

Analytical Method Comparisons

Challenge



Client needed to demonstrate interchangeability of technology

- Client needed to change from a costly and low through-put analytical technology, to an easier, faster high through-put assay

Solution



Develop fit-for-purpose Bayesian model to assess interchangeability

- Design appropriate experimental study and sample size to allow demonstration of comparability
- Define acceptance criteria to assess methods of comparability
- Appropriate Bayesian data modeling of the key outcome to demonstrate method of comparability and interchangeability

Outcome



Significant cost saving of >50%
New technology fully validated according to latest regulation

- The new assay was implemented and led to:
 - Increase of through-put for the analytical results obtained, thus improving process and product characterization
 - Confidence in the analytical results obtained by the new technology
 - Easy comparison between old and new technologies