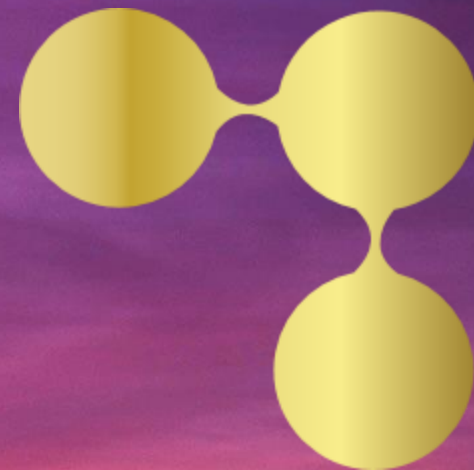


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PHARMA





Simplifying Deviation Investigations and Accelerating Time to Insights with PI Event Frames

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Indianapolis API Manufacturing

- Drug Substance Manufacturing Site in Indianapolis, Indiana
- Multiple products produced across many unit operations
- API is sent to downstream formulation, fill, and packaging lines

My Story: Transitioning from Continuous to Batch

Continuous Process

Steady State Conditions

Transient Start-Ups and Shut-Downs

Minimize Downtime

Minimal Discrete Events

Batch Process

Transient Conditions

Same Equipment, Different Products

Inherent Downtime

Many Discrete Events

Equipment performance
during a phase?

Parsing clean-in-place vs
drug product batches?

Determining phase
start and end times?



Less Processing + More Analysis = Better Outcomes

CHALLENGE

- Batch manufacturing is inherently transient
- “Traditional” data analysis can be cumbersome and inefficient
- Too much data processing, not enough data-driven conclusions

SOLUTION

- Easily access batch recipe context with PI Event Frames
- Minimize labor-intensive mapping of process data to batch data

RESULTS

- More time for SMEs to interpret data of interest
- Minimize assumptions and incorporate all available data
- Output more robust CAPA plans from investigations

Leveraging PI Event Frames for Batch Context

- Event Frames (EF) contextualize time-series data related to specific events, such as batch recipes
- ISA-88 Procedural Control hierarchy is maintained
- EF attributes mapped to Capsule Properties
- EF database queried directly in Workbench as Conditions

Event Name	Event Template	Associated Unit	Start Time	End Time	Duration	Batch ID
Unit Procedure A	Unit Procedure	TK1234	24-Dec-24 01:22:23	25-Dec-24 00:30:56	23:08:33	ABC1234
Operation 1	Operation	TK1234	24-Dec-24 03:25:07	24-Dec-24 20:28:36	17:03:29	ABC1234
Operation 2	Operation	TK1234	24-Dec-24 20:28:36	25-Dec-24 00:30:43	4:02:07	ABC1234
Phase 2A	Phase	TK1234	24-Dec-24 20:28:37	25-Dec-24 00:18:01	3:49:24	ABC1234
Phase 1A	Phase	TK1234	24-Dec-24 03:25:09	24-Dec-24 03:50:18	0:25:09	ABC1234

Table 1. Example PI Event Frames batch information obtained via PI DataLink for imaginary Batch ABC1234.



Event Frames as Seeq Conditions

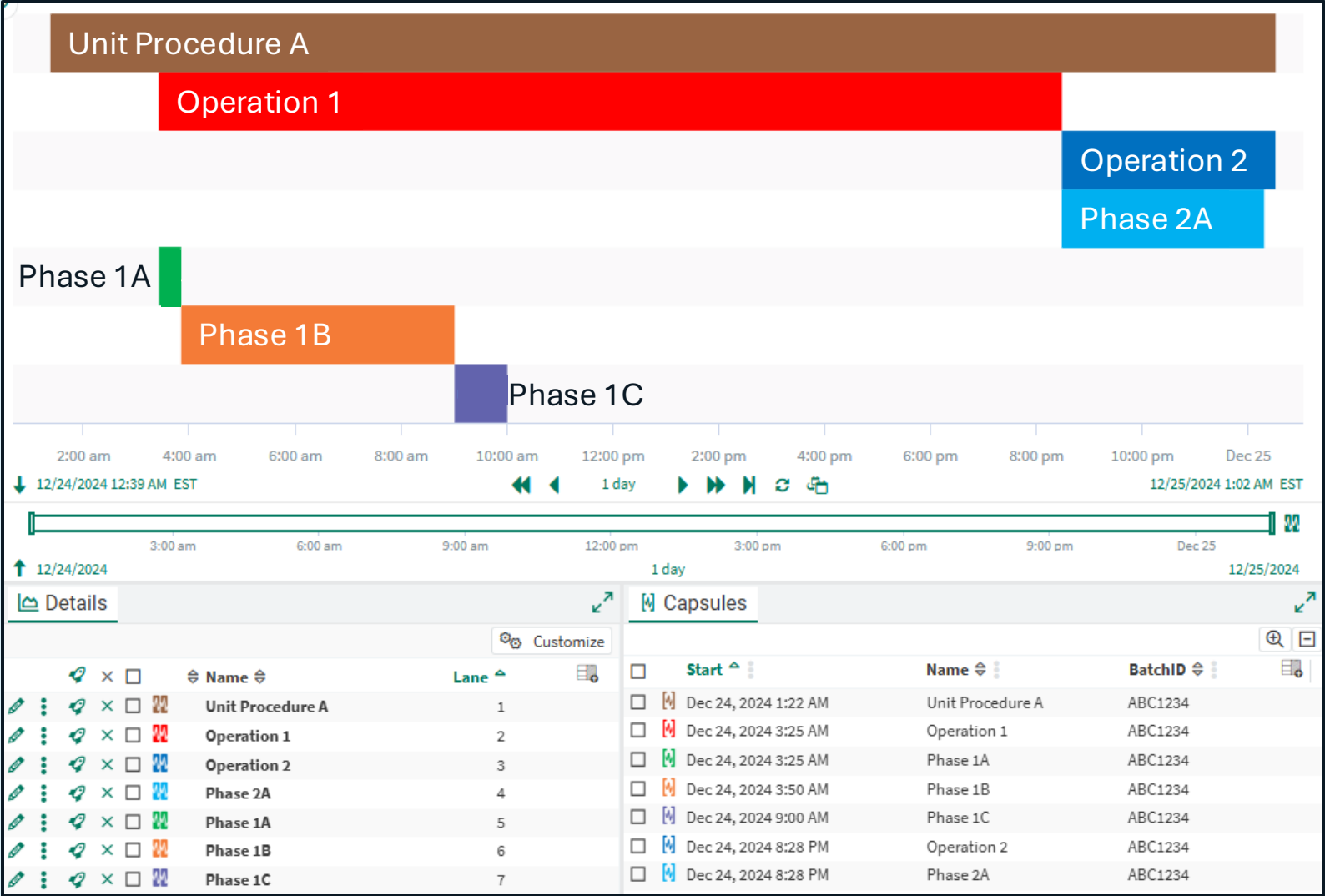


Figure 1. Example PI Event Frames as Conditions in Seeq for imaginary Batch ABC1234.

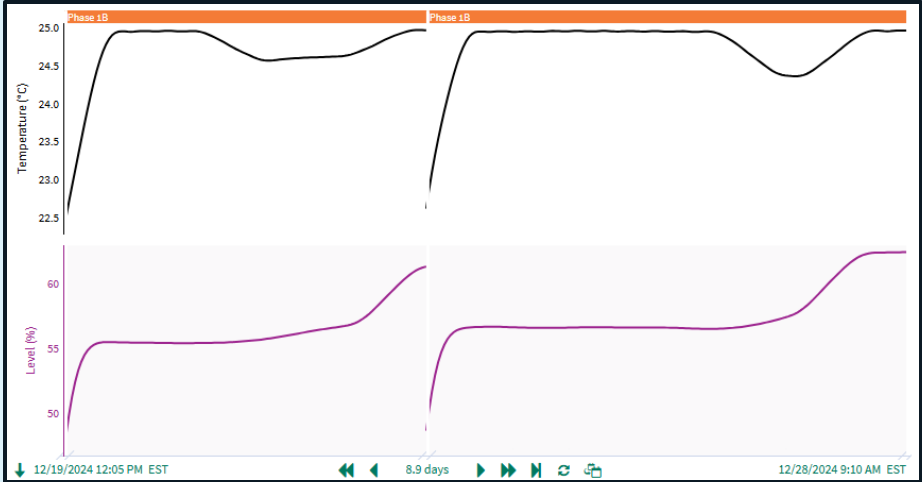


Figure 2. Chain View for Phase 1B, with temperature and level.

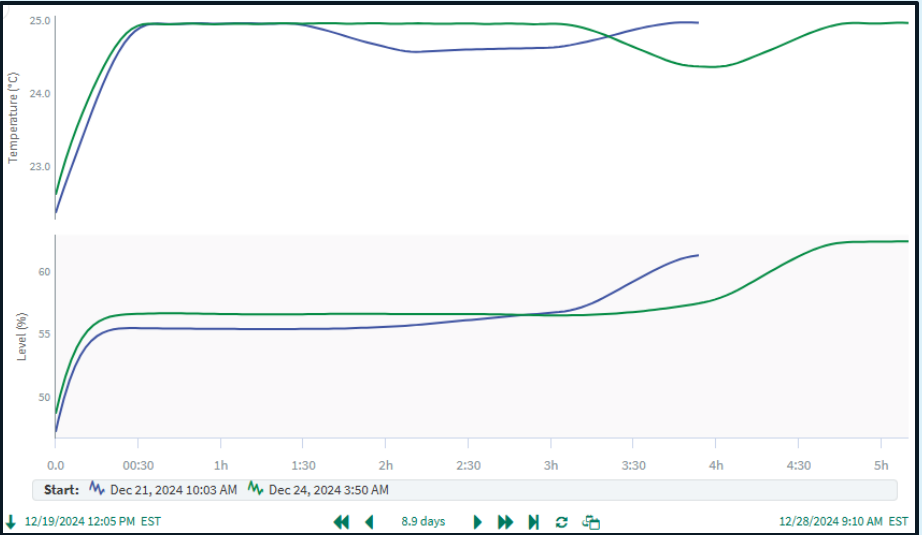
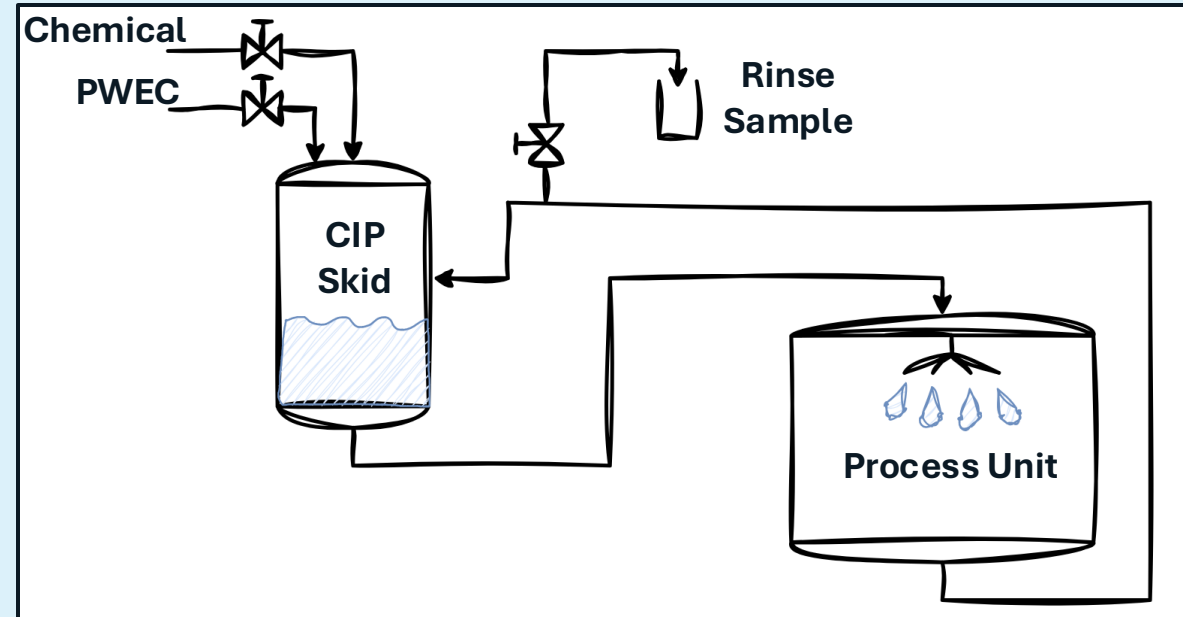


Figure 3. Capsule View for Phase 1B, with temperature and level.

Use Case: CIP Cleaning Verification Sampling

⚙️ Process Background

- Process units are cleaned with a common CIP skid
 - CIP = Clean-In-Place
- Post-CIP, sample solution to verify cleanliness
- Concentration ensures residual product is dissolved
- Procedure instructs when to sample



Use Case: CIP Cleaning Verification Sampling

⚠ Problem Identified

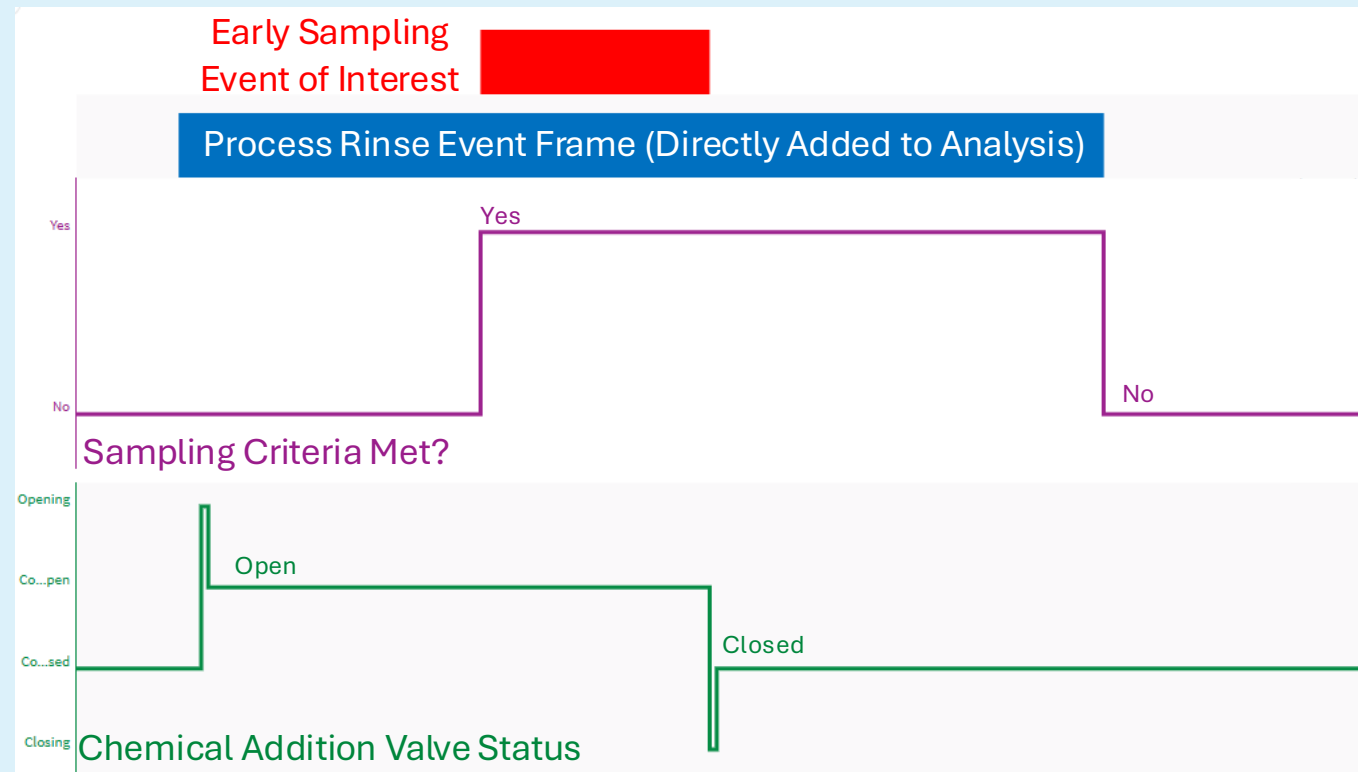
- Sampling can occur prior to completion of chemical addition
- Chemical concentration lower than target → impacts solubility and sample validity

🔍 Analysis Needed

- How many times could this have happened?
- On what process units?
- What were the specific CIP batches?
- How long was the time window for an early sample to be taken?

Identify One Event, Then Scale-Up

- CIP Rinse Phase EF Condition with Batch ID and Unit Capsule Properties
- Formula Condition when sampling criteria is met, but chemical addition ongoing
- Combine EF and user-defined Condition to generate events of interest



Data Overload to Meaningful Insights

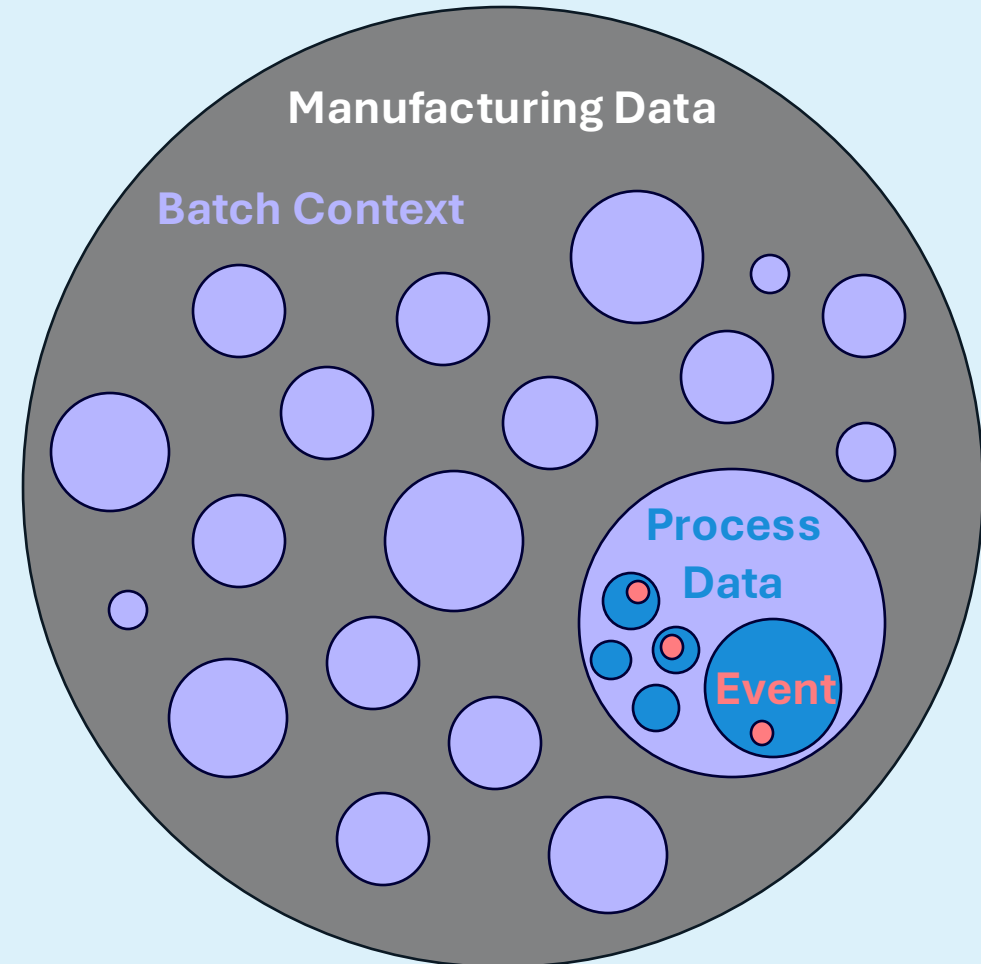
Investigation Scope

3 Years Manufacturing Data

21 Process Units

3,000+ Batches

525,600 min Active Skid Use



Events of Interest Diluted by Large
Amount of Data with No Context

Data Overload to Meaningful Insights

Investigation Scope

3 Years Manufacturing Data

21 Process Units

3,000+ Batches

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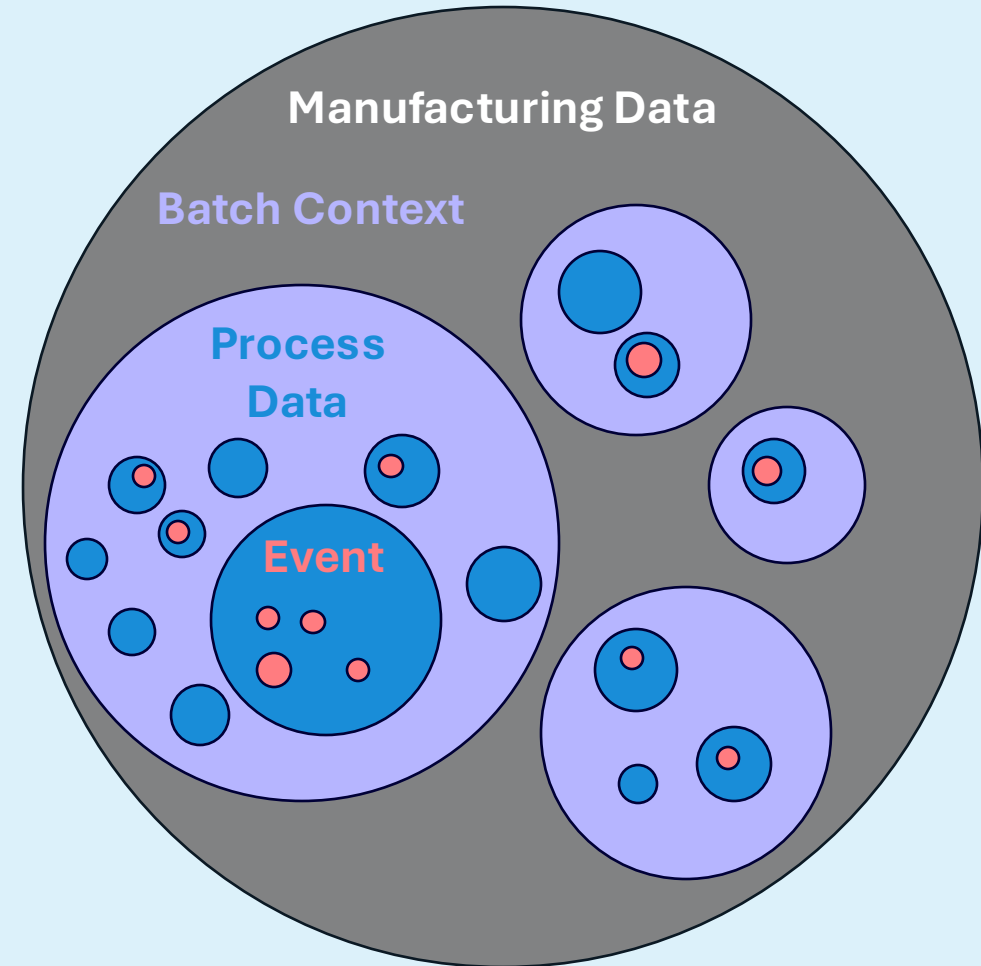
Results

2 Hours vs 2+ Days for Analysis & Report

5 Process Units of Interest

40 Batches of Interest (1%)

2.8 min Avg (110 min Total, 0.01%)



Context via EF Provides Clarity and
Eliminates the Noise

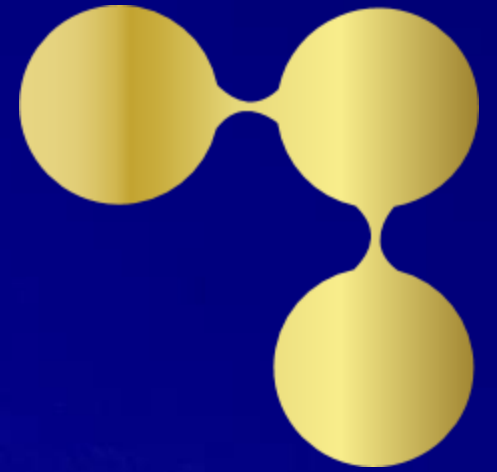
Technical Report & Validation

- Report detailed analysis to ensure repeatability
- Second Person Verifier re-created analysis and confirmed final results
- Events of interest provided to cleaning SMEs, including:
 - Start/End Time of Potential Early Sampling
 - Duration of Potential Early Sampling Period
 - Batch ID
 - Process Unit
- Data-driven batch impact evaluation
- Cleanliness confirmed via redundant cleaning metrics and downstream testing

Takeaways and Opportunities

- EFs quickly add batch context to process data
- Simple frontline wins are a catalyst for Seeq adoption
- How is your site structuring data to make it accessible for end users?
- Do you utilize PI Event Frames? Are they connected to Seeq?
- Are all end users aware of the data available to them?

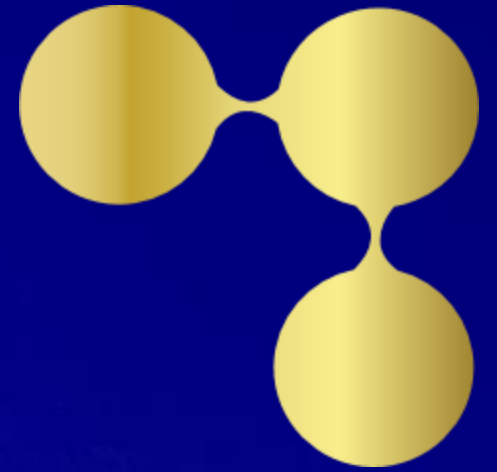
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Questions?



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Thank You

