

PAT and Batch Recipe Execution

Process Analytical Technology (PAT) provides the ability for real-time, online quality control during batch recipe execution. To achieve this benefit, manufacturers must incorporate a PAT solution into their existing batch framework while leveraging existing assets and minimizing risk to existing recipes.

Emerson Process Management can assist you with implementing a PAT solution that will give you a better view of your process – the ability to predict when your quality attributes are out of specification – and when and what action is needed to avoid product quality issues.

Emerson’s solution for incorporating PAT into batch recipe development and execution is composed of the following components:

- 1) the Emerson Data Analytics modeling tool
- 2) the Optimal synTQ® PAT data management package, and
- 3) a recipe configured in the DeltaV™ digital automation system or in Syncade™ Smart Operations Management Suite.

The first step in implementing a PAT solution is determining the Critical Quality Attributes (CQAs) and developing a process model.

The next step is incorporating the CQAs and process model into a PAT solution. Figure 1 illustrates how Emerson’s integrated PAT architecture allows for the incorpo-

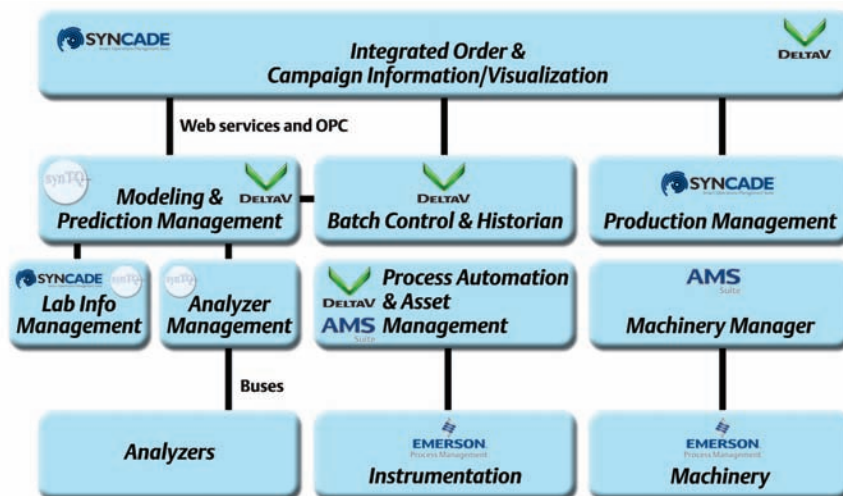


Figure 1: Emerson Integrated PAT Architecture

It is important to note that this architecture supports the capability for customers to select the analyzers and modeling packages that best fit their particular PAT requirements.

ration of batch-context-sensitive data from machinery or equipment, instrumentation, process control systems, online analyzers, and laboratory data into the models used to predict Critical Control Parameters (CCPs) or CQAs. The models may be run as part of a Syncade or DeltaV recipe or run as part of a standalone synTQ installation.

One important advantage of this architecture is that it allows the user to develop the PAT system in a “step-by-step” manner, starting with a simple PAT measurement system and then incorporating a more sophisticated approach that utilizes the Syncade or DeltaV system. This ground-up approach is central to the effective development of PAT

systems because it minimizes the up-front cost and complexity of the system, but allows for an expanded scope for its future development.

The Emerson architecture and deployment methodology provides the following key differentiators:

- True scalability from lab to production
- Costing that properly matches the scalability
- Instrument and modeling package independence (allowing the customer full choice of solution)
- Flexibility in implementation format and integration with existing products
- Full integration between the various components
- Easy data import and export in a variety of formats

There are four scenarios supported by the Emerson PAT architecture as shown in Figure 1.

- 1) **PAT integrated into Syncade recipes** – This configuration allows synTQ to act as a transparent slave to Syncade, facilitating MES-level control of PAT processes.
- 2) **PAT integrated into both DeltaV and Syncade recipes** – This provides the ultimate degree of systems integration and flexibility. The user can select where control lies within the system, and process information is fully available throughout the integrated system, supporting the generation of manufacturing information at the appropriate level.
- 3) **PAT model execution as a standalone application** – An example of this type of application would be where a synTQ model would report results to DeltaV, but would not be driven from DeltaV recipes, although this is the next step in upgrading the system. Other synTQ installations demonstrate the capability to link with any existing infrastructure to minimize initial costs.
- 4) **PAT integrated into DeltaV recipes** – From the operator perspective, synTQ can act as a transparent slave to the controlling DeltaV recipe, making operation simple and minimizing the need for retraining of production staff.

Data Transfers

Data transfers can easily be achieved in all scenarios. synTQ provides mechanisms for importing data from a variety of sources, and can provide data export to external systems in real time (through OPC and ODBC).

It can also export data off-line for use in external packages in a variety

of standard formats (e.g., CSV, SPC, PDF, etc.). The form of off-line export depends upon the package selected. In the case of supported packages the data is transferred directly into the input mechanism associated with the package, thus avoiding 21CFR11 issues associated with intermediate files. In cases where no input mechanism is available for a package, a more general export can be accomplished using an intermediate file.

Recipe Development

The next step in implementing PAT is creating a recipe. Recipes can be created using the Syncade Recipe Authoring tool or the DeltaV Recipe Studio application. For the purposes of this paper, it will be assumed that the Syncade recipe authoring tool is used.

Syncade provides sequencing of manual and automated building blocks. One of the building blocks available to a recipe author is the synTQ interface work instruction.

The synTQ interface work instruction provides a listing of available orchestrations that can be utilized at runtime. An orchestration is a sequence of function blocks in synTQ that provides for the collection of data as input to a model, the model execution, and the output of the results of the model. A sample orchestration is shown in Figure 2.

One of several different orchestrations may be selected, depending upon product parameters (e.g., dosage, product form, API). The recipe work instruction is able to pass a restricted range of parameters into the orchestration. These parameters are in two primary groups – run-time parameters for recording within the orchestration, and preset parameters for use within the

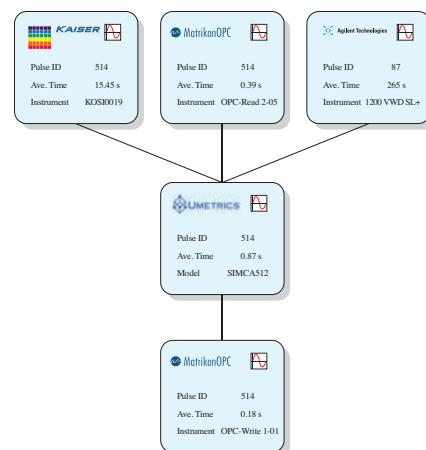


Figure 2: synTQ Orchestration

orchestration. This allows for the configuration of the appropriate orchestration to be run for the specific stage of the process on the specific equipment being used for that stage.

synTQ is also able to collect real-time external data from any source supporting OPC or ODBC transfers as part of the orchestration. Data generated during the operation of the orchestration may be passed out to the recipe, or may be written to external systems using OPC or ODBC transfers.

When the orchestration is complete, synTQ is able to return calculated values for CQAs and/or CCPs to the recipe work instruction. The CQA values can then be used to determine that a process has completed (i.e., termination values).

In addition to providing the capability of running PAT processes through the explicit assessment of CQAs, this system also provides flexibility in meeting the local and corporate objectives for a particular process. For instance, the models may be easily tuned to meet the unique manufacturing requirements at a site, as well as ensuring a consistent, high-quality product is delivered.

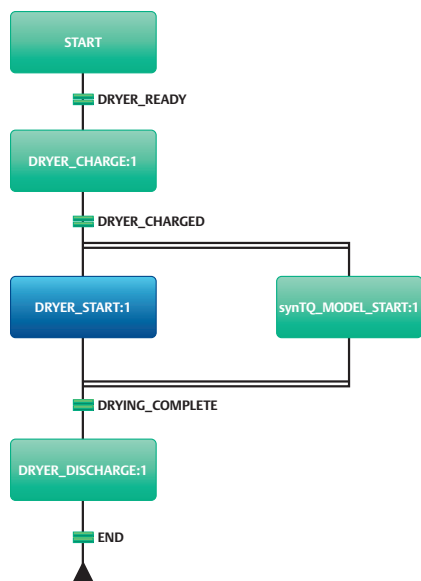


Figure 3: Syncade Recipe

An example of a Syncade recipe is shown in Figure 3.

Once the process is complete, all the data stored within synTQ (including measurement data, configuration data, batch data, and calibration data) is available for export. synTQ provides mechanisms for sorting, selecting, and exporting this data.

Recipe Execution

Once the recipe has been developed, recipe execution is performed using Syncade Workflow. As process orders are released and approved for execution, the corresponding recipes are launched in Workflow. Workflow provides any combination of sequential, parallel, and branch instruction processing.

At run time, the configured synTQ orchestration is launched and the interface instruction provides the appropriate parameters. Once the synTQ orchestration has completed, control transparently returns to the

recipe and the results of the model orchestration execution are available to be used in the recipe logic. An example of a typical data flow that would occur to support the execution of a model is shown in Figure 4.

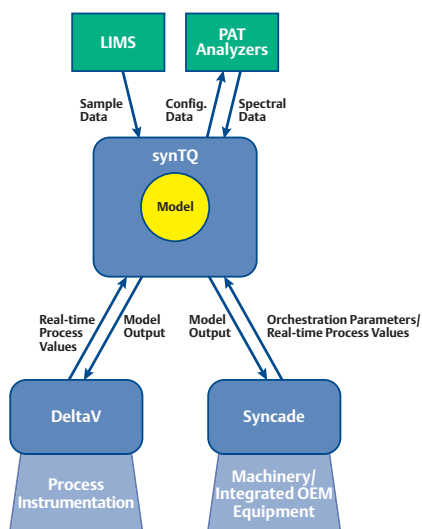


Figure 4: Typical Data Flow

In this example, both DeltaV and Syncade are being used as data sources to the input blocks of a synTQ orchestration and the synTQ orchestration is integrated into a Syncade recipe work instruction.

In the case of a standalone synTQ installation (no DeltaV or Syncade), all data would flow directly into synTQ input blocks and be passed to the model. Outputs could then be provided visually to the operator, or through a standard communication block to the existing control system.

As the recipe is executed, an Electronic Batch Record (EBR) is generated. The EBR collects, reports, and maintains all required data for complete traceability of

materials, equipment and suite usage, and operator activities such as cleaning, calibration, preventive maintenance, repair, validation, and use. Included in the information collected is a record of the PAT model that was executed, its version information, the parameters passed to the model, and the model results.

Recipe Completion

At the completion of a recipe, a comprehensive record of the recipe execution is available for batch reporting. This record could include:

- CQA model execution parameters and model results, and orchestrations
- Executed work instructions, formulas, parameters, transitions, and deferrals
- Signature expressions, behaviors, and prompts
- Linked orders, branch selection, and voiding
- Comments, attachments, SOP, and references
- Execution reporting
- Batch events and history

The final batch format is dependent on site batch reporting requirements, including review-by-exception business cases. This could include links to synTQ historical records for the executed batch such as CCP and CQA data from each measurement cycle.

For more information on how Emerson's PAT solution can help you improve product quality with real-time monitoring and control, contact Saroj Patnaik at 512-832-3718 or by email at Saroj.Patnaik@Emerson.com.

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