Biosimilarity assessment on multiple CQAs

Challenge

Required multiple CQAs assessment in EU and US

- How to deal with multiple Critical Quality Attributes (CQAs) in the assessment of a new biosimilar in compliance with EU and US regulations?

Solution

Parallel implementation and analysis of national regulatory requirements

- Implemented the adequate approaches in parallel to cover all EU and US regulatory requirements, adapted to the criticality level of each CQA
- Completed the univariate analysis of each CQA by a multivariate sensitivity analysis to mitigate the multiplicity issue when testing many attributes
- As regulatory guidance was poorly written (and now totally withdrawn), an important methodological development was needed to ensure statistical consistency of the results

Outcome

Biosimilar dossier approved in EU; review still ongoing in the US

- Methodological developments pave the way towards better, more reproducible assessment of Biosimilarity
- Despite the mathematical challenge, all tasks were delivered within defined time frame
- Direct input in customer regulatory dossier