Success Story

Advanced Data Management and Compliance for Pharmaceutical Manufacturing

YOKOGAWA
Co-innovating tomorrow™

Industry: Pharmaceutical
Solutions: CI Server, SMARTDAC+

One Data Gap Can Cost Millions in an FDA Audit

For a pharmaceutical manufacturer, a single missing record can stall a shipment, trigger a finding, or close the door to an entire market. That's the risk facing many contract manufacturers running aging data systems. Whenever the SCADA loses communication with dataloggers or controllers, staff are forced to collect data by hand — a slow, error-prone scramble to rebuild reports that regulators expect to be complete, secure, and audit-ready under GMP, FDA 21 CFR Part 11, and PIC/S Data Integrity guidance.

"Every manual data pull was a risk to our compliance and a drain on our team. We needed a system we could trust when it mattered most — in front of an auditor." **— Technical Services Manager**

The Challenge

A pharmaceutical contract manufacturer specializing in non-sterile, semi-solid and liquid formulations needed to modernize its manufacturing data management. Its legacy system couldn't guarantee data continuity, fast reporting, or the validated records that customer audits and FDA readiness demand. The manufacturer's technical services and quality assurance teams were pushing toward broader market readiness — but manual data collection and time-consuming report generation stood in the way of the compliance and speed they needed.

The Solution

Yokogawa deployed an architecture built on CI Server and SMARTDAC+, creating a single, GMP- and Part 11-compliant platform for environmental monitoring — pressure, temperature, humidity, and PLC utilities. Key wins:

- **Single-click reporting** — operators pull alarm history (with acknowledgment reasons) and parameter-change logs instantly, with automatic periodic report generation.
- **Zero-downtime integration** — "zero" impact on existing wiring, thanks to native multi-vendor compatibility.
- **Guaranteed data continuity** — automatic backfill from SMARTDAC+ to CI Server whenever communication drops, so no record is ever lost.
- **On-demand custom features** co-developed with the customer during rollout.

"What used to take our team hours now takes minutes — and when the auditors came, our records were complete and defensible." **— Quality Assurance Lead**

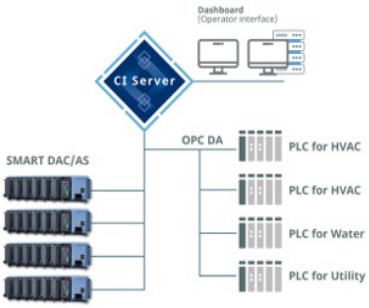
Key Advantages

Challenge	Traditional Approach	Yokogawa Solution	Impact
Data loss & manual reporting	Time-intensive device checks	Automated backfilling & single-click reports	~50% faster compliance prep
Multi-vendor integration	Disruptive rewiring	Native compatibility, zero downtime	Seamless scalability
Audit readiness	Fragmented records	Centralized GMP-compliant platform	**Passed FDA audit**

The Result

The manufacturer passed its FDA audit — expanding its market opportunities — and gained a single, reliable platform with a clear path to consolidating production and environmental monitoring data.

The result: greater efficiency, stronger compliance, and a strengthened position in the competitive contract-services sector.



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