

Drug Product Release Specification Justification

Challenge



Client lacks knowledge of critical quality standards for drug product release

- Specifications are critical quality standards that are crucial for approval when submitted to the authorities

Solution



Used data and statistical modeling to define methodology

- Used historical validation and clinical batches data to justify new specifications
- Defined appropriate size of release specifications thanks to proper statistical modeling
- Detailed description of the methodology and results interpretation for file submission to authorities

Outcome



Authorities accepted new specifications and client reduced batch rejection rate by 15%

- All tasks delivered within defined time frame