
canary
Canary User Conference
August 11- 14 State College, Pennsylvania
canary

Implementation of Industry 4.0 Automation Solutions in the Pharmaceutical Industry

Eric Reisz
Sr. Automation Consultant

About Eric and his Experience in Automation

- B.S. Chemical Engineering, Widener University
- ~15 year working Automation within the Pharmaceutical Industry
- Experience across Manufacturing, R&D, Small & Large Molecule, APIs, Laboratory and Benchtop Scale, Testing and Analytics, and Cell & Gene Therapy
- 2020 Engineering Leader Under 40 Award
- 2023 Firebrand Award for Industry 4.0 Project
- Multiple Publications and Conference Speaking Engagements

canary

Presentation Objectives

Discuss the implementation of automation solutions utilizing modern open platform systems deployed with an Industry 4.0 approach in the Pharmaceutical & Life Sciences Industries.

Challenges: Examine unique Automation and Data Challenges we face in the Pharmaceutical Industry.

Architecture: Define Automation and Data Management architectural components and the approach for utilizing Industry 4.0 technological solutions.

Canary System: Discuss where Canary fits into the Data Management architecture and the advantages of using Canary.

Value: Through practical, real-world examples demonstrate measurable ROI and implementation advantages.

canary

Pharma & Life Science: Unique Perspective & Challenges

Pharmaceutical and Life Science companies must meet regulatory compliance standard related to data integrity that are unique to the industry when developing a data management system.

Regulatory Compliance:

- ✓ Data Integrity Requirements
- ✓ 21 CFR Part 11 Compliance and ALCOA+

Validation Costs:

- ✓ System qualification, change control, and life cycle documentation requirements.

Regulatory Scrutiny:

- ✓ FDA inspections, audit trails, and traceability requirements.
- ✓ Increasingly more emphasis placed on implementing digital solutions.

canary

Business Questions for Developing a Data Management System

What Data do we have? → **What does our Data mean?** → **How is our Data related?** → **What can our Data tell us?** → **How can our Data work for us?**

Generation

Contextualization

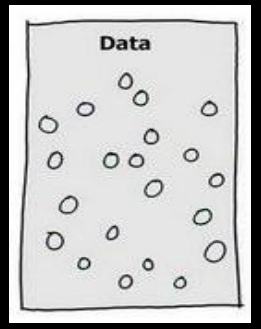
Association

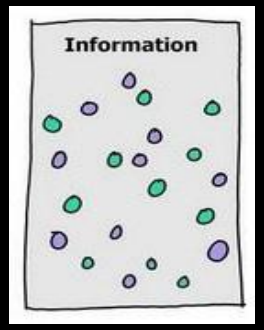
MES

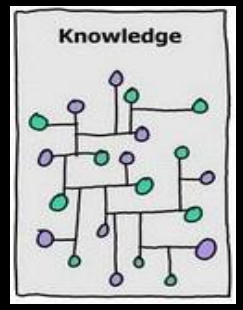
Availability

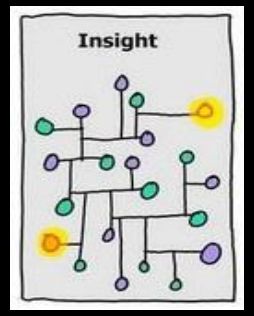
Advanced Analytics

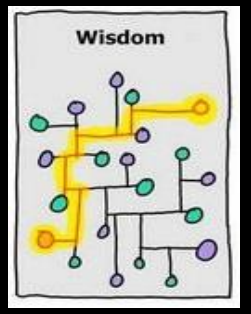
AI











Collection

Historization

Metadata

Analytics

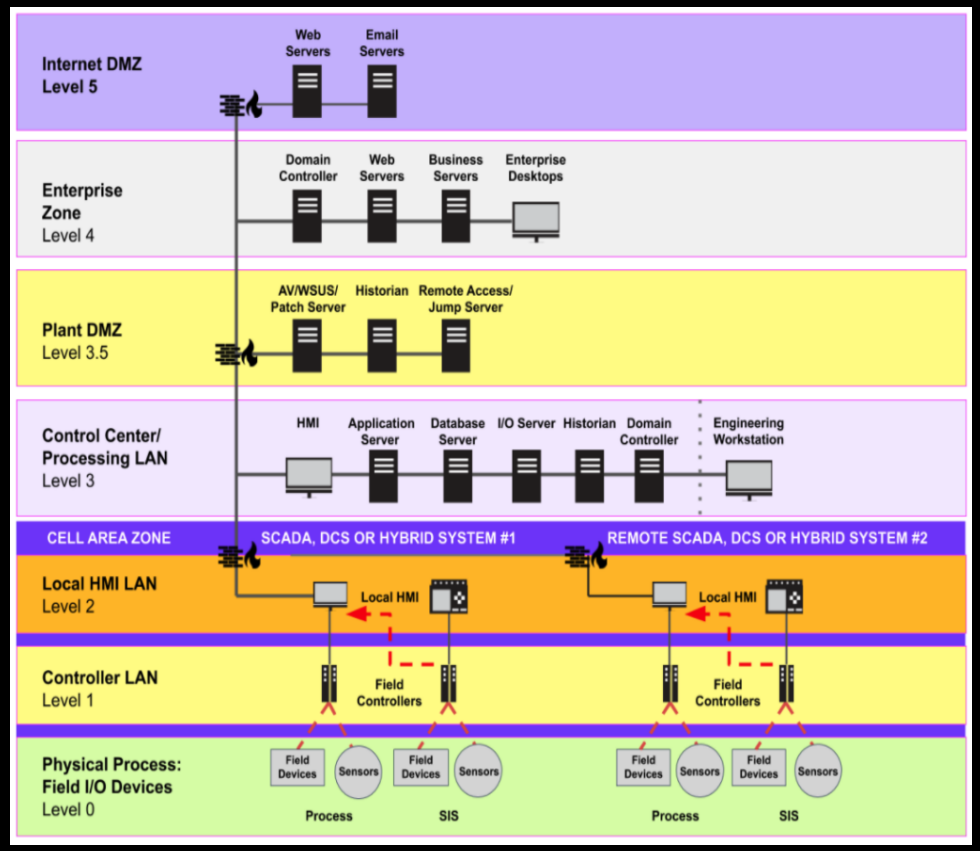
Notifications

Reporting

Machine Learning

canary

Purdue Model vs Industry 4.0 Data Web Architecture



Data Management Tech Stack

Core Components

1. Field I/O and edge devices (lvl0-2)
2. Time series data archive
3. Relational data storage
4. Plant-level systems (lvl3)
5. User Interfaces and Dashboards
6. Process Control & MES
7. Enterprise-level analytics and reporting (lvl4-Cloud)

Modern platforms that are highly flexible, scalable and secure that support open platform and data integration.

Pharmaceutical Cloud Deployment Considerations

The Cloud isn't a Storage Solution

The cloud's a platform for data analytics and distribution. Its role is further contextualization of data subsets from multiple sites to provide a higher level, holistic view of operations to high level stakeholders.

Audience-Driven Design

Understand who the audience is and the roles of the various stakeholders interfacing with the cloud layer and what data and information are required to support their decision making.

Build the Data Modeling First

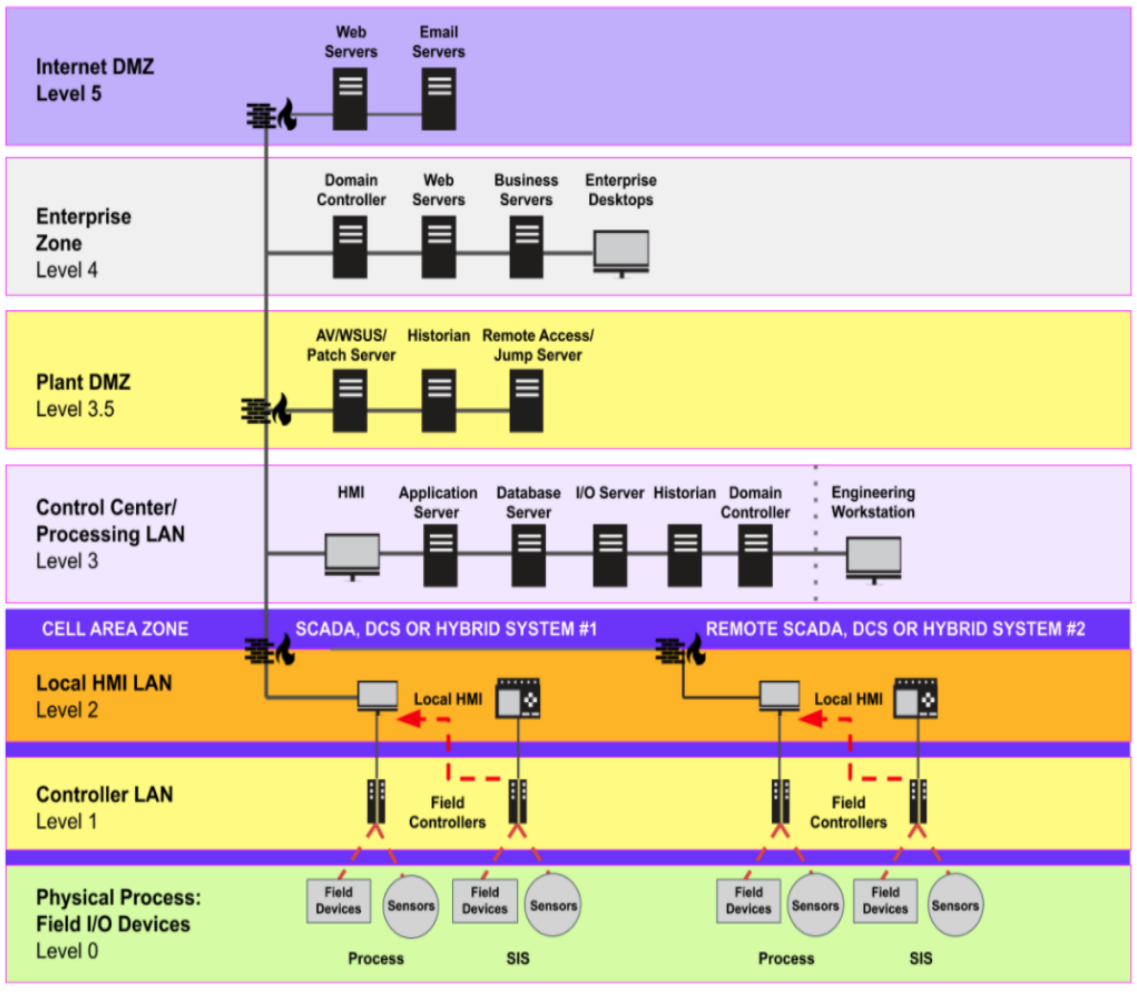
Structure data before cloud deployment. Determine what data is needed in the cloud, from where, who wants it, and why.

Appropriate Data Subsets

Not everything belongs in the cloud. Determine what data and metrics are valuable to users.

canary

Where Does Canary Fit In?



- **Cloud Implementation:** High level operational analytics and reporting providing centralize, holistic cross-facility view of company operational performance.
- **Level 4 (Enterprise Systems):** Integration with ERP, LIMS, reporting, and quality systems.
- **Level 3 (Manufacturing Operations):** Plant-wide or Area historian for data aggregation, contextualization.
- **Edge Deployment:** Local data collection and contextualization.

canary

Canary's Key Advantages

- **Seamless Integration:** Integrates seamlessly with the rest of the preferred tech stack.
- **Native Connectivity:** Built in OPC, MQTT, ODBC, Web & gROC API connections
- **Batch Capabilities:** Equipment organization, meta data addition, events, advanced analytical capabilities for contextualization and data association which all can be deployed in support of batch operations.
- **Axiom:** Built-in trending for troubleshooting, no separate client software
- **Lower TCO :** Typically, 40-60% estimated lower than alternatives.
- **Quick Tag Deployment:** 95% reduction in time required for tag deployment and verification.

canary

Why should I use Canary instead of PI?

1. **System Footprint:** Requires less VMs and corresponding overhead
2. **Deployment Simplicity:** Single installer vs complex multi-system setup.
3. **Integration Capabilities:** Designed to integrate with other system.
4. **Performance & Reliability:** "It Actually Works!" Real-world performance
5. **Regulatory Compliance:** Canary is 21CFR Part11 Compliant
6. **Cost Structure:** Flexible licensing models at significantly lower costs
7. **Modern Architecture:** Built for Industry 4.0 from the ground up
8. **Future Proofing:** Built to be infinitely expandable with Scalability, Data Integrity, and Security primary design considerations as the code base is continually being modernized to adopt new technologies.

canary

Real-World ROI Example of Industry 4.0 Advantages

Use Case: Adding 10,000 data point to and existing system

Legacy Technology and Validation Approach:

- Point addition and verification at a rate of ~120 points per day
- Consultant rate $125 per hour (cheap!)
- Work Time: >80 Workdays (4 Months)

4 Resources, ~1 Month, Cost: ~$85,000

Industry 4.0 Approach

Using Canary, Ignition, Opto22 and taking advantage of their MQTT capability:

1 Resource, 1 Week, Cost:<$5,000

canary

Thank You

Eric Reisz
Sr. Automation Consultant

Questions ?

canary