WEBCAST-SERIES

FORUM
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PharmaFORUM Webcast Biologics 2020

Development, Quality and Regulatory Affairs

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

THE UPCOMING WEBCASTS AT A GLANCE

- Immunogenicity
- Quality part of the IMPD and IND for biologics and ATMPs
- Preclinical and clinical R&D: present and future
- Extractables and leachables (EL): from regulatory expectations to laboratory studies
- Biosimilar development: quality and non-clinical parts
- Future digitalisation trends in submission and labelling
- ICH Q14 and revision ICH Q2

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

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

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
Interface Regulators and HTA Bodies, early parallel consultations for RA together with Market Access • The current procedure for EMA: EUnetHTA parallel consultation • Parallel consultation briefing book • Parallel consultation vs single national consultations • Overview of the upcoming EU-HTA	16 January 2020	Dr Maren von Fritschen Dr Simone Breitkopf
Immunogenicity • Why are therapeutic proteins immunogenic? • Why and how to test immunogenicity? • Immunogenicity risk assessment • How to predict and mitigate immunogenicity	4 February 2020	Dr Daniel Kramer
Quality part of the IMPD, IND (biologics, ATMPs) • The GTMP regulatory landscape • IMPD structure and key sections for GTMPs • Data requirements for manufacture and control • Gene therapy product class specificities • Extent of data with respect to clinical development	3 March 2020	Dr Matthias Renner
Topic to be announced	29 April 2020	Dr Karsten Roth
Preclinical and clinical R&D: present and future • Pharmacology, toxicology, pharmacokinetics • First-in-human trials • Safety and efficacy in patients: clinical development and drug safety • Analytics in preclinical and clinical settings	14 May 2020	Dr Matthias Germer
ATMPs, specifically gene therapy: CMC challenges for development and registration • ATMP product classes • Starting materials, their suitability and control • Drug substance and drug product definitions • Control strategies for ATMPs • Comparability after process changes	22 June 2020	Dr Robert E. Zoubek

Programme, dates and experts

Starts at 14:00 CET

Your Programme	Date	Your Expert
CMC requirements for ATMPs: interface production and RA • Legal and regulatory requirements: EU and USA • CMC requirements from development to marketing • Common pitfalls and key regulatory issues • Intergrating RA into CMC development covering the product lifecycle	9 July 2020	Dr Christopher Mann
Extractables and leachables (EL): from regulatory expectations to laboratory studies • Contamination with leachables: manufacturing, storage and administration materials • A proper control strategy: EL assessment • Material risk evaluation, quantitative EL laboratory studies (high-risk materials) and toxicological evaluation of EL compounds	22 July 2020	Dr Michael Jahn
Biosimilar development: quality and non-clinical parts • What regulators expect • Statistical approaches • New regulatory developments	29 September 2020	Dr Nils Jost
Future digitalisation trends in submission and labelling • eSubmission update and standards in the EU: Further harmonisation at the ICH level? • ePI in the EU: status of current EMA action plan • Update and maintenance of ePI: anticipated improvement of the labelling process	23 October 2020	Dr Peter Bachmann – requested –
Topic to be announced	12 November 2020	Dr Bernd Liedert
ICH Q14 and revision ICH Q2 • ICH Q14: a new Quality Guideline on Analytical Procedure Development • ICH Q2(R1): revision of the Guideline on Validation of Analytical Procedures	3 December 2020	Dr René Thürmer – requested –

Your experts

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HOW TO REGISTER

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REGISTRATION FORM

Yes, I want to join the

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☐ email; and/or ☐ telephone.
I may withdraw my consent at any time.

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Fee:
Membership of the PharmaFORUM Webcast Biologics 2020 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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- Multiple choice test and personal certificate after each webcast

CANCELLATION POLICY

Our general terms and conditions (as of1 January 2016) apply and are available upon request.We can send them to you at any time. Alternatively, you can access them online at www.forum-institut.com/t&c

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