

Accelerate Time to Market and Improve Manufacturing Performance

Using the Life Sciences Software Suite from the DeltaV Automation Platform to Address the Key Industry Challenges

Pipeline Acceleration

Flexible Manufacturing

Operational Integrity

Real-Time Release

Sustainable Operations

Summary

Accelerate Time to Market and Improve Manufacturing Performance

Using the Expanded DeltaV Platform for Life Sciences to Address the Key Industry Challenges

Photography Showcase

How to Use This Showcase



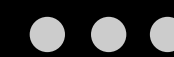
Interactive

This document includes many interactive elements. To take full advantage of these features, we recommend downloading this file and using Adobe Acrobat.



Audio

Hear real-life stories shared by our experts. This element requires Adobe Acrobat.



Navigation

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Bill Carey
Showroom Manager,
Life Sciences



Challenge

Manual product and process definition and transfer:

- Time-consuming
- Costly
- Prone to error
- Siloed application storage
- Hard to access data digitally

Solution

Use single source of truth for digitized recipe management:

- Lifecycle collaboration platform
- Enterprise access to data
- Single source of truth for product definitions and parameters
- Risk assessment history available

Impact



Accelerate knowledge sharing between Process Development and Manufacturing



Standardize process terminology and structure across the enterprise



Replace manual, paper-based recipe management with an intuitive enterprise platform



Reduce time to market and enable longer patent protected production



Theme: Transfer Product and Recipe Knowledge Across the Enterprise

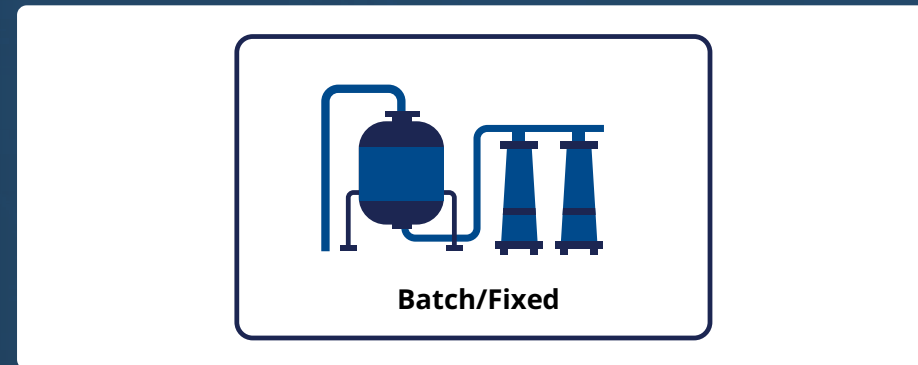
Enabling Technologies: DeltaV Process Specification Management, DeltaV Process Risk Assessment



Bob Lenich
Business Director,
Life Sciences



Challenge

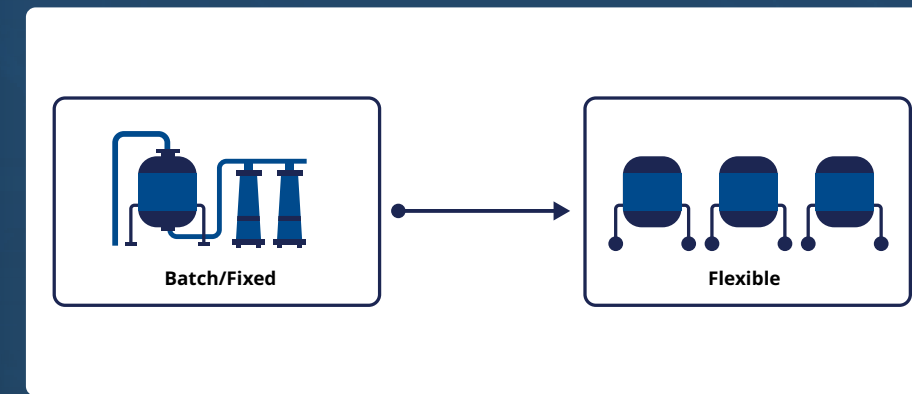


Significant effort to manage new product introductions and changeovers

Manufacturing multiple products requires detailed knowledge of various system and product capabilities such as:

- Process control strategy capabilities in the automation system
- Workflow options
- Detailed parameter definitions

Solution



Manage product definition and parameters in conjunction with MES and DCS building blocks

- Build standard library of product definition building blocks
- Provide standard library of business activity objects / no customization
- Utilize equipment-based activity focused on specific unit operation capabilities
- Incorporate dynamic transitions / connections between the "blocks"
- Use parameter-based philosophies for master batch record creation

Impact



Minimize time spent copying / entering configuration into automation systems



Only change parameters needed for a new therapy



Reduce time and effort testing and documenting configurations and changeovers



Bring a new therapy into production faster and change over to an existing product faster



Theme: Parameterized Recipe Management for Flexibility

Enabling Technologies: DeltaV Process Specification Management, DeltaV MES, DeltaV DCS

Keith Hope
Solution Consultant,
DeltaV Real-Time Scheduling



Challenge



Stuff happens, schedules change, adjusting is required

- Significant effort to keep an up-to-date schedule
- Resource planning challenges
- Effects of equipment issues
- Process issue delays
- Maintenance activity planning and interruptions
- Other deviations impact the schedule

Solution

Maximize productivity with bottoms up dynamic integrated production scheduling

- Always current schedule for operators, maintenance, supervisors, QA
- See impact of process delays, equipment issues, etc. immediately
- Plan maintenance based on real-time production schedule information
- Automatically capture current state via integration manufacturing systems

Impact

Maximize productivity



Improve coordination of resources : operators, technicians, supervisors, equipment, CIP, SIP, buffer prep, etc.



Reduce maintenance costs by optimizing the planning process



Increase production efficiency



Theme: Shop Floor Bottoms Up Real Time Integrated Scheduling
Enabling Technologies: DeltaV Real-Time Scheduling

Bruce Greenwald
Business Development Sales
Director, DeltaV Platform



Challenge



Manual sampling and testing

- Time consuming
- Error prone due to sampling, sample handling, tracking, storage, and manual testing processes
- Materials, resources, energy wasted with “early sampling” or “late sampling”
- Inventory held while waiting for release tests
- Real-time control not achievable with off-line sampling

Solution

Monitor and control critical quality and performance attributes in real-time with analytical technologies

- Build chemometric model in Aspen Unscrambler or Simca
- Deploy model in DeltaV function block to:
 - Control parameter with PID
 - Control via Model Predictive Control
 - Replace off-line tests
- Use Aspen Process Pulse for additional model visualization and model management

Impact

Real-time, tighter control of critical process parameters and critical quality attributes



Minimize inventory by reducing quarantined inventory and decreasing release timelines



Prevent batch losses



Reliably meet production schedule commitments



Theme: Real-Time Monitoring and Control of Critical Process Parameters and Critical Quality Attributes
Enabling Technologies: DeltaV DCS with Spectral PAT

Michalle Adkins
Director of Marketing
Life Sciences



Challenge

Delays in identifying exceptions and capturing observations and data as the event occurs

- Many reviewers involved to ensure all exceptions are captured
- Tracking down people to understand what happened
- Timely capture of data
- Sharing information across investigation team

Solution

Use imbedded tools to capture, document, and track exceptions through batch record closure

- Automatically identify exceptions in real-time from Syncade workflow and DeltaV

Impact

Real-time identification of exceptions; quick capture of pertinent information; faster decisions



Prevent product losses



Reduce resources required to review and close records



Release batches faster



Reduce inventory carrying costs



Theme: Electronic Batch Record Review by Exception
Enabling Technologies: DeltaV MES Quality Review Manager

Rachel Wright
Sales Enablement,
Life Sciences



Challenge

Energy optimization and plant waste management

- Leaking steam traps
- Too much paper
- Manual processes
- Schedule optimization efforts

Solution



Monitor energy and water usage; eliminate manual and paper processes; and plan and operate with always realistic schedules:

- Wireless transmitters
- Monitoring system
- Automation
- Electronic batch records
- Bottoms-up integrated scheduling

Impact



Monitor steam traps and respond quickly to reduce energy usage



Automate and enforce workflow processes to decrease deviations, minimize inventory storage energy costs, and reduce discarded materials



Optimize schedules to eliminate repeating of energy intensive and waste generating activities (e.g.; repeating cleaning and sterilization of equipment due to suboptimized schedules)



Theme: Reducing Energy and Waste

Enabling Technologies: Rosemount Wireless Transmitters, Plantweb Insight, DeltaV DCS, DeltaV MES, and DeltaV Real-Time Scheduling



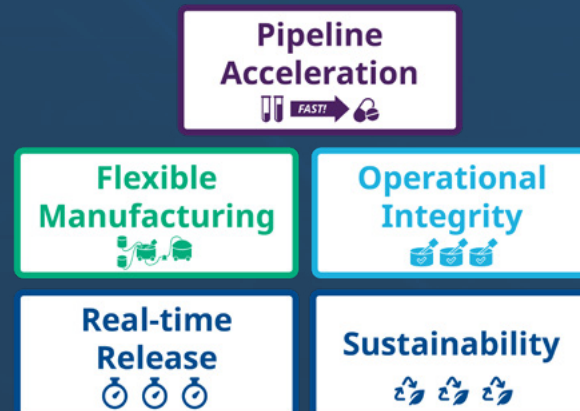
Challenge

Solution

Impact

Nikki Bishop

Vice President of Marketing
Life Sciences



- **Pipeline Acceleration:** get new products to market quickly
- **Flexible Manufacturing:** fast product introductions and changeovers
- **Operational Integrity:** safe, reliable supply of quality products
- **Real-Time Release:** release batches as soon as possible
- **Sustainable Operations:** rigorously support ESG goals

Work with a proven partner and their industry experts to apply the Life Sciences Software Suite from the DeltaV Automation Platform.

- Reach patients in need as soon as possible and increase duration of patented manufacturing
- Decrease tech transfer timelines and change management costs
- Reliably supply products to patients in need
- Decrease inventory and associated storage costs



Theme: Be a Life Saver for Patients in Need

Enabling Technologies: Life Sciences Software Suite from the DeltaV Automation Platform

