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### Deep Digital: Enabling AVEVA PI System connection to MES through a UNS SESS-47

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# DEEP DIGITAL SOLUTIONS GROUP

Enabling AVEVA PI System connection to MES Systems through a Unified Namespace (UNS)

April 2025

### Who are we ?

- Global Consultants/SME's, Focusing on the DATA space
  - Data Consultancy / Data Integration / Data Utilization
  - Utilizing diverse data infrastructure solutions, including AVEVA PI, to enhance data accessibility and integration
  - Driving data democratization through Unified
     Namespace (UNS) and DataOps strategies.
- 2 Primary Offices
  - Head Office Dungarvan, Ireland (EU / CH & ROW)
  - o USA Office Philadelphia, PA, USA
- Global Engagements
  - Working with 7 of the top 10 Pharma companies
  - Extensive partnerships with AVEVA on customer engagements





- 01 Digital Challenges in Life Sciences
- 02 Introduction to Unified Namespace (UNS)
- 03 AVEVA PI System and MES Data
- 04 Validating UNS
- 05 Scalability and Flexibility
- 06 Lessons Learned and Key Takeaways



Speaker: Nathan O'Connor

### The Digital Challenge in Life Sciences

- 'Best in Class'..but.. Disconnected systems: PI System, MES, ERP, LIMS, IoT
- Compliance burdens: Data integrity, audit trails, traceability
- Point-to-point integrations = fragile and hard to scale
- Need for real-time, context-rich, validated data





## Introducing the Unified Namespace (UNS)

- A centralized, structured data layer (S95)
- Acts as a digital backbone
- Real-time, contextualized, standardized information
- Enables scalable, loosely coupled architecture
- MES Vendor and version agnostic



### **Traditional Architecture vs UNS**

- Legacy (spaghetti) vs UNS (hub-and-spoke)
- Fewer connections, easier to maintain
- Promotes clean data flow and system reliability



## **Key Concepts of IT/OT Integration**

 Two key frameworks are essential in understanding equipment and processes in industrial environments: ISA-95 (S95) and ISA-88 (S88).

ISA-95 & ISA-88	Taxonomy	Interrelation	Goal
<ul> <li>Standard for integrating enterprise and control systems</li> <li>ISA-88 (S88): Standard for batch control</li> <li>Focus: Defines models and terminology for manufacturing operations</li> </ul>	<ul> <li>Method of classifying and organizing information</li> <li>Ensures consistency across teams</li> <li>Focus: Defines categories, relationships, and attributes</li> </ul>	<ul> <li>ISA-95 defines the hierarchy of systems and data flow</li> <li>ISA-88 provides a framework for batch processes</li> <li>Both standards benefit from a well-defined taxonomy for clear communication.</li> </ul>	<ul> <li>Improved Communication</li> <li>Consistency in Data Management</li> <li>Alignment Across Teams</li> </ul>

- Taxonomy, a method of classifying and organizing information, maintaining consistency <u>across teams</u>.
- Understanding the relationship between these frameworks and taxonomy is essential for effective communication and integration.



### Why is Nomenclature / Taxonomy so Important

- 1. It provides a KNOWN convention for USERS to access the data they need.
  - ✓ LOCAL USERS / Local Requirements
  - ✓ CORPORATE Users / CORPORATE Requirements
  - LOCAL and Corporate requirement CAN be similar but most often are distinctly different

#### 2. It provides a systematic methodology for PLATFORMS to 'consolidate' data

- ✓ Alignment of ASSET Nomenclature across platforms (MES / LIMS / SDMS)
- Alignment of ASSET Attributes Nomenclature conventions across platforms
- LOCAL and Corporate requirement CAN be similar but most often are distinctly different

#### 3. It provides a common language for users to "talk" data

- You call it an OPERATION .... I call it a PHASE
- Cross-Propagation of knowledge / education / capabilities across teams
- The UNIT Name = ASSET NAME = MACHINE Name = RE-101



### **AVEVA PI as a Critical Data Source**



- Captures time-series data: Equipment, batch, utilities
- Rich contextualized history and real-time insights
- Foundation for continuous improvement and analytics
- Often siloed and difficult to contextualize



# What Data Should Flow between PI System & MES?

System	Detail Level	Key Data	Granularity	Primary Role
SAP	Batch, Order	Batch ID, BOM, Orders, Inventory, Quality Status	Coarse (mins/hrs, transactional)	Business layer, batch definition and movement
MES	Step, Equipment	EBRs, Execution Steps, Operator Logs, Exceptions	Medium (secs/mins)	Execution tracking, procedural context
PI	Process Variables	Temperatures, Trends, Equipment States, Event Frames	High (sub-sec to secs)	Real-time process data, time-series insights





### Reasons to Connect PI Systemand MES Data (#1) PI System as MES Enabler

#### Infrastructure Implemented and Qualified.

- Networking infrastructure implemented and reliability challenged
- Data flow / infrastructure qualified
- Equipment is 'Data Enabled'
  - Equipment Remediation Identified & executed & data flow active
  - Data resolution requirements defined and implemented

#### Process Knowledge Enhanced

- 6/9 months DATA available for data analysis.
- Fully contextualized data-sets available for Process Refinement
- "I know .. but .. This is what the process data is presenting"
- Process Knowledge BES Systems Enhancements / Remediation
  - Example : Contextualization Triggers.
  - Example : Looping Phase(s) itemization
- MES Authoring / Prioritization
  - Leverage AF & Class Templates for Recipe Authoring
  - Live data-sets liked to standards templates nomenclature standardized
  - MES / Process Data Linkage enabled by default

IT – 'Network & security infrastructure needs to be implemented and qualified'

**OT** – 'That equipment will require remediation to data-enable for bi-directional data access'

MES – 'I know that is what you say the process is ... but this is what the data is telling me'

MES – 'I Need to specifically know what the ID of each phase executed is'

**OT** – 'I have all the class libraries for MES enabled – just author based on the agreed Libraries, so data is available as standard'



# Reasons to Connect PI System and MES Data (#2)

### PI System as MES Data Enhancement

- MES Focus / Priority
  - MES focus is within manufacturing regulatory compliance
  - Acquires data from DIVERSE systems
     Examples : ERP / CAPA / LIMS / DMS / HR & PROCESS DATA
  - Provides RICH & HIGHLY CONTEXTUALIZED data sets
- The Need for Higher Resolution Data
  - MES requires KPI data sets ONLY (Temperature... not Temperature Profile)
  - PI & tightly integrated MES / PI provides access to higher resolution data sets
  - Process Data and MES data closely integrated 'by default'

#### Systems Interconnectivity - NOMENCLATURE

- MES / LIMS / Process Data Integration capability enhanced (nomenclature)
- Fully contextualized (near-Realtime & high Historical & data-sets available)
- Interconnectivity KNOWN and ENFORCED through recipe Authoring

#### AVEVA PI – Historical Data

- PI provides High Resolution AND highly contextualized historical data set
- 'BIG DATA' data acquisition simplified considerably
  - MES : Process KPI's / ERP / LIMS / CAPA / DMS
  - PI : High Resolution Data-Sets for enhanced data Analytics



JNJ users Conference Slide 2018



### Reasons to Connect PI System and MES Data (#3) PI System & MES & Alarms

- What is an Alarm ?
  - Is it a PROCESS ALARM / SAFETY ALARM / EVENT ?
  - Is it a BOOLEAN alarm ?
  - Is it an ALARM Message String? Does it contain all required details?
  - Are there ALARM Messages being 'SILENCED'
- Should MES acquire Alarm Messages ?
  - If it is a KPI PROCESS Alarm YES !
  - If the PROCESS LIMITS are Aligned to the process Limits in MES YES !
  - If limits (in source) alighted to PROCESS PHASE Limits YES !
  - If source configured to operate against PRODUCTION Times YES !
  - If the Alarm / Event capability in source is qualified and managed YES !
  - If none of the above NO! (possibly overly complex with little value)

#### Where should MES acquire Alarms from ?

- Process Data Captured from PI so acquire from PI
- The Why #1 Most likely used in PI to generate Batch Context.
- The Why #2 Process values acquired from PI.
- The Why #3 AF/EF already providing suitable structure for acquisition.
- The Why #4 Efficient storage of all messages.



PI System is an **excellent** Repository for Alarm / Event / Audit messages – although it may **not** be the **final** destination for all messages if comprehensive data analytics purposes.

### Reasons to Connect PI System and MES Data

#### **Real-Time Data Visibility**

Access real-time production and process data for faster decision-making and issue resolution.

#### **Better Traceability and Compliance**

Seamless integration ensures full traceability and helps meet regulatory requirements.

#### **Contextualized Data Set**

Connect PI and MES to enrich data with business context, such as equipment IDs, batch numbers, and operator actions. This allows for advanced analytics on both raw process data and business-relevant metadata, providing a deeper understanding of operations.

#### Manufacturing Equipment Classifications



PI is the best-in-class platform for real-time manufacturing systems data integration / data storage / data contextualization



#### Laboratory Equipment Classifications

### Reasons to Connect PI System and MES Data

#### **Advanced Analytics and Reporting**

Leverage integrated data for comprehensive analysis, improved reporting, and actionable insights.

#### **Enhanced Automation**

Bidirectional data flow enables automated responses and actions based on real-time conditions.

#### **Reduced Integration Costs to Source Equipment**

By using a unified data platform, integration of equipment from different sources becomes simpler and cheaper, eliminating the need for complex point-to-point connections.

#### **Manufacturing Equipment Classifications**



PI is the best-in-class platform for real-time manufacturing systems data integration / data storage / data contextualization



#### Laboratory Equipment Classifications

### **Connecting Pl System to MES Through UNS** Note : MES = KPI + LIMS + CAPA + ERP + DMS ; PI = High Fidelity Process Data

- **Real-time Data Integration:** Data is pulled from the PI System to the UNS in real-time.
- MES Data Subscription: The MES subscribes to relevant topics from the UNS for real-time updates.
- Bidirectional Communication: The PI System can pull data from the MES via the UNS. Enables seamless, two-way data exchange between PI and MES.
- No Direct PI-MES Link: No need for a direct point-to-point connection between the PI System and MES; data flows through the UNS for better scalability and flexibility.

"\_name": "ComboData", "\_model": "Combo", Aveva Pl " timestamp": 1720170318993, 'PI BatchID": "RTY8243". "PI BatchStartTime": "2024-02-06T10:15:42.586Z", <u>[;;;;</u> "PI BatchEndTime": "2024-02-013T08:52:24.458Z", "PI\_LotSize": "800", OFF "OEE\_OEE": "1.985213", "OEE\_OEETarget": "60", "OEE\_RTE": "14", 1010 "OEE\_RTETarget": "75", 1010 "PLC\_PressureIndicator": "125", PLC "PLC Status": "Running", "PLC\_JacketTemp": "95", "PLC\_BeltSpeed": "50", "MES CycleTime": "1025", "MES\_ProductionRates": "150", "MES\_ScrapQuantities": "12", MES "MES\_NumberofDefects": "9", "area": "Building 1" "processCell": Fill-Finish S95 "unitID": "FL-1234"

#### Closely coupled PI / MES data provides standardized ENHANCED data sets



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Client/Dublin/Building 1/Fill-Finish/FL-1234/ComboData

### **Practical MES Use Cases Enabled by UNS**



### Validated UNS

- Treat the UNS like a GxP system: Plan, document, test
- Validate data flows: PI System to UNS, UNS to MES
- Ensure audit trails, version control, access control





### **Validation Flow/Considerations**

#### Scope

- Implementation of UNS
- Integration of existing/new systems
- Data Migration & Management
- User Access and Security Controls
- Compliance
- Objectives
  - Regulatory Compliance
  - Functional Verification
  - Data Integrity & Security
  - Operational Readiness

- Responsibilities
  - Identification of responsible persons for deliverables, ownership and accountability.
- Validation Strategy
  - Next Slide for Details
- Risk Assessment
  - Identification
  - Evaluation
  - Mitigation Strategies



### **Validation Flow/Considerations**

- IQ/OQ/PQ
  - Procedures
  - Documentation Review
  - Testing
- Documentation
  - Validation Plan
  - Requirement Specification
  - Risk Management Plan
  - Test Plans and Use Cases
  - Validation Summary

- Change Control
  - Change Control Process
  - Document proposed changes
  - Assess Impact
  - Approvals
  - Re-Validation Plan
- Training
  - End User and System Admin Training
- Approval
  - Validation Report Approved by Validation team, PM, PO and QA before UNS Solution Go-Live



## **Validation Strategy**

#### **Functional Requirements**

- Data Management (Integration Capabilities (MES, PI etc), Data Output to existing Systems (UNS, Cloud etc), Real-time data access, One True Data Source, Data Entry & Retrieval
- User Roles & Permissions
- Audit Trails
- **Output Topic**



#### Non Functional Requirements

- Performance
- Security
- Usability

#### **Compliance Requirements**

All requirements are documented in a specification documents, with a version-controlled system in place

Specification

Detailed records of

ensuring clarity and

**Documents** 

requirements

completeness



### **Governance Strategy**

Compliance and Regulatory Framework



- Relevant Regulations: Understand and integrate requirements from the companies Quality guidelines pertaining to data integrity.
- Compliance Procedures: Develop/Refer to standard operating procedures (SOPs) for data handling, validation, and audit trails to meet regulatory expectations.

#### **Risk Management**

- Risk Assessment: Identify risks related to data breaches, system failures, and lack of user adoption through engagement with stakeholders and key users.
- Mitigation Strategies: Implement robust security measures, provide comprehensive user training, and establish contingency plans for system outages.

#### Monitoring and Evaluation

- Key Performance Indicators: Define & evaluate metrics such as data accuracy rates, system uptime, issues, connections, models and compliance audit outcomes
- Dashboard to show metrics/future downtimes or issues
- Review Timetable: Conduct quarterly/PI reviews to assess project progress, implementations, compliance status, and areas for improvement.

#### Documentation and Record Keeping

- Documentation Standards: Establish/Refer to guidelines for documentation practices, ensuring all processes are recorded and accessible.
- Centralized Repository: should be a secure digital repository for all project documentation, ensuring compliance with GxP record-keeping requirements.

#### Change Control

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• Systematic approach to manage changes in processes, connections, model configuration, or systems. This is critical to ensure compliance with GxP ways of working. Change control process should follow the below steps.

#### **Change Management**

- Change Management Plan: Develop/Align to strategies to manage resistance, including stakeholder analysis, communication strategies, and training programs.
- Training Programs: Offer tailored training sessions for different user groups, focusing on system functionality, data management best practices, and compliance requirements.



### **Steps for Validation Readiness**

- Establish data model and naming conventions
- Define user roles and security policies
- Document interfaces, transformations, logic
- Leverage automated testing and CI/CD pipelines





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### **Strategic Benefits of a Validated UNS**

- Standardized, trusted data for all systems
- Faster change control and updates
- Improved data integrity and traceability
- Ready for AI/ML, analytics, and digital twins





## Scalability and Flexibility

- Easily extend to ERP, LIMS, IoT, cloud platforms
- Add equipment or sites without major rework
- Support edge processing, MQTT, OPC UA, REST





### **Lessons Learned from the Field**

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Start small: single use case or production line



Get IT + OT alignment early



Define clear success metrics



Don't skip documentation and governance



## **Key Takeaways**

- UNS enables PI to become a strategic asset
- MES benefits from real-time, contextualized data
- Validation is manageable with the right approach
- Start with high-impact, low-friction integrations





# Questions?

## DEEP DIGITAL SOLUTIONS GROUP



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