

CMC Statistical Network Europe



Who We Are

Chemistry, Manufacturing, and Control (CMC) statisticians based in Europe, working within pharmaceutical companies and CROs involved in R&D.

We are committed to collaboration and knowledge exchange on precompetitive topics in our field.

Our Mission

Applying statistics, data science, modeling, and computational methods to advance CMC technical development.

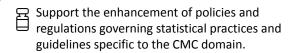


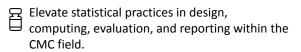
Serve as a platform for CMC statisticians in Europe to provide input on regulatory guidelines



Organize workshops to share technical insights, novel methodologies, and established approaches.

Our Focus





Foster research to create tools that enhance decision-making and deepen the understanding of scientific studies in the CMC space.

Activities: Workshops



Upcoming Webinar:

Stability Modelling Tuesday, October 21st 2025 In the context of the current ICH Q1 Annex 2 quidance



Dissolution Testing: Time for Statistical (r)Evolution Tuesday, March 18th 2025

Activities: Input on Regulatory Guidelines



Presented at:

EMA QIG Listen & Learn Focus Group Meeting on platform technologies, November 2024 Presentation Title:

Statistical approaches to develop data-driven prior knowledge into a platform.



Organized meetings to exchange ideas and coordinate feedback, July 2025

025 EFSPI Regulatory Workshop Panel Discussion

Steering Committee

Name	Company
Kevin Lief (Chair)	GSK
Jens Lamerz	
Martin Otava	Johnson & Johnson
Beate Presser	Boehringer-Ingelheim
Christian Schmid	Roche

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