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TITLE: Determination of Acceptance Criteria and Designs for Analytical Method Validation to support ICH Q2(R2) implementation

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Hugo Zuin and Marion Berger are Sanofi employees and may hold shares and/or stock options in the company.

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ABSTRACT: The new edition of ICH Q2(R2) guideline, made effective in June 2024, shows a significant regulatory shift in analytical method validation, requiring accuracy and precision to be assessed using confidence intervals rather than point estimates. This renders previously established and commonly used practices no longer appropriate, necessitating an adaptation of both acceptance criteria and study designs.

This presentation investigates a simulation-based methodology to determine acceptance criteria for the accuracy and intermediate precision CV, controlling both producer's and consumer's risk.

BRIEF SPEAKER BIO:

Hugo Zuin

Hugo Zuin is a Principal Scientist Biostatistician at Sanofi supporting early to late-phase development of Synthetics small-molecule product. His expertise lies in the application of Quality by Design (QbD) using Design of Experiments (DoE), and in providing statistical support for analytical method development, validation, transfer, and regulatory compliance.

Marion Berger

Marion Berger leads the statistical team supporting the Synthetics division and oversees the development of statistical tools across several Sanofi domains. Having provided statistical support in preclinical and clinical areas earlier in her career, she has focused on the CMC statistical support for over 10 years.