TATSOFT

Tatsoft is a premier Software Platform Developer for real-time data monitoring, SCADA, HMI, Data Aggregation, Analytics and Advanced Visualization tools. With over 25+ years of experience solving complex problems, the Tatsoft team has industry-proven expertise working with leading companies worldwide, delivering robust industrial applications in a wide variety of industries, from plant floor to the Enterprise.

FactoryStudio for Sterile Environmental Monitoring

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Industry	Location	Market
Pharmaceutical	New Jersey	Global business with 31 manufacturing plants and 7 R&D centres

Challenge

Industry 4.0 requires better data access. Therefore, the company needed to replace their closed non-expandable honeywell GR series graphic chart record. Their old system recorded the data in a proprietary data structure, which needed a separate product to access. That meant they had less security and non-flexible reporting.

Solution

The company chose FactoryStudio powered by FrameworX because it provided a full Solution for Trending, Alarming, Reporting, data storage and graphic displays with redundancy and multiple remote clients. FactoryStudio also includes many real-time devices drivers like OPC UA and an MQTT Broker to allow secure access to other systems.

> "*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*

Results

With the new system, the client could use data historian technology redundancy to handle the increasing data loads and storage requirements while maintaining acceptable user response. They also gained:

1 **Remote access** to the data and **open access** to recorded data, making reporting easier and faster.

2 **Enhanced trending functions**, replacing paper chart recorders and increasing **security**.

3 Flexible security to meet **FDA 21 CFR Part 11**

A changing industry

The FDA requires a validated system for monitoring, alarming, trending and reporting of environmental sensors in sterile environments. These systems are also subject to FDA 21 CFR Part 11 requirements which includes audit trails, password rotation and strength policies, and electronic record verification with e-signatures.
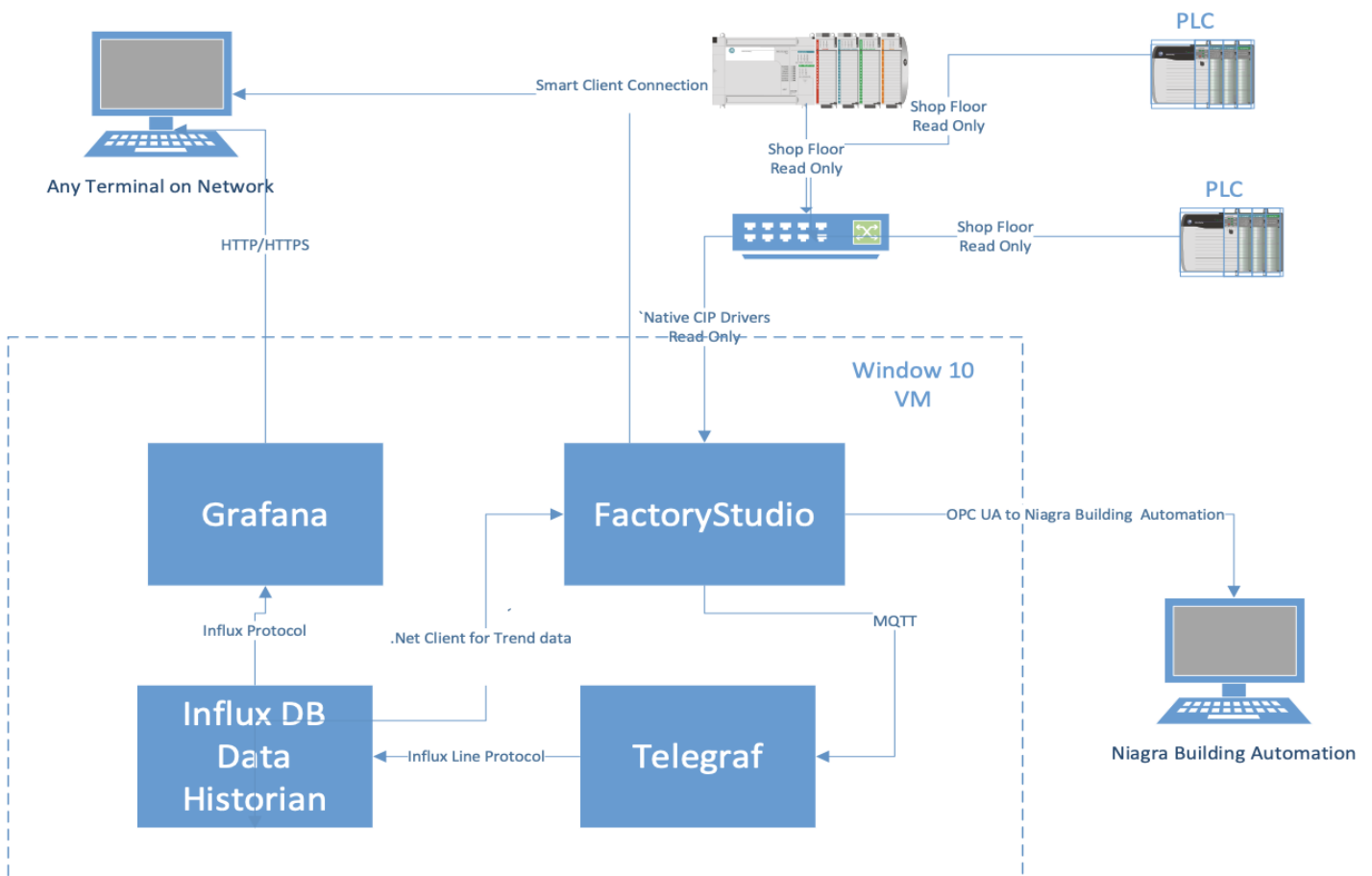
Traditionally pharmaceutical companies have used closed stand-alone or vendor specific systems to handle these requirements. However, there is an increasing need for this information to be available to operations, quality analysts and planners for production decisions (ie. batch quality assessment, cleaning requirements, capacity planning).

There is also a need for systems that are flexible enough to meet FDA regulations and security requirements and are open enough to distribute key production data to needed users.

FactoryStudio powered by FrameworX came through

FactoryStudio was chosen for system requirements based on the following factors:

1. Built in historian (Tatsoft Canary Historian from Canary Labs)
2. FDA 21 CFR Part 11 features (LDAP, E-signature, custom audit trails)
3. Open environment and .Net scripting language
4. Enhanced Trending functions
5. Client-Server model for allowing economical access for unlimited remote users.
6. Redundancy included in base system
7. Works with multiple data sources for trending and alarms.
8. Pricing – Low base system cost, Low remote client cost, free 500 tag historian
9. No vendor lock in – can work with mostly all major PLCs and sensor vendors via native drivers.

A list of benefits the company gained

1. Replacement physical chart recorders
2. Electronic records with database security and CFR part 11 compliance
3. Built in reporting with PDF and XPS formats
4. Open access to recorded data via SQL and data historian APIs
5. Open access to real-time values via OPCUA and MQTT
6. Enhanced Trending functions with custom calculations and statistics (ie. MKT)
7. Native drivers to read data from PLCs, and instrumentation via numerous protocols.

Controlware: our Tatsoft System Integrator Partner

Controlware, LLC. had been providing automation system design, development and integration services, for manufacturing organizations since 1990. They deliver solutions ranging from SCADA, Manufacturing Execution Systems, Batch management in regulated industries. They also specialize in integration to Enterprise Resource Planning, Supply Chain Management, and existing business systems.

To be competitive in today's global marketplace, manufacturing excellence is not enough. Modern businesses require the ability to quickly analyze data from Finance, Sales, Marketing, and Engineering as well as the shop floor, and convert it into information that supports management with effective decision-making. The requires the ability to communicate the results of those decisions appropriately effectively with clients, employees, partners and suppliers in real time. To meet this need Controlware also provides business intelligence solutions, that analyze complex data and present actionable information in the form of executive dashboards, ad hoc reporting tools, real-time database with machine learning.

They also pride themselves on expertise in robotics, machine vision, statistical process control, data and content management. To ensure an optimized solution and overall customer satisfaction, they utilize a disciplined system design and development methodology. This enables them to provide exceptional value by using industry best practices, best of breed products and services, and robust project management in an open, collaborative, and a transparent environment.

"FrameworX easily and cost effectively allowed us to handle many use cases and requirement 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 of Controlware

User nodes

The system went in with fifteen users: four concurrent ones.

Tags/communication points

Native protocol drivers, OPC, MQTT, and connectivity to InfluxDB open source real-time historian.

Engineering time

The full engineering time came up to one month.

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