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
A discrepancy trend was identified in April 2019 during an **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

Inoculum Train

Production

N-3 80L
N-2 400L
N-1 2000L
N 12000L

2x 1ml Ampule
250ml Spinner
500ml Spinner
1L Spinner

Thaw and spinners

20L Seed Train Bioreactor

Small Volume Media and Solution Preparation
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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.
Examples of the Automation in System Platform

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.
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.
Examples of the Automation in System Platform

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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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)

**Pre-ToG average HEs:**
- Seed Train: 22 / month
- SVMP: 4 / month

**Post-ToG average HEs:**
- Seed Train: 3 / month
- SVMP: TBD

Awareness communication
Recipe implementation
# 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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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.

Thank you!
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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.

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