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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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AVEVA

Agenda

Project Description

Challenges and Goals

Results, Benefits, and Efficiency gained

Project Description

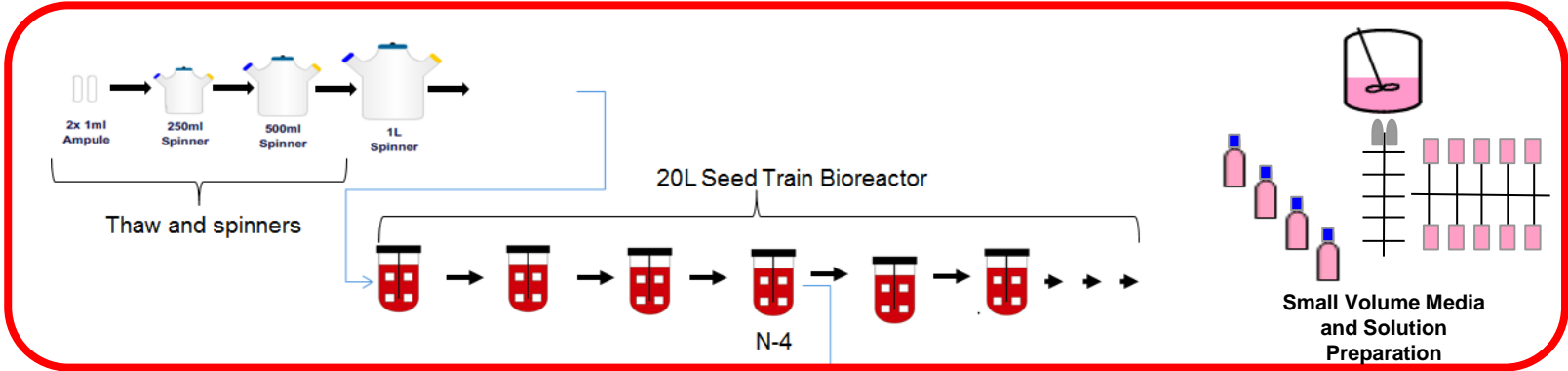
A discrepancy trend was identified in April 2019 during a **Internal Self-Inspection Audit** for operator / verifier documentation errors.

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.

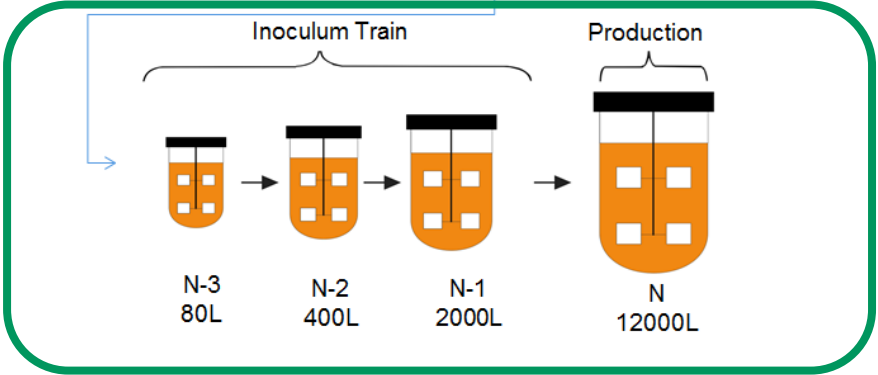
- Ticketed operations were performed sequentially. As a result of this, information required in tickets may be captured in a different ticket requiring operators to **transcribe information from ticket to ticket and from step to step**.
- Based on the operation, operators may be recording data on **multiple 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

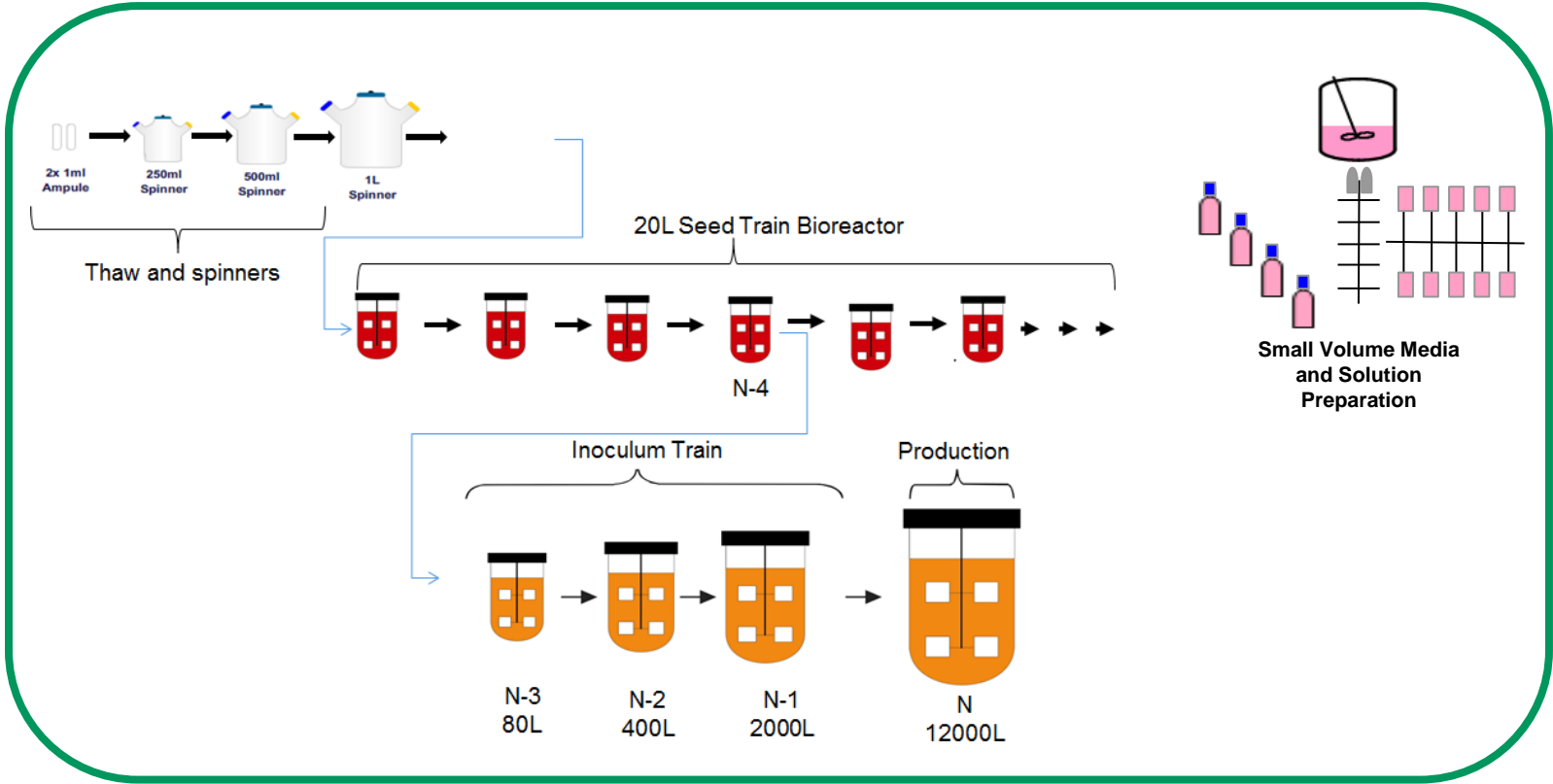


Paper Batch Records



Electronic Batch Records

Background: Seed Train and Small Volume Media Prep Operations



Electronic
Batch Records

Agenda

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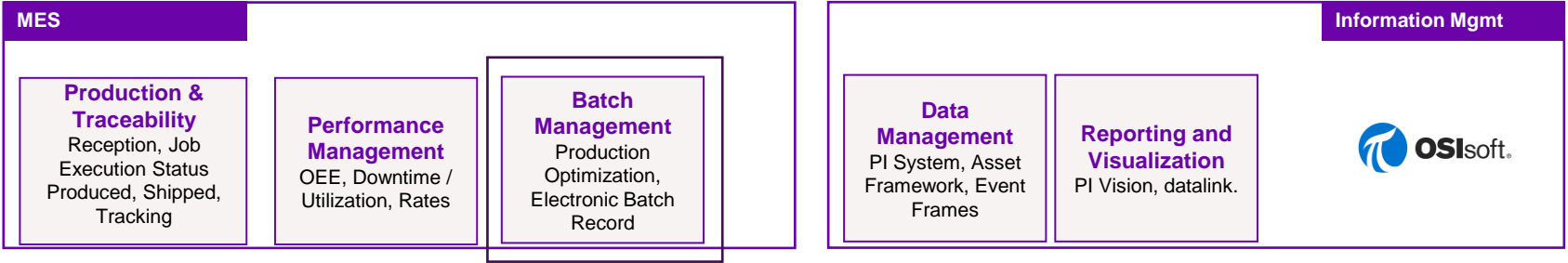
Core Functionality & Architecture

L4
FINANCIAL
SYSTEMS



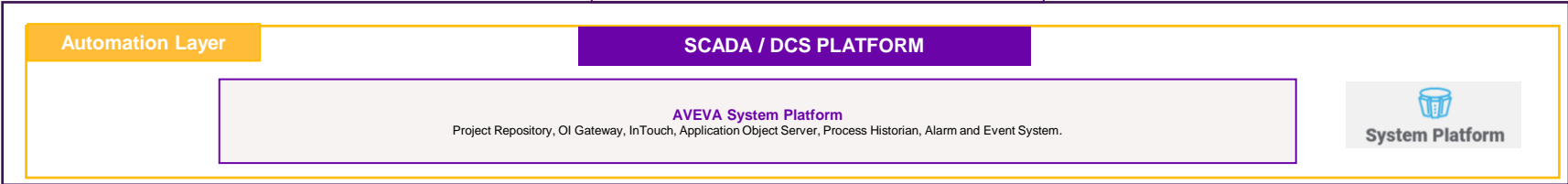
Enterprise Integration

L3
MES &
INFORMATION
MGMT.



Automated Message / Data Exchange,
Store & Forward, History

L1-2
Controls



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.

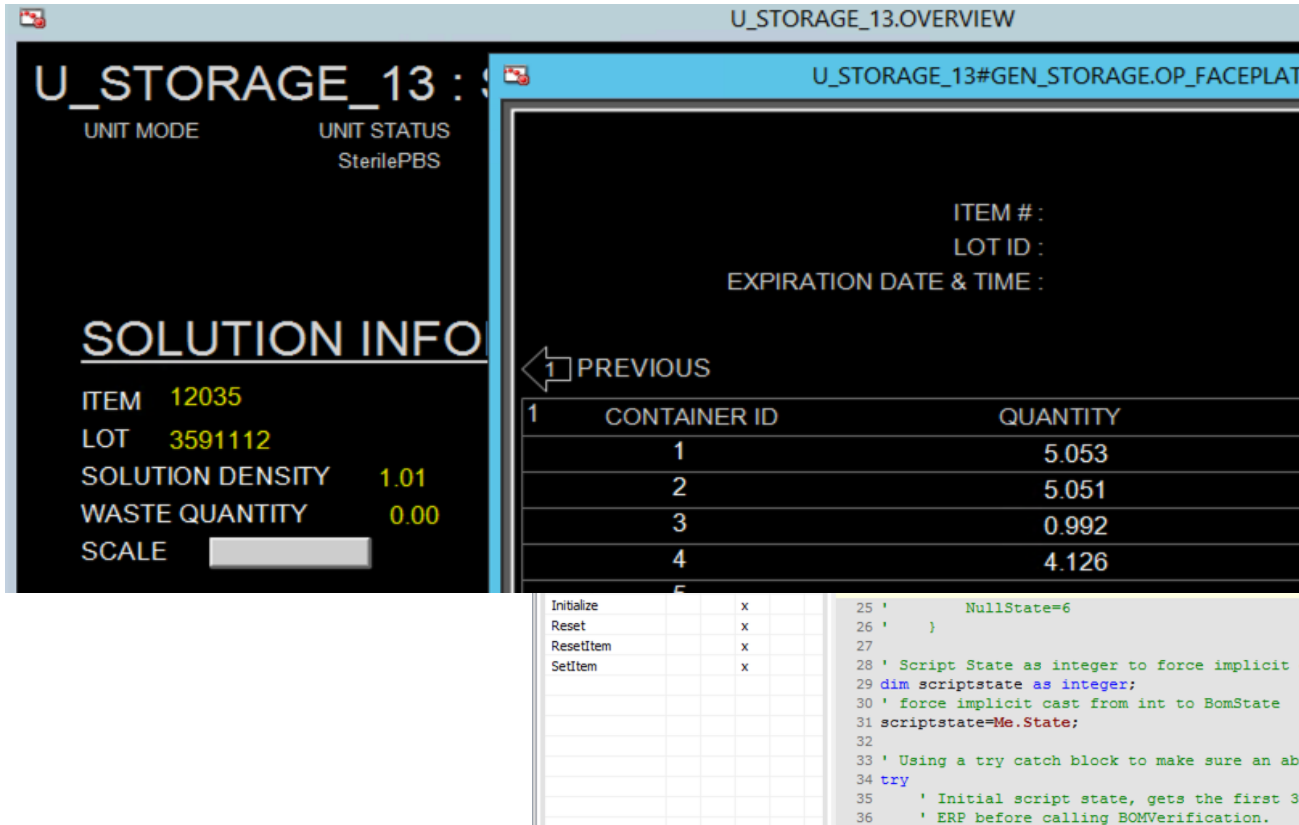
Challenges and Goals: Seed Train and Small Volume Media Prep Operations

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



U_STORAGE_13 : \$

UNIT MODE UNIT STATUS
SterilePBS

SOLUTION INFO

ITEM 12035
LOT 3591112
SOLUTION DENSITY 1.01
WASTE QUANTITY 0.00
SCALE

U_STORAGE_13#GEN_STORAGE.OP_FACEPLAT

ITEM # :
LOT ID :
EXPIRATION DATE & TIME :

← PREVIOUS

CONTAINER ID	QUANTITY
1	5.053
2	5.051
3	0.992
4	4.126
5	

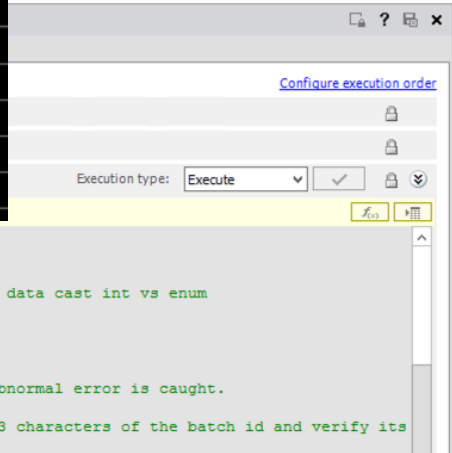
```

Initialize      x
Reset           x
ResetItem      x
SetItem        x
  
```

```

25 '      NullState=6
26 '  }
27
28 ' Script State as integer to force implicit data cast int vs enum
29 dim scriptstate as integer;
30 ' force implicit cast from int to BomState
31 scriptstate=Me.State;
32
33 ' Using a try catch block to make sure an abnormal error is caught.
34 try
35 '   Initial script state, gets the first 3 characters of the batch id and verify its
36 '   ERP before calling BOMVerification.
  
```

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



Configure execution order

Execution type:

Examples of the Automation in System Platform

U_SCALE_01.OVERVIEW

U_SCALE_01 : SCALE UNIT INFORMATION

UNIT MODE	UNIT STATUS	BATCH ID #	LOT NUMBER
	WtChecked		

U_SCALE_01

ALL IN AUTO

SCALE INFORMATION

SCALE EIN 10056245

SCALE WEIGHT RANGE 0 - 32100g

WEIGHT CHECK EXPIRATION DT#2023-08-27-19:36:45

WEIGHT INFORMATION

CURRENT TARE 1.55

CURRENT WEIGHT -1.554

REGISTERED WEIGHT 2.361

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

Scripts:

Name	St	On	Ex
InBatchPhaseLogic_Running			x

Aliases:

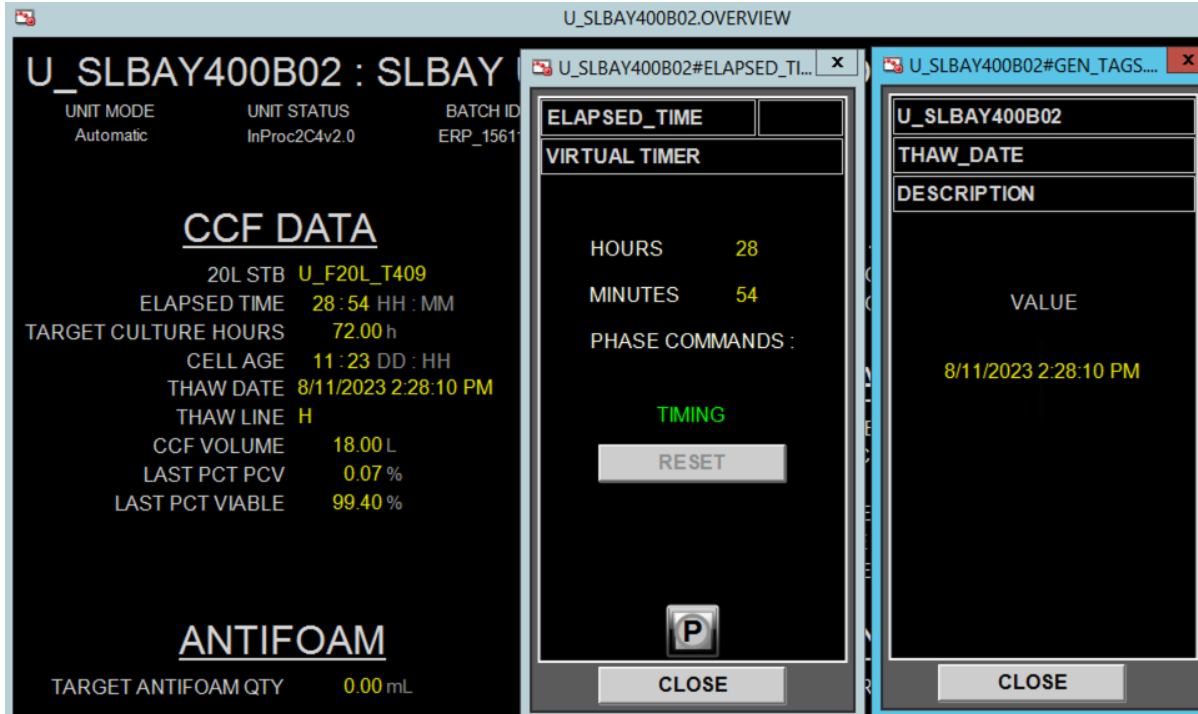
Declarations:

Scripts: Execution type: Execute

```

91      ' mirkoc: initialize phase attributes and first question to the operator.
92      Me.SOFTPHASE_STEP_STARTTIME=System.DateTime.Now;
93
94      ' himmelmd: Set the input source to the local scale attributes.
95      Me.SCALE.CURRENTWEIGHT.TARE.InputSource=System.String.Concat(Me.SCALE.UNIT,
96      Me.SCALE.REGISTEREDWEIGHT.NET.InputSource=System.String.Concat(Me.SCALE.UN:
97
98      # If Me.DPPR=f31...
          
```

Examples of the Automation in System Platform



The screenshot displays a control system interface for 'U_SLBAY400B02 : SLBAY'. It features three main panels:

- CCF DATA:**
 - UNIT MODE: Automatic
 - UNIT STATUS: InProc2C4v2.0
 - BATCH ID: ERP_1561
 - 20L STB: U_F20L_T409
 - ELAPSED TIME: 28:54 HH : MM
 - TARGET CULTURE HOURS: 72.00 h
 - CELL AGE: 11:23 DD : HH
 - THAW DATE: 8/11/2023 2:28:10 PM
 - THAW LINE: H
 - CCF VOLUME: 18.00 L
 - LAST PCT PCV: 0.07 %
 - LAST PCT VIABLE: 99.40 %
- VIRTUAL TIMER:**
 - ELAPSED_TIME: 28 HOURS, 54 MINUTES
 - PHASE COMMANDS: TIMING
 - RESET button
 - Close button
- GEN_TAGS:**
 - U_SLBAY400B02
 - THAW_DATE: 8/11/2023 2:28:10 PM
 - DESCRIPTION: VALUE
 - Close button

At the bottom, there is an **ANTIFOAM** section with 'TARGET ANTIFOAM QTY: 0.00 mL' and a 'P' button.

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_I
25   if startTime == System.DateTime.Parse("0
26       Me.START_TIME = System.DateTime.UtcN
27   endif;
28
29 ' Create the Me.END_TIME value by using

```

Inherited scripts:

Examples of the Automation in System Platform

U_F20L_T400_2 : 20 L FERMENTOR OVERVIEW

UNIT MODE: Automatic | UNIT STATUS: InProc2C4v1.0 | BATCH ID #: ERP_1564737 | LOT NUMBER: 3594426

U_F20L_T400_2: ALL IN AUTO

BASE FILTER TIME: 7:23 DD:HH
BASE FILTER END DATE: 14Oct2023
CLEAN EXPIRATION

U_F20L_T400_2 OP_FACEPLATE

CAMPAIGN ID: 29013 | LOT ID: 3594426 | PRESSURE: 0.00
RECIPE ID: P_2C4v10_20LSOL | PRESSURE LIMIT: 0.00
BATCH ID: ERP_1564737
RECIPE NAME: P_2C4v10_20LSOL
BATCH SIZE: 1
BATCH STATUS: Run
BATCH MODE: Automatic
ALLOCATION STATUS: Allocated
LAST RECIPE ID: P_2C4v10_20LSOL
UNIT STATUS: InProc2C4v1.0
EXPIRE DATE & TIME: DT#2023-08-27-08:58:17

1	STATUS	EXPIRED STATUS	EXPIRATION TIME (HOURS)
◆	InProc2B8v1.2	BatchedExp	120
◆	InProc2H7v1.0	BatchedExp	120
◆	InProcTH2H7v1.0	BatchedExp	168
◆	InProc2C4v2.0	BatchedExp	120
◆	InProcTH2C4v2.0	BatchedExp	168
◆	InProc2C4v1.0	BatchedExp	120
◆	InProcHER2v1.1	BatchedExp	168
◆	InProcE25v1.0	BatchedExp	120
◆	Clean	CleanExp	2160
◆	Sterile	SterileExp	168

NEW STATUS: [] | NEW EXPIRED STATUS: [] | NEW EXPIRATION TIME: [] HOURS

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

Script name: ExpiryOnStatusChange

Name	St	On	Ex	Of
AllAuto			x	
AllocationChange			x	
Arbitrate			x	
ArbitrateTimeout			x	
ExpiryCheck			x	
ExpiryDateUpdate			x	
ExpiryOnStatusCha...			x	

```

20 ' Variable used to reset the object
21 dim reset as boolean;
22 reset = false;
23 ' Variable used within the for each statement to hold the
24 dim expstat as string;
25 expstat = "";
26
27 ' Verify the status doesn't match an expiry status
28 for each expstat in Me.EXPSTAT[]
29     if Me.Status <> expstat then
30         reset = true;
  
```

Examples of the Automation in System Platform

U_SLBAY400A01#V_CONSUME_MATL.CFG_FACEPLATE

U_SLBAY400A01	PHASE STATUS: RUNNING
V_CONSUME_MATL	PHASE ELAPSED TIME: T#0D0H0M16S320MS
VIRTUAL PHASE	

CURRENT STEP MESSAGE:
 Obtain lot of material [12345] to be added.
 Scan item and lot information from label.
 Click Acknowledge to proceed.

CONFIRM CURRENT STEP MESSAGE

SELECT A RESPONSE LISTED BELOW TO THE FOLLOWING QUESTION:

CONDITIONS REQUIRED TO PROCEED:

PRIORITY	MESSAGE	EXCEPTIONS :

○ Msgs 1-16
 ● Msgs 17-24 Except 17-24 Not Active

PARAMETER LIST:

ADD_QUANTITY	BULK_EXP	BULK_LOT
	BULK_ITEM	

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

Name	St	On	Ex
ActivePhase			x
InBatchPhaseLogic_Abort			x
InBatchPhaseLogic_Hold			x
InBatchPhaseLogic_Reset			x
InBatchPhaseLogic_Restart			x
InBatchPhaseLogic_Start			x
InBatchPhaseLogic_Status			x
PackAlarmWord			x
TicketWrite_HandShake			x

Declarations:

Scripts:

Execution type: Execute

```

17 '
18
19 'Initialize the variables
20 index = -1;
21 phaseName = Me.Tagname;
22
  
```

Configure execution order

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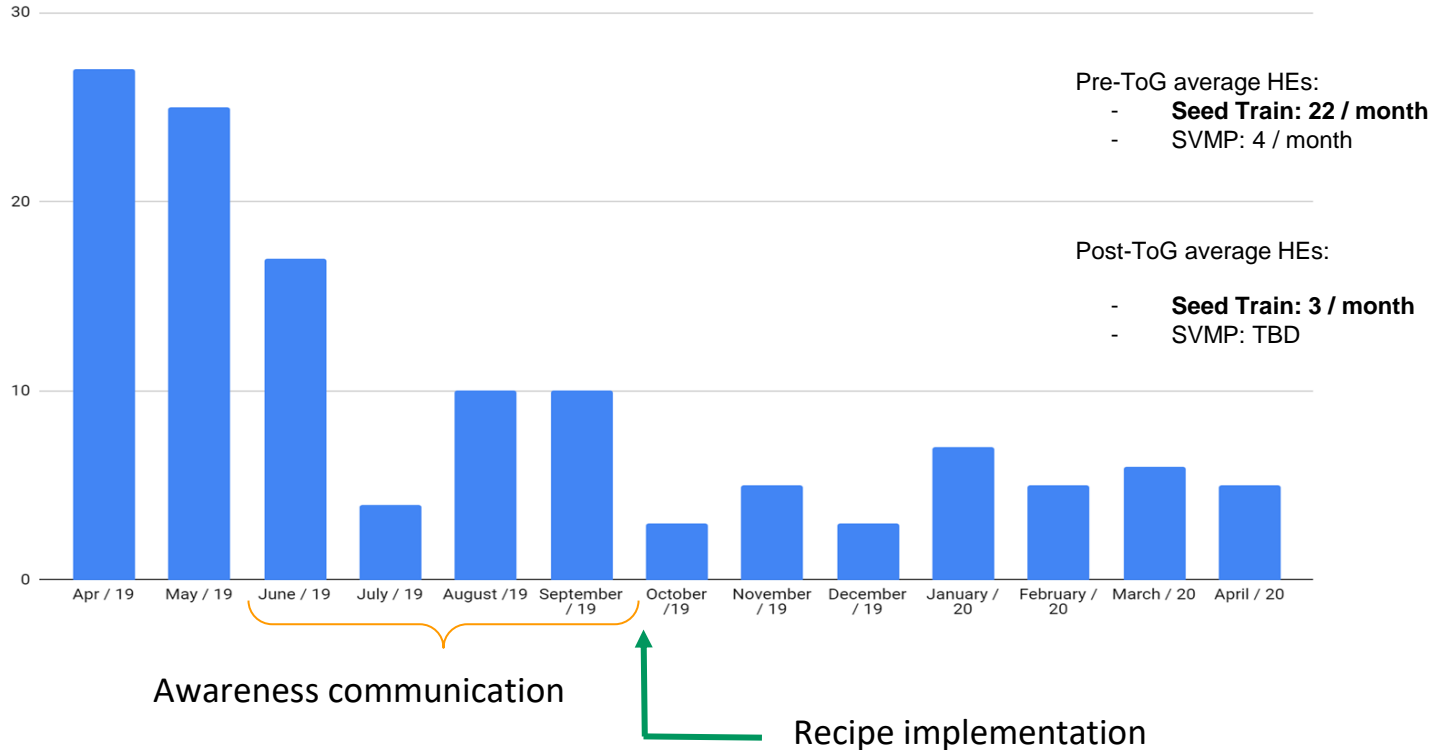
Results, Benefits, and Efficiency

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

of HEs / Month (Seedtrain and SVMP)



Summary of Benefits

Right First Time 	Simplification and Streamlining of Processes 	Simplification and Streamlining of Processes 
<ul style="list-style-type: none"> ● 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 	<ul style="list-style-type: none"> ● 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) 	<ul style="list-style-type: none"> ● 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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Questions?

Please wait for the microphone.
State your name and company.



Please remember to...

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



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