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Use of GAMP, ISA-S88 and Integrated C&Q to Speed Plant Startups

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(Note: For reference, a list of acronyms is found at the end of the article.)

Introduction

One of the most critical choices in the plant design phase is how to break up the plant systems and their controls into logical and manageable chunks. The better the breakout, the more flexible the plant will be and the easier it will be to manage the validation effort as it expands. Using an ISA-88/GAMP facility design strategy and an integrated commissioning and qualification (C&Q) approach can help reduce plant timelines by:

- defining clear validation boundaries up front to avoid costly over-validation;
- defining clear process train boundaries to reduce the impact of downstream changes and expansions;
- providing a framework to make informed choices as to whether a system should be custom designed or OEM designed; and
- reducing the duplication of work between the commissioning effort and validation.

Plant Controls Layout Using the ISA-S88 Model at the Process Train Level

The following rules of thumb can be used to divide the plant systems and their controls into logical and manageable groupings.

- Place utility systems that serve more than one process train onto a separate PLC and keep them separate from the process trains and their PLCs. This prevents changes in any given process train from affecting utilities that serve all trains.
- When the entire process train is custom designed, place all of the controls for the train on the same PLC. This allows interlocks among units to be passed within the logic of one PLC and not among multiple PLCs.
- When the process train is comprised of a number of OEM units, use either a DCS or S88 software batch engine to tie them together. In either case, ensure that there is a dedicated high-speed communication bus between each OEM PLC on a process train and the DCS or batch engine.
- Isolate the controls for validated and non-validated systems. This allows for clear boundaries and allows for the validation resources to be concentrated on the systems with the most GMP impact.

Custom vs. OEM Equipment

Another series of critical choices is whether equipment (and their controls) should be supplied by OEM vendors or custom designed. The following rules of thumb can be used when making this decision.

- Select an OEM vendor when the equipment and controls can be purchased completely off the shelf.
- Select an OEM vendor when a system is truly stand-alone (i.e. when there is very little interlocking with other plant systems).
- Select an OEM vendor when the OEM equipment is expected to be pre-optimized by the OEM and will not need upgrades or receive complex PAT initiatives.

Where these rules do *not* apply, custom-designed equipment or OEM equipment with custom controls may be a better choice. Generally, OEM skidded systems are less expensive to purchase and implement than custom-designed systems. Additionally, OEM systems are less expensive to validate and tend to come with good canned validation packages. Thus, the result is often a "best of breed" approach, where the various units in a process train come from a number of different OEM vendors with different control systems. If the design assessment leads to this type of architecture, it is critically important that adequate integration resources be leveraged to ensure that the process train functions smoothly as an integrated unit via a DCS or batch engine.

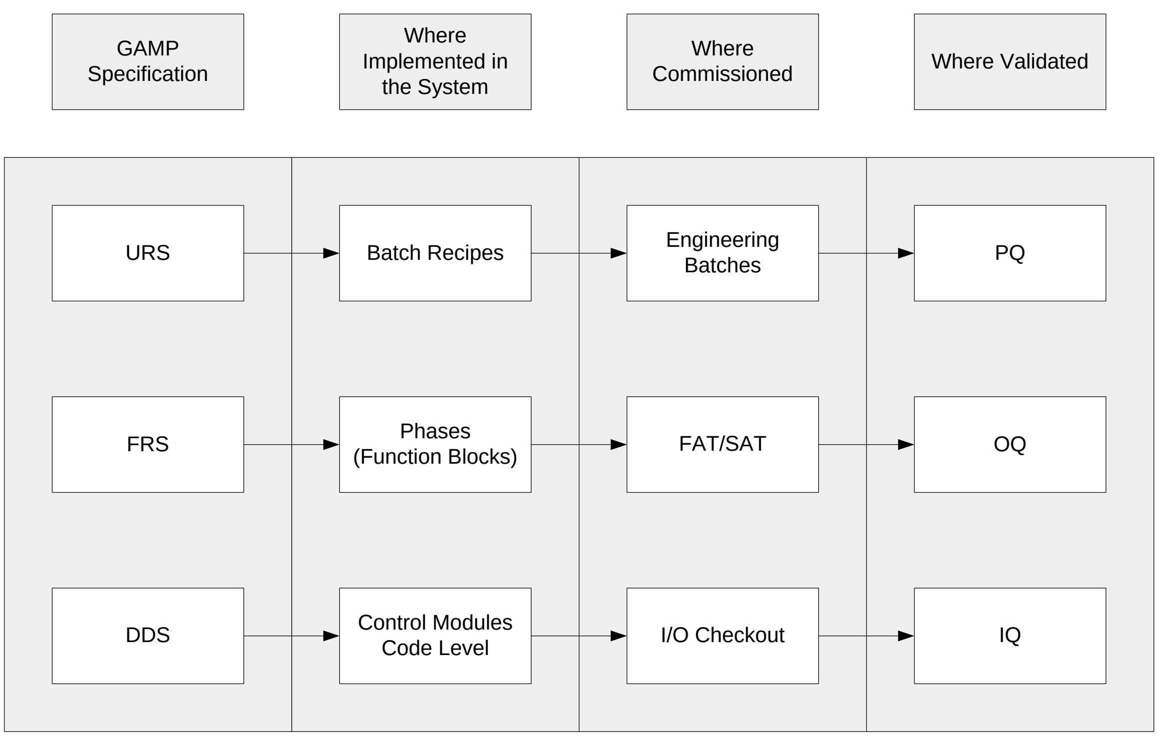
Standardized ISA-S88 Modular Design Reduces Costs and Time

A benefit of the S88 Control Module approach is that all devices of a given class operate in the same way, share the same PLC code subroutine and have a common HMI faceplate design. Standardizing custom control systems across a plant in this way saves time and reduces costs; and the more systems that use the standard library of control modules, the greater the benefit.

- The logic of each control module (including the alarm and fault logic) can be challenged offline to ensure that it performs as specified. This reduces the validation effort to I/O checkout and alarm set point review.
- An I/O checkout procedure can be developed for each control module class. This standardized approach dramatically simplifies the generation of the I/O checkout protocols.
- The standardized code and consistent HMI look and feel allows for rapid execution of the I/O checkout.

GAMP and ISA-S88

Pharmaceutical Engineering/Validation departments have embraced the GAMP design and validation model developed by ISPE. GAMP provides a framework for managing the life cycle of automated systems and directly maps to the S88 model and the traditional FAT/SAT commissioning models, as shown below.



In the URS, the top level requirements for a system are defined. These are implemented within the S88 Batch Recipes, commissioned during the engineering batches and validated in the PQ.

In the FRS, the equipment sequencing, faults and interlocks are defined. These are implemented in the S88 Phases, commissioned in simulation at FAT and on the equipment at SAT and validated at OQ.

In the DDS, the control modules, I/O alarms, I/O cabinets and field wiring are defined. These are implemented in the S88 Control Modules, commissioned as part of I/O checkout at the SAT and validated at IQ.

C&Q Strategies

Traditional C&Q strategies fall into two categories. In the first, validation is conducted when a plant is mechanically complete, but prior to process development. As the process development effort progresses, there will be an inevitable need for I/O and function block changes that will fall under change control (since validation has already been conducted). This adds significant overhead and time to the process development effort and leads to an “it’s good enough” approach to commissioning.

In the second, validation is conducted *after* commissioning and process development is complete. This allows I/O and function block changes to take place before the onset of change control. But without a change management framework in place to track issues, changes and resolutions, and to update the design documents and ETOP’s, these activities usually do not take place. Before validation can start up, an as-built specification/drawing set needs to be reverse engineered and the impact of the changes during commissioning needs to be assessed. If the changes are significant, it becomes difficult to leverage the commissioning effort towards validation. This results in a time-consuming and costly validation effort where all of the testing done under commissioning needs to be repeated and documented in a GMP fashion.

A newer approach gaining acceptance in the industry is to integrate the C&Q by focusing on defined efforts during the pre-commissioning work and leveraging these efforts to minimize the downstream work needed to complete the validation program. This approach requires that the FAT is executed under protocol. To avoid the need to write a lengthy and detailed test protocol, the current Phase FRS is printed and each function tested accordingly. During testing, as each function is challenged, the FRS is initialed and dated indicating that testing was performed.

If issues are found with the system, a one-page incident form is opened that calls out what changes needed to be made to the system or the documentation and the outcome of the retest. This scheme allows for changes to be tracked in a GMP fashion and referenced by the validation effort.

Similarly, the SAT is executed under protocol and separated into the I/O checkout and the function block checkout. This tracks the I/O checkout from the equipment end devices, though the field wiring and I/O to the PLC/DCS and out to the HMI screens. The function block tests and the associated PID loop tuning effort are also tracked in the same manner.

If issues are found with the system, incident forms are used to document the issue, the solution and the retest. This again allows for changes to be tracked in a GMP fashion so that the end product can be referenced by the validation effort. This change management scheme is held open until process development is complete to preserve a record of changes made throughout the interval. This overall sequence of events is shown in the chart below.

Phase (Function Block) FRS

Control Module SDDS and HDDS

Software FAT
At Integrator

Capture Changes as part of the
FAT Change Management

Hardware FAT
At Panel Shop

Implement at Site

SAT
I/O checkout

Capture Changes as part of the
SAT Change Management

SAT Effort Requires Phase
(Function Block) changes

Capture Changes as part of the
FAT Change Management

SAT PID Tuning Effort Requires
I/O changes

Capture Changes as part of the
SAT Change Management

Process Development Start

PD Effort Requires Phase changes

Capture Changes as part of the
FAT Change Management

PD Effort Requires I/O changes

Capture Changes as part of the
SAT Change Management

Process Development End

Close Out FAT and SAT with Summary Reports. List all system changes and describe the retesting that has occurred. Merge in all redlines to the Design Specification and Drawing Set to create an "As-Built" set.

Validation Start - IQ and OQ heavily reference SFAT and SAT data and summary reports

Recommendations

The methods described have yielded smoother startups with improved time schedules. However, this has not been achieved without learning important lessons that form the basis for the following guidelines.

- Review the FRS level documentation for each Phase as it is developed. Holding off until all of them are complete makes review insurmountable.
- Pre-planned design reviews are critical to the success of the project. Too many design review meetings are preferred over too few. Waiting until FAT for a design review is way too late.
- Although Phases are less portable from project to project, having a full library jump starts the project.
- Take full advantage of FAT activity. While the FAT needs to be executed by an integrator, it is an opportunity for the engineering staff to see the system run and fault. This is a chance to test multiple simultaneous failures, recovery from process upset, and refine prompt and alarm text.
- Better results are obtained when the SAT checkout is executed by the plant operators and support personnel. It takes a little bit longer but is an unparalleled training opportunity.

Acronyms/Glossary

C&Q – Commissioning and Qualification
FRS – Functional Requirements Specifications
DDS – Detailed Design Specification
DCS – Distributed Control System
FAT – Factory Acceptance Test - Tests performed at equipment manufacturer or automation integrator shop that ensures the equipment or automation software meets the design intent prior to shipment.
GAMP – Good Automated Manufacturing Practices
I/O – Input/Output
ISA-S88 – A publication of the International Society of Automation that describes common terminology and structure for Batch Manufacturing.
OEM – Original Equipment Manufacturer - Company that designs and builds equipment.
PLC – Programmable Logic Control
SAT – Site Acceptance Test – Tests performed after installation of equipment or automation software at a site to ensure that it works properly
URS – User Requirements Specification

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Jack Greene is an independent contractor specializing in the design, commissioning and validation of Plant Wide and Enterprise Wide Solutions for GMP environments. Jack's experience includes work at Altus, Alkermes, Genzyme and Serono. He has worked with a variety of IT, Manufacturing and Laboratory systems including PLC/DCS/SCADA Solutions, BAS/BMS Systems LIMS/Chromatography Management Systems, and IT infrastructure systems. You may reach Jack at jack.greene1@gmail.com ■