GUIDE

Introduction to

BATCH PROCESSING WITH S88

Hallam-ICS
AN EMPLOYEE OWNED COMPANY

WWW.HALLAM-ICS.COM

Table of Contents

Manufacturing Process Methods

Discrete Process: A discrete manufacturing process involves the production of individual parts that move from one station to the next. The item gains value at each stop in the process. At the end of the process each item retains its individual identity. Examples of applications using a discrete manufacturing process are disposable razor blades, micro-chips, box knives, furniture, light bulbs, and staplers.

Continuous Process: A continuous process involves the continuous flow of a material through the manufacturing equipment. The amount of product produced depends directly how long the equipment is turned on. The process will produce a consistent product no matter how long the operation may run. Gasoline and oil refinery processes are prime examples of a continuous process.

Batch Process: A batch process produces a finite quantity of material using an ordered set of activities over a finite period of time. Where a continuous process may run for days or weeks a batch process will consistently require the same amount of time to produce the same amount of material. The finite amount of material produced at the end of the process is referred to as a batch.

Batch processes are not discrete. That is to say that when batch is complete you cannot easily separate the individual parts of the batch. For example if you have a box of batteries you can separate the individual batteries from one another. However, if you have a batch of ice cream you could separate the individual containers, but the ice cream inside the boxes are part of the same batch. You could not distinguish one box from the next.

Examples of batch processes include special chemical manufacturing, the production of pharmaceuticals, and the manufacturing of food products.

The S88 Standard

S88 is a standard created by a committee in an effort to resolve the lack of a universal model regarding batch control, and the difficulties engineers were experiencing in creating an effective batch control system.

The standard was originally created in 1995 by the SP88 committee and updated in 2010 to include the following parts:

- ANSI/ISA-S88.01-2010 Batch Control Part 1: Models and Terminology
- ANSI/ISA S88.00.02.2001 Batch Control Part 2: Data Structures and Guidelines for Languages
- ANSI/ISA S88.00.03 Batch Control Part 3: General and site recipe models and representation
- ANSI/ISA S88.00.04 Batch Control Part 4: Batch Production Records

The S88 standard provides a design philosophy to manufacturing processes. Using S88 enables system designers to simplify changes to the process, reuse program modules, significantly decrease time to market, simplify documentation and validation activities, and lower the cost of automating your process.

Separation of Recipe and Equipment

The standard essentially separates the equipment from recipes. Engineers would traditionally program the recipe or steps required to create a specific product with the code to control each piece of equipment. As a result if a new ingredient was needed in the process a large number of man-hours would be required to make the necessary changes to the program.

Incorporating recipe and equipment logic also creates a problem with other parts of the program. For example if a new ingredient is added to recipe A how does that affect recipe B. S88 moves the recipe logic to a higher level in the architecture and isolates it from the logic needed to run the equipment.

When a new ingredient is added only the steps in the recipe need to be changed, and the program that controls the equipment is left alone.

Common Terms and Definitions

S88 defines a common set of terms and definitions used for the various parts of a process. The standard breaks the equipment model down into the following modules: Enterprise, Site, Area, Process Cell, Unit, Equipment Module, and Control Module.

The recipe module is broken down into the following modules: General Recipe, Site Recipe, Master Recipe, and Control Recipe.

The control recipe can be broken down further into the following: Procedure, Unit Procedure, and Phase.

Benefits of a Good S88 Design

Improve Recovery from Abnormal Events

S88 provides guidelines on how to recover from abnormal events. Specific system states are created to temporally stop the process if an abnormal condition exists. This allows operators or engineers to correct the situation and then resume the process when ready.

Track data in the context of the process

It can often be difficult trying to correlate process events with the appropriate sequence event in a batch. Batch software will track events that occur during the process and relate them to specific steps in the batch recipe. This makes it easy to determine which part of a recipe a certain event occurred. It also helps in determining a possible root cause if a contamination occurs.

Simplified Validation Activities

The concept of reusable modules and the separation of the recipe from equipment provide validation departments an opportunity to reduce the quantity of testing required when changes are needed. Changes that are limited to process steps and do not necessarily affect equipment will only require high level testing to validate the recipe. Usually the same equipment module will be used over and over again for several recipes and only needs to be validated one time.

Process Engineers Can Now Make Automation Changes

Traditionally a process engineer would have to work closely with an automation engineer to implement a change to the control system. S88 separates the process from the equipment and as a result a process engineer and re-define a recipe without regard to how the equipment is arranged or programmed. A process engineer can simply add a new ingredient, adjust cook times, or temperatures from the recipe development tools, with which they are familiar.

Other Possible Benefits to a System Designed With S88

- Reduced Batch Cycle Time
- Increase the Number of Successful Batches Per Year
- Reduced Change Over Time
- Improved Batch Consistency or Yield
- Improved Recipe Development Time
- Reduce Batch Costs
- Improved Material Tracking
- Improved Equipment Utilization
- Improved Data Capture
- Reduced Time To Edit Recipes
- Improved Up Time

S88 Diagram Nomenclature

Relationships

S88 breaks the process down into separate modules that relate to one another. These relationships are described using E-R diagrams (Entity – Relationship Diagrams). The following section describes the definitions of the diagrams used in this paper.

Crows Foot Notation

Figure 1 - One to One Association

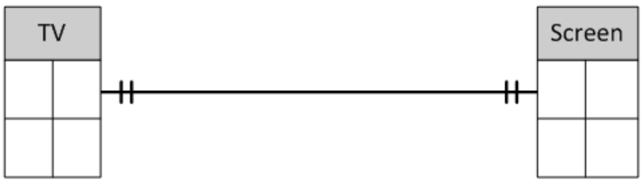


Figure 2 - Zero or One Association

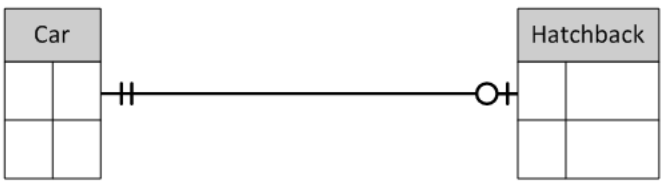


Figure 3 - One or More Association

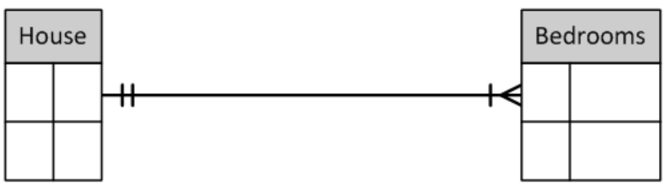
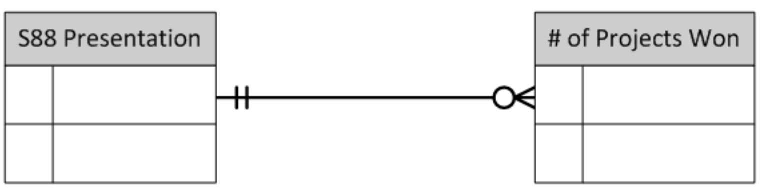


Figure 4 - Zero or More Association



Sequential Function Chart

Figure 5 - Simple SFC

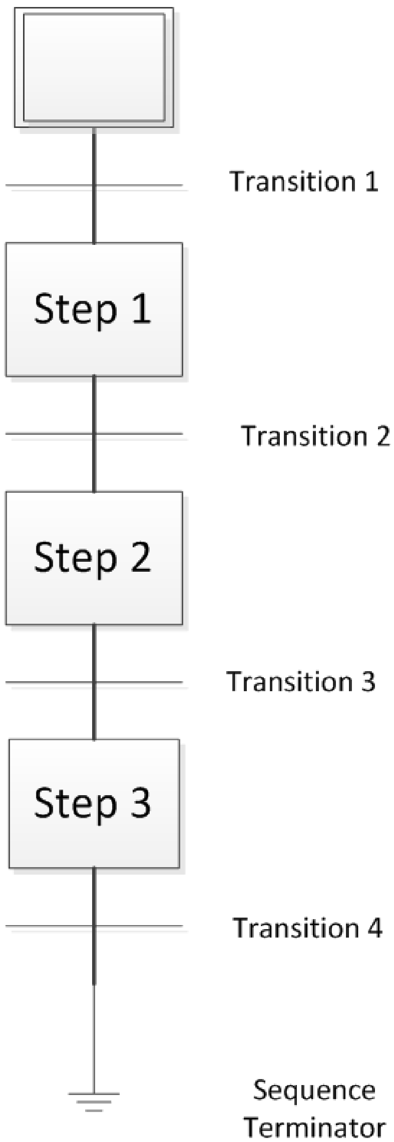


Figure 6 - Divergence Sequence

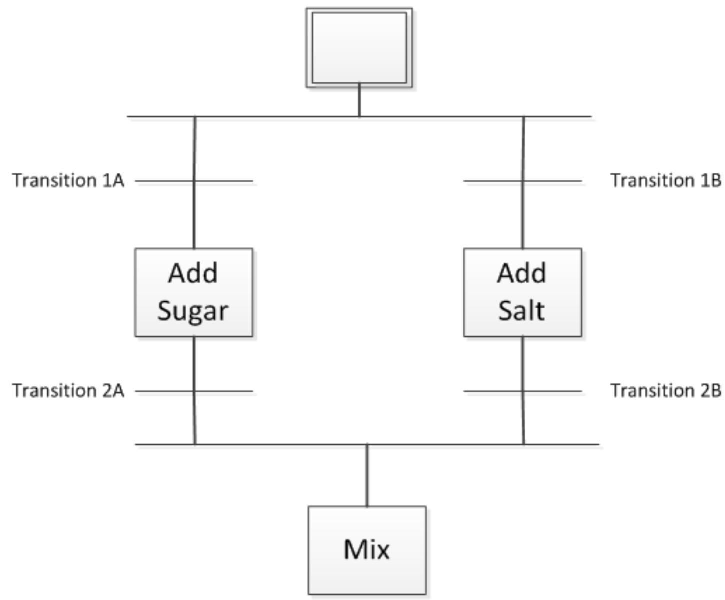
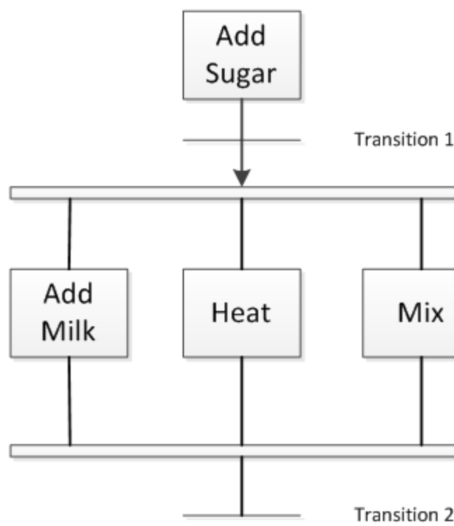


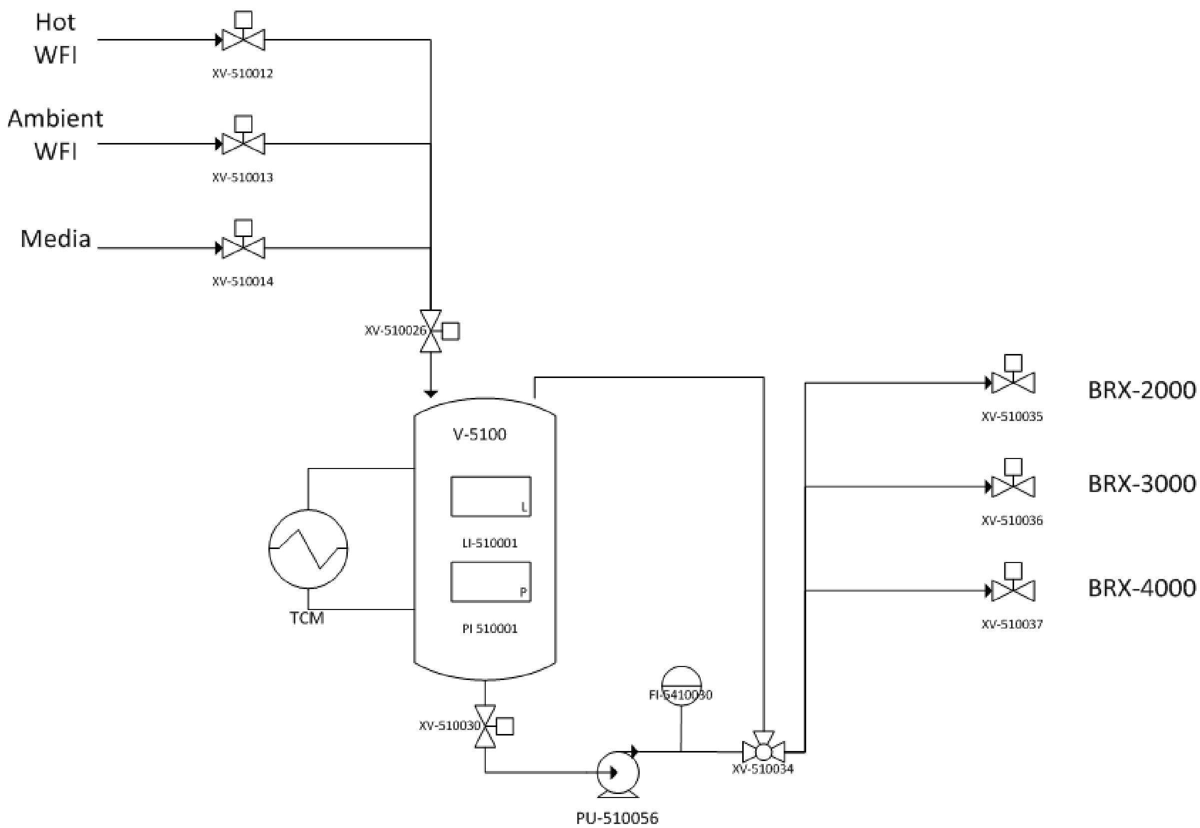
Figure 7 - Simultaneous Convergence



Process Example

In our example we will use the following equipment to produce a batch of media needed for a pharmaceutical product

Figure 8 - Example Media Mix Vessel



Make Media Procedure

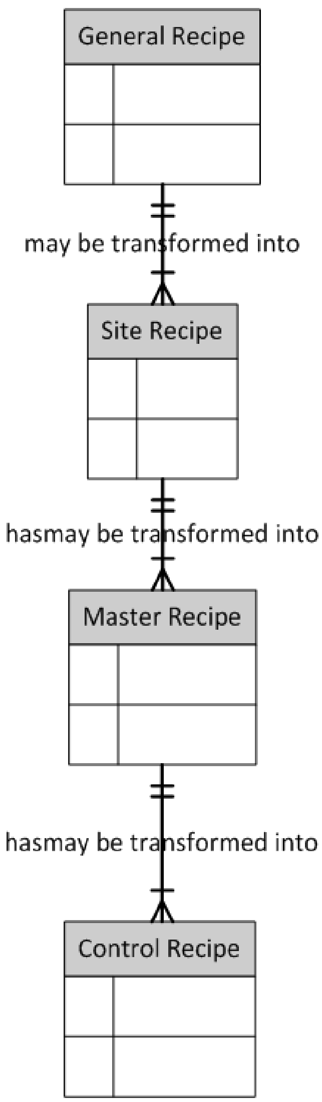
1. Add 500 kg of ambient WFI
2. When level is greater than 20% run the agitator at 20%. Let agitator run until the end of the procedure, adjust agitator setpoint as instructed.
3. Add 300 kg of liquid media, and 400 kg of solid media through the manhole.
4. Adjust agitator setpoint to 80%, add 1500 kg of hot and ambient WFI.
5. Heat solution to 80°C and mix for 120 minutes while recirculating material
6. Cool the solution to below 30°C.
7. Transfer to the destination reactor

Recipe Model

The amount of detail required in a recipe depends greatly on who is reading the recipe. An R&D group may be concerned about specific properties and procedures to create a product, but may not care about the specific equipment used to execute the recipe. A site engineering group may need to the type of equipment needed but may not need to know exactly which equipment is needed for each batch. Operators will need to know the materials, procedures, and the exact equipment needed to produce each individual batch.

To include all the information required by everybody in an organization in a single recipe becomes overwhelming and cumbersome to maintain. To resolve this problem S88 include four types of reci-pes: general recipe, site recipe, master recipe, and control recipe.

Figure 9 - Recipe Model



General Recipe
- Processing information
- No equipment listed
- Can be used for planning or investment decisions or activities

Site Recipe
- Site-Specific information
- In local language
- Based on local raw materials
- Considers sire storage constraints

Master Recipe
- Process cell-specific information
- Dependent upon equipment types or classes
- Required in any S88-aware solution to be template for control recipes

Control Recipes
- Equipment specific information
- Batch-specific information: batch ID, batch size, raw material used, processing steps

General Recipe

The general recipe is used at the company level and defines raw materials and their quantities as well as the process required to produce the product. The general recipe does not take into account the requirement to make the product at any particular site or any of the variations from local sources of raw materials. Often a general recipe will come from R&D for a particular product and can be used at various sites throughout the enterprise.

Site Recipe

The site recipe, as its name suggest contain more detailed information regarding a specific site, the general equipment at that site and local raw materials. Site recipes may differ from site to site based on geographical locations. For example two site recipes may be created for a site in Germany and another in the U.S. The site recipe in Germany would be written in German while the site recipe for the U.S. would be written in English.

Local ingredients may result in differences in site recipes as well. Two sites producing the same ice cream product may need to make adjustments to their site recipes because of the difference in fat content in the local supply of milk.

Master Recipe

The master recipe is the also the template for the control recipe and is the recipe used regarding S88 aware software such as FactoryTalk Batch. The master recipe will depend on specific equipment types or classes. Quantities of specific materials may be called out. It may contain product-specific information used for scheduling, such as equipment requirements.
A master recipe is required to generate the control recipe as it is the template for the control recipe.

Control Recipe

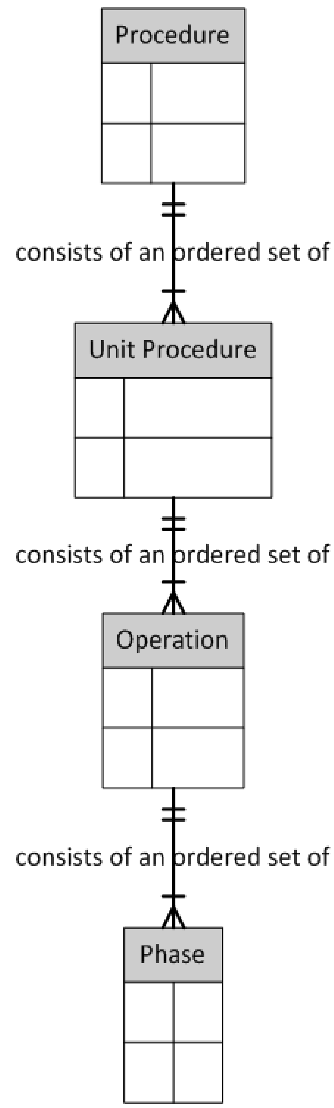
The control recipe is usually created by the S88 aware software from the master recipe. It is used to direct the activities of a specific batch. It may include information such as batchID, batch size, characteristics of raw materials on site, and the actual equipment to be used. When an operator is following a recipe to produce a batch it is the control recipe they are using.

Most S88 aware software start managing recipe from the master recipe level and in our example going forward that is where we will begin as well.

Master and Control Recipe Procedures

Master and control recipes are made up of a procedural model that is broken down further into four types of procedures: Procedure, Unit Procedure, Operation, and Phase.

Figure 10 - Master and Control Recipe Procedural Model



Procedure

The procedure is the highest level in the hierarchy and is required if the batch requires more than one unit (a unit is a major piece of equipment used to process the batch) to make the batch. It contains the general strategy for making the batch and is created using an ordered set of Unit Procedures.

In some situations a procedure level isn't required because processing only occurs in a single unit, but to be consistent, it is often desirable to create a procedure level for recipe regardless of the number of units required. We will create a procedure called SF38 Growth Media that will contain the unit procedures we need to make the media and transfer it to the destination reactor.

Unit Procedure

The unit procedure is created using an ordered set of operations carried out on a single unit. S88 requires that only one unit procedure may run on unit at a time. A batch cannot be processed on one unit then transferred to another, then back again within the same unit procedure. S88 does allow multiple unit procedure to run at the same time, but the must run on different units.

For example a batch cannot run a unit procedure to make media while at the same time run a unit procedure to CIP the same vessel. In our example we will create one unit procedure called Make Media.

Operations

An operation is an ordered set of phases that are executed on single unit. The S88 standard encourages the design engineer to create the operation boundaries at points in the process where the process can be safely suspended. The standard assumes that only one operation will be executed at a time.

This is often difficult to accomplish without making the operations extremely complicated. For example, it is frequently required to run an agitator and a TCM module to maintain temperature during the entire processing time. While it is possible to include these phases in each individual operation, it is often desirable to break them out into their own operation and run them in parallel at the unit procedure level. In our example we will create two operations: Make Media and Transfer Media.

Phases

The phase is the smallest module in the procedural model. It is usually the level that links to the equipment model and the devices controlling the equipment. Phases perform unique, basic, and generally independent functions. Examples of phases could be heat, pressurize, mix, transfer, recirculate, charge, or react.

Often S88 aware software will allow the designer to give phases "multiple personalities" using something known as control strategies. For example, instead of simply pressurizing a vessel the equipment may be capable of several different types of pressure control. It may be able to pressurize to a setpoint, or pressurize to setpoint using a ramp and soak profile, or instead of pressurizing pull a vacuum. Perhaps instead of pressurizing to a setpoint, all that is needed is to open the vessel to the atmosphere. The designer could create separate phases for each of these functions but it is often convenient for to create a single phases with multiple control strategies to accomplish each task.

Example Recipe

Using our example system described above let's put together a sample master recipe using all the whole procedure model.

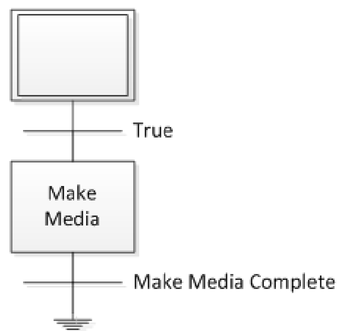
Procedure: SF38 Growth Media

Our recipe is very simple and only requires a single unit. A procedure level recipe is not required, we could start at the unit procedure level, but to keep all the recipes consistent it can be preferable to create a procedure level recipe.

Our procedure will contain only a single unit procedure and define all the material additions that will be passed down the hierarchy.

SF38 Growth Media Recipe Material Specifications	
Batch Size	2700 kg
Initial Ambient WFI Charge	500 kg
Liquid Media Charge	300 kg
Solid Media Charge	400 kg
Final Ambient WFI Charge	750 kg
Final Hot WFI Charge	750 kg

Figure 11- SF38 Growth Media Procedure

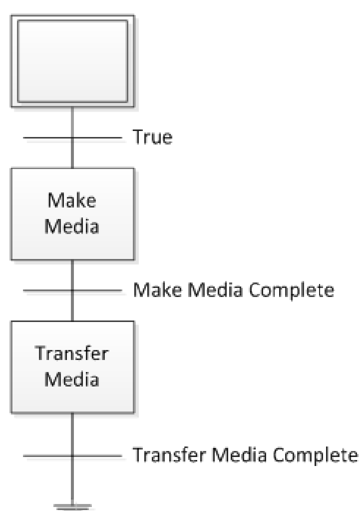


Unit Procedure: Make Media

The Make Media unit procedure will have two operations: Make Media and Prepare Transfer. The Make Media operation will contain the necessary steps to mix and manufacturing the media, while the prepare transfer will contain steps required to get the unit ready to transfer the material to a destination.

Make Media Recipe Material Specifications	
Initial Ambient WFI Charge	Amount Passed from Procedure
Liquid Media Charge	Amount Passed from Procedure
Solid Media Charge	Amount Passed from Procedure
Final Ambient WFI Charge	Amount Passed from Procedure
Final Hot WFI Charge	Amount Passed from Procedure

Figure 12 - Make Media Unit Procedure



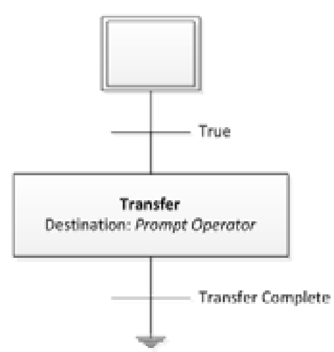
Operation: Make Media

The make media operation will contain the steps necessary to manufacture the media defined by the recipe. The raw material quantities defined in the procedure level are passed down to the operation through the unit procedure then passed to the individual phases of the operation. This mechanism of passing parameter values provides the process engineer the ability to create multiple media solutions by simply copying the procedure level recipe and modify the material amounts. The same operation is used, but different material quantities are used.

Make Media Recipe Material Specifications	
Initial Ambient WFI Charge	Amount Passed from Unit Procedure
Liquid Media Charge	Amount Passed from Unit Procedure
Solid Media Charge	Amount Passed from Unit Procedure
Final Ambient WFI Charge	Amount Passed from Unit Procedure
Final Hot WFI Charge	Amount Passed from Unit Procedure

Figure 13 - Make Media Operation

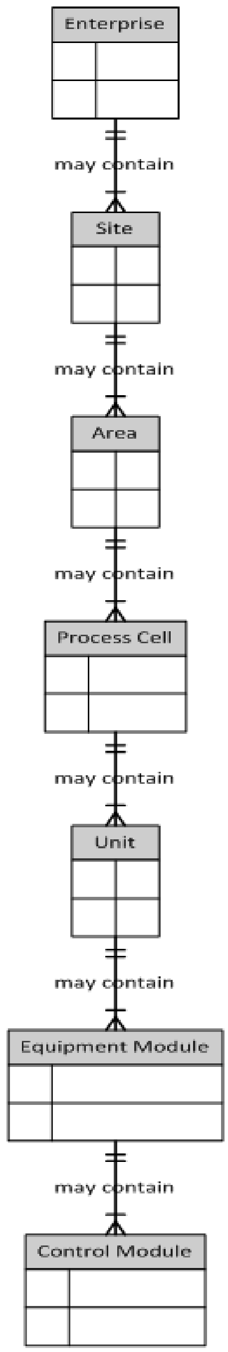
Figure 14 - Transfer Operation



Physical Model

The other half of the S88 standard defines the physical model or the equipment layer. The physical model defined in S88 is broken into seven blocks: Enterprise (Company), Site, Area, Process Cell, Unit, Equipment Module, and Control Module.

Figure 15 - Physical Model



Enterprise

The enterprise level refers to the company.

Site

The site level refers to the plant manufacturing the product. A company may have multiple sites producing the same products. Generally sites are determined by geography, but that doesn’t mean two sites cannot be physically adjacent.

Area

The area level refers section within a site. Not every area in a site must be associated with the site, especially if the area doesn’t have anything to do with batch control. For example the administration area in the site most likely doesn’t need to be included. However, process areas can be included such as media prep, buffer prep, cell culture, and purification could be designated as areas.

Process Cell

The process cell also referred to as a “process train” includes all the equipment required to produce a batch. A process cell may contain more than one train, but a train cannot breach the boundaries of a process cell.

A process cell may process more than one batch at a time, and batch need not use all of the equipment in the process cell.

Unit

Most batching activities are focused around the unit. A unit is a piece of equipment where one or more major processing activities take place. Generally they include equipment such as reactors, mixing vessels, or CIP skids. The do not include storage tanks or holding vessels. One way to help determine if a piece of equipment should be considered a unit is to decide whether you need it to run a recipe. All recipes require a unit to execute them. Storage tanks will generally be acquired by another unit and used in its recipe.

Some things to keep in mind about units is that they can only operate on one batch at a time. They can only execute a single unit procedure at a time. They generally hold the entire or a portion of the batch and perform some processing to add value to the batch.

It is helpful to consider CIP (Clean In Place) skids a unit and treat CIP activities similar to batching activities. Technically CIP activities are not a batch process because a product is not produced, but CIP can be recipe driven and the S88 standards and rules can be made to apply to the CIP activities.

Control Module

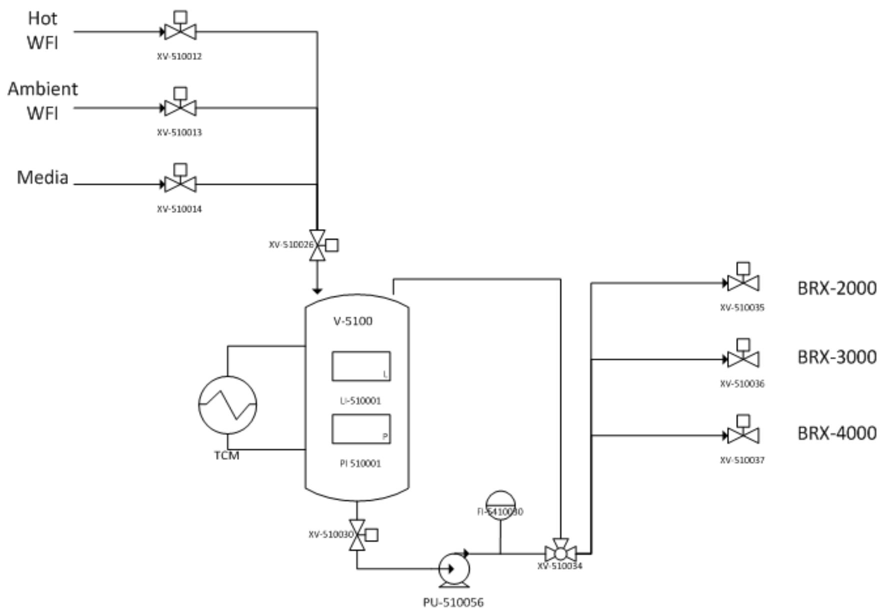
The control module is model of a specific device such as a valve or pump. Control modules may contain other control modules but this can get confusing when trying to distinguish between a control module and equipment module. The control module should be a single entity and is the direct connection to the input and outputs to the actual device. The modules often contain automatic and manual modes, simulation functions, the ability to set permissives and interlocks, and process alarms.

Equipment Module

The equipment module is a collection of control modules. The equipment module should provide a finite list of commands and perform a define set of functions. The idea is that your recipe should not command each control module individually but the equipment will drive the control module based on the requested commands.

The advantage of grouping control modules into functional groups is that the detail in controlling each device is abstracted by the equipment module layer.

An example would be the outlet line in our example system shown in figure 8. It is displayed again below for convenience.



The outlet line equipment module might contain the following control modules: XV-510030, PU-510056, XV-510034, XV-510035, XV-510036, XV-510037.

The module then could provide the following functions:

- Idle – All valve closed and pump de-activated
- Recirculate – XV-510030 and PU-510056 is energized to recirculate the material
- Transfer to BRX-2000 – XV-510030, PU-510056, XV-510034, and XV-510035 is energize
- Transfer to BRX-3000 – XV-510030, PU-510056, XV-510034, and XV-510036 is energize
- Transfer to BRX-4000 – XV-510030, PU-510056, XV-510034, and XV-510037 is energize

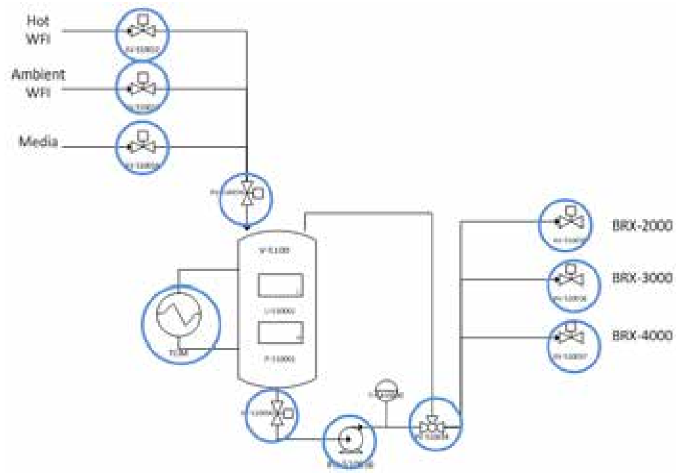
The phase logic called by the batch control system would then simply take ownership of the equipment module and issue the transfer to BRX-3000 command or recirculate command. The phase logic doesn't need to know which control modules are needed to execute the command because the equipment module takes care of that.

Another big advantage of this architecture is that the commands to the equipment modules can be common to all equipment modules of a similar type. That is to say all the outlet lines may have the same set of commands so from the phase's point of view it doesn't matter which module it is work with, the logic is the same.

The differences in the outlet lines from unit to unit are handled by the equipment module and abstracted to the phase logic commanding it.

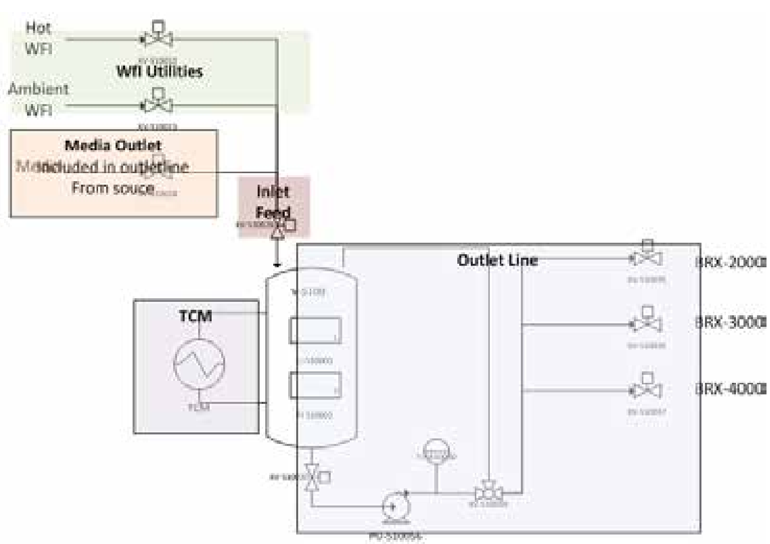
Example: Physical Model

In our example system we are focused on a media vessel that is located in the Media Prep Area in our model. Each device shown in the P&ID drawing would be considered as a control module as shown below.



Technically input devices, flow meter, or level meter for example, are control modules as well, but it can be beneficial not to include them in the equipment module definition unless it makes sense to do so. It makes sense to include pressure in a pressure equipment module that also includes valves and a controller to manipulate pressure, but level may be on its own and used by several separate equipment modules and phase. It can be difficult where to place these types of devices, and sometimes it is best to include them with the unit definition.

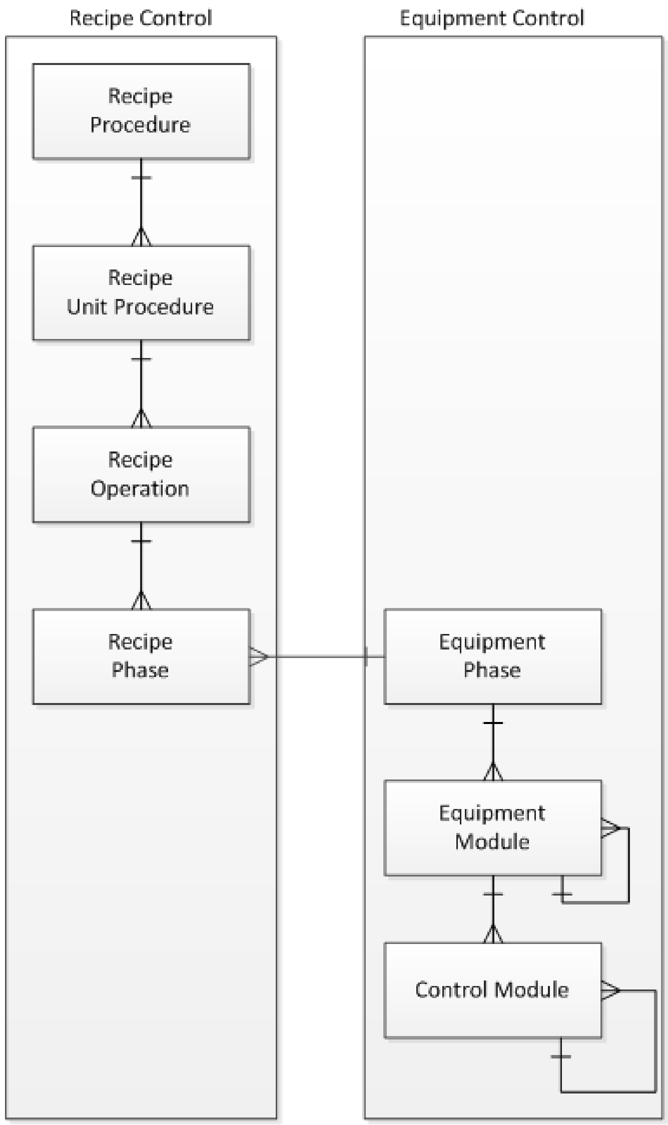
The next step is to group the control modules into functional groups. The outlet line is pretty straight forward in our example. However, the inlet lines where the material additions occur can be problematic. It may seem like a good idea to group all of the inlet valves together as an equipment module, but this can sometimes make controlling transfers from the source tank difficult. If situations like a WFI loop where the material is supplied to several vessels as a utility and several vessels can draw on that utility simultaneously then creating a separate EM for material makes sense. When the material is coming from a storage tank where only a single transfer can occur at a time, it is best to include the all of the control modules in the outlet line of the source tank. The equipment modules for our example:



Linking Recipes to the Physical Model

Thus far we have shown how S88 isolates the process recipe from the equipment, but how do they interact with each other?

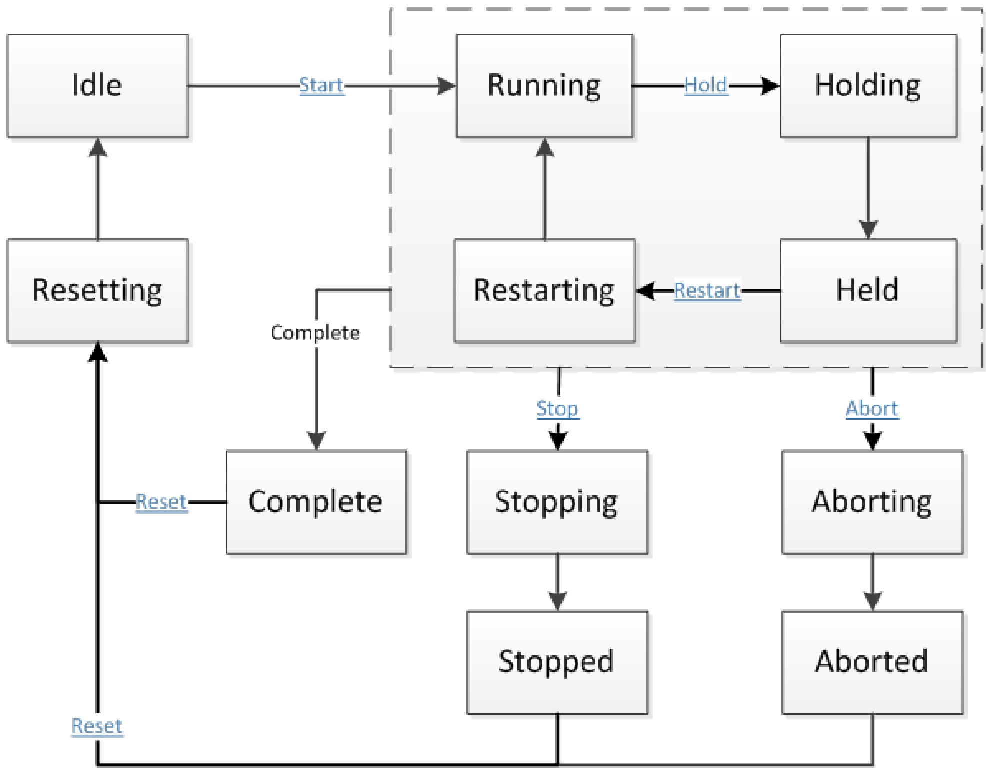
Instructions from the recipe are delivered to the equipment layer via communication between the recipe phase and the equipment phase. The phases are mirrored in both the recipe and physical model to facilitate communication between the models.



Equipment Phase State Model

In our example system we are focused on a media vessel that is located in the Media Prep S88 clearly defines the command structure of the link between the recipe phase and equipment phase modules. The recipe phase issues commands to the equipment phase, which changes to the appropriate state. The following figure shows the state transition diagram used by the equipment phase.

Figure 16 - Equipment Phase State Diagram



Idle

In the idle state the phase is not running and is waiting for the start command to transition into running.

Running

The running state is the normal operating state for the phase. From the running state the recipe phase may issue a hold, stop, or abort command to transition the phase to handle an abnormal condition. The phase may also run to a normal completion, then transition to a complete state.

Complete

The phase transitions to complete after running through its normal operation. The phase is now waiting for a reset command to return the idle state.

Holding

The phase receives a hold command while in the running state and executes separate logic to place the appropriate equipment into a held condition. Once the holding logic completes the state machine automatically transitions to the held state.

Restarting

The phase receives a restart command while in the held state and executes separate logic to restart the phase to safely return to the running state.

Stopping

The phase receives a stop command and executes the stopping logic. After the stopping logic completes the state machine automatically transitions to the stopped state. A stop command can be issued while the state machine is in running, holding, held, or restarting. Generally the stop command is used to cleanly bring the phase to safe stop, and return the equipment to a recoverable state. It can also be used with phases that do not have a clear stopping point. Agitation frequently requires an external stop command to bring the phase to an end.

Aborting

The phase receives an abort command and executes the aborting logic. After the aborting logic completes the state machine automatically transitions to the aborted state. Similar to the stopping state the command can be issued during the running, holding, held, or restarting states. Abort can be used to bring the phase to an immediate stop. Operators usually need to manually manipulate the equipment to bring back into a useable condition.

Resetting

The phase receives a reset command while in the completed, stopped, or aborted states and executes logic to reset the phase. After the resetting phase completes phase automatically returns to the idle state, waiting for the run command to begin again.

A Case Study Link

To view a project example of an S88 implementation

CLICK HERE

What's Next

We hope you will find this Guide to Batch Processing with S88 helpful. For further assistance, please reach out to the process controls experts at Hallam-ICS.

www.hallam-ics.com/control-and-automation-systems

Info@Hallam-ICS.com

1-800-287-0800

References

Parshall, Jim and Lamb, Larry. Applying S88 Batch Control from a User's Perspective ISA, 2006. Print

Parshall, Jim and Lamb, Larry. www.BatchControl.com Batch Control.com LLC

www.Hallam-ICS.com

Connecticut | 363 Main Street, Suite 303, Middletown, CT 06457 | **Tel: 860-788-6815 | Fax: 802-658-1457**
Massachusetts | 575 West St., Suite 220, Mansfield, MA 02048 | **Tel: 508-821-9759 | Fax: 508-821-9739**
New York | 107 Hermes Rd., Suite 130, Malta, NY 12020 | **Tel: 518-289-5582 | Fax: 802-658-1457**
North Carolina | 3801 Lake Boone Trail, Suite 100, Raleigh, NC 27607 | **Tel: 919-821-4145 | Fax: 919-821-4147**
Vermont | 38 Eastwood Drive, Suite 200, So. Burlington, VT 05403 | **Tel: 802-658-4891 | Fax: 802-658-1457**