and post-launch ▌ Stability programmes ▌ Use of bracketing/matrixing ▌ Extrapolation of the shelf life ▌ Stress stability studies ▌ Stability indicating methods ▌ Container closure integrity testing	August 2019 (date will be announced)	Dr Rainer Ilg
Comparability – similarity assessment ▌ Differences and common features ▌ ▌ Assessment of critical quality attributes ▌ Demonstration of analytical comparability ▌ Demonstration of analytical similarity ▌ ▌ Different approaches to show similarity in US and EU ▌ ▌ Justification of differences	17 September 2019	Dr Beatrix Metzner and Dr Manuel Wittner
CMC lifecycle management: ICH Q12 and others ▌ Post-approval change management protocol (PCMP) ▌ How to achieve regulatory flexibility? ▌ Requirements regarding tech transfer	15 October 2019	Dr Steffen Groß

Your experts

Dr Dorothee Ambrosius
Boehringer Ingelheim Pharma GmbH & Co. KG
Head of CMC Strategy Biologicals

Dr Katrin Buss
-requested-
Expert for pharmaceutical Quality and Regulatory Affairs, Bonn, Germany

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Boehringer Ingelheim Pharma GmbH & Co. KG
Senior Associate Director Bioprocess and Analytical Development

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Head of Global Tech RA

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National Institute for Biological Standards and Control (NIBSC), United Kingdom
Director

Jessica Stolzenberger
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Head of Laboratory, Late Stage DSP Development

Dr René Thürmer
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Expert for pharmaceutical Quality, Bonn, Germany

Dr Manuel Wittner
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Registration under
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Registration Form

Yes, I want to join the

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How to register

- **Registration: +49 6221 500-500**
- **Conference-No. 19 10 279**

- **Fee:**

Membership of the PharmaFORUM Webcast Biologics is available for one year.
The annual membership fee of €1,800 (plus German VAT) for twelve webcasts is due upon registration.

Membership is automatically extended by one year, unless written notice has been submitted no later than six weeks before the end of the membership.

A 12-month membership may be started at any time.

If you are interested in a group account, please contact us.

Benefits:
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- Documentations for your personal download
- Multiple choice test and personal certificate after each webcast

Questions and information:

I am gladly at your disposal should you have any further questions about the Webcast series.

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Cancellation Policy

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