Chart Recording Use Case

Sterile Environmental Monitoring Case Study
FDA 21 CFR Part 11 compliant environmental monitoring replacing legacy chart recorders with open data access.
Industry: Pharmaceutical

Quick Facts

Attribute	Value
Customer	Hikma Pharmaceuticals
Location	New Jersey
Scale	31 manufacturing plants, 7 R&D centres globally
Users	15 total, 4 concurrent
Development	1 month
Legacy System	Honeywell GR series graphic chart recorder
Compliance	FDA 21 CFR Part 11
Integrator	Controlware, LLC

The Challenge

Challenge: Replace closed non-expandable Honeywell GR series graphic chart recorder with an open, flexible system meeting FDA requirements for sterile environment monitoring.

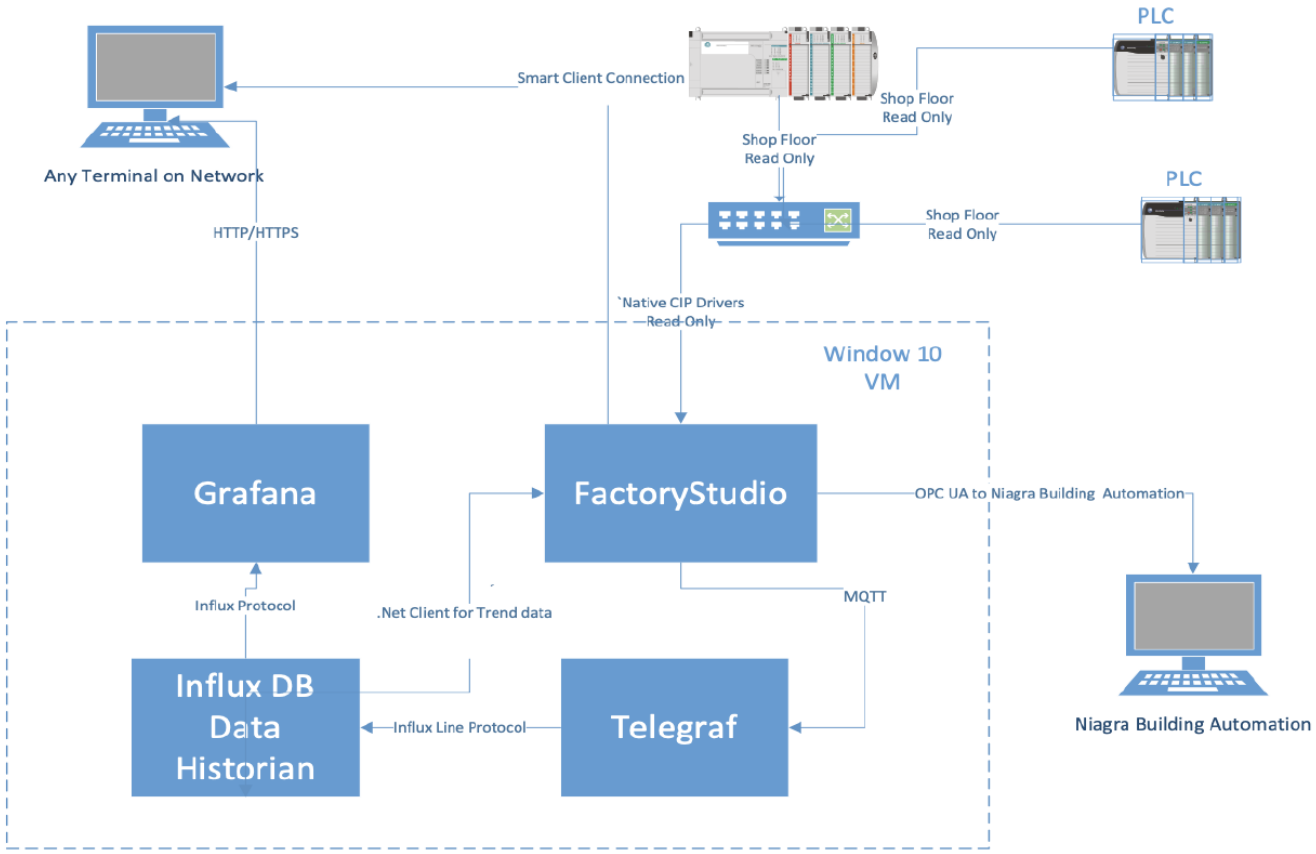
Specific pain points:

- Old system recorded data in proprietary data structure
- Required separate product to access recorded data
- Less security and non-flexible reporting
- Closed stand-alone system couldn't share data with operations, quality analysts, planners
- Industry 4.0 requires better data access for production decisions (batch quality assessment, cleaning requirements, capacity planning)
- FDA 21 CFR Part 11 compliance required (audit trails, password rotation, e-signatures)

Impact: Proprietary data structures prevented efficient reporting and data sharing across the organization for quality and production decisions.

The Solution

Architecture



Tier	Component	Capabilities
Field	PLCs, Sensors	Native CIP drivers, instrumentation
Building	Niagara Building Automation	OPC UA connectivity
Central	FrameworX (Windows 10 VM)	Trending, alarming, reporting, displays
Historian	InfluxDB + Canary Historian	Open source real-time data storage
Analytics	Grafana	Dashboard visualization
Collection	Telegraf	Data aggregation
Clients	Smart Client, Shop Floor Read Only	Remote access via HTTP/HTTPS

Connectivity

Protocol	Application
OPC UA	Niagara Building Automation
MQTT	Secure access to other systems
Native CIP	PLC communication
Influx Line Protocol	Historian data
.NET Client	Trend data to Grafana

FDA 21 CFR Part 11 Features

Feature	Implementation
LDAP Integration	Centralized authentication

E-Signatures	Electronic record verification
Audit Trails	Custom tracking of all changes
Password Policies	Rotation and strength requirements
Electronic Records	Database security and compliance

Key Enablers

FrameworX capabilities that made this solution possible:

Capability	Application
Built-in Historian	Canary Historian included
CFR Part 11 Features	LDAP, e-signature, custom audit trails
Open Environment	.NET scripting language
Enhanced Trending	Custom calculations and statistics (MKT)
Client-Server Model	Economical unlimited remote users
Redundancy	Included in base system
Multi-Source Data	Multiple data sources for trending/alarms
No Vendor Lock-In	Works with major PLCs and sensor vendors

The Results

- **Replaced Physical Chart Recorders** — Electronic records with database security and CFR Part 11 compliance
- **Open Data Access** — Recorded data accessible via SQL and data historian APIs
- **Real-Time Access** — Live values available via OPC UA and MQTT
- **Enhanced Trending** — Custom calculations and statistics including MKT (Mean Kinetic Temperature)
- **Built-In Reporting** — PDF and XPS format generation
- **Flexible Security** — FDA 21 CFR Part 11 compliance out of the box
- **Remote Access** — Reporting easier and faster with multiple remote clients
- **Redundancy** — Data historian technology handles increasing loads while maintaining response

Customer Testimonials:

> "FrameworX was the perfect SCADA platform to meet our sterile Environment Monitoring system requirements. Its built-in features, allow for full CFR Part 11 compliance out of the box. From the low-cost remote clients, integrated data historian, redundancy, and ease of customization, are key value adds, with no hardware vendor lock-in."
>
> *— Sam Khodak, Pharmaceutical Data Integrity Specialist*

> "FrameworX easily and cost effectively allowed us to handle many use cases and requirements that are hard and/or expensive to implement with other SCADA packages. It also contains multiple tools and interfaces for creating a modern flexible and open architecture system. The SCADA world is not just about working with PLC/Controllers anymore. FrameworX is built to integrate information from smart sensors, MES, ERP, and cloud. With its native .NET scripting, built-in drivers and data connectors, it allowed us to accomplish this without the need for third-party add-ins."
>
> *— Richard Benamy, Controlware*

Resources

Download case study: CaseStudy_ChartRecording.pdf

This case demonstrates FDA 21 CFR Part 11 compliant environmental monitoring with open data access replacing legacy proprietary chart recorders.

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