

## 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](mailto:office@megra.org) via email.**

#### Speakers

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

## Program

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

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