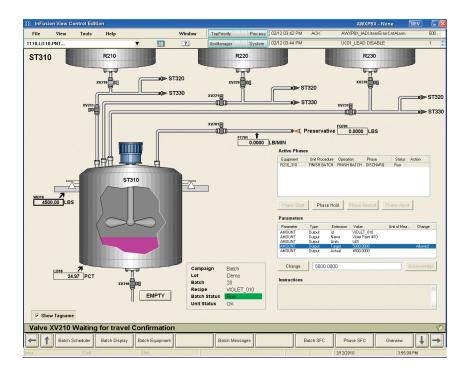
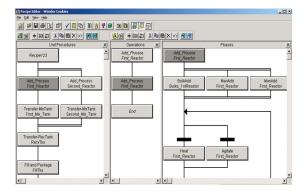
# Flexible batch management

Wonderware InBatch is control system independent software that can be used for the most complex batching processes that require a high level of flexibility. Sophisticated equipment arbitration and concurrent batch management capabilities maximize asset utilization, plant throughput and operational efficiency. Recipes are easily created, modified and simulated against a model of the process - fully independent from the underlying control systems. InBatch software streamlines new product introductions through recipe and batch management standardization across all of your plants.







Consistent with the ISA-88 standard on batch control, InBatch software offers batch management capabilities, including recipe management, batch execution management, equipment history, material genealogy, stringent security, web-based reporting and the ability to facilitate the design and implementation of systems that are compliant with FDA 21 CFR Part 11 regulations.



#### **SUMMARY**

Wonderware InBatch software effectively manages flexible, multi-stream and multi-product batch operations found in the process industries.

#### **BUSINESS VALUE**

InBatch software is a flexible batch management system that automates batch processes to deliver consistent quality to recipe specifications, providing a complete batch history.

- Higher asset utilization and operational efficiency
- Empowerment of process engineers to create and modify recipes
- Faster time to market for new products

# Batch Management Designed to Maximize Asset Utilization

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

InBatch software's batch management consists of scheduling, initializing, equipment arbitration, allocation and release, coordinating the processing of batches with the control system, interfacing with operator runtime clients, and directing batch activity, material consumption and production records to the historical database. Specific alarms and batch execution events associated with a particular batch are generated and communicated to notify operators or initiate automated workflows.

# Flexible Process Modelling and Recipe Management

InBatch offers high flexibility in recipe creation and modification by using a defined interface to phase control blocks, eliminating the need to change control code with recipe procedure changes. InBatch recipe management is based on the ISA-88 Process Model by defining the plant's equipment and processing capabilities, as well as the control and information requirements. Integration of a comprehensive material model eases the process modeling and enhances the batch management capabilities. Once the process model is defined, recipes can be easily created, modified and simulated, without any line of control code defined.

#### Material Management and Traceability

InBatch is unique in its comprehensive process capabilities model, going beyond ISA-88 to include connection equipment and transfer phases. This enables the batch engine to manage flexible product paths, allowing simultaneous multi-product and multi-stream batch execution on shared equipment and connections while documenting all material flows. The InBatch specific model extensions reduce the system engineering efforts and enable InBatch software to provide detailed material traceability out of the box.

InBatch 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.

### Electronic Batch Record (EBR) Automation and Regulatory Compliance

Wonderware InBatch offers comprehensive batch execution and equipment history with full product genealogy through automatic electronic records to

including material consumptions, movements and inventory levels contribute to a comprehensive Electronic Batch Record (EBR) in accordance with requirements found in FDA 21 CFR Part 11 and cGMP Annex 11 regulations. InBatch secures reliable batch execution documentation with store and forward buffering in case of history database unavailability, as well as a full redundant batch server architecture option. InBatch offers a large set of interactive Web-based reports off the shelf and automated batch report creation; for

# the historical database. Built-in security and material management capabilities example, at the end of each batch.

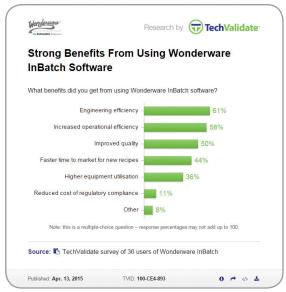
#### Streamline your New Product Introduction (NPI) Process

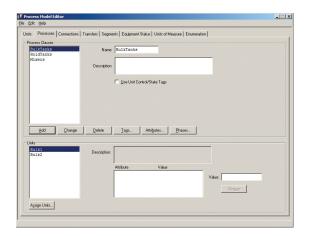
Fully control system independent InBatch allows for standardization of recipe and batch management across all your plants. Equipped with easy to use recipe configuration tools, process engineers can quickly create or change recipe procedures and formulas without requiring any expertise in the underlying control systems. Recipes can be quickly adopted and optimized in the individual plants to secure consistent quality across the business. Such flexibility makes organizations more agile to respond to change in demand, and take new products faster to market.

#### **Process Modeling**

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

- A "unit" is a piece of equipment that processes materials such as reactors, mixers, blenders. A unit can also simply 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," with their parameters, are used to describe capabilities of process classes.
- "Transfer phases," with their parameters are used to describe capabilities of transfer classes.



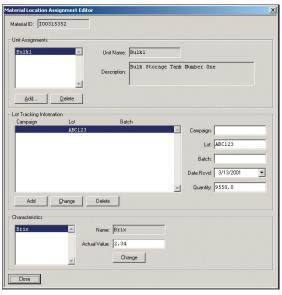


Process models for batch facilities are based on two primary modeling approaches: the **comprehensive model** and the **connectionless model**. You can also use a hybrid model that contains elements of both.

The **comprehensive model** uses all of the available configuration tools of the InBatch software including process classes as well as 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 transfer phases that are assigned to a process class rather than to a transfer class.

An integral part of process modeling involves defining specific tags for units, processes, connections, and transfers. Tags allow mapping data between InBatch and controllers or within Wonderware System Platform.



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#### **Materials Management**

InBatch 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. Materials can change location with no effect on recipe execution.

The batch management system updates the material database when ingredients are used and when intermediates and finished goods are produced. InBatch provides access to work-in-process (WIP) information and 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.

#### **Regulatory Compliance**

InBatch 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. InBatch software has played a critical role in the creation of many FDA-validated applications in the food and beverage and pharmaceuticals industries.

InBatch enables enforced batch sequencing; 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 CFR 21 Part 11 requirements.

#### Recipe Management

#### **Recipe Configuration**

InBatch coordinates configuring and managing recipes in accordance with the guidelines outlined in the ISA-88 Batch Control Standard. The InBatch Recipe Editor supports all three sublevels of the recipe procedure and provides an IEC 61131-3 graphical environment to configure, copy, and modify master recipes.

The InBatch Recipe Editor uses the information in the process model and materials management as part of recipe procedure development. An InBatch 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 InBatch 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 InBatch Recipe Editor features a BatchML standards-based XML file import and export that allows you to move or share recipe information between multiple InBatch or third party systems. The Batch Markup Language (BatchML) is courtesy of the World Batch Forum, and consists of a set of XML schemata. InBatch continues to support a proprietary RCP binary file for export and import as well.

#### Recipe Version History And Recipe Comparison

InBatch 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 InBatch recipe comparison allows analyzing the differences of two selected recipe version documents in an interactive drill down report. A "print report" function provides for printing of a comparison report.

#### **Batch Management**

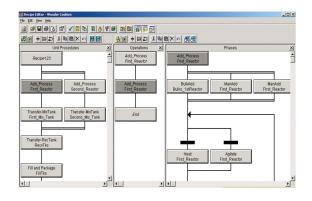
The Batch Management System from InBatch schedules, initializes, and coordinates the processing of batches with the control system, interfaces with operators, and directs batch records to the historical batch database.

#### **Batch Scheduling**

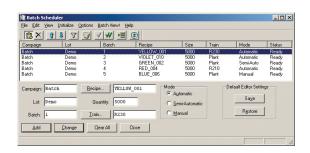
A batch is scheduled by entering campaign, lot, and batch ID, as well as the desired batch size. A recipe as well as the train need to be selected.

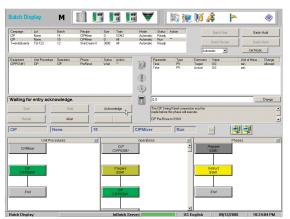
When the batch size entered is greater than the defined maximum batch size of the recipe, the Batch Scheduler opens a dialog box to confirm the splitting into multiple batches. Once confirmed, the proposed number of batches is automatically generated and are added to the list.

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.











#### **Batch Validation**

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

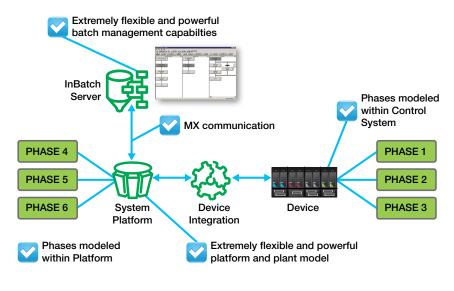
The Batch Manager directs and supervises the processing of each batch by interpreting a recipe and enabling the control system. Based on the recipe procedure, the Batch Manager activates phases to run. Before activating a phase, the Batch Manager verifies that the phase is ready to be processed. If so,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

#### Batch History — Electronic Batch Record (EBR)

InBatch 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, and any alarms associated with a particular batch. InBatch also maintains a complete trail of all security system events.

#### **Batch Reports**

InBatch software includes a comprehensive set of more than 25 Web-based production reports, leveraging Wonderware® Information Server. InBatch 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 your batch processes and help to eliminate paper records and reduce batch release cycles.



# **Enhanced Manufacturing Operations Management**

#### Wonderware System Platform Integration

InBatch's rich functionality can be used stand alone, but it is best leveraged and easily extended with the power of Wonderware System Platform. InBatch provides batch object templates for units, connections, segments and phases and a model import utility to automatically build and synchronize the InBatch process model in the Wonderware Application Server 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. InBatch execution information is available to be directly leveraged by other software, such as Wonderware Historian, to document process data in high resolution or by Wonderware MES Software, to provide activities such as OEE monitoring and quality sample plan execution and statistical process control.

The InBatch Server is an Event Provider to the Wonderware System Platform Event Services using the ArchestrA Service Bus (ASB) for sending and receiving data. Batch events are primarily related to state changes during the execution of batches. InBatch sends event type and context data which can be used to perform external actions such as triggering Wonderware Skelta BPM 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.

#### Wonderware Intelligence

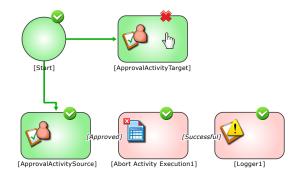
Wonderware Intelligence (Enterprise Manufacturing Intelligence) comes with a preconfigured data model, dashboards and interactive reports for InBatch. For advanced analytics and reporting, Wonderware Intelligence can be used to calculate operational performance metrics and create a real-time oriented information model by contextualizing InBatch history data and other data sources including process historians, alarm history, shift schedule and enterprise resource planning (ERP) system data. Powerful analytics and interactive dashboard visualization in a self-service access approach empowers operational stakeholders with visibility of real time KPI's, insights of improvement potentials and helps to drive higher business performance.

#### Server

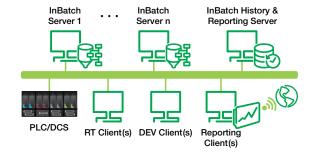
The InBatch Server hosts a process model, material and recipe information, coordinates batch execution, and facilitates operator interaction by either being directly connected to a control system or via Wonderware System Platform integration. Multiple InBatch Servers can be configured to share a single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

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

- InBatch 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 InBatch 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.
- InBatch supports Microsoft Hyper-V and VMware vSphere virtualization platform options to implement HA (High Availability) and DR (Disaster Recovery) architectures.







#### Clients

InBatch software provides remote development and runtime client applications, as well as ActiveX Controls that can be easily integrated into Wonderware InTouch® HMI process graphic displays, providing operators with an integrated user interface to the batch server. The Terminal Server Edition for InBatch clients is a cost-effective solution for applications that benefit from central administration and maintenance of multiple InBatch clients.

#### Interfaces

InBatch software includes a set of programmatic interfaces to develop custom batch interface applications, providing access to the material and the recipe databases, to access the batch function interface and to extend the capabilities of the Batch Manager.

#### Connectivity

InBatch offers connectivity for real-time communication to any control system or plant floor device through Wonderware DA Servers. External databases and other software systems can be connected through Wonderware System Platform.

#### **Operating Systems**

### Wonderware InBatch software supports the Windows® platform, including:

#### Server

- Windows Server 2008 R2 Standard or Enterprise Edition (64-Bit)
- Windows Server 2012 Standard or Data Center Edition (64-Bit)
- Windows Server 2012 R2 Standard or Data Center Edition (64-Bit)

#### Client

- Windows 7 Professional or Enterprise (32 Bit and 64 Bit)
- Windows 8 Professional or Enterprise (32-Bit and 64-Bit)
- Windows 8.1 Professional or Enterprise (32-Bit and 64-Bit)

#### **Database Technology**

#### Wonderware InBatch software supports the following databases:

- Microsoft SQL Server 2008 in Standard or Enterprise Edition (32-Bit)
- Microsoft SQL Server 2008 R2 in Standard or Enterprise Edition (32-Bit and 64-Bit)
- Microsoft SQL Server 2012 in Standard or Enterprise Edition (32-Bit and 64-Bit)
- Microsoft SQL Server 2014 in Standard or Enterprise Edition (32-Bit and 64-Bit)

#### Virtualization

Wonderware InBatch Software supports the following virtualization platforms including options for High Availability (HA) and Disaster Recovery (DR):

- Microsoft® Hyper-V™
- VMware vSphere 5.x

#### To Learn More

For more information on Wonderware InBatch software please contact your local Wonderware representative or visit <a href="https://www.software.schneider-electric.com/">www.software.schneider-electric.com/</a> products/wonderware/manufacturing-operations-management/inbatch-software.

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