

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

Program

Integration of Modeling Tools into Regulatory Filings

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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