



**TITLE: EFSPI CMC Statistical Network Europe: Recent Achievements, Future Directions, and Position Papers on dissolution and ICHQ6**

**SPEAKER and COAUTHORS:** Kevin Lief, Martin Otava, Christian Schmid, Beate Presser, Jens Lamerz

**ABSTRACT:** The EFSPI CMC Statistical Network Europe continued to strengthen cross-industry collaboration in 2025 through a series of well-attended webinars and interactive round-table discussions addressing key CMC topics such as dissolution methodologies, modern stability modelling, and emerging considerations related to ICH Q6. These activities highlighted the growing need for harmonized, statistically sound approaches to support regulatory expectations and to improve the statistical plausibility of health authority guidelines.

In 2026, the Network will also explore the role of agentic AI concepts in the CMC landscape, with a focus on embedding statistical rigor into AI-supported workflows, including validation standards, scientific integrity, and regulatory readiness.

In parallel, two cross-company working groups are developing on high-priority topics:

The first position paper addresses the statistical and regulatory limitations of the “Expected f2” approach for dissolution profile comparison, summarizing grave theoretical and mathematical concerns, and the reduced statistical power in dissolution profiles with high variability.

The second discussion revolves around modern statistical perspectives on ICH Q6, advocating for patient-centric, risk-based specification setting and clarifying the role of contemporary statistical methodologies in bridging clinical relevance and manufacturing capability.

This presentation will provide an overview of the Network’s recent achievements, share insights from both position paper initiatives, and outline future activities aimed at advancing statistical foundations in CMC practice.