Contribution ID: **29** Type: **not specified**

Robustness Evaluation by Design of Experiments in Vaccine and Pharmaceutical Development

Thursday, 29 May 2025 10:40 (20 minutes)

The current state-of-the-art in vaccine and pharmaceutical R&D is based on the "Quality-by-Design"paradigm, emphasizing risk-based and data-driven decisions. A key aspect is the classification of process parameters into critical and non-critical based on a series of Designs of Experiments (DoE). This process aids in understanding the relationship between Critical Process Parameters (CPPs) and Critical Quality Attributes (CQAs) and assists in defining the Design space. According to the ICH guidance Q8, design spaces are characterized as the subspace of process parameter combinations that ensure "quality assurance".

Within this framework, the robustness of a process refers to its ability to maintain quality specifications despite changes in experimental conditions. In parallel to the classical equivalence test, using two one-sided tests (TOST), a DOE for robustness (or 'flatness') adapts this method to a multi-dimensional scenario involving various continuous or categorical factors, such as temperature or protein type. This can be evaluated through the predicted mean response or by analyzing contrasts between the means of each experimental condition and a reference point, typically the standard experimental condition. The design space is thus identified as the area within the multi-dimensional space where the predicted mean responses meet specification requirements or demonstrate equivalence to the reference level, confirmed by the confidence intervals of mean or mean contrasts lying within the specifications.

Our approach will be showcased with practical applications and case studies from CMC statistics at GSK, highlighting the analysis and interpretation using statistical intervals and the probability of success.

Type of presentation

Contributed Talk

Primary author: FRANCQ, Bernard (GSK)

Co-author: LIEF, Kevin (GSK)

Presenters: FRANCQ, Bernard (GSK); LIEF, Kevin (GSK)

Session Classification: Session

Track Classification: Spring Meeting