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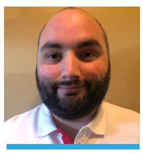
Unified Namespace Implementation in a Pharmaceutical CDMO

The Center for Breakthrough Medicines (CBM), an industry-leading cell & gene therapy contract development & manufacturing organization (CGT CDMO), needed a way to seamlessly monitor their 40+ manufacturing suites to collect and contextualize environmental and equipment data. After looking at typical system architectures, CBM realized that a traditional solution would never allow for the functionality and flexibility they needed without breaking the bank. After much deliberation, they decided on implementing an Industry 4.0 architecture, complete with a Unified Namespace (UNS), Opto22 groov EPIC controllers, Inductive Automation's Ignition platform, and Canary Labs Historian.

ABOUT THE AUTHORS

Mario Robles II is an MES engineer with experience in configuring and commissioning industrial MES, SCADA, and automation systems in life sciences. He is a certified Industry 4.0 professional from 4.0 Solutions. Mario has been working with Skellig since 2021.



Josh Glass is a Sr. Automation Engineer with a background in IT, which enables a unique ability to bridge the gap between IT and OT. Having completed Industry 4.0 projects for Biotech's and CDMO's he has a proven track record of understanding client needs to deliver value. Josh began his career in 2015 and joined the Skellig team in 2021.

James Cheng is an MES Engineer with a background in automation engineering in life sciences. He has valuable experience in working with well-established industry leaders on distributed control systems (DCS), Industry 4.0 projects, as well as commissioning, qualification, and validation (CQV). James has been on the Skellig Team since 2021.

Background

As pharmaceutical manufacturing continues to grow in complexity and scale, the demand for robust data collection and contextualization increases. A single pharmaceutical manufacturing plant can be as large as 400,000+ sq. ft. and have thousands of pieces of equipment, each of which may have hundreds of critical tags that need to be captured to ensure drug safety and compliance. Most industry standard controllers, SCADA systems, and historians have lagged the pace of innovation seen in other technology.

Many standard offerings come with vendor lock-in, a lack of flexibility, high price tags, and a staggering level of complexity that makes systems difficult and costly to integrate and maintain.

In recent years, manufacturers in a variety of industries have started to implement UNS system architectures, which have several advantages over traditional architectures.

A UNS integrates information from different data sources into a common data model that can be used as a single source of truth for all data[1]

This eliminates silos of information, reduces the risk of errors, and can streamline regulatory compliance. A UNS also enables better scalability when configured correctly, making it easier to integrate new products, equipment, manufacturing areas, etc. into the system architecture without significant disruptions. Despite these benefits, few pharmaceutical manufacturers have implemented this architecture in their business due to concerns with the time it takes to develop a high-functioning UNS, disruptions to existing business processes and systems, compliance concerns with the FDA, and the uneasiness that comes with new technology.

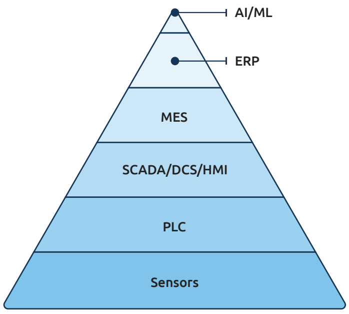
The Problem

The automation team at CBM had two primary constraints when choosing a system architecture:

- The design needed to be flexible and scalable to adapt to the rapidly changing environment of a CDMO
- Data needed to be centrally available and could not be siloed to individual systems

Traditional architectures are often rigid and inflexible, strictly adhering to the ISA95 framework. It is very common for a Level 1 System such as a PLC to only be able to communicate one level down to a sensor and one level up to the SCADA system. The Center for Breakthrough Medicines, as a cutting-edge CDMO, did not find this acceptable and wanted data shared more freely between the ISA95 levels.

Traditional 3.0 Automation Stack



4.0 Unified Namespace

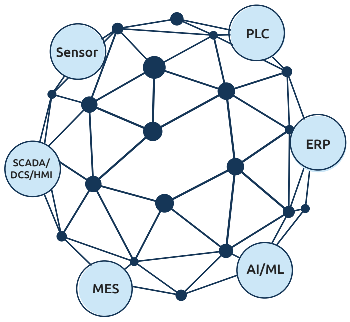


Figure 1: Traditional 3.0 automation stack vs. example UNS diagram. Note: CBM did not have an AI model, WMS, BMS, or ERP system connected at the time this paper was published.

CBM found the typical system level communication protocol, OPC UA, lacking.

OPC UA is a closed protocol, meaning OEMs need to pay to include OPC UA functionality with equipment, increasing cost.

OPC UA is not stateful (it has no way of checking the current state of connection) making current tag values untrustworthy. As a result, OPC UA reports by poll-response, which means that tag updates are pulled on a timer whether the tag values have changed or not. OPC UA transmissions are also heavy and take up significant bandwidth with every transmission. Both qualities make it undesirable in modern smart manufacturing plants with thousands of connected devices.

The MQTT communication protocol[2] is an improvement over OPC UA in multiple ways. It is an open protocol, reports on exception (whenever a value changes) and is lightweight and stateful. Another improved feature MQTT has is Store and Forward. In the event a connection goes down, data is stored locally at the client until connection is restored. Despite these improvements over OPC UA, few OEMs have updated their products to include MQTT support, which would enable businesses to take advantage of a fully networked factory. This made it difficult to find systems that can communicate using the MQTT protocol.

Selected Systems

Inductive Automation's Ignition platform was a clear choice to be used as the SCADA. Ignition supports MQTT communication via available modules curated by Cirrus Link. It is easily scalable and incredibly flexible, allowing it to be refined as business needs change. Highly customized HMIs, tag templates known as User-Defined Templates (UDTs), and alarm pipelines can be created to address the exact needs of the business.

Opto 22's groov EPIC was a natural fit within the architecture as it supports Ignition and comes with MQTT functionality out of the box. It also supports OPC UA connections to ensure that legacy equipment is still usable within a smart factory environment.

Finally, Canary Labs' Canary Data Historian was selected due to its native support of the MQTT protocol and native integration with Ignition. This allows for the groov EPIC to publish tag data from the Edge Ignition gateway acting as the SCADA system for a specific manufacturing area to the Core Ignition gateway acting as the central SCADA for the entire site and the Canary Historian directly. This is impossible in most traditional system architectures that rigidly adhere to ISA95. Compared to a traditional historian like AVEVA PI, Canary is cheaper to implement[3] and maintain, has reduced storage and hardware requirements, and integrates directly with Ignition.

Solution

Skellig was able to successfully tailor a UNS solution to creatively and efficiently address CBM's current business needs, at the same time establishing a solid groundwork for future growth. Skellig used an iterative, trial-and-error development approach, creating functional modules that could be easily modified individually without affecting other modules. This kept the project from bottlenecking on changes to the user requirements, which are all too common in a start-up environment. By anticipating these changes, Skellig was able to reduce the amount of rework needed to arrive at an efficient and reliable final product.

As CBM continuously expands to grow beyond its start-up phase, different manufacturing areas with unique equipment types will need to be added to the UNS at different stages of the business' expansion. Each manufacturing area has an Opto22 groov EPIC running a dedicated Ignition gateway. To integrate a new area into the facility's primary SCADA, the Ignition gateway running on the Opto22 groov EPIC seamlessly pushes tag data via MQTT to the main Ignition gateway that captures all tag data for every manufacturing area in the facility.

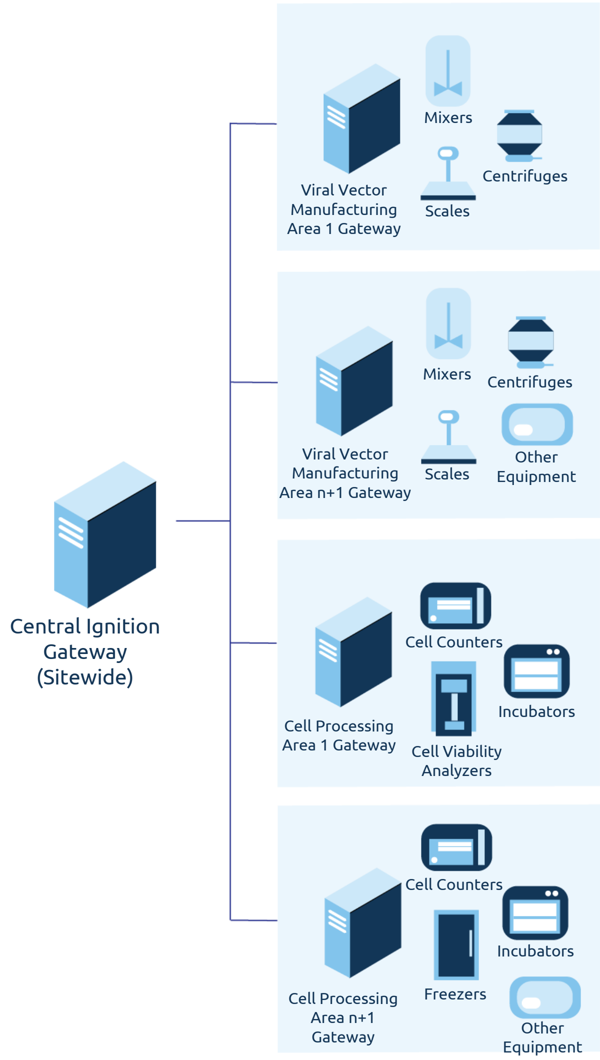


Figure 2: A central Ignition gateway collects data from every local area's Ignition gateway. Local area gateways collect process data directly from sensors and equipment on the plant floor.

To avoid repetition of work, Ignition's User Defined Types (UDTs)[4] were used extensively to create tag "templates" of manufacturing equipment and sensors. For example, the same model of temperature sensors (with the same scaling and alarm mechanism) is used in every manufacturing suite. When a new suite is integrated into the Environmental Monitoring System in Ignition, an instance of the Temperature Sensor UDT already containing all relevant tags and parameters is created for each temperature sensor in the suite. Each UDT is validated at the time of creation so there is no need to validate each UDT instance. This drastically reduces the time needed for validation.

Another unexpected time saver was the Canary Historian itself.

Unlike some of its competitors that can take weeks, standing up Canary's infrastructure only took a couple days

The Canary MQTT features made it easy to subscribe to tags and it even automatically creates new tags when they are added to the SCADA, eliminating the need to validate tag additions to the historian. Canary includes Axiom, a full HTML5 application to view tag data, in the basic installation. On day one, Canary delivered a graphical interface to view tag data that has since been used for multiple investigations and troubleshooting. Canary has been the "set it and forget it" historian that continues to impress even as more and more devices are integrated continuously in all areas of the business.

Skellig set up and tested all components and systems used in the UNS individually to ensure they would work together. As part of validation, Skellig reviewed all vendor-provided documentation pertaining to commercial off-the-shelf (COTS) functionality and ensured any validation done by the vendors is up to site requirements. Should there be any gap or custom code, Skellig took necessary measures to validate objects to GAMP 5 Category 5 standards.[5] With this approach, Skellig was able to significantly reduce overall time spent on validation while being able to devote more time to refining custom code, resulting in a more polished delivered product to CBM.

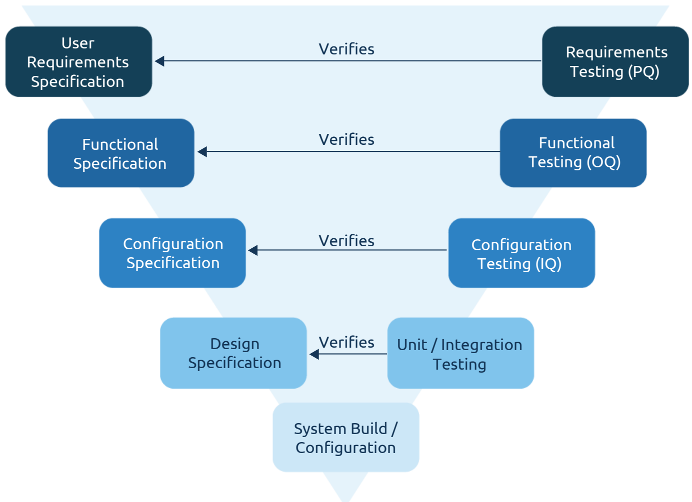


Figure 3: The GAMP 5 V model describes the activities and deliverables needed for the risk-based validation of computer systems.

Results & Outcome

After implementing a UNS with the assistance of Skellig, the Center for Breakthrough Medicines has seen significant improvements in their processes and scalability. CBM was able to stand up and validate a sitewide data management system and historian within a year.

The system architecture has allowed CBM to integrate their data sources and systems in a way that reduces the time and effort the engineering teams need to manage data and equipment, which allows the business to access critical data faster and make better, more-informed decisions.

CBM is also able to stand-up and integrate new manufacturing suites to the larger UNS within days. Using a legacy system architecture would take weeks. Skellig's expertise and support throughout the implementation process has helped to ensure that the project was executed smoothly and effectively. This partnership has enabled CBM to reap the benefits of a smart factory, allowing them to quickly adapt and grow their manufacturing capabilities into the future.

ACKNOWLEDGEMENTS

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Citations (APA)

1. Canary. (2020, April 23). Data historian pricing comparison for Aveva Pi, Ignition, and Canary. Canary Blog. https://blog.canarylabs.com/canary-ignition-and-osisoft-pi-pricing-comparison

2. GAMP 5 Categories, V model, 21 CFR part 11, EU Annex 11. AmpleLogic. https://amplelogic.com/brief-on-gamp-5-categories-v-model-and-21-cfr-part-11-eu-annex-11/

3. Manditereza, K. (2022, December 7). What is Unified Namespace (UNS) and Why Does it Matter? https://www.hivemq.com/article/what-is-unified-namespace-uns-iiot-industry-40/

4. Inductive Automation. (n.d.). User defined types - UDTs. Ignition Documentation. https://docs.inductiveautomation.com/display/DOC81/User+Defined+Types+-+UDTs

5. Inductive Automation. (2023). The Best Industrial IOT Solution for Efficiency, Connectivity & Data Insights. Build an IIoT Solution with the Power of MQTT | Ignition IIoT Software. https://inductiveautomation.com/solutions/iiot#:~:text=Ignition%20uses%20MQTT%2C%20the%20leading,and%20secured%20with%20TLS%20technology