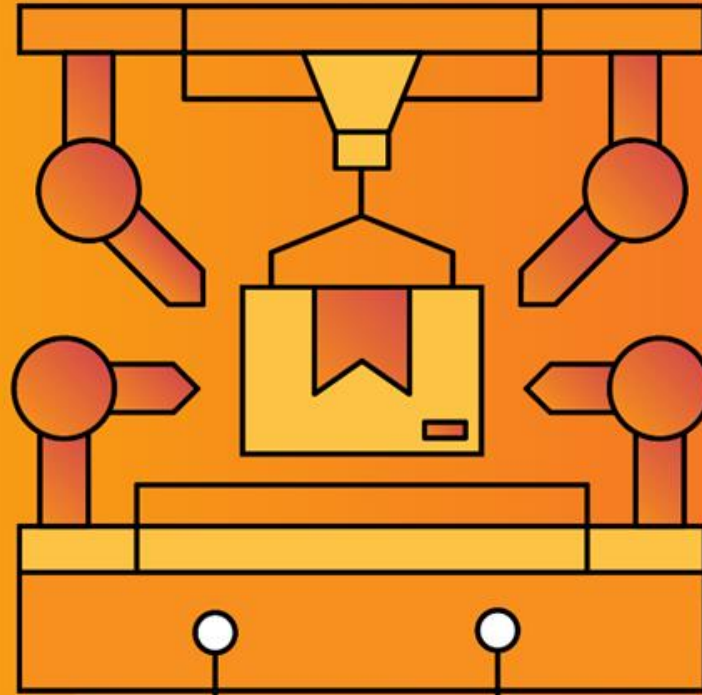


Breakthrough Batch Manufacturing Solutions



Moderator



Kent Melville

Director of Sales Engineering
Inductive Automation

Guest Speakers



Tom Hechtman

President/CEO
Sepasoft



Jeff Fitch

Product Development Manager
Sepasoft

Agenda

- Introduction to Ignition
- Batch Processing Challenges & Solutions
- Real-World Use Cases
- Audience Q&A

Ignition!

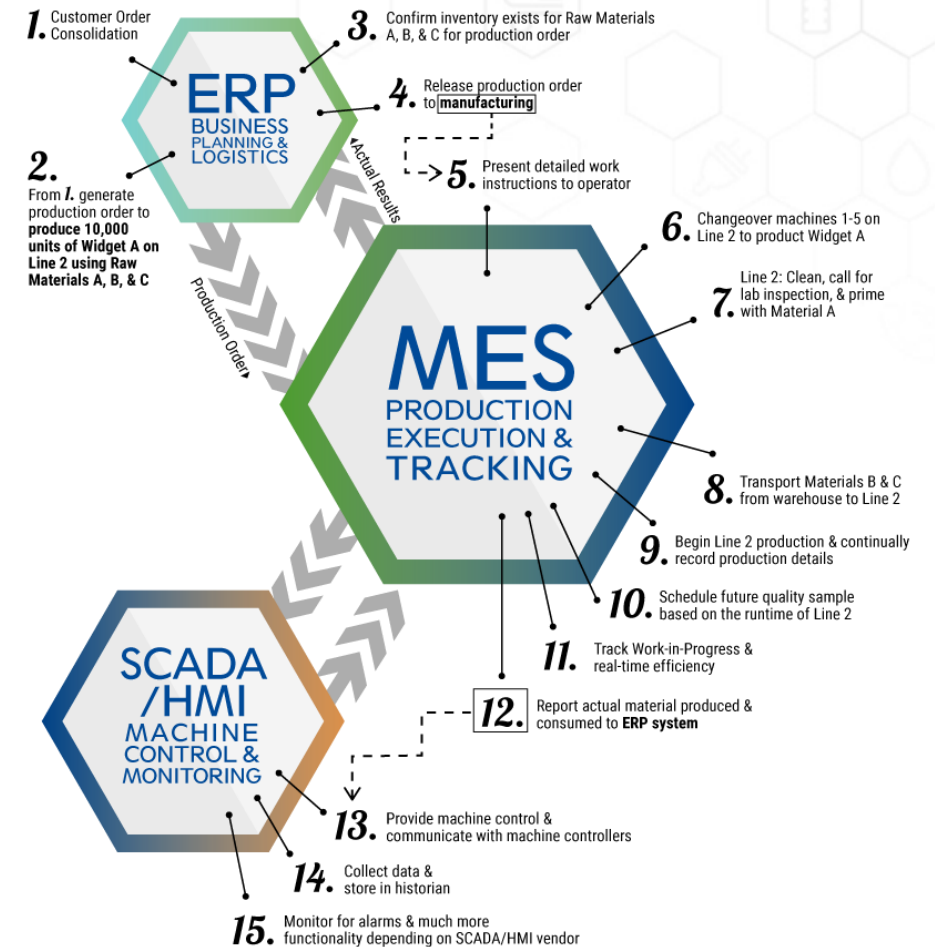
by inductive automation

**The Unlimited Platform for
SCADA and So Much More**

- **Connect, Design, Deploy Without Limits:**
 - One central hub for everything on the plant floor
 - Create any kind of industrial application
 - Web-deploy clients to desktops, industrial displays & mobile devices
- **Unlimited licensing**
- **Industrial-strength security and stability**
- **Trusted by thousands of companies worldwide**

Introduction

Sepasoft provides MES solutions for the Ignition platform used to control, track, and document the transformation of raw materials to finished goods in real-time.

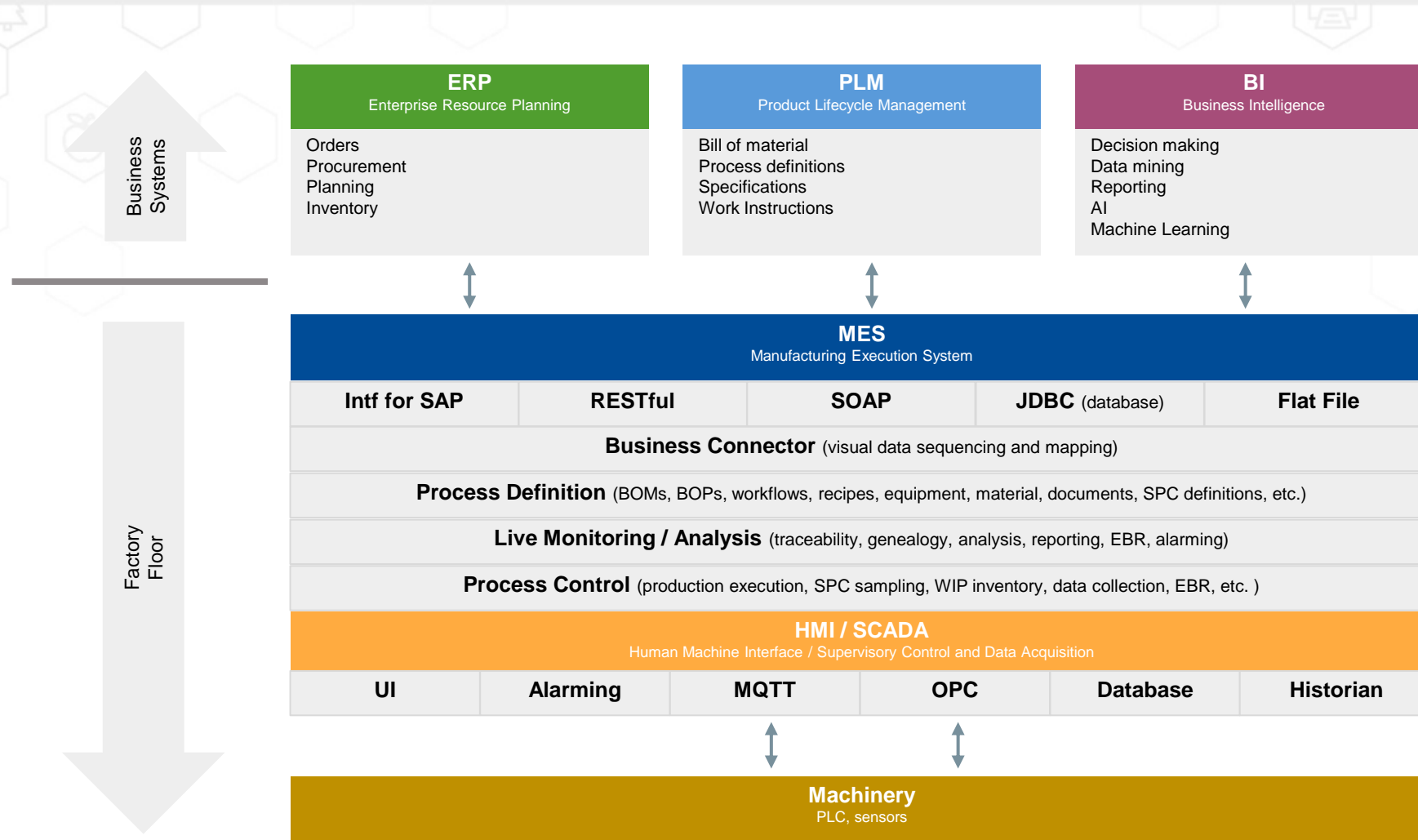


Seamless HMI/SCADA Integration

Common Platform

- Single Configuration Designer
- Unified HTML5 User Interface
- OPC
- MQTT
- Reports
- Security

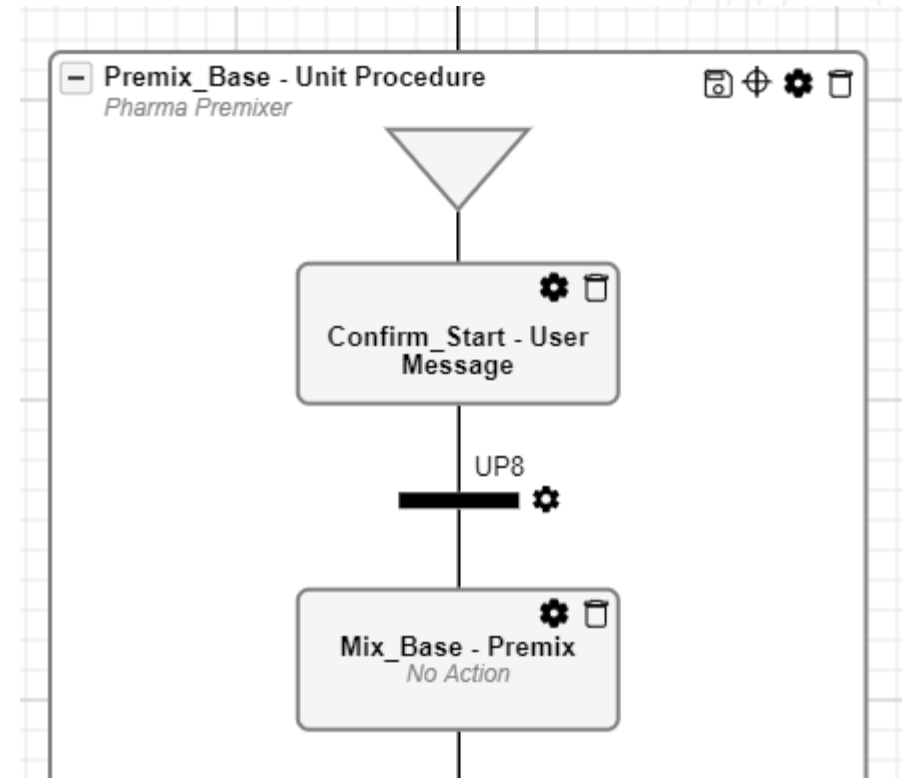
Introduction



The Power of Batch and Procedure

What is Batch and Procedure?

- Workflow manager
- Separate authors from engineers
- Low-code
- Visually build production procedures
- Supports automated and manual tasks and processes



Traceability and WIP Inventory

Overview

- No-code integration between batch, traceability, and WIP inventory
- Pre-allocation of materials
- Batch lots or serialized items
- Visual trace graph
- Genealogy/reports



Batch and Procedure Demo



21 CFR Part 11 Overview

FDA Regulation and set criteria for electronic records and e-signatures



11.1.a The regulations in this part set forth the criteria under which the agency considers electronic records, electronic signatures, and handwritten signatures executed to electronic records to be trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.

- **Electronic signature** means a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.
- **Electronic record** means any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system.

21 CFR Part 11 Compliance

Controls for Closed Systems

- Electronic signatures
- Record generation
- Record protection
- Digital audit trails
- Permitted sequencing of steps
- Authority checks
- Document control
- Signed electronic records
- 2-person Integrity
- More...

Part 11 Requirements	Notes
Subpart B - Electronic Records	
§ 11.10 Controls for closed systems	
(a) Validation	 Customer See FDA Guidance for Industry
(b) Record generation	 Sepasoft supports EBR (Electronic Batch Records) and components to view EBRs.

Electronic Signatures

Features

- Signature expressions
- Multi-person verification
- Add as production step
- Recorded in EBR



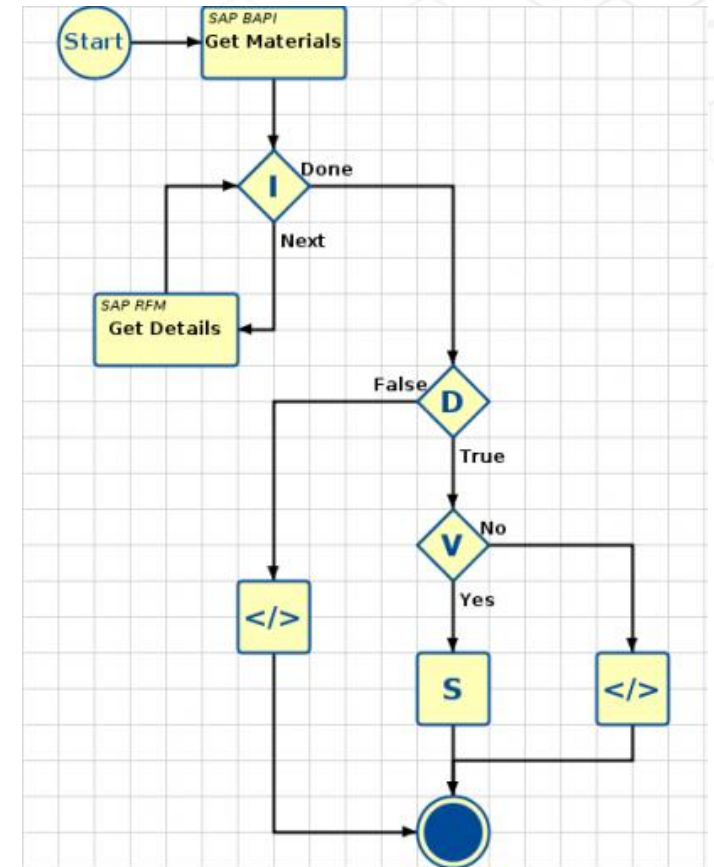
E-signature and EBR Demo



Business Connector

Features

- Visual configuration tool
- Low-code
- Business Process Execution Language (BPEL)
- Data point mapping
- Interface for SAP
- Web Services
- Database (Ignition named queries)



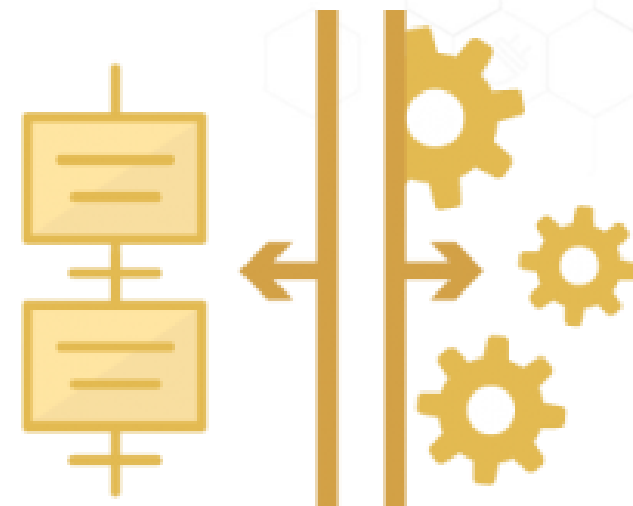
Real-World Examples

- Stone Brewing
 - Brewing staff are now able to manage recipes with little to no training
 - Started up with no waste
 - Expanding
- Major equipment manufacturer
 - Manufactures equipment
 - Parallel operations
 - Numerous options
 - Documents for instructions and quality checks
 - ERP



Summary

- Separation of engineering and recipe author expertise
- Graphical interface/no-code
- Supports automated and manual steps
- Native integration with Document Mgmt and Track & Trace
- 21 CFR Part 11 Compliant
- EBR includes all changes made during manufacturing
- Ignition platform integration





Ready to Try Ignition for Yourself?

Download the full version for free at:
[inductiveautomation.com](https://www.inductiveautomation.com)



inductiveuniversity.com

*Ignition User Manual also available at:
docs.inductiveautomation.com*



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Submission Deadline: April 28, 2023

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Contact International Distribution Manager Yegor Karnaukhov at: ykarnaukhov@inductiveautomation.com

Questions & Comments



Call us at: **800-266-7798**

Call Sepasoft at: **800-207-5506**



**Jim
Meisler**
x227



**Ramin
Rofagha**
x251



**Lester
Ares**
x214



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