NCS Non-Clinical Statistics Conference
Padua, IT / 23 – 25 September 2026

TITLE: A statistical risk-based framework for sunsetting one-sided release tests: from limited data to regulatory approval

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ABSTRACT: Manufacturing control strategy changes such as removing routine release tests ("sunsetting") require a defensible quantitative assessment of residual quality risk. While this may appear straightforward, it is statistically challenging due to the irreversible nature of the decision and the frequent reliance on limited historical batch data that are often heavily left censored.

We present a pragmatic statistical framework designed to quantify the probability of missing future out of specification batches. It integrates well established statistical tools, including process capability analysis with confidence bounds to account for finite sample uncertainty, predictive probability statements, and Bayesian posterior predictive modelling.

The framework is illustrated using an established drug product for which sunsetting of release testing was approved by both FDA and EMA. The discussion subsequently focuses on early lifecycle scenarios with limited and highly censored data. Throughout, the emphasis is on statistical judgment: making assumptions explicit, acknowledging identifiability limits, and supporting transparent and defensible decision making when data are far from ideal.

BRIEF SPEAKER BIO: Aniek Sies is a Senior Scientist in Manufacturing Science and Technology (MSAT), working on the application of statistical methods to manufacturing risk assessment and regulatory decision-making. She previously worked as a non-clinical statistician in several biotechnology companies, supporting development and CMC programs. She holds a PhD with a focus on statistical methodology for estimating optimal treatment regimes.