solvias

From Variability to Validation:

GMP BIOASSAY SUCCESS THROUGH PARTNERSHIP

Solvias helped a biopharma customer transform an underperforming bioassay into a GMP-validated, reliable platform — reducing failure rates from 25% to <1%.

When a biopharmaceutical company sought GMP validation for an established bioassay, they turned to Solvias for both scientific rigor and a seamless partnership. While the assay had demonstrated early potential, transitioning to a GMP environment revealed several challenges. By working closely with the customer's technical and quality teams, Solvias identified and addressed key barriers—ultimately ensuring a robust, compliant, and reproducible method.

THE CHALLENGES

- Procedural Alignment: Minor method adaptations made during early development had not been fully captured in formal documentation, leading to executional variability in a GMP setting.
- Tight Acceptance Criteria: Initial criteria did not fully reflect the assay's natural variability, increasing the risk of non-conformance despite correct execution.
- Sample Viscosity Effects: Subtle viscosity differences introduced variability during pipetting, affecting consistency in test results.

OUR COLLABORATIVE APPROACH

1. Harmonizing Method Execution for GMP

Following an initial failed validation attempt, Solvias hosted the client at our facility to observe real-time GMP execution. This collaborative review helped both teams identify how procedural timing, real-time documentation, and compliance requirements were influencing assay performance. As a result, we jointly refined the workflow to better suit GMP constraints — without compromising method intent.

2. Optimizing Criteria for Realistic, Reproducible Outcomes

Cross-site technical discussions revealed that observed system suitability test (SST) failures were driven by inherent assay variability rather than execution errors. Together, we updated the acceptance criteria and implemented a CAPA strategy to better align internal processes and expectations. These updates significantly reduced variability while ensuring regulatory readiness.

3. Mitigating Viscosity-Driven Pipetting Bias

Through joint root cause analysis, we determined that sample viscosity was affecting pipetting performance. To address this, Solvias introduced standardized pipetting techniques and added a verification step to ensure accurate solution concentration — improving consistency and reliability across runs.

THE RESULTS

Focus Area	Before	After
Assay Failure Rate	~25%	<1%
Documentation Practices	Variable	Fully GMP-compliant
Acceptance Criteria	Misaligned	Optimized for variability
Sample Handling	Inconsistent	Standardized and verified

CONCLUSION

This collaboration highlights the value of working with a partner who combines scientific depth with operational flexibility. Solvias delivered:

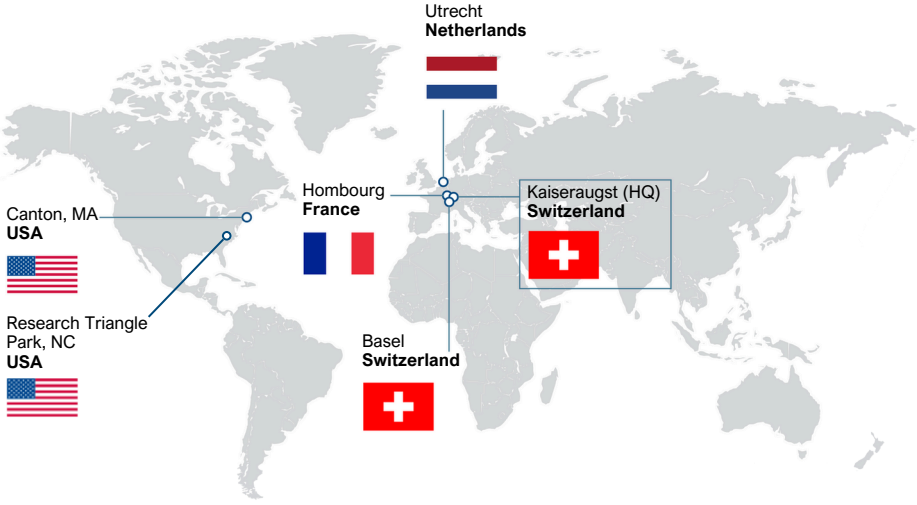
- A reliable, validated assay ready for GMP manufacturing.
- Reduced failure rates and enhanced reproducibility.
- A positive, solutions-oriented working relationship.

Whether troubleshooting complex methods or scaling for clinical supply, Solvias makes it easy for partners to achieve success through science, service, and seamless execution.

Looking for more insights? Explore our full library of free cell-based bioassay resources here: **CBBA**

WHY PARTNER WITH US?

- CDMO/CRO
- Founded in 1999
- 800+ team members
- 175+ PhD-level scientists
- GMP, GLP, ISO9001 certified
- 22.5K sqm of lab capacity
- 700+ customers worldwide
- 6 centers of excellence



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