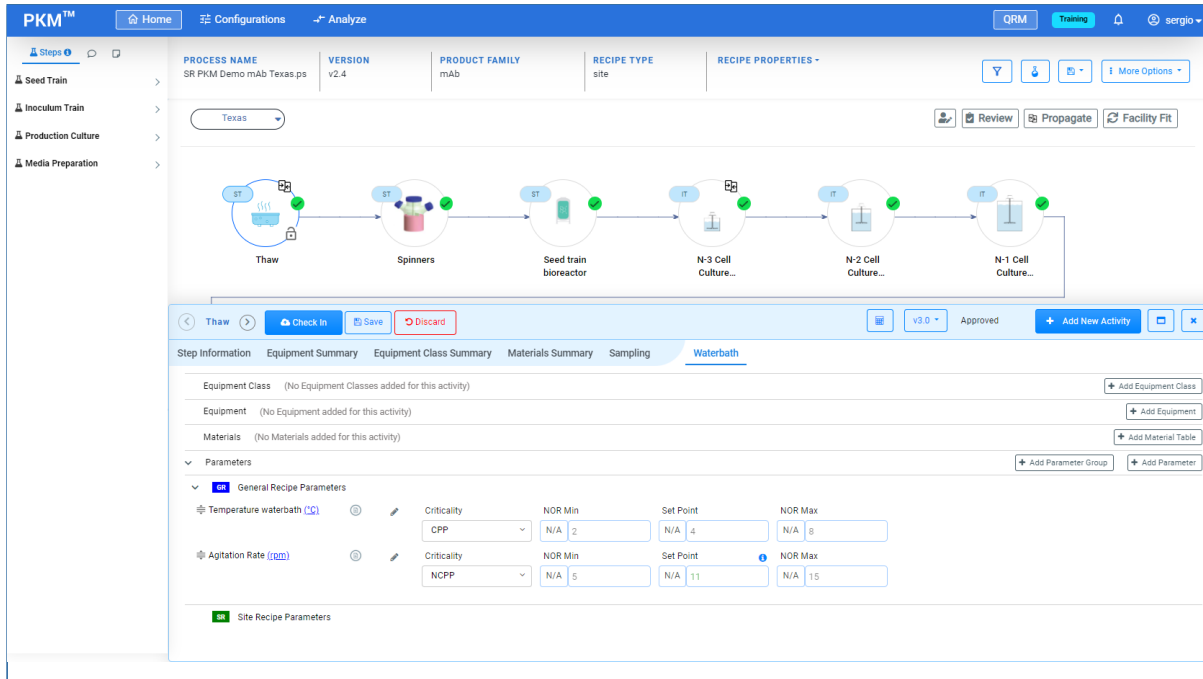


DeltaV™ Process Specification Management



Emerson's PKM™ provides a structured repository for process specifications and a collaboration model that facilitates drug development

- Easy, no-code, digital management of process specifications
- Accelerated technology transfers
- Standardized development and manufacturing processes
- Increased flexibility and re-usability across products and processes
- Seamless collaboration among cross-functional teams
- Integration to Emerson execution systems such as DeltaV™ DCS and DeltaV MES, as well as non-Emerson execution systems

Introduction

Scaling drug development and performing technology transfers from research through commercialization is effort-intensive and error-prone. This is mainly due to the manual way in which disparate processes and data are managed and validated. Current solutions do little to alleviate this problem, leading to silos of knowledge. As a result, significant effort is spent in managing paper-based documentation and associated processes.

Emerson's Process Knowledge Management (PKM™) software suite provides a structured repository and a flexible manufacturing specification model, and a digital collaboration environment for recipes covering multiple development phases. PKM suite includes:

- DeltaV Process Specification Management (PSM)
- DeltaV Process Risk Assessment (PRA)
- DeltaV Recipe Transfer Management (RTM)

DeltaV PSM software is a web-based application that seamlessly manages both product and process specifications throughout the drug development lifecycle. Inherently designed to facilitate collaboration, it enables global sites, cross-functional teams, and contract manufacturing organizations (CMO), to work together to scale recipes and execute technology transfers. In addition, because it is built using modern digital technologies, it provides enterprise-grade security, scalability, and the ability to integrate with other systems such as Enterprise Resource Planning (ERP), Electronic Lab Notebooks (ELN), Laboratory Information Management Systems (LIMS), Manufacturing Execution Systems (MES), and Distributed Control Systems (DCS).

Benefits

DeltaV PSM creates a continuum of process knowledge through the entire drug development lifecycle, from early-stage research through late-stage commercial manufacturing.

Accelerate technology transfers among production sites. DeltaV PSM provides centralized recipe translation and management to create a single source of truth and accelerate information sharing.

Standardized development and manufacturing process. DeltaV PSM standardizes the product definition, specification structures, and process terminology through the research and clinical phases before the recipe is sent to execution systems such as MES or DCS.

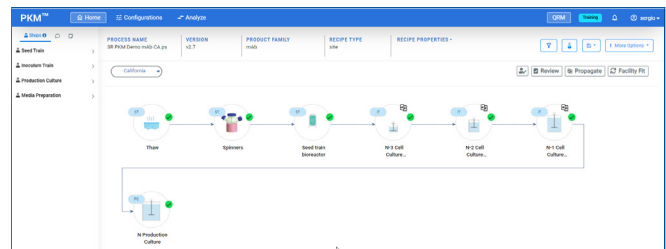
Increased flexibility and re-usability across product and processes. Full configurability and workflow management enables a standardized approach across the enterprise. DeltaV PSM help define, templize, and reuse process manufacturing specifications during the development and manufacturing of pharmaceuticals.

Seamless collaboration among cross-functional teams. Facilitates knowledge and collaboration on recipe development, manufacturing, and technology transfers across internal teams and contract development and manufacturing organizations (CDMO). Cross-functional teams can simultaneously access recipes, tag comments, attach documents, check-in/check-out unit operations, and utilize built-in workflows to manage approvals.

Product Description

Intuitive User Interface to Visualize Process Flows

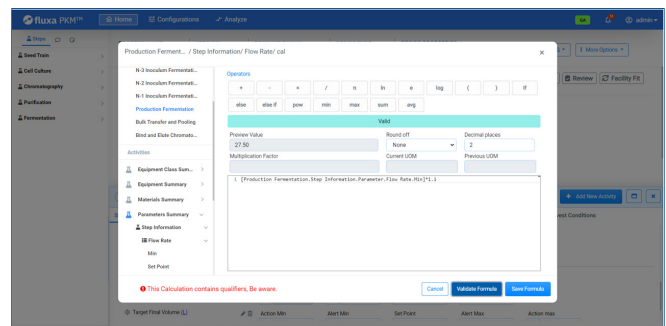
DeltaV PSM provides a web-based, intuitive, drag-and-drop user interface that simplifies and standardizes the creation of products and processes in conformance to ISA-88 on a user-friendly canvas.



Intuitive, Drag-and-Drop User Interface.

Parameter Calculation Engine

A structured, configuration-driven approach to efficiently manage process parameters and calculations without the need of Excel.



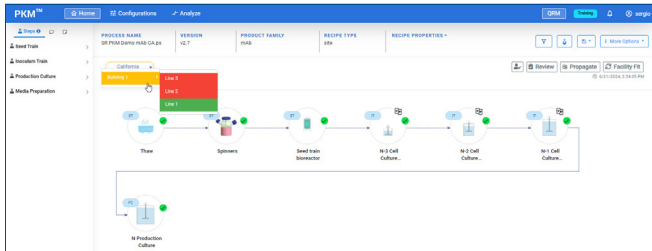
Built-in Calculation Capabilities for Process Parameters.

One-Click Compliance Document Creations

Eliminate manual data collection and review cycles with automatic Word and Excel document generation.

Real-time Facility Fit

A critical aspect on tech transfers is the facility-fit assessment. DeltaV PSM conducts facility-fit scenarios via predictive algorithms and easily identifies gaps through exception reporting.



Real-time Facility-fit Assessment.

CFR-Compliant

Designed to operate in a regulated environment, DeltaV PSM provides full audit logging, electronic signatures, version management, and role-based access to meet the regulatory requirements of the Life Sciences industry.

Easy Connectivity with Other Enterprise Systems

DeltaV PSM easily interface with other mission-critical enterprise systems such as ELN, ERP, MES, and DCS among others.

Typical PKM Implementation

DeltaV PSM implementation typically starts with a trial period where a few unit operations are configured into DeltaV PSM to ensure alignment to current process. This pilot period usually lasts 3 months. Once the pilot has ended, DeltaV PSM is implemented at one site, and it might include interfaces to systems like ERP or MES. The final implementation phase built on the success at the first rollout and PKM is deployed at multiple sites.

Licensing Ordering Information

DeltaV PSM is licensed based on the total number of user licenses. Contact your local Emerson sales office or representative for pricing specific to your system.

Related Products

- **DeltaV Process Risk Assessment** leverages process information to perform risk assessments such as FMEA studies.
- **DeltaV MES** improves manufacturing operation to drive production goals and creating an optimized manufacturing environment for Life Sciences organizations.
- **DeltaV DCS** is an easy-to-use automation system that simplifies operational complexity and lowers project risk.
- **DeltaV Real-Time Scheduling** allows customer to visualize the facility constraints, accommodate variability, maximize production, and understand the implications of any change in the manufacturing process.

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