SRE-Driven Automation of FLEX2 Analytics in AMBR250 Upstream Biologics Workflows

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About the Speaker

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Based at the Malvern, Pennsylvania site, working within regulated upstream biologics process development. Core focus: analytical automation, qualification, validation, and operational reliability in high-throughput cell culture environments.

Upstream Process Development

Analytical Automation

Regulated Environments

Agenda

A 30-minute walkthrough of how SRE principles drove the automation of a critical analytical workflow in regulated biologics manufacturing.

01

The Problem

Manual workflows, reliability risks, and scaling challenges in AMBR250 operations

02

The Platform

AMBR250 microbioreactor system and BioProfile FLEX2 analyzer overview

03

The Journey

Dec 2022 – Aug 2024: evaluation, qualification, and validation

04

Equivalency Studies

Four structured experiments demonstrating analytical comparability

05

Results & Scale-Out

Outcomes, labor savings, and multi-site enablement

The Problem: Manual Workflows Don't Scale

Reliability Risk

Operator-dependent sampling introduced variability in critical analytical measurements

Operational Overhead

High manual labor per AMBR run limited throughput and increased error exposure

Compliance Burden

In regulated environments, inconsistent manual execution creates audit and data integrity risks

Platform Context: AMBR250 & FLEX2

Sartorius AMBR250

A high-throughput microbioreactor platform widely adopted in upstream biologics process development. Supports parallel operation of multiple 250 mL vessels, enabling rapid process screening under controlled, instrumented conditions.

BioProfile FLEX2

An automated cell culture analyzer capable of multi-parameter measurement including metabolites, blood gases, electrolytes, osmolality, and cell health metrics from a single sample. Designed to support high-throughput analytical workflows with minimal operator intervention.

Why These Two Platforms Together?

The AMBR250 generates high volumes of samples across parallel vessels. Without automated analytics, each sample requires manual preparation and individual instrument runs a throughput mismatch that grows with scale.

Multi-Parameter in One Run

FLEX2 consolidates metabolite, gas, electrolyte, osmolality, and viability measurements into a single automated analysis eliminating the need for multiple instruments

Sample Volume Alignment

FLEX2 is designed for the small sample volumes produced by AMBR250 vessels, making it a natural analytical partner for the platform

Regulatory Compatibility

FLEX2 supports audit trails and data export formats compatible with regulated GxP workflows, aligning with Janssen's compliance requirements

Implementation Timeline: Dec 2022 – Aug 2024

The FLEX2 integration followed a structured, phase-gated approach to ensure controlled adoption and maintain data integrity throughout the transition.

1

Dec 2022

Independent evaluation initiated assessing FLEX2 analytical capabilities against existing standard analyzers

2

2023 Q1–Q2

Instrument qualification (IQ/OQ/PQ) protocols authored and executed for FLEX2 and associated AMBR systems

3

2023 Q3–Q4

Four structured equivalency experiments designed and executed to demonstrate analytical comparability

4

2024 Q1–Q2

Validation protocols completed; super user training deployed across Malvern and Spring House sites

5

Aug 2024

Full operational implementation FLEX2 supporting routine AMBR250 analytical operations in production workflows

Equivalency Studies: The SRE Approach to Transition Risk

Before decommissioning existing analyzers, four structured comparability experiments were designed to provide statistical and operational evidence that FLEX2 results were analytically equivalent to established methods a key principle borrowed from SRE change management: **validate before you migrate**.

Study Design Principle

Paired sample analysis the same AMBR250-derived samples were run on both FLEX2 and the existing standard analyzer simultaneously

Parameters Evaluated

Glucose, lactate, glutamine, glutamate, ammonium, pH, pCO_2, pO_2, osmolality, viable cell density, and viability

Acceptance Criteria

Pre-defined comparability thresholds aligned with internal method validation guidelines and regulatory expectations

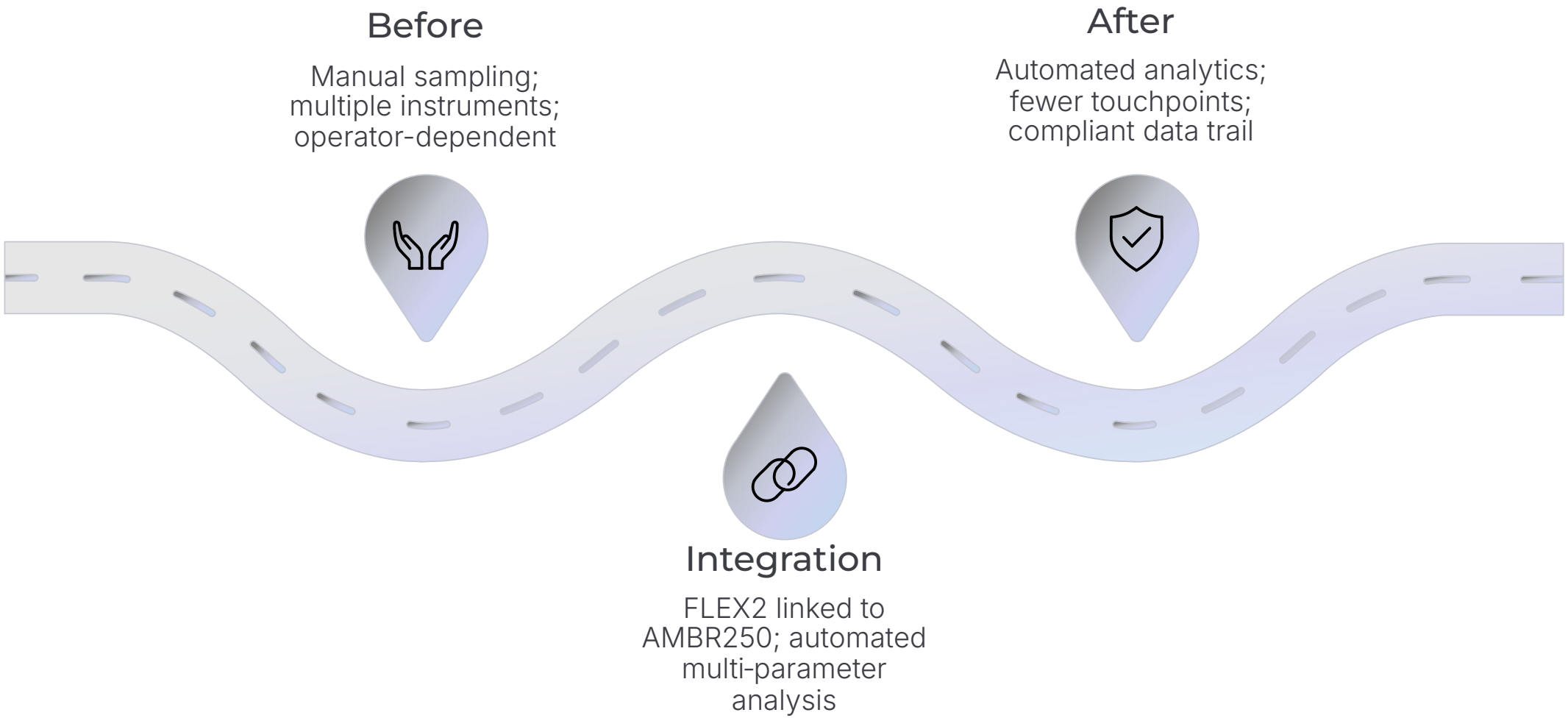
What the Equivalency Studies Demonstrated

All Four Studies Met Acceptance Criteria

Across all parameter groups, FLEX2 demonstrated analytical comparability to established standard analyzers within pre-defined acceptance thresholds.

This provided the documented evidence required to support a validated, compliant transition removing analytical risk from the automation migration.

The Integrated Workflow: What Changed



The integration eliminated the need for operators to run multiple instruments sequentially. A single FLEX2 run now delivers the full analytical panel required per AMBR250 sampling event, with structured data automatically available for downstream review and trending.

Operational Impact: By the Numbers

40%

Reduction in Manual Labor

Across routine AMBR250 analytical workflows per run

4

Equivalency Studies Executed

Covering all critical analytical parameter groups

12

Super Users Trained

Across two Janssen sites in Pennsylvania

2

Sites Enabled

Malvern and Spring House, PA both operating independently

Qualification & Validation: Building a Compliant Foundation

What Was Authored and Executed

Qualification and validation protocols were developed for both the AMBR250 systems and the FLEX2 analyzer as part of an advanced manufacturing technology initiative ensuring every instrument in the automated workflow was independently qualified before integration.

- Installation Qualification (IQ) — verified instrument installation against vendor and site specifications
- Operational Qualification (OQ) — confirmed instrument performs within defined operational parameters
- Performance Qualification (PQ) — demonstrated consistent, fit-for-purpose analytical performance under routine conditions

Super User Model: Scaling Operational Ownership

To sustain the automation investment beyond implementation, a structured **super user enablement model** was deployed a deliberate strategy to distribute operational expertise and reduce single-point-of-failure risk.

Malvern, PA

8 super users trained primary site for AMBR250 operations and FLEX2 routine use

Spring House, PA

4 super users trained secondary site enabling independent operation and local troubleshooting

SRE Principles Applied to Biologics Analytics

This implementation was not just an instrument swap it applied core SRE thinking to a regulated laboratory environment.

→ Eliminate Toil

Manual, repetitive sampling tasks were automated, freeing scientists for higher-value analytical work directly analogous to eliminating operational toil in software systems

→ Reduce Error Budget Consumption

Equivalency studies and validation protocols ensured the automation did not introduce new failure modes change was controlled and evidence-based

→ Observability and Data Integrity

FLEX2 structured data outputs created a consistent, auditable analytical record improving observability of the cell culture process

→ Distributed Ownership

The super user model mirrors on-call rotations and runbook ownership expertise is shared, not siloed

Thank You

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Questions, discussions, and feedback are welcome.

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