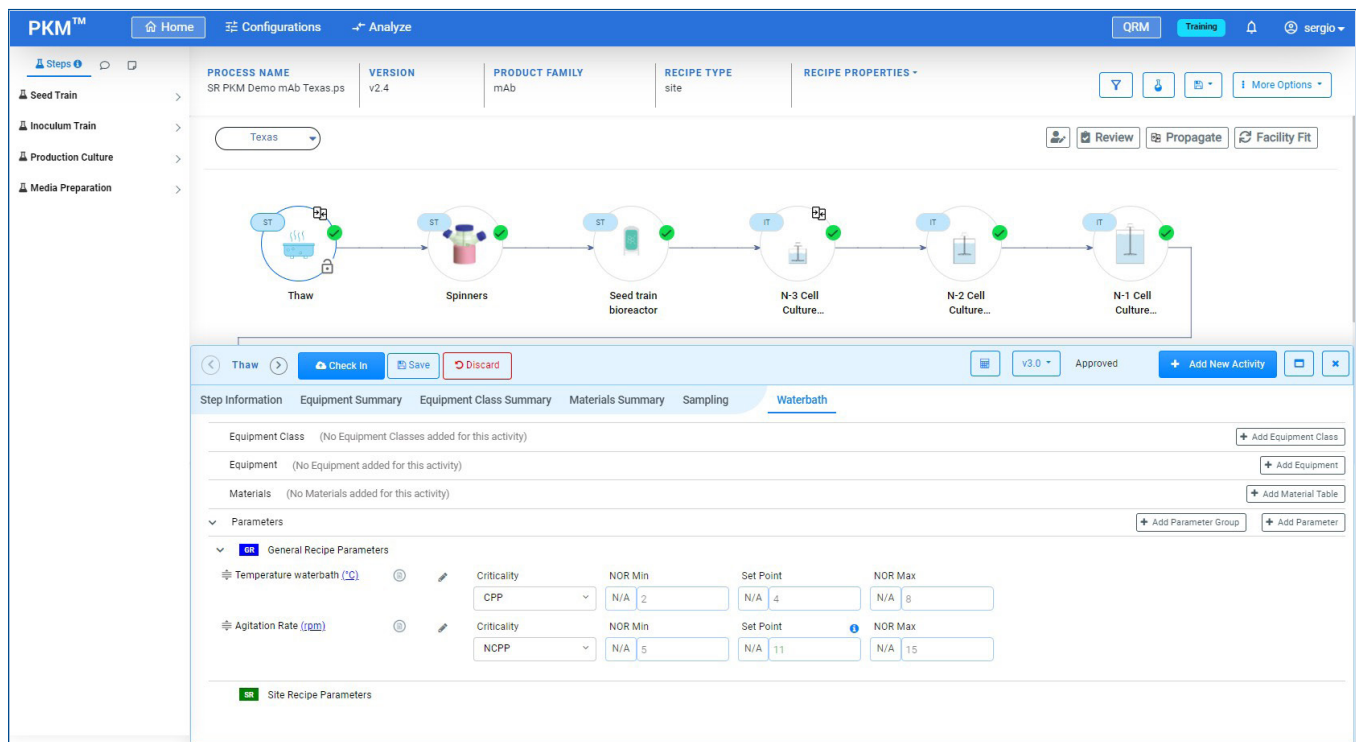


DeltaV™ PKM Modality Library



Emerson's DeltaV PKM™ Modality Library provides a pre-built, proven, and customizable set of specification elements to enable life sciences innovators and manufacturers to rapidly deploy an enterprise change management and collaboration tool.

- Software building blocks for a modular approach
- Pre-built, proven, and customizable set of Life Science specific elements
- Digital foundation for faster innovation and process knowledge transfer
- Facilitate integration into execution systems
- Fast enablement of a fully digital path to technology transfer

Introduction

Life Sciences innovators are continually searching for ways to improve alignment between process development and manufacturing to speed time to market while maintaining compliance and quality. Yet, many still rely on documents and manual processes to define and transfer product specifications, including technical documents to describe process descriptions, spreadsheets that are handed off from donor site into the receiving sites, and all validation and characterization documents. All these disconnected documents lead to tremendous inefficiency and are prone to data integrity errors. As a result, life science innovators face significant risk, and their product pipelines are held back.

Emerson's Process Knowledge Management (PKM™) software suite provides a centralized repository for process specifications through the entire lifecycle, which serves as a single source of process information, enabling seamless data flow throughout the end-to-end process.

The DeltaV PKM Modality Library further standardizes process specification elements and relationships. For example, by replacing the static documentation with standardized, reusable, and connected process modules, the DeltaV PKM Modality Library enables faster deployment and utilization of DeltaV PKM.

Benefits

The DeltaV PKM Modality Library provides a set of software building blocks for faster deployment and utilization of DeltaV PKM.

Software building blocks for a modular approach.

The use of standard objects reduces the overall amount of master data object management needed to define processes.

Pre-built, proven, and customizable set of specification elements. The DeltaV PKM Modality library provides a pre-built, customizable set of specifications elements for a given modality. This includes examples of underlying process steps, activities, key process parameters, and critical quality attributes. These elements have been proven and refined through several years of industry use. This pre-built framework **cuts months off development and organizational alignment efforts.**

Digital foundation for faster innovation. Integrating the centralized repository of standard process descriptions into the wider digital landscape enables the use of high-quality, repeatable data across different use cases. For example, standard product data pipelines simplify the transfer and transformation of recipe specifications. By combining process specification data with MES batch reports, organizations can automate regulatory filings and accelerate compliance. This unified, high-quality taxonomy and ontology also unlocks new opportunities for advanced analytics and machine learning.

Facilitate integration into execution systems. A repeatable, expected data structure (e.g., bill of equipment, bill of parameters, bill of materials, bill of samples, etc.) directly translatable to a MES master recipe layer where data is enriched and combined with manufacturing recipe templates. The automated and validated transfer of thousands of parameters directly into MES and DCS recipes, **eliminates the need for human transcription and the entire review cycle** for master production records, leading to a significant reduction in effort.

Enabling a fully digital path to technology transfer.

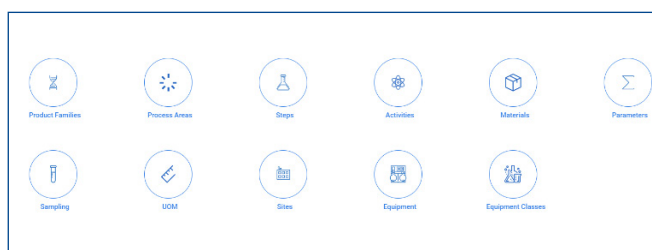
A digital process definition enables expedited, automated batch record generation for new product transfers.

Product Description

Master Data Objects

The DeltaV PKM library includes examples of:

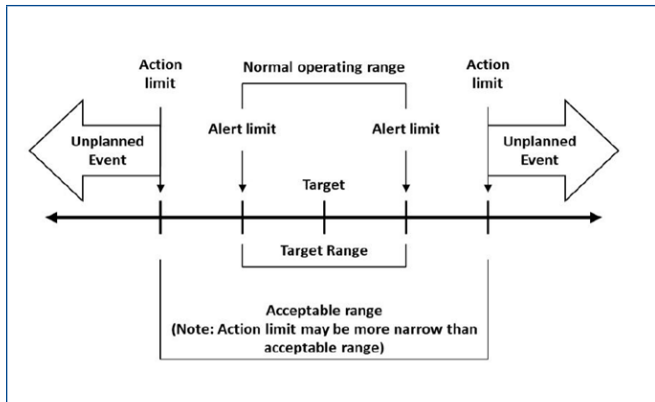
- Product Families
- Process Areas
- Over 70 process step templates
- Over 80 activity templates
- Over 410 process parameters
- Over 100 parameter attributes (qualify and manufacturing)
- Over 180 units of measure and unit conversions
- Over 100 analytical methods
- Over 30 material tables
- Over 50 equipment configurations



Master Data Objects in PKM.

Parameter Attributes

A standard set of attributes are associated with the majority of numerical parameters associated with templates. Because templates are created to “fit” many processes, some attributes may not apply to a given process or lifecycle phase. It is important to understand which attributes are appropriate for the recipe that the recipe builder is describing.



Standard Parameter Attribute Set.

Step Templates

The proven, pre-built step templates have been structured to accommodate the majority of processes followed at all sites in a “one-size-fits-all” approach. Step templates include activities, parameters, equipment, material tables and sampling tables as a base structure. Although step templates are created with the intent to “fit” as many processes as possible, some steps may still not apply to the process being described.

When creating a new product-specific recipe from scratch, it is advised to add only the steps that are applicable. When starting from a recipe copy, then it is advised to delete the steps that don't apply for the new recipe.

Additionally, an Activity Applicability parameter is located on each activity of a step to specify whether the activity is applicable or not in the step.

Calculations

The PKM Modality library includes key pre-built calculations for various scale specific process elements that reference already configured elements like equipment and process parameters. This not only reduces data redundancy and the risk of data entry errors, it also helps improve data quality. In the recipe canvas, a user simply needs to fill in the input parameters and click the trigger calculation button. Then PKM will automatically calculate the value of the output parameter in the recipe.

Example of using scalable calculations.

Sampling Plans

PKM allows you to define the samples required throughout the manufacturing process. Sampling Plan templates are provided at the process step level, with an “Activity” column that makes it easy to see which samples apply to each activity. Sampling plans can be utilized for samples taken once during the process (i.e. QC samples) or samples that are taken multiple times through the process (i.e. 2x daily viability or pH checks).

The sampling plans were designed to align the PKM step to corresponding MES recipes and sample definitions in LIMS.

Phase Appropriate Filtering

The following product development phases are pre-built into the library to support overall product life-cycle management.

- Early development
- Pre-Tox
- Tox
- Phase I
- Phase II
- Phase III
- PPQ (Qualification)
- Commercial Manufacturing
- Commercial

Based on the phase selected, only appropriate attributes could be displayed. For example, for a given recipe specification, early development recipes will only display attributes associated with the target while commercial manufacturing recipes will include limits.

Typical Implementation Using the DeltaV PKM Modality Library

The DeltaV PKM Modality Library implements a three-tier architecture.

- Harmonized terminology and standard objects at the product level provide the right level of process context and description while conserving a class-based approach.
- A scale-agnostic recipe (general recipe).
- An instantiated site-specific recipe that inherits information at the process development level from the general recipe.

PKM uses a hierarchical data model. Processes are defined by process areas. Each process area contains several steps. Those steps are defined by the activities and procedures performed within them. Steps and activities are further enriched by individual parameters. Finally, the parameter attributes describe each parameter's components. Using this architecture, the PKM Modality library establishes a master data ownership model with consistent terminology across development, all the way through commercial launch.

Licensing Ordering Information

DeltaV PKM Modality Library is licensed based on the particular modality. Contact your local Emerson sales office or representative for pricing specific to your system.

Related Products

- **DeltaV Process Specification Management** provides a structured repository for process specifications and a collaboration model that facilitates drug development.
- **DeltaV Process Risk Assessment** leverages process information to perform risk assessments such as FMEA studies.
- **DeltaV Recipe Transfer Management** provides a standardized toolset to get recipe specification information in and out of PSM and PRA.
- **DeltaV MES** improves manufacturing operation to drive production goals and creates 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 schedule.

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