

Acceptance criteria for Bioassay validation

Challenge



Client was in urgent need for a more cost-effective solution for Bioassay validation

- According to USP standards, parallelism between a pair of dose – response function needs to be tested prior to validating a potency bioassay
- Developing acceptance criteria for one specific assay require to measure the reference product numerous times
- These processes cost a tremendous amount of time and money

Solution



Develop advanced statistical models to define acceptance criteria

- Use only the data that is developed in the laboratory for the validation of the assay
- Simulate a large amount of the reference product using advanced statistical methods
- Derive the acceptance criteria from the simulated data

Outcome



Substantial reduction in workload

- No need to measure more data than the existing ones
- Weeks of work and hundreds of thousands of dollars saved