

Case Study CSV

Standardizing Workflows in Empower 3.6.1 to Eliminate Calculation Errors for a Pharmaceutical Manufacturer



Client Overview

A global generics pharmaceutical manufacturer using Empower 3.6.1 was facing recurring QC deviations due to non-standardized workflows and incorrect calculation templates leading to delays in batch release and increased OOS investigations.

Left unresolved, the recurring deviations posed a direct regulatory risk across US and EU markets.

Root Cause Identified

Lack of standardization and validation across:

- Processing methods
- Report templates
- Instrument configurations

Resulting in non-reproducible results and calculation errors

Key Challenges

- Inconsistent peak detection parameters across processing methods
- Unvalidated custom fields causing calculation mismatches in COA
- Variation in integration settings across instruments
- Misaligned user roles with Part 11 & Annex 11 compliance
- Frequent deviations impacting operational efficiency

Our Approach

Workflow Assessment & Standardization

- Mapped user roles, processing methods, and report templates
- Reviewed **HPLC & UPLC** instrument configurations
- Identified gaps in integration settings and calculation logic
- Standardized templates for custom fields, reports, and integration rules

Validation Execution

- Revalidated **processing methods** with scientifically justified parameters
- Executed **OQ/PQ** across:
 1. Multi-instrument data acquisition
 2. Complex sample scenarios
 3. Reprocessing workflows
- Ensured consistency and reproducibility of **analytical results**

Compliance & Governance

- Conducted **Part 11 assessment**:
 1. Audit trails
 2. Electronic signatures
 3. Access control
- Strengthened **SOPs** for user management, data review, and system usage
- **Implemented** structured change management for future updates

Business Impact

- 100% consistency in analytical results
- Zero calculation-related deviations
- Faster batch release timelines
- Improved QC efficiency & reliability
- Fully audit-ready and compliant system

Conclusion

The organization transformed its Empower system into a reliable, compliant, and high-performance analytical environment — with **Brisk's domain expertise** ensuring zero recurrence of pre-validation deviations.