

Dilution recipe for vaccine production

Challenge



Required support to avoid batch rejection due to poor assay performance

- A vaccine manufacturer produced a bulk Drug Substance (DS)
- Dilution with a formulation buffer is made to obtain a Drug Product ready to be filled in syringes
- However, the titration of biologic material is subject to large uncertainty due to poor assay performance, leading to frequent and costly batch rejection

Solution



Provided comprehensive assessment of optimal dilution and assay format

- Calculated a safe and optimal dilution to meet the specifications, using process simulations, accounting for assay uncertainty, that may give titration results far from the unknown truth
- Assessed the assay format to obtain fit-for-purpose reportable results, balancing the cost of performing complex assays to the high cost of discarding a drug product batch

Outcome



Vaccine production meets specifications, despite assay and process uncertainty

- Client is competitive in rapid vaccine development
- Substantial increase in accuracy resolved in significant cost – savings
- All tasks delivered within defined time frame