MITTELEUROPÄISCHE GESELLSCHAFT FÜR REGULATORY AFFAIRS e.V.

MEGRA §

Invitation to the MEGRA CMC Series

Webinar

Integration of Modeling Tools into Regulatory Filings

18 March 2026
02:00 – 04:00 pm

Purpose of the webinar

The webinar will explore how modeling tools can be integrated into regulatory filings by discussing personal experience of our speaker, Joey Studts, Director Downstream Development at Boehringer Ingelheim:

“This talk will explore the journey Boehringer Ingelheim has taken to calibrate, validate, and implement mechanistic models in support of commercial control strategies for downstream processing. Our clear objective was to gain regulatory approval for this novel technology, enabling broader application across our portfolio. To achieve this, we pursued a multi-year strategy involving publications and conference presentations to establish scientific precedence. We also integrated the technology into high-visibility projects to ensure exposure to regulatory authorities.

I will briefly present the mathematical foundation of our approach, distinguish mechanistic modeling from statistical models, and clarify how it differs from the current definitions of digital twins—as I understand them. Finally, I will walk through the now-accepted strategy for validating mechanistic models for commercial use, highlighting key applications and sharing insights gained from Boehringer Ingelheim’s experience.

The goal of this talk is to foster an open discussion on how this technology can help shift the paradigm that greater process understanding necessarily requires greater investment. We will explore the significant advantages mechanistic modeling offers, as well as the potential pitfalls and limitations that must be carefully considered.”

Group of participants

This seminar is intended for employees of the pharmaceutical industry dealing with process development, CMC and preparation of regulatory filings.

This webinar series is intended to be a forum for scientific exchange and discussion: Therefore we invite all participants to take actively part in the discussion. You can also provide any questions you would like to discuss beforehand to the speaker by contacting office@megra.org via email.

Speaker

Joey Studts
Director Downstream Development, Boehringer Ingelheim Pharma GmbH & Co KG

MITTELEUROPÄISCHE GESELLSCHAFT FÜR REGULATORY AFFAIRS e.V.

MEGRA

Program

Integration of Modeling Tools into Regulatory Filings

18 March 2026
02:00 – 04:00 pm

02:00 – 02:05 p.m.	**Welcome and introduction**	all
02:05 – 03:30 p.m.	**Integration of Modeling Tools into Regulatory Filings**	Joey Studts
03:30 – 04.00 p.m.	**Questions and discussion**	all

Registration

See our Homepage: https://www.megra.org/veranstaltungen/veranstaltungen.html

Fee € 220,-- for MEGRA members

Fee for participants of all 3 webinars: € 180 per webinar

The MEGRA membership is mandatory for all participants. In case you are not yet member of MEGRA you can apply for membership when registering for this webinar. Cost of membership is € 140,-- per calendar year.

Cancellation fees:

until 4 weeks prior to the event: 10 % handling fee

until 2 weeks prior to the event: 50 % cancellation fee

until 1 week prior to the event: no refund

MITTELEUROPÄISCHE GESELLSCHAFT FÜR REGULATORY AFFAIRS e.V.

MEGRA

Invitation to the MEGRA CMC Series

Webinar

Update on the revision of ICH M4Q / Development of new ICH M16

30 April 2026
02:00 – 04:00 pm

Purpose of the webinar

This webinar provides an overview on the revision of ICH M4Q ("The Common Technical Document for the Registration of Pharmaceuticals for Human Use: Quality"). During this webcast the key objectives of ICH M4Q(R2), including the expanded scope, the improved organization of quality and manufacturing information, and the alignment with current international standards will be introduced. Participants will gain an overview of how the revised guideline enhances regulatory efficiency and better captures pharmaceutical development and control strategies.
In addition, the seminar will also introduce the newly developed ICH M16 guideline ("Structured Product Quality Submissions (SPQS)"), which provides a harmonized framework for the electronic structured submission of medicinal product information. M16 aims to ensure consistent, high-quality data exchange across regions by defining standardized formats for product, substance, and regulatory content.
.

Group of participants

This seminar is intended for colleagues from CMC/Regulatory Affairs, process and product development, and all those preparing or maintaining regulatory dossiers.

This webinar series is intended to be a forum for scientific exchange and discussion: Therefore we invite all participants to take actively part in the discussion. You can also provide any questions you would like to discuss beforehand to the speaker by contacting office@megra.org via email.

Speakers

Helen Louise Newton, MSD and Laurent Lefebvre, Novartis

MITTELEUROPÄISCHE GESELLSCHAFT FÜR REGULATORY AFFAIRS e.V.

MEGRA

Program

Update on the revision of ICH M4Q / Development of new ICH M16

30 April 2026
02:00 – 04:00 pm

02:00 – 02:05 p.m.	**Welcome and introduction**	all
02:05 – 03:30 p.m.	**Update on ICH M4Q / ICH M16**	Helen Louise Newton/ Laurent Lefebvre
03:30 – 04.00 p.m.	**Questions and discussion**	all

Registration

See our Homepage: https://www.megra.org/veranstaltungen/veranstaltungen.html

Fee € 220,-- for MEGRA members

Fee for participants of all 3 webinars: € 180 per webinar

The MEGRA membership is mandatory for all participants. In case you are not yet member of MEGRA you can apply for membership when registering for this webinar. Cost of membership is € 140,-- per calendar year.

Cancellation fees:

until 4 weeks prior to the event: 10 % handling fee

until 2 weeks prior to the event: 50 % cancellation fee

until 1 week prior to the event: no refund

MEGRA e.V. – Leopoldstr. 11A – D 80802 München – Tel. +49 89 61440526 – Fax + 49 89 61440528
email: office@megra.org – www.megra.org

MITTELEUROPÄISCHE GESELLSCHAFT FÜR REGULATORY AFFAIRS e.V.

MEGRA §

Invitation to the MEGRA CMC Series

Webinar

How can AI and Prior Knowledge streamline QbD product and process development?

19 May 2026
02:00 – 04:00 pm

Purpose of the webinar

Industry and regulatory authorities expect to see streamlined quality by design (QbD) development of new pharmaceutical products and optimized processes using AI in order to reduce development time and obtain reasonable cost of goods for future medicinal products.

While QbD terminology is already broadly used in most MAA / BLA dossiers, many experiments (e.g. analytics and/or process) and resulting data reveal during dossier review period or later in pre-approval / license inspections that the AI-driven prior knowledge data evaluations as well as the experimental designs and statistical concepts applied not necessarily support a QbD approach.

Reliable analytical methods and statistically valid results are prerequisites for a lean development of products and processes.

Using potency as one of the most critical quality attributes in product and process development, combining quality, safety and efficacy, we want to discuss DOs and DON´Ts of a QbD concept.

The goal is to provide recommendations for a stepwise approach for the development of product and process and accompanying analytics (e.g. potency) to reduce the overall number of experiments needed in product and process development, characterization and validation, applying state-of-the-art software and modelling, relying on meaningful and validated AI data assessments and thus reducing time and cost of a QbD development.

Group of participants

This seminar is intended for employees of the pharmaceutical industry dealing with product and process development, CMC and preparation of regulatory filings.

This webinar series is intended to be a forum for scientific exchange and discussion: Therefore we invite all participants to take actively part in the discussion. You can also provide any questions you would like to discuss beforehand to the speaker by contacting office@megra.org via email.

Speakers

Dr. Martin Vanselow and Dr. Heike Volkmer
VBC Team GmbH

MITTELEUROPÄISCHE GESELLSCHAFT FÜR REGULATORY AFFAIRS e.V.

MEGRA

Program

How can AI and Prior Knowledge streamline QbD product and process development?

19 May 2026
02:00 – 04:00 pm

02:00 – 02:05 p.m.	**Welcome and introduction**	all
02:05 – 03:30 p.m.	**How can AI and Prior Knowledge streamline QbD product and process development?**	Dr. Martin Vanselow / Dr. Heike Volkmer
03:30 – 04.00 p.m.	**Questions and discussion**	all

Registration

See our Homepage: https://www.megra.org/veranstaltungen/veranstaltungen.html

Fee € 220,-- for MEGRA members

Fee for participants of all 3 webinars: € 180 per webinar

The MEGRA membership is mandatory for all participants. In case you are not yet member of MEGRA you can apply for membership when registering for this webinar. Cost of membership is € 140,-- per calendar year.

Cancellation fees:

until 4 weeks prior to the event: 10 % handling fee

until 2 weeks prior to the event: 50 % cancellation fee

until 1 week prior to the event: no refund

MEGRA e.V. – Leopoldstr. 11A – D 80802 München – Tel. +49 89 61440526 – Fax + 49 89 61440528
email: office@megra.org – www.megra.org