

# System suitability control limits for assay with format

## Challenge



Client lacked sufficient knowledge of System Suitability Control (SSC)

- For assays, scientists develop SSC, to mitigate large assay variability with biologics and vaccine, samples are frequently analyzed in replication over multiple runs, and the mean of all the results is taken as reportable value
- Variability analysis of these replicates could lead to the detection of assay problem (sample preparation, etc.) but specifications for simultaneous, replicated determinations do not exist to obtain an easy pass / fail decision process

## Solution



Developed fit-for-purpose solution finely tuned to specifically answer the challenge

- Understood variance components analysis of routine / trending data
- Modeled the data structure of replication, and the effective sample size
- Derived simultaneous tolerance intervals that can be used as a new type of SSC

## Outcome



Scientists have a new tool to automatically detect data

- Methodology was rolled out over all assays for all products, eliminating risk of future release of bad products
- The new tool automatically detects highly variable assay instead of using their subjective analysis