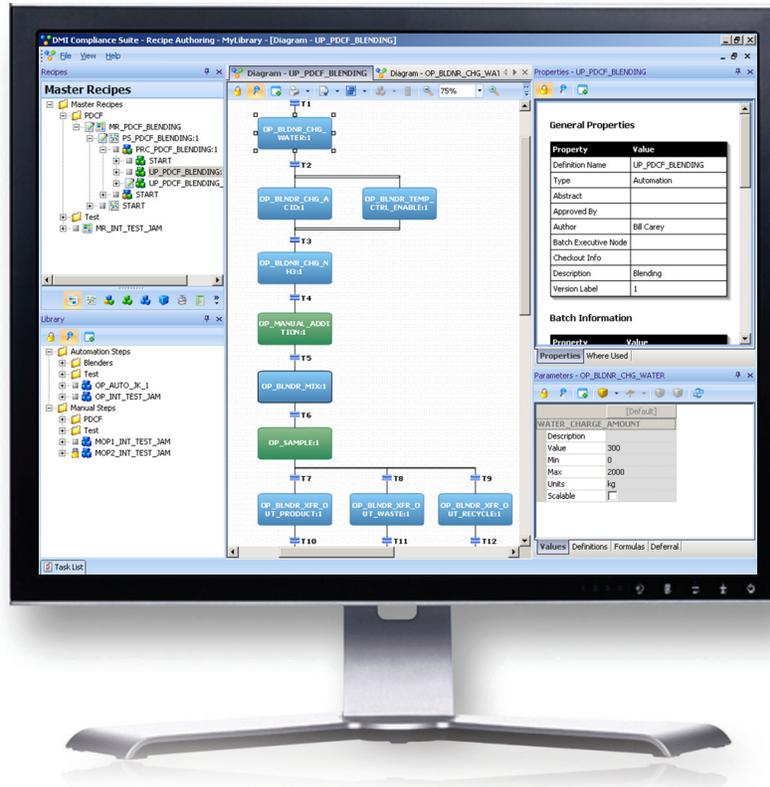# Authoring Comprehensive Recipes

This white paper discusses life cycle benefits of implementing a system that delivers recipe authoring tools that creates a single S88 recipe and downloads the recipe to the MES and DCS system, making it transparent to the user that the manufacturing automation is executed between two different systems.

Contents

EMERSON™
Process Management

Introduction

The life sciences industry is implementing Manufacturing Execution Systems (MES) as a strategy to improve overall manufacturing performance. MES are information technology (IT) solutions that support the primary production processes in a production plant. These applications close the gap between ERP systems and production equipment control, distributed control systems (DCS), programmable logic controllers (PLC), and/or supervisory control and data acquisition (SCADA) applications. MES applications have become essential to support real-time production control, as well as data collection and reporting that are required in order to improve production performance.

The integration of MES with DCS is being implemented to increase right-first-time manufacturing by extending electronic procedural control over manual paper-driven processes. When used in combination with traditional batch automation systems, this integration provides comprehensive manufacturing automation from scheduling through product disposition.

Developing an integrated solution by combining an MES system managing control over manual workflow with batch control DCS systems performing automated equipment control offers a variety of design, implementation, and life cycle management challenges that must be addressed. In the plant floor manufacturing domain, challenges arise from the fact that a single S88 recipe must be implemented across the two different systems.

The MES provides the recipe to drive the manual activities through electronic work instructions, and the DCS recipe controls the instrumented equipment. How are the actions of each system coordinated? This is a vital issue that needs to be addressed at the early stages of technology evaluation. When this issue is not considered, the project becomes exposed to large unplanned costs or the loss of a substantial part of the expected value of the system.

This whitepaper reviews this challenge and defines the life cycle benefits of implementing a system that delivers recipe authoring tools that creates a single S88 recipe and downloads the recipe to the MES and DCS system, making it transparent to the user that the manufacturing automation is executed between two different systems.

S88 Recipe Includes Both Manual and Automated Workflow

All life science, plant floor manufacturing requires both processing steps that are manually performed by operators and automated steps that are performed by a batch control system. Manual processing steps include material charges, filter changes, verifying equipment status, etc. Automated processing steps are involved when the processing can be performed by reading instruments and sequencing values, such as heating phases, agitation, and material transfers. When developing the S88 procedural model for plant floor manufacturing, the design will necessarily include manual and automated processing. See Figure 1 for an example of a simplified media preparation recipe. Automated steps are shown in blue and manual steps are shown in green.

The execution recipes requires coordination of manual and automated process steps. In plants with only batch automation systems, the manual process steps are defined in the paper batch record documents and SOPs, with the automated steps executed by the batch control system. In this case, coordination of the manual and automated steps is accomplished by DCS batch prompts, operator radio communication, or SOPs.

When an MES system is adopted with electronic batch records as the objective of the system, the manual process steps are executed electronically by the MES using electronic work instructions, and there must be coordination of automated steps executed by the DCS and the electronic work instructions executed in the MES. As shown in Figure 2, the MES and DCS system traditionally have separate systems and recipes configured into each system. Each system will only know about the processing steps run under its domain and the overall S88 context of the complete recipe is lost.
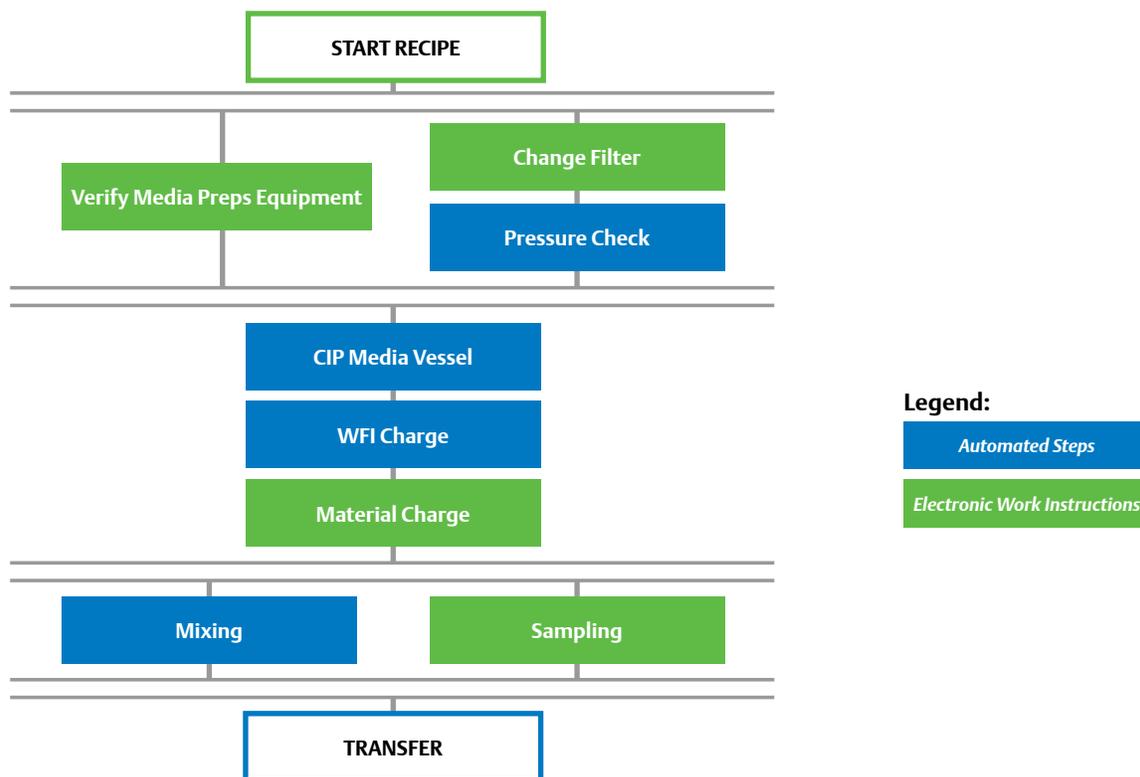

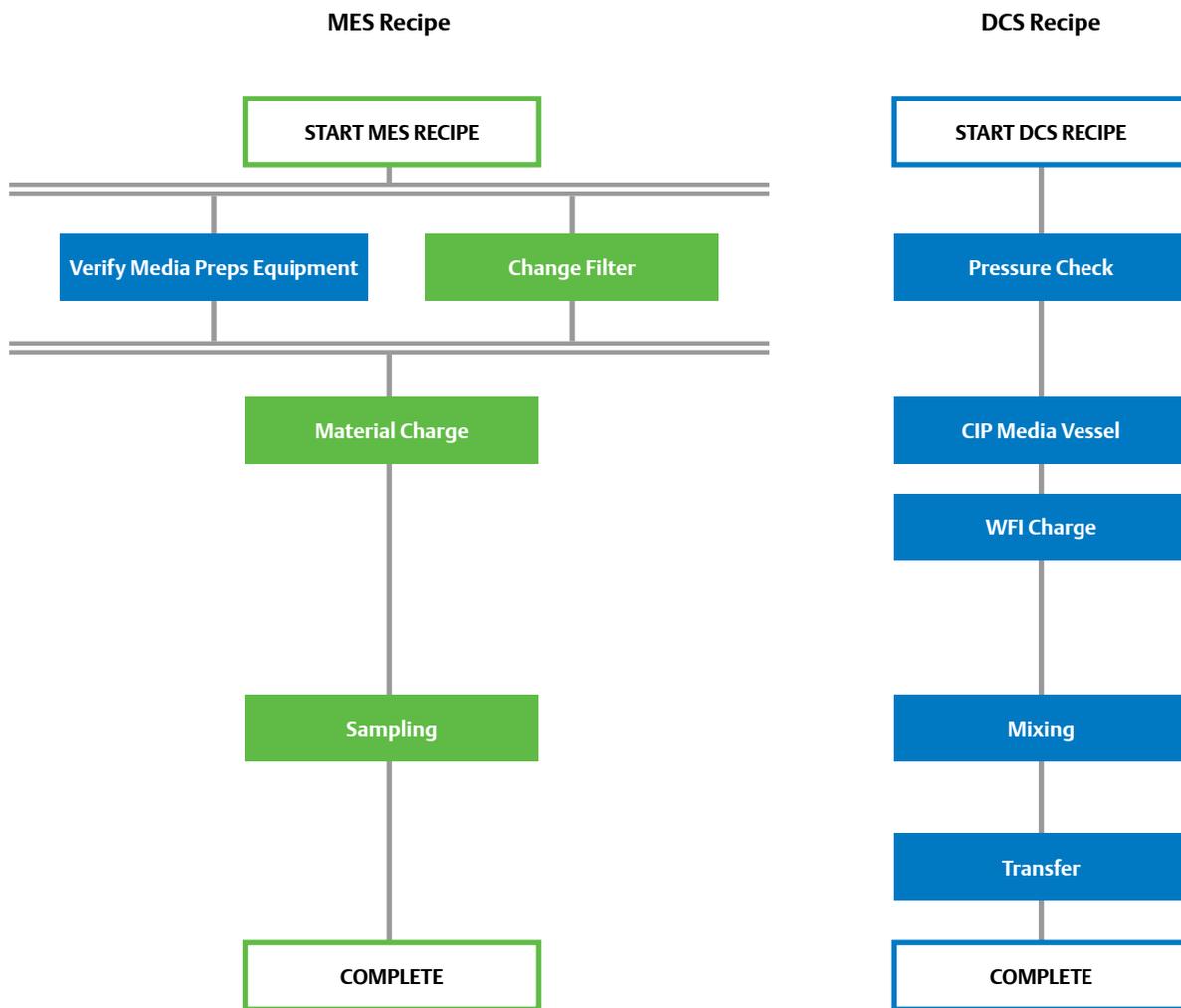*Figure 1: Manufacturing recipes include manual and automated steps.*

MES Recipe   **DCS Recipe**

```
       START MES RECIPE                          START DCS RECIPE

  Verify Media Preps Equipment    Change Filter        Pressure Check

           Material Charge                           CIP Media Vessel

                                                        WFI Charge

              Sampling                                    Mixing

                                                         Transfer

              COMPLETE                                   COMPLETE
```

Figure 2: DCS and MES recipes

Using the scenario detailed in Figure 2, many considerations need to be made, including:

■ How does Pressure Check know that is has to execute after Change Filter?

■ How does CIP Media Vessel know that completion of Verify Media Prep Equipment and Change Filter are required before it can run?

■ How does Material Charge know that WFI Charge needs to be completed before it can run?

■ How does Mixing know that Material Charge needs to be completed before it can run?

Combining MES and DCS Recipes with an Engineered Solution

The MES implementation shown in Figure 2 is referred to as "paper on glass." Choosing to implement systems based on this design results in many right-first-time manufacturing benefits being lost.

In order to enable the correct sequencing of steps between the MES and DCS systems, effort must be expended to engineer an interface between the two systems to:

- Initiate sequencing from one system to the other

- Define coordination and synchronization between the recipes running in the two systems

- Share status information between the systems during run time so that synchronization and coordination can occur.

Figure 3 illustrates how an engineered (custom) integration will be required to develop the overall recipe and share status information. This integration can be done using technologies such as OPC, XML web services, Visual Basic programming; however, this engineered approach is custom software and has a negative impact on the total life cycle costs.
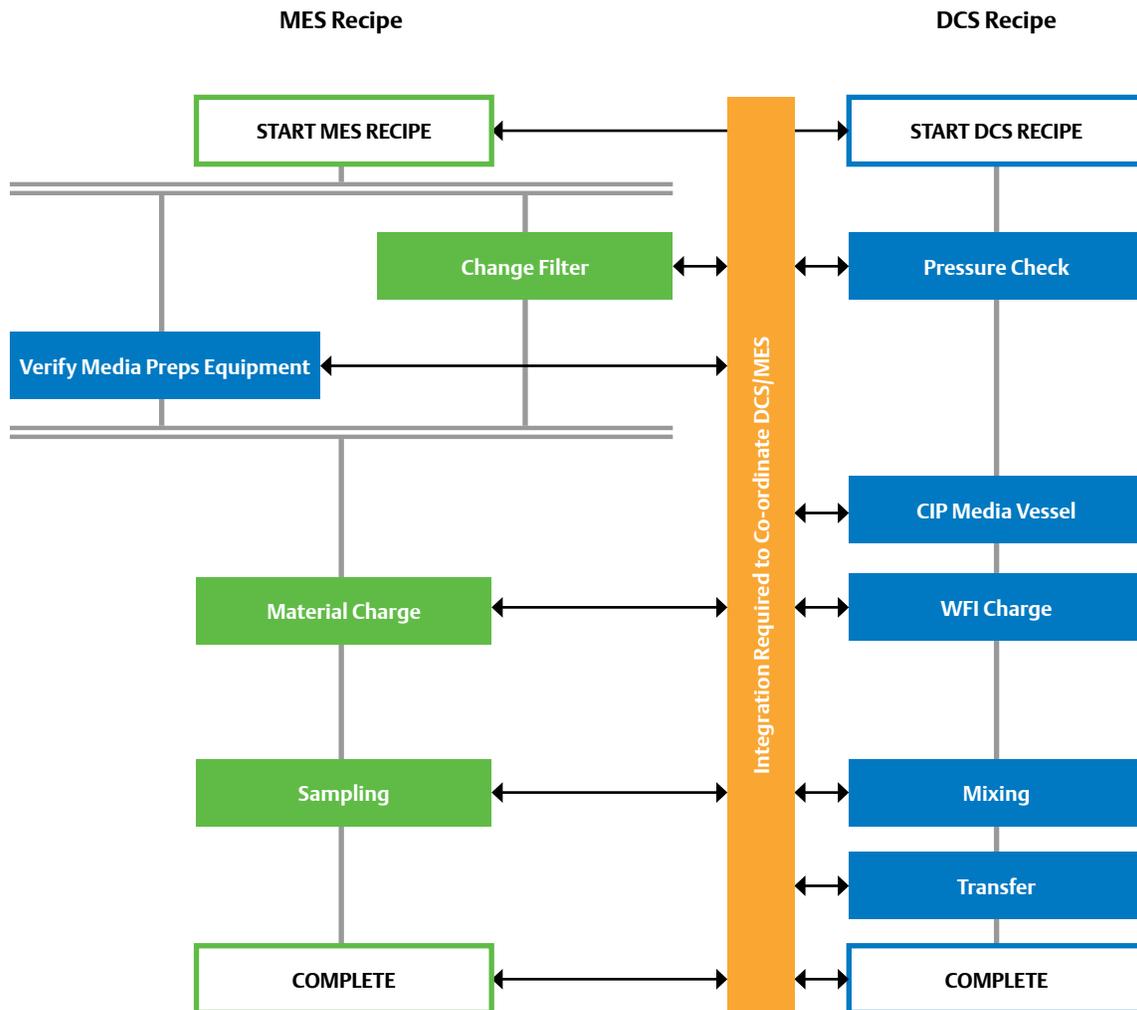
Figure 3: Engineered recipe integration

In order to achieve custom engineered integration, you will need to:

- Define a technical environment in which the interfacing can be performed. Will a software program be written? Will soft phases be used? Can this be done using "interface control modules"? An overall approach needs to be designed.

- Identify an automation and/or IT specialist to knit the two recipes together.

- Document the interface.

- Develop a testing strategy for the interface (GAMP Level 4).

- Develop a validation plan for the interface.

- Support the interface on an ongoing basis.

The cost to develop this custom integration needs to be budgeted. The estimated cost to design, document, and test the overall interface infrastructure is $150,000. The additional cost of recipe creation is highly dependent upon the number of recipes and the number of logical synchronizations required within the recipe. It is estimated that for each logical touc point between the systems, an additional 3 hours of engineering/ IT / test / documentation / validation time will be required to implement and maintain the system interface. For a process with 100 recipes, averaging 10 sync points per recipe, an additional 3,000 hours of engineering time should be planned, in addition to the cost of developing the interface infrastructure.

The real challenge in managing this custom integration is that the "interface" is specific to each recipe. This solution is not a standard IT systems interface, which can be designed and tested once. Each time a recipe is created or undergoes substantial modifications, the interfaces will need to be modified.

After the recipes are developed, there is cost to maintain the recipes. As they are modified and changed, the coordination / synchronization points need to be maintained. This cost is dependent on the frequency of recipe changes in the facility, resulting in an annual estimated cost of 10%-30% of the initial recipe development costs.

The cost of upgrading the system should also be factored into the integration software's life cycle cost. As the MES and DCS are upgraded to new software versions, maintaining the engineered solution between the systems will add to the cost of the upgrade.

Cost of Ownership of an Engineered MES / DCS Interface Solution

Using an engineered solution that coordinates the recipe between a DCS and MES has cost-of-ownership issues that should be considered. These include:

Infrastructure development	$150,000
Initial recipe development[1]	$100,000 - $500,000
Annual recipe maintenance[2]	$20,000 - $100,000
Software upgrade costs[3]	$50,000 per software upgrade

---

[1] Dependent on number of recipes and complexity. Estimated as 2 hours per synch point between recipes

[2] Dependent on frequency of changes made to the recipes

[3] Cost to support engineered interface as version upgrades to MES and DCS system are made.

Product Integrated Recipe Management

The best approach toward an integrated MES/DCS solution is a single recipe using a recipe authoring tool that spans the MES and DCS applications, making it unnecessary to develop custom software. Emerson's Syncade Recipe Authoring enables recipes to be written by process and manufacturing personnel and executed on both systems to substantially lower the total life cycle cost.
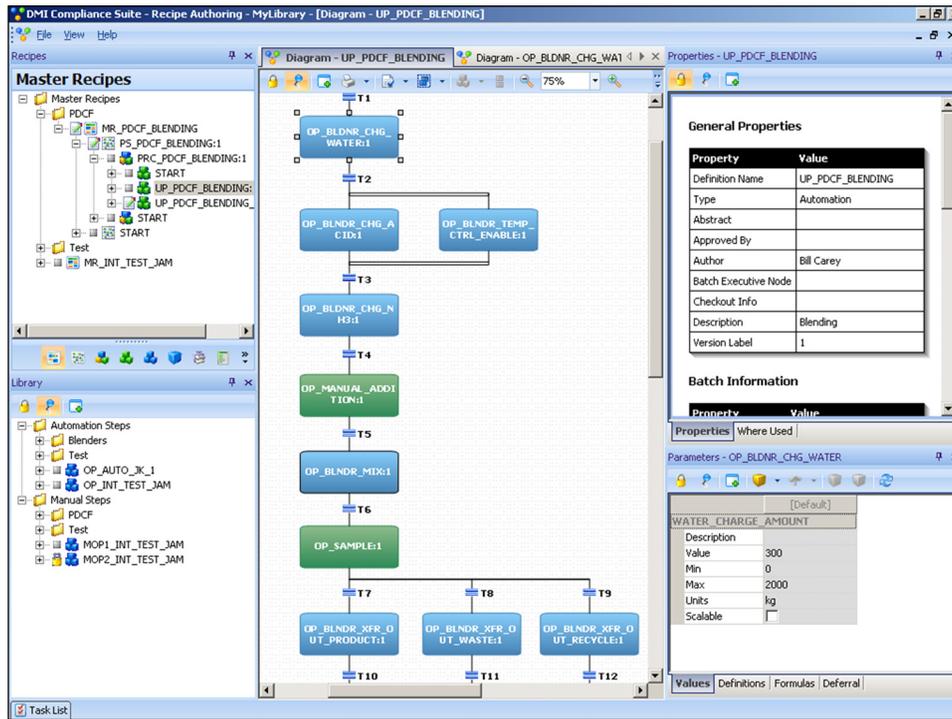

Figure 4: Syncade Recipe Authoring delivers a single recipe for MES and DCS

Rather than the recipe being developed and implemented in two different systems with a custom-engineered interface, the better approach is to develop a single S88 manufacturing recipe that can be seamlessly downloaded to the DCS and MES.

Figure 4 illustrates how Syncade creates a single recipe. The color coding of the recipe indicates manual steps to be executed via MES electronic work instructions in green and automated steps to be executed by the DCS in blue. Syncade manages the communications between the DCS phases and MES electronic work instructions for the user, making a complete recipe definition possible in a single visual recipe authoring tool.

The benefits of using a standard product instead of a custom solution to develop a single comprehensive S88 recipe include:

- Improved right-first-time recipe development

- Increased productivity during recipe development

- Lower cost to maintain recipes

- Easier to create Master Batch Record

EMERSON™
Process Management