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Genentech: Digitization of Master Batch Records Processes

Support by AVEVA™ System Platform™, Batch Management, and AVEVA™ PI System™ solutions

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Agenda

Project Description

Challenges and Goals

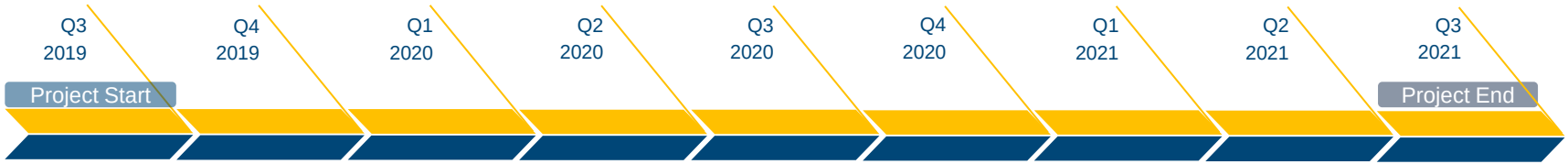
Results, Benefits, and Efficiency gained

Project Description

A discrepancy trend was identified in April 2019 during a **Internal Self-Inspection Audit** for operator / verifier documentation errors.

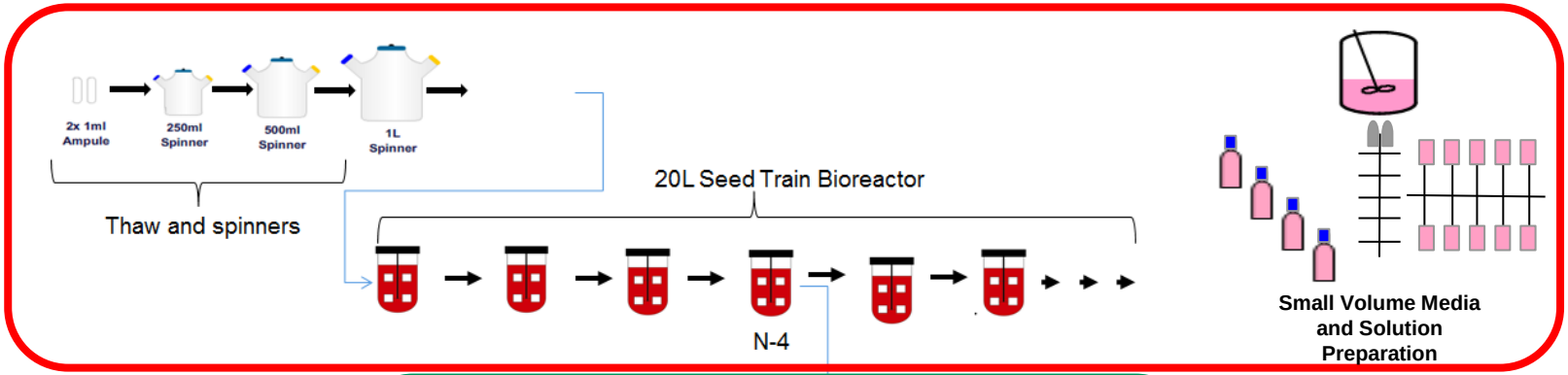
While some of the errors noted were the result of human errors, most of the errors were the result of poor layout of the Master Batch Record used during Seed Train and Small Volume Media Prep areas. The following factors were identified that contribute to missed verification steps.

- Ticketed operations were performed sequentially. As a result of this, information required in tickets may be captured in a different ticket requiring operators to **transcribe information from ticket to ticket and from step to step**.
- Based on the operation, operators may be recording data on **multiple tickets**, as many as 8 tickets at a time where observed. Making it easy to lose track of where you are on a given ticket.
- Operators may be entering data on tickets while interacting with **multiple systems** (MES, SAP, and Tracking Sheets).
- Materials, Tickets and MES require different units of measure and operators must **convert units of measure** between systems manually.

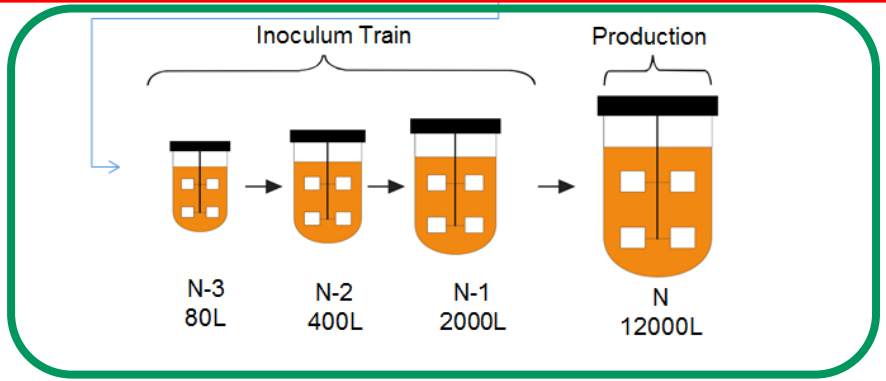


Background: Seed Train and Small Volume Media Prep Operations

Paper Batch Records



Electronic Batch Records



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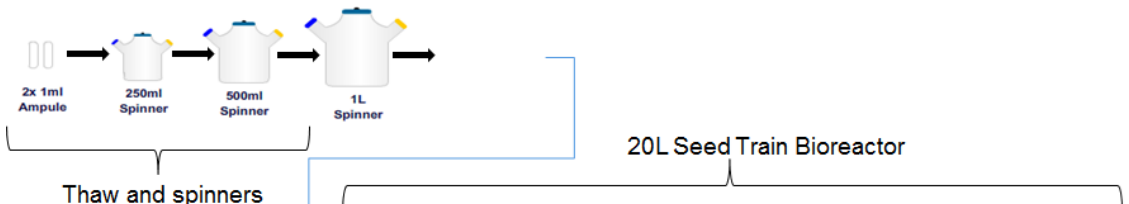
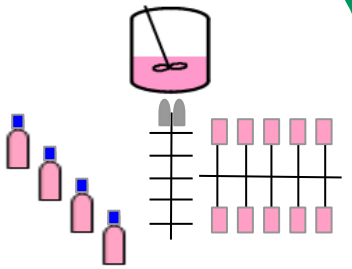




Small Volume Media and Solution Preparation

Agenda

Project Description

Challenges and Goals

Results, Benefits, and Efficiency gained

Core Functionality & Architecture

L4
FINANCIAL
SYSTEMS

L3
MES &
INFORMATION
MGMT.

L1-2
Controls

Enterprise Layer

SAP

SAP PROD P01

Power BI

Enterprise Integration

MES

Production & Traceability
Reception, Job Execution Status Produced, Shipped, Tracking

Performance Management
OEE, Downtime / Utilization, Rates

Batch Management
Production Optimization, Electronic Batch Record

Information Mgmt

Data Management
PI System, Asset Framework, Event Frames

Reporting and Visualization
PI Vision, datalink.

OSIsoft.

Automated Message / Data Exchange,
Store & Forward, History

Automation Layer

SCADA / DCS PLATFORM

AVEVA System Platform
Project Repository, OI Gateway, InTouch, Application Object Server, Process Historian, Alarm and Event System.

System Platform

PLC's

Field Devices

AVEVA System Platform and InBatch

Genentech at the Vacaville site has been using System Platform and InBatch for over 10 years. This project focused going from **Paper Tickets** to **InBatch Recipes** with supporting objects within **System Platform** to achieve the goals outlined in the project.

AVEVA InBatch is a recipe driven solution that provide S88 (ISA-88) standard batch process control development platform through the use of procedures, operations, and phases.

AVEVA System Platform is a SCADA (supervisory control and data acquisition) driven solution that provide extensible customizable solutions that works with and along AVEVA InBatch and various control layer solutions. System Platform at the Vacaville site is used to transport data to and from control systems, provide data context, customization, and supervisory control.

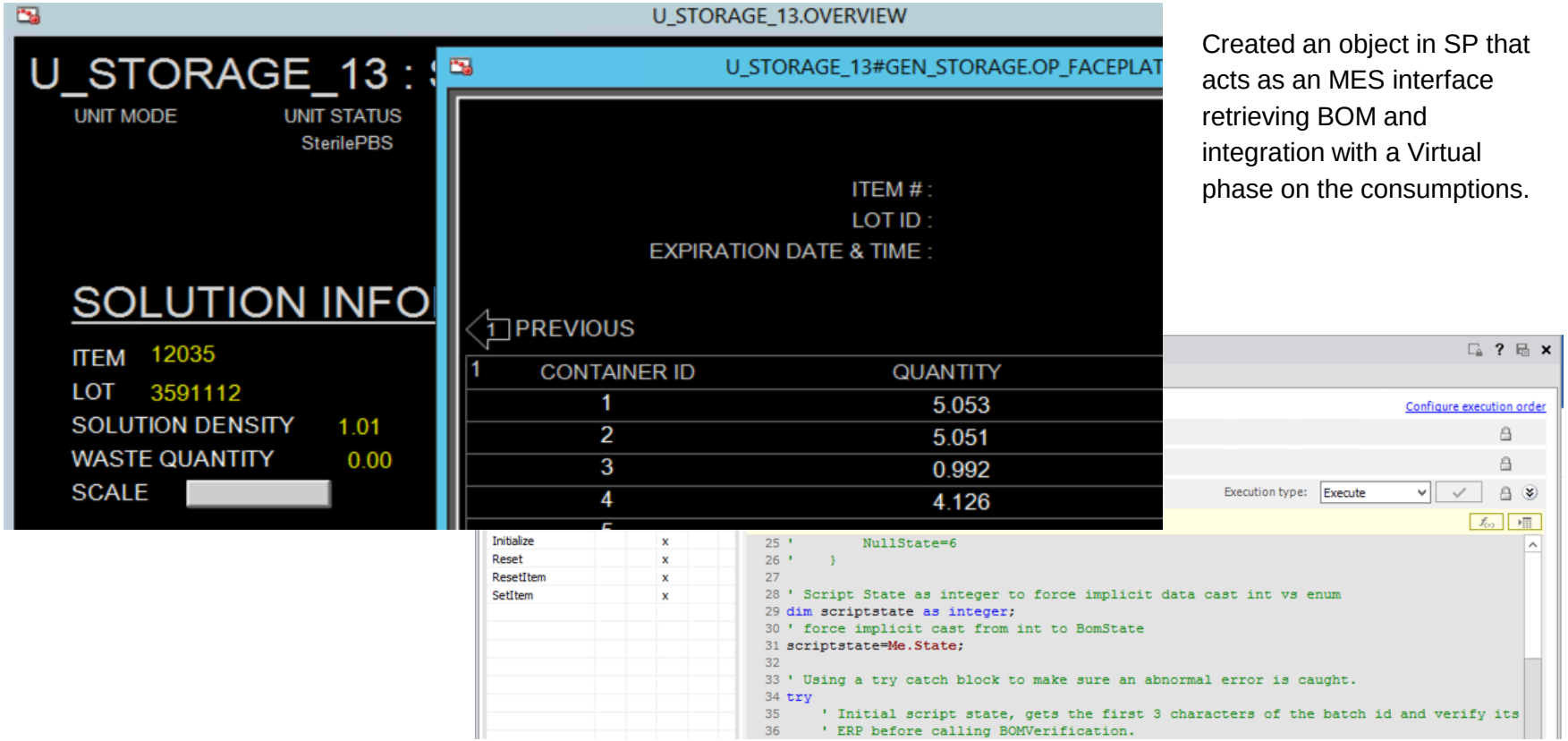
Challenges and Goals: Seed Train and Small Volume Media Prep Operations

Seed Train and Small Volume Media Prep areas have very limited IO or none at all. This was very challenging to replicate large scale operations and produce similar recipe designs.

Example of basic automation functionality that were not existent prior to this project that were **Goals** during the project:

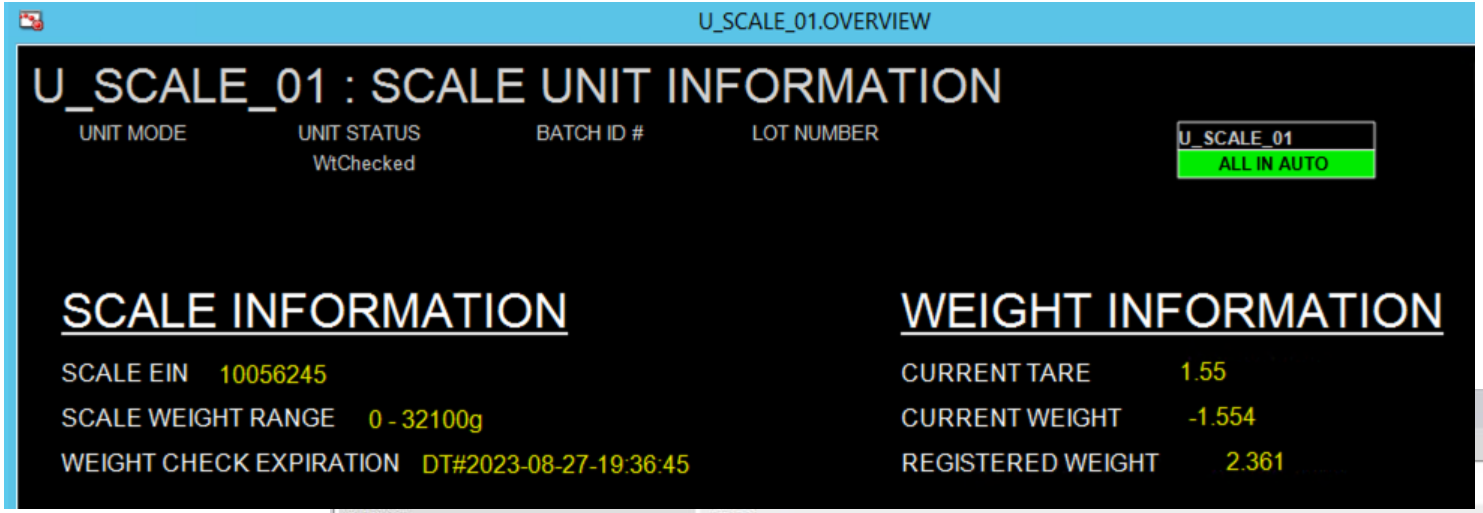
- **Benchtop Scale Integration** in both Seed Train and Small Volume Media Prep to reduce the amount of manual scale recording and verification.
- **MES integration** for material consumption tracking of raw material to eliminate manual consumption recording and verification.
- **System Timers** to track expiration time for units, filters, and product fermentation tracking. These were tracked manually prior to this project.
- **Equipment** (Unit) and **Phase Control** where no IO is present. To align with large scale operations.

Examples of the Automation in System Platform

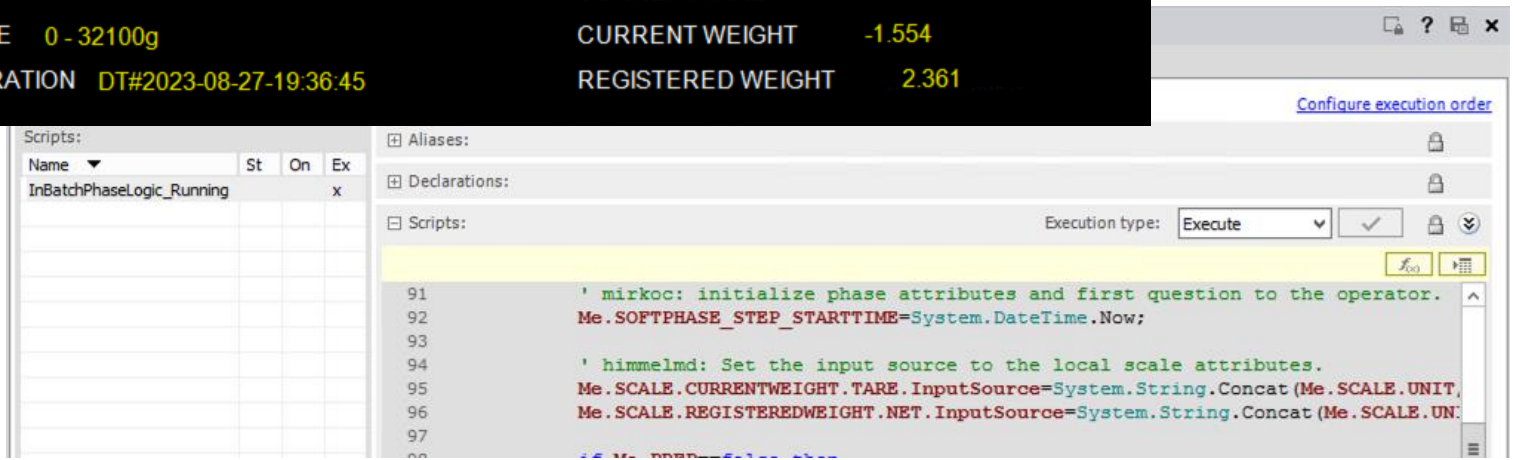


Created an object in SP that acts as an MES interface retrieving BOM and integration with a Virtual phase on the consumptions.

Examples of the Automation in System Platform



Integration of the Bench Top Scales through OI Gateway to a virtual IO object and then back into a Virtual Phase for data reading.



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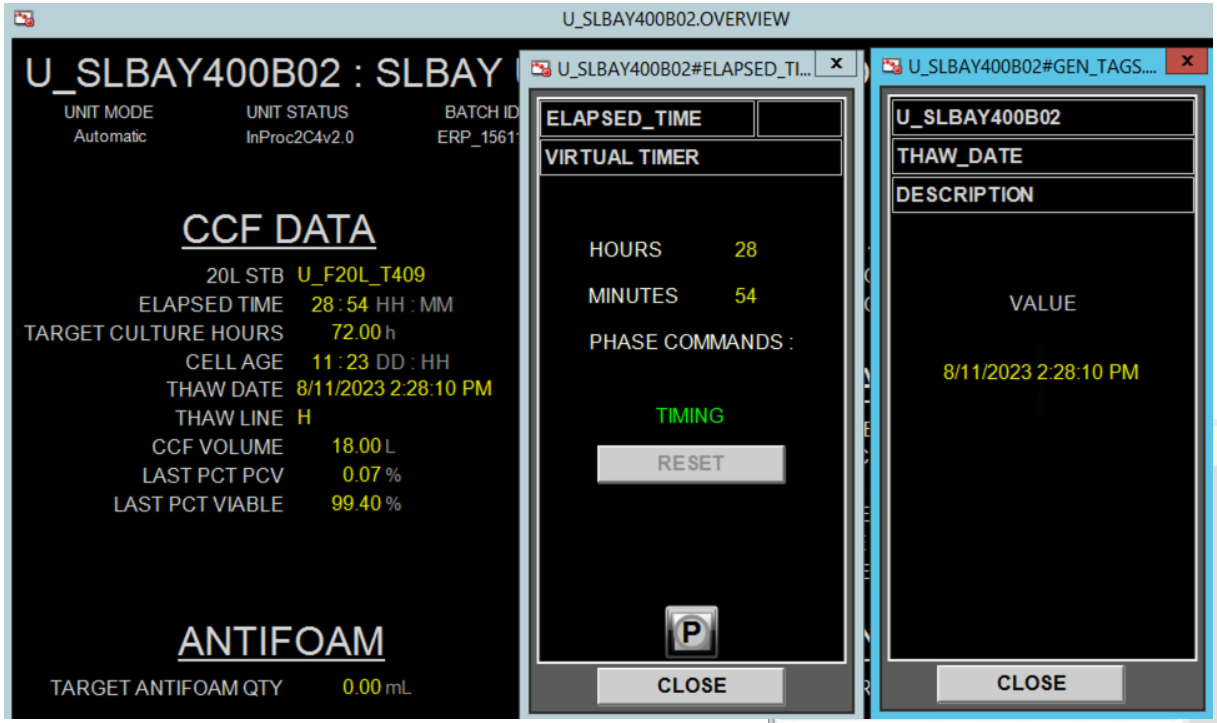


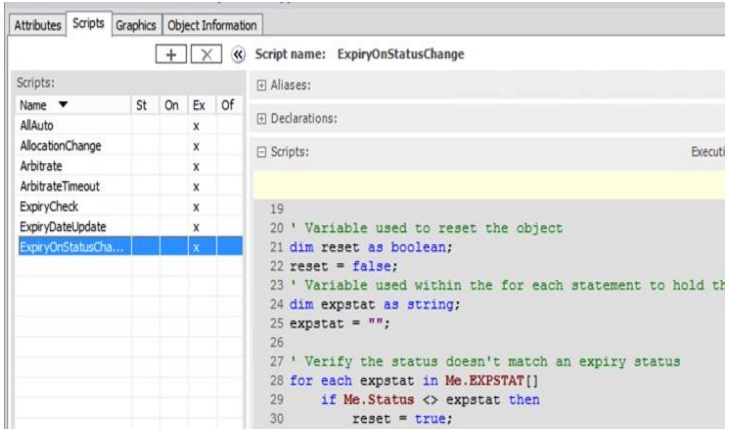
Created a Virtual Timer object in SP that mimics large scale control system timers utilizing Microsoft System.DateTime class. This timer improves on the control system timer design and is extremely configurable and highly reliable.

```
18
19 ' Try/Catch for the Parse, AddDays, AddHours
20 try
21     ' Create the Date/Time object to read fr
22     dim startTime as System.DateTime;
23     startTime = Me.START_TIME;
24     ' Check to see if we have the Me.START_T
25     if startTime == System.DateTime.Parse("0
26         Me.START_TIME = System.DateTime.UtcN
27     endif;
28
```

Inherited scripts:

Examples of the Automation in System Platform

Replicated Equipment (Unit) control within a virtual object in SP that gives similar control as large scale operations with hygienic status tracking and alarming.



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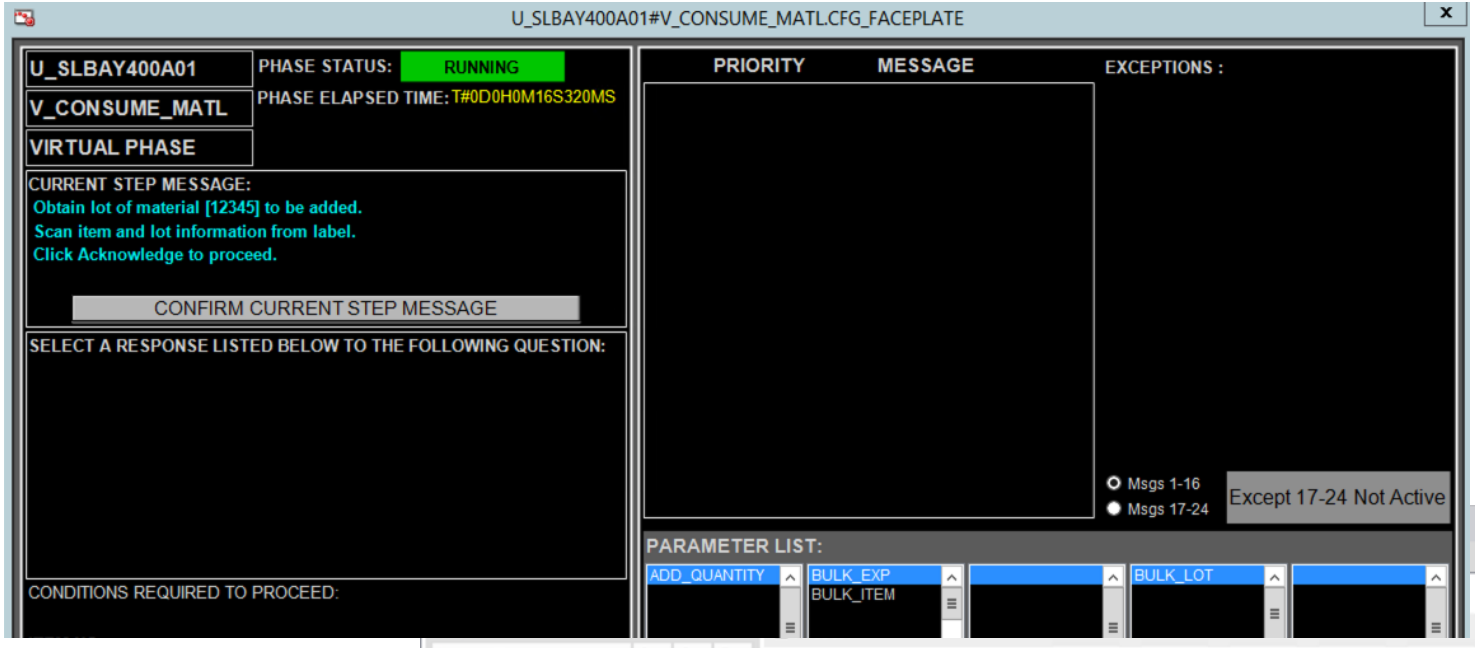

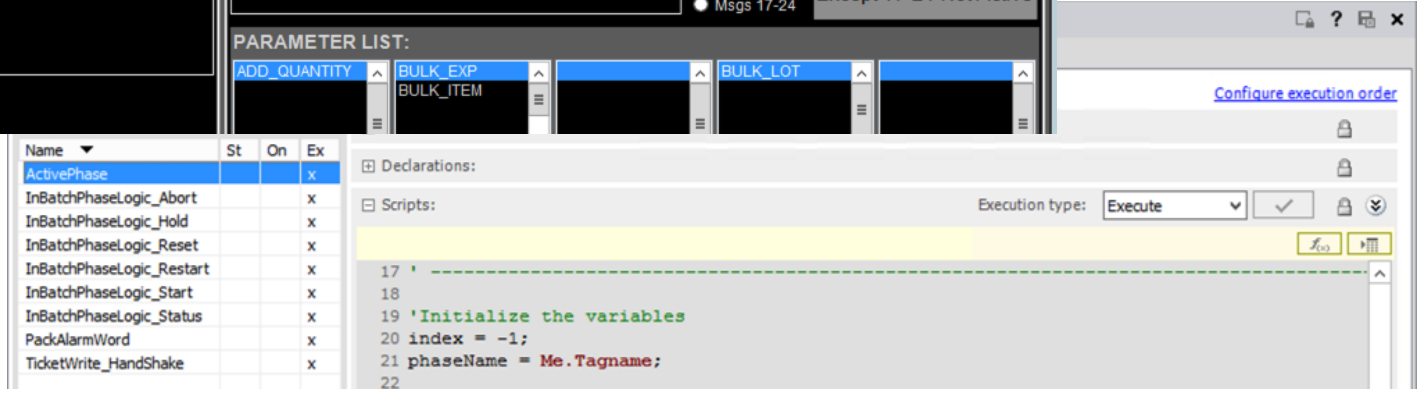

Replicated phase execution within a virtual object in SP that mimics phase control in large scale with Batch control including customizable phase running scripts.

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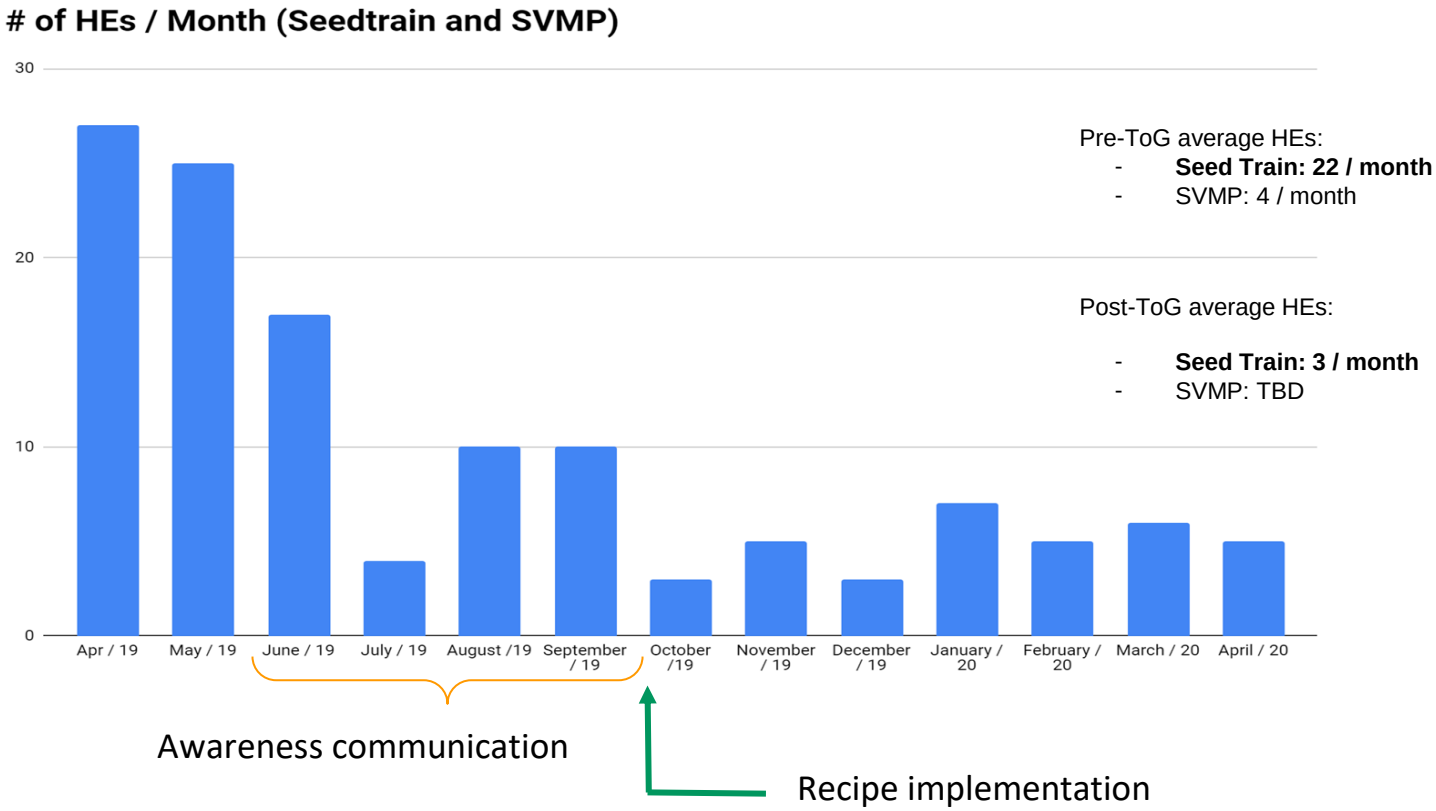
Summary of Seed Train and Small Volume Media Prep ToG Changes

- Tickets (manual batch records) converted to DCS recipes
  - 103 new recipes
- Seed Train recipe were all built from a single source that provides consistency across 60+ recipes and 10 product lines.
- Small volume media - recipes contain combined media preparation and filtration operations
- IoT - DCS integration of scales to reduce transcriptions
  - New Scale Units in System Platform via OI Gateway
- Creation of New Units in the System Platform for the DCS
  - Spinner Units, 20L Tank Units, Bay Units, UDAF Hoods, Nalgene Units, Storage Units, and Virtual Scale Units

Benefits After Phase I: Human Error (HE) Reduction



Summary of Benefits

Right First Time

- Automated calculations
- Automation controls for status checks and acceptable ranges
- Integration of scales to the DCS to reduce manual transcriptions
- New units eliminated risk of acquiring wrong recipes

Simplification and Streamlining of Processes

- Automated data transfer
- Unit Hygienic status tracking and alarming
- Virtual Implementation of Timers
- MES with BOM Integration for consumption
- Recipe data available for future analysis (level loading)

Simplification and Streamlining of Processes

- Recipes reviewed by exceptions within Batch Historian
- Elimination of use of 28 FNs requiring processing and archiving
- Elimination of tickets = 3832 hours of ticket processing and operational time savings in Seed Train and SVMP per year
- $172,400 estimated savings per year

Fun Fact

- Since going paperless from seed train and small volume media tickets in 2019, we have saved **2 trees** * **/ year**
- SVMP solution tickets = **0.5 tree* / year**

** typically, a 40 ft pine tree, 6-8 inches in diameter, yielding 8,333.3 sheets*

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AVEVA

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Navigate to this session in the mobile app to complete the survey.

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Over 20,000 enterprises in over 100 countries rely on AVEVA to help them deliver life's essentials: safe and reliable energy, food, medicines, infrastructure and more. By connecting people with trusted information and AI-enriched insights, AVEVA enables teams to engineer efficiently and optimize operations, driving growth and sustainability.

Named as one of the world's most innovative companies, AVEVA supports customers with open solutions and the expertise of more than 6,400 employees, 5,000 partners and 5,700 certified developers. The company is headquartered in Cambridge, UK.

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