



BATCH MANAGEMENT

Flexible Batch Management

Maximize asset utilization, plant throughput and recipe agility with sophisticated equipment arbitration and concurrent batch execution capabilities. The control system independent Batch Management software can be used for complex batch processes that require a high level of flexibility.



Summary

Effectively manage flexible, multi-stream and multi-product batch operations found in the process industries, including life sciences, fine chemicals, food and beverage and consumer packaged goods (CPG). Adhering to the ISA-88 standards for batch control, Batch Management provides guidance and oversight to both recipe management and batch execution. The control system independent batch management software automates batch processes to deliver consistent quality to recipe specifications and genealogy for a complete history.

Business Value

Using AVEVA Batch Management software, manufacturers improve yields through increased product quality and operational efficiency. Recipe and batch management standardization across plants also enables companies to reduce time to market.

Benefits

- Consistent quality to recipe specification.
- Reduce risk associated with complex products and product variations.
- Increase asset utilization and operational efficiency.
- Empower process engineers to create and modify recipes.
- Faster time to market for new products.
- Reduce cost of regulatory compliance.
- Multi-site recipe and batch management standardization.

Overview

Secure Consistent Quality and Maximize Asset Utilization

Batch Management's batch management engine excels at automating complex batch processes and maximizing the use of available plant capacity by simultaneously managing concurrent execution on networked equipment.

The Batch Management system consists of batch scheduling and initializing, equipment arbitration, allocation and release. It also coordinates the processing of batches with the control system, interfaces with operators, and directs batch and material tractability records to the historical database.

Batch Management secures reliable batch execution with a redundant batch server architecture.

Material Management and Traceability

Batch Management is unique in its process capability model, going beyond ISA-88 to include connections to the equipment and transfer phases. The comprehensive material model eases process modeling and enhances batch management capabilities. It enables the batch engine to manage flexible product paths, allowing simultaneous batch execution while documenting all material flows with detailed material traceability records.

Electronic Batch Record (EBR) Automation

The software offers comprehensive batch execution and equipment history with a full product genealogy and material traceability record, and comes with a large set of interactive web-based reports off the shelf.



Rapid Process Modelling

Recipe management is based on the ISA-88 Process Model by defining the plant's equipment and processing capabilities as well as its control and information requirements. Once the process model is defined, recipes can be easily created, modified and simulated without any lines of control code.

Flexible Recipe Management

Equipped with easy to use configuration tools, process engineers can quickly create or change recipe procedures and formulas without any expertise in the underlying control systems. Batch Management uses a defined interface to phase control blocks, eliminating the needs to change control code with recipe procedure changes.

Multi-site Standardization

Fully control system independent Batch Management allows for standardization of recipe and batch management across multiple plants. Recipes or formula variations can be quickly adopted across individual plants. Such standardization helps to streamline the new product introduction (NPI) process and makes organizations more agile in responding to changes in market demand.

Regulatory Compliance

Built-in role based security and electronic done by/check by signatures contribute to a comprehensive Electronic Batch Record (EBR) in accordance with requirements found in industry regulations such as FDA 21 CFR Part 11 and cGMP (EudraLex, Volume 4, Annex 11).

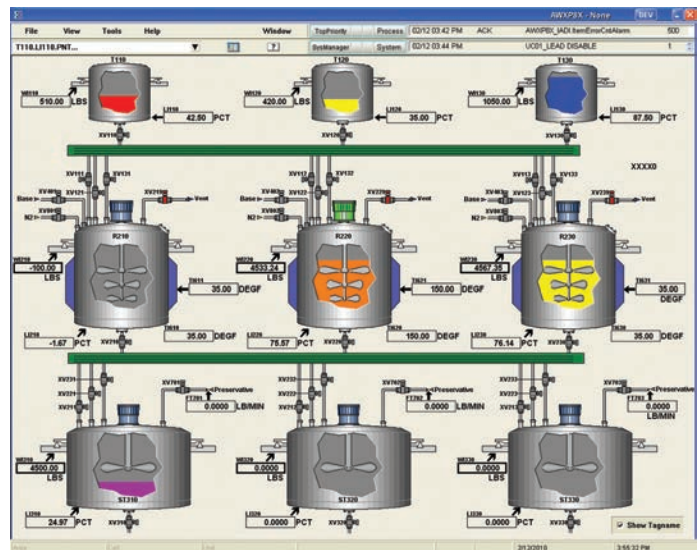
Strong Benefits From Using AVEVA Batch Management Software

What benefits did you get from using Batch Management Software?



Source: TechValidation survey of 36 users of AVEVA Batch Management

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Modeling

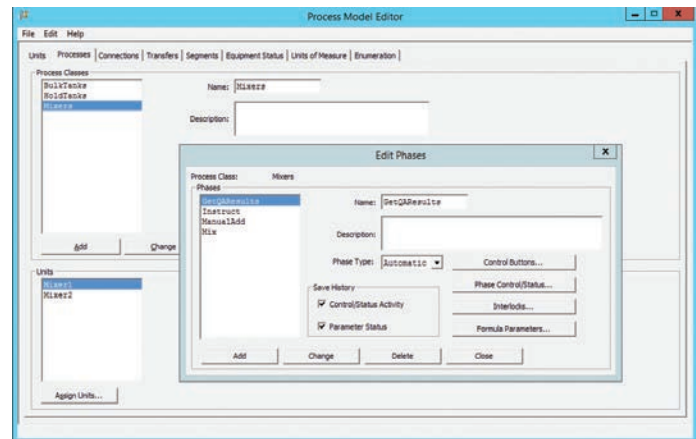
A model of the process is created using the Process Model Editor. A batch processing plant is made up of units, process classes, connections, transfer classes, process, and transfer-phases.

- A unit is a piece of equipment that processes materials such as reactors, mixers and blenders. A unit can also hold materials such as holding tanks and bulk storage vessels.
- Process classes are used to define process capabilities.
- Each unit in the class has the same processing capabilities and/or performs the same functions.
- Connections define equipment that transfers material from a source unit to a destination unit.
- Transfer classes are used to define transfer capabilities where all source units are in the same process class and all destination units are in the same process class.
- Process phases and transfer phases are used to describe capabilities of process and transfer classes respectively.

Process models for batch facilities are based on two primary modeling approaches: the comprehensive model and the connectionless model. You can also use a hybrid model.

- The comprehensive model uses all of the available configuration tools including process and transfer classes.
- The connectionless model deals only with the definition of process classes. In this case, the movement of material between units is accomplished using complementary process phases and unit-to-unit management by operator or control system.

An integral part of process modeling involves defining specific tags for units, processes, connections, and transfers. Tags allow



Materials

Materials Management is used to provide materials tracking and tracing. Materials are defined as ingredients, intermediates, finished goods, by-products and others, and include the characteristics of each material. The batch manager uses the materials' location data to access specific details, such as ingredients during the manufacture of a batch. This capability allows master recipes to be independent of a materials' location.

The Batch Management System captures actual quantities in vessels and material characteristics during the batch process, which can be used to reconcile materials and inventory including the ability to dynamically adjust and apply formula parameters at runtime.

The system updates the material database when ingredients are used and when intermediates and finished goods are produced. Access to work-in-process information can be used to update higher level management systems and Enterprise Resource Planning (ERP) with ingredient usage, work-in-process and finished goods production information.



Recipe Management

Recipe Configuration

Recipe configuration and management is coordinated in accordance with the guidelines outlined in the ISA-88 Batch Control Standard*, supports all three sub levels of the recipe procedure and provides a graphical environment to configure, copy and modify master recipes.

The Recipe Editor uses the information in the process model and materials management as part of recipe procedure development.

A master recipe may or may not be size specific and can be assigned to any process line that fits the equipment requirements defined in the recipe. All formula quantities for ingredients, intermediates, by-products and finished goods are configured as either actual quantities or scalable as a percent of the batch size.

A recipe validation function allows you to validate recipes to verify that the process model, the material information and the reports used in the recipe exist; minimum, maximum, and default batch sizes are defined, and formula parameters are linked appropriately. Additionally, all transition logic, including loop logic is validated.

A master recipe becomes a control recipe when it is initialized by the Batch Management System after it is scheduled to run on a train. Formula quantities expressed as percentages are automatically scaled. At batch completion, an operator with the appropriate security role may save the control recipe with all phase parameter edits and/or the equipment used as a new master recipe.

Recipe Import/Export Featuring BatchML

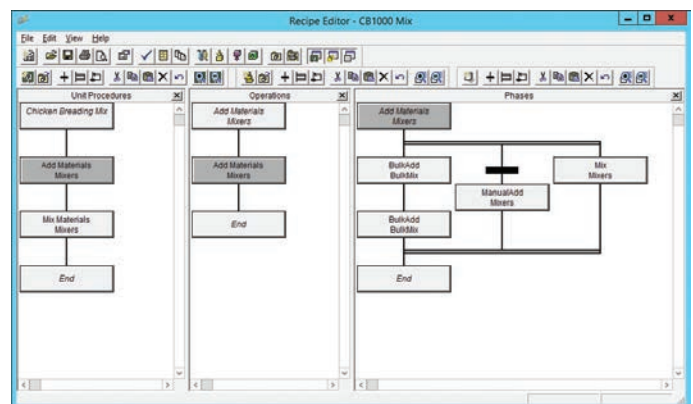
The Recipe Editor features a BatchML standards-based XML file import and export that allows you to move or share recipe information between multiple Batch Management or third party systems. The Batch Markup Language (BatchML) is courtesy of Mesa International, and consists of a set of XML schemas. Batch Management continues to support a proprietary RCP binary file for export and import as well.

Recipe Versioning and Recipe Comparison

Batch Management software maintains the history of a master recipe with date and time stamp, author name, and optional comments. Up to five levels of recipe approvals can be implemented.

The system can be configured to save the recipe version as a BatchML document to disk each time a recipe is saved or approved.

The provided recipe comparison functionality allows analyzing the differences of two selected recipe version documents in an interactive drill down report. A "print report" function allows you to print a comparison report.





Batch Management

The Batch Management System schedules, initializes and coordinates the processing of batches with the control system, interfaces with operators, and directs batch records to the historical batch database.

Batch Scheduling

A batch is scheduled by entering campaign, lot, batch ID, and the desired batch size. A recipe and the train need to be selected.

When the batch size entered is greater than the defined maximum batch size of the recipe, the Batch Scheduler opens a dialog box to confirm the splitting into multiple batches. Once confirmed, the proposed number of batches is automatically generated and is added to the list.

The batch scheduling function maintains a list of batches to be produced. The user can opt to select any listed batch for execution unless the system has been configured to enforce batch execution in order.

Capability Validation

The batch initialization performs several checks to ensure that the batch can be properly processed.

Validation includes verification of recipe existence in the database, process model and materials references. Equipment requirements are satisfied by the train and batch size against the allowed boundaries.

Batch Execution

The Batch Manager directs and supervises the processing of each batch by interpreting a recipe and enabling the control system. Based on the recipe procedure, the Batch Manager activates phases to run. Before activating a phase, the Batch Manager verifies that the phase is ready to be processed. If so, phase

parameter values are downloaded and the phase is started. The Batch Manager also interfaces with the batch display modules to provide operators with information enabling interaction on the batches running in the system..

Regulatory Compliance

Batch Management software provides comprehensive capabilities to facilitate the design and implementation of systems, applications and solutions that comply with regulations such as FDA CFR 21 Part 11 and cGMP Annex 11.

Batch sequencing is enforced by the Batch Management Software; the operator is restricted to execute only the currently active step. In addition, each step can have "done-by" and "check-by" security applied, to ensure that the steps are performed in the order presented.

The "done-by/check-by" security becomes an electronic signature in the batch record to comply with regulatory requirements of computerized systems used in manufacturing.

Electronic Batch Record (EBR)

Batch History

Batch Management software automatically captures and stores all data associated with the batch execution. This includes material genealogy, batch events, phase events and equipment arbitration, including allocation and release, equipment status

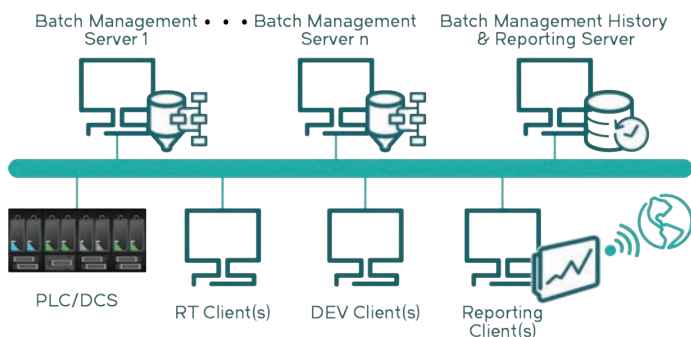
changes, operator actions and comments, any alarms associated with a particular batch and a complete trail of all security system events.

Batch Management secures reliable batch execution and documentation with store forward buffering in case of history database unavailability as well as a full redundant batch server architecture option.



Batch Reports

Batch Management software includes a comprehensive set of 25 Webbased production reports. The Batch Management Server can automatically trigger reports during batch execution or at the end of a batch. Reports can be customized to help users easily schedule, generate and view batch reports within a browser. Automatic capture of records and related reporting capabilities provide immediate access to accurate information from batch processes and help to eliminate paper records and reduce batch release cycles.



Software Architecture

Server

The Batch Management Server hosts a process model, material and recipe information, coordinates batch execution, and facilitates operator interaction by either being directly connected to a control system or via System Platform integration. Multiple Batch Management Servers can be configured to share a single Batch History database.

Batch Management facilitates the deployment of solution architectures to meet the needs of critical batch applications and high availability:

- Batch Management Server Warm Restart Capability – Batch Manager has the ability to restore a previously known-good state of the system upon restart after unexpected system shutdown.

- Redundant Batch Management Server Option – the Redundant Batch Server mirrors the operations of the primary server. In the event that a hardware issue occurs on the primary server, the back-up server automatically assumes the status as the primary server and continues the batch execution.
- Batch Management supports Microsoft Hyper-V and VMware vSphere virtualization platform options to implement HA (High Availability) architectures.

Clients

Batch Management software provides remote development and runtime client applications, as well as Controls that can be easily integrated into InTouch HMI process graphic displays. The Remote Desktop Server Edition for Batch Management clients is a cost-effective solution for multi-client applications that benefit from central administration and maintenance.

Interfaces

Batch Management software includes a set of programmatic interfaces to provide access to the material and the recipe databases for integration with third party software such as Enterprise ResourcePlanning (ERP) systems or to access the batch function interface and to extend the capabilities of the Batch Manager.

Connectivity

Batch Management offers connectivity for real-time communication to any control system or plant floor device through Device Integration Servers. External databases and other software systems involved in batch execution can be connected through System Platform.

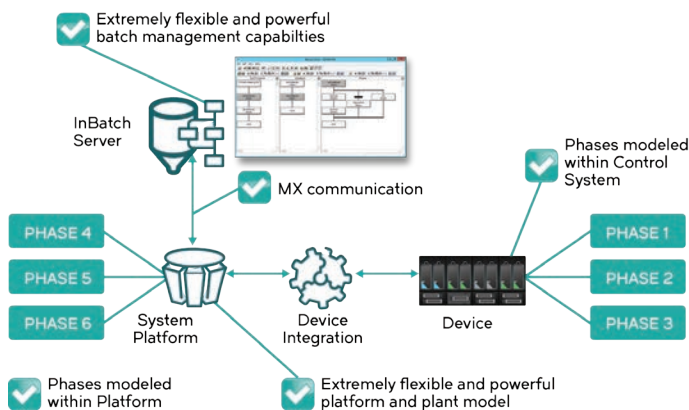


Integrated Manufacturing Operations Management

System Platform Integration

Batch Management's rich functionality can be used stand alone, but it is best leveraged and easily extended with the power of System Platform. Batch Management provides batch object templates for units, connections, segments and phases and a model import utility to automatically build and synchronize the Batch Management process model in the Application Server plant model.

This platform integration simplifies building a common real time data model across all manufacturing operations which may span across receiving, batching, filling, packaging and shipping. Batch Management execution information is available to be directly leveraged by other software functionality such as Historian or by MES Software.



Electronic Workflow And Standard Operations Procedure Management

The Batch Management Server is an Event Provider to the AVEVA common software services. Batch events are primarily related to state changes during the execution of batches.

Batch Management sends event type and context data which can be used to perform external actions such as triggering Workflow Management workflows to enforce standard operating procedures for end of batch sign-off approvals, product quality related procedures, as well as preventive or corrective actions in response to any planned or unplanned event.

Manufacturing Intelligence

AVEVA's Intelligence software reveals hidden information from batch execution records and additional plant data sources by assembling and organizing them into a single information model for easy reporting, analysis and visualization.

Easy-to-use configuration tools help define production, quality, energy, material consumption, cost and other metrics.

The software computes those metrics at the right time through automation of data acquisition from multiple sources, aggregation, contextualization and storage into a single, business-friendly information model.

A preconfigured data model and ready to use dashboards and interactive reports for Batch Management offer a fast time to value. The data model provides the foundation for contextualizing Batch Management history data with information from other data sources including process historians, alarm history, shift schedule and ERP system data.

Powerful analytics and interactive visualization eliminates the need for IT services to create reports and dashboards, allowing users to create desired artifacts on their own. Operational stakeholders are empowered with visibility of real time KPI's and drill down analyses for improvement opportunities.

Batch Management Technical Specifications:

Batch Management Server

- Windows Server 2012 or newer, Standard or Data Center Edition

Batch Management Clients

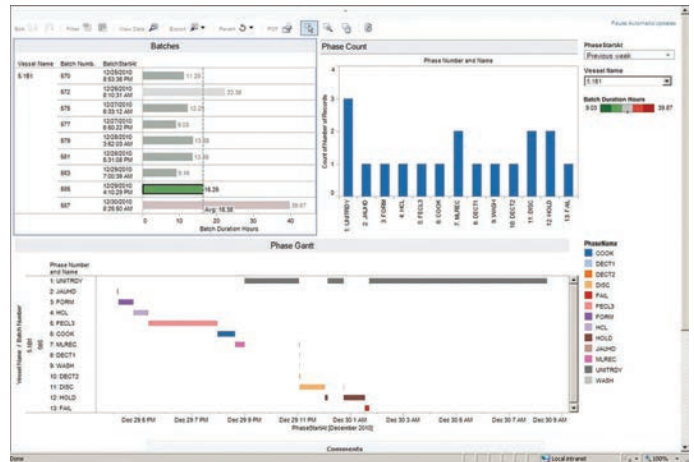
- Windows 8.1 or newer, Professional or Enterprise Edition (32-Bit and 64-Bit)

Database Technology

- Microsoft SQL Server 2012 or newer, Express, Standard or Enterprise Edition

For more information on AVEVA Batch Management software and other Manufacturing Operations Management solutions, please visit:

sw.aveva.com/operate-and-optimize/batch-and-hybrid-process/batch-management



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