



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.

Activities: Workshops



Upcoming Webinar:

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



Past Webinar:

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

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.

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.



ICH Q1 (Stability Testing):

Organized meetings to exchange ideas and coordinate feedback, *July 2025*



2025 EFSPi Regulatory Workshop Panel Discussion

Our Focus



Support the enhancement of policies and regulations governing statistical practices and guidelines specific to the CMC domain.



Elevate statistical practices in design, computing, evaluation, and reporting within the CMC field.



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

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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