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EDITORIAL Q&A FOR THE BATCHEM™ SOLUTION SERIES FROM CASCADE SOLUTIONS

Q: What is BatchEM™?

A: BatchEM™ is a recipe management package combined with implementation services developed by Cascade Solutions that automates various skid-based equipment applications on the plant floor, such as centrifuges, CIP skids, and batch fermentors. Unlike other traditional batch management solutions, BatchEM™ does not require a stand alone batch server. The BatchEM™ solution has been implemented and running at customer sites for the last 18-24 months.

Q: Why hasn't batch software been available on skid-based software before?

A: Traditional batch recipe manage packages were designed to meet and exceed the structures of the entire S88 standard. The focus by software vendors was to ensure the software would enforce the entire structure, in many instances making the decision to utilize S88 an all-or nothing-decision resulting in a price tag exceeding project budgets. The essence of S88 was to create a guideline and common terminology to describe batch processes with the intent that the model be scaleable and collapsible to address all batch processes simple to the most complex systems.

Traditional recipe management systems were designed by these criteria, but the result was a great software package to manage a multi-unit, multi-product system. This has overwhelmed users who have just a simple, single unit batch process, such as the typical skid-based equipment process. BatchEM™ bridges this gap, and provides a user interface and simplified recipe construction designed specifically to meet the needs of the skid-based equipment user. Manufacturers in the food, beverage, pharmaceutical, and biotechnology industry have been clamoring for simplified batch solutions - in other words, for equipment that matches their way of viewing and managing their process.

Q: How is a BatchEM™ configuration different from a traditional server-based batch recipe management configuration?

A: A traditional batch recipe management configuration will require the explicit construction of a detailed equipment model for which the recipe model is based. Within BatchEM™ the process cell, and Unit equipment model entities are implied,

because the equipment being controlled is the process cell and unit. The solution will require the construction of control modules (CMs) with interface to the I/O, and equipment modules(EMs) which contain the interfacing logic necessary to communicate to BatchEM™. The recipes are constructed within the BatchEM™'s Recipe Editor and are made up of phases only which act upon the EMs.

This structure streamlines the development time and simplifies the batch standard down to the level necessary for operating and maintaining equipment. Additionally, it is usually necessary to operate individual equipment modules independently of a recipe, especially during the commission and validation of the equipment. As part of Cascade's solution, each equipment module has associated with it a standard HMI user interface allowing the user to acquire the EM, adjust parameters, and start execution. This is unique to Cascade's solution, unlike standard recipe management systems requiring operation of a phase through the recipe management system. The BatchEM™ Solution simplifies the S88 structure for use with equipment management to make the system easy to configure, maintain, and modify for future process requirements.

Q: Does BatchEM™ have an execution engine?

A: Yes, it is resident in the HMI Server as a Windows service.

Q: Can the equipment be run without BatchEM™?

A: Absolutely. Each equipment module is exposed to the operator through a specifically designed operator equipment module HMI user interface, faceplates. This exposes to the operator the parameters and setpoints to modify with the proper security and execute the equipment module complete with messaging and data historization.

Q: Are all of the events captured within an event journal of some type?

A: Yes, this is a required base function which is delivered with a BatchEM™ solution. This solution was specifically designed for operation of skid-based equipment derived from user requirements within the pharmaceutical and biotechnology industry.

Q: Does BatchEM™ provide any type of messaging interface to the operators?

A: Absolutely. Batch Messaging is an area Cascade Solutions takes very seriously and has developed functionality far exceeding the industry norm based upon customer needs. Typical batch software packages provide very little message capability or functionality usable to customers. Cascade provides messaging relative to the batch at two layers, within the Equipment Module and the recipe layer. The messaging at the equipment module layer are information only prompts, specific to an equipment module. At the batch layer, there are acknowledgeable prompts notifying the operator to take an

action or to indicate when the action is complete to proceed. Both have been very effective in broadcasting information to the operator.

Q: Does BatchEM™ work with popular HMI applications for batch?

A: Yes, and this is the preferred implementation. Some equipment providers utilize the flat panel screens which represent a low cost alternative to HMI-based solutions. Cascade has implemented a scaled down version of BatchEM™ to work with these applications, but highly recommends the use of a standard off the shelf HMI solution with a pointing device or industrial screen.

Q: How does BatchEM™ compare to the approach of batch applications on an I/O card?

A: The industry has seen some vendors attempting to provide end users a batch controller card within a specific hardware chassis with the goal of providing reliability, speed and unfortunately, platform dependence. These goals can be addressed with BatchEM™. Reliability has to do with proper design and understanding of the control platform, software limitations and application. Speed is a relative term and typically does not apply to a batch application. In the rare case that speed is an issue, the proper place to address it is within the design of the EM. BatchEM™ in contrast is platform independent. With any controller card solution an end user will be locked into a specific platform. The BatchEM™ solution makes the proper division, however, between control and recipe execution maximizing performance with the platform of choice.

Q: How is Cascade Solutions able to design this, and what makes it unique?

A: Cascade Solutions has 10 years of experience as a systems integrator for the process industries, and its founders have twenty years of experience designing and implementing process manufacturing projects. The methodology in which Cascade breaks up and modularizes the equipment functionality makes it unique. Most equipment manufacturers don't think of running their equipment as small, easy-to-assemble modules. Cascade's combination of deep industry knowledge, understanding of batch processes, and blend of process, process automation and programming talent has served as the catalyst for BatchEM™'s development.

Q: Who are the target users?

A: Manufacturers in the biotechnology, pharmaceutical and food & beverage markets who typically have very modular processes and/or with isolated processing areas. These customers purchase skid-based equipment in which the entire process is contained within the room or skid prior to moving to the next station. Additionally BatchEM™ will be beneficial to equipment manufactures/suppliers looking for a way to deliver state-of-the-art technology to their customers without the overhead costs and knowledge base associated with a typical recipe management system.

Q: Does the series follow the S88 standard? Has anyone from the S88 committee reviewed it?

A: Yes, the BatchEM™ series follows the S88 guidelines for batch applications and terminology. The S88 standard is a collapsible model allowing for certain variations with regard to which components are exposed for configuration by the user. With BatchEM™, the controller does have the configuration of the I/O, Control Modules, and Equipment Modules resident within the controller. The recipe is made up of phases which communicate to the equipment modules. The recipe does not contain operations and the concept of a unit procedure is implied. Therefore, the recipe is just the execution of the phases and the associated recipe level logic. For multi-product applications, multiple recipes can be created.

Dennis Brandl, former secretary of the S88 committee, has reviewed the functionality and intended use for BatchEM™ and was very pleased to see the essence of the standard was being implemented by customers, system integrators, and OEMs alike. It has only been the software vendors, not the S88 committee, who have tried to force a structure and programming environment typical of off-the-shelf packages.

Q: How many licenses/copies are needed per plant?

A: The typical application for a BatchEM™ solution would be one per operating piece of equipment or skid. For more complex systems, experience will determine the correct level of modularization and configuration.

Q: Where has this solution been implemented?

A: BatchEM™ Centrifuge has been implemented already at a large biotechnology manufacturer (multiple installations) and BatchEM™ CIP has been implemented at a bioprocess manufacturing firm, both under cGMP guidelines.

Q: Can other markets besides biotechnology and pharmaceutical use the BatchEM™ series?

A: The BatchEM™ series was generated out of requirements from the biotechnology and pharmaceutical industry, but is very well suited for industries like food and beverage.

Q: How is it sold? Will it be available to customers or OEMs as an independent package?

A: The BatchEM™ series is delivered as part of Cascade's services offerings to end user clients or can be sold by skid manufacturers as an OEM service. Cascade's expertise in batch applications ensures that the projects are successful. It is not available stand-alone. An important and unavoidable aspect of batch applications is the amount of

structure that falls outside the per se batch software package. This aspect is sometimes not emphasized enough by larger software vendors selling batch solutions. The majority of the work to ensure success is the correct foundation (I/O configuration, control module configuration, and equipment module design). Once this is done properly, the recipe management system can be useful to end users.

BatchEM™ achieves the most success through the capability and knowledge of the batch automation engineer. The best way to illustrate this concept is through the use of a calculator. A scientific calculator is a useful tool; but to someone who does not understand mathematics, it does not ensure the correct answer. Similarly, it is helpful to understand that the value of batch engines lies not so in the engine, but in how the engine is applied.

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