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## **Modular & Concurrent Design using Standardized Interfaces for accelerating design process**

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### **KEY WORDS**

**Modular Design, Standardized Interface, Validation Planning, Accelerated Design, Skid Vendors,  
System Brand Independent, S88, S95**

### **ABSTRACT**

The successful execution of an accelerated project from Concept to Process Qualification within 1 year with extensive usage of multiple Vendors requires a paradigm change for the Batch and Automation part of the project. Traditionally one Automation supplier has delivered and configured the complete Batch & Control system and a number of Skid Vendors has supplied only equipment, machinery & piping. To accelerate the project execution to meet the 1 year goal requires a Modular approach, where the Design, Implementation, Construction and Validation are done concurrently and where the Validation is planned from day one and included in the design. Skid Vendors must take responsibility of the Batch & Control system as well as the mechanical part and deliver a complete package that is validated to the extend possible before installation on-site. The different Skid Vendors may use different Batch and Control system products, and thus demand a very high level of standardization, especially regarding structuring (S88) and interfacing (OPC, S95 etc.). The Batch and Control system products on the market today do enable this high level of standardization, but when it comes to things like Material tracking and local inventory, there is still a need to have one Master system managing this. Initiatives like BatchML & B2MML published by WBF for the S88 & S95 standards will ease the integration, but the Systems available today still have too much formatting information that needs to be included to really make the integration easy.

## MOTIVATION

Engineering projects for the pharmaceutical industry are facing many challenges as the pharmaceutical firms are requesting faster and safer projects. For new products market penetration/potential is often difficult to estimate, and new products are under tight time-constraints between clinical trials and market introduction. For pharmaceutical companies facing this situation speed is a key goal. At the same time start-up of many facilities have been significantly delayed due to regulatory requirements for the facilities. This is particularly the case for large, automated process facilities for bulk production of pharmaceuticals. The risk associated with this type of projects may favor projects with less extensive use of automated systems.

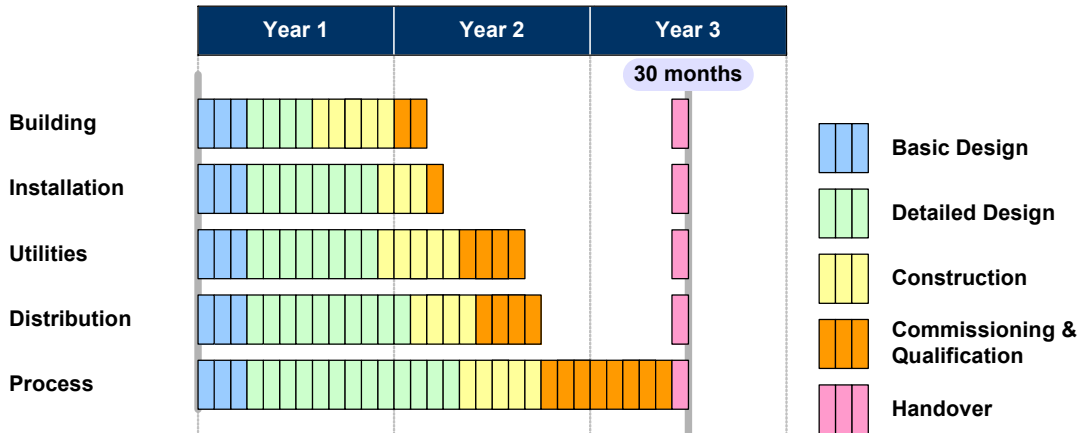
## MODULARIZATION

The key to shortening project cycles is modularization. Only with an efficient breakdown of the project is it possible to simplify the many space, time, and organization dependencies of a large project. Modularization should bring the following goals:

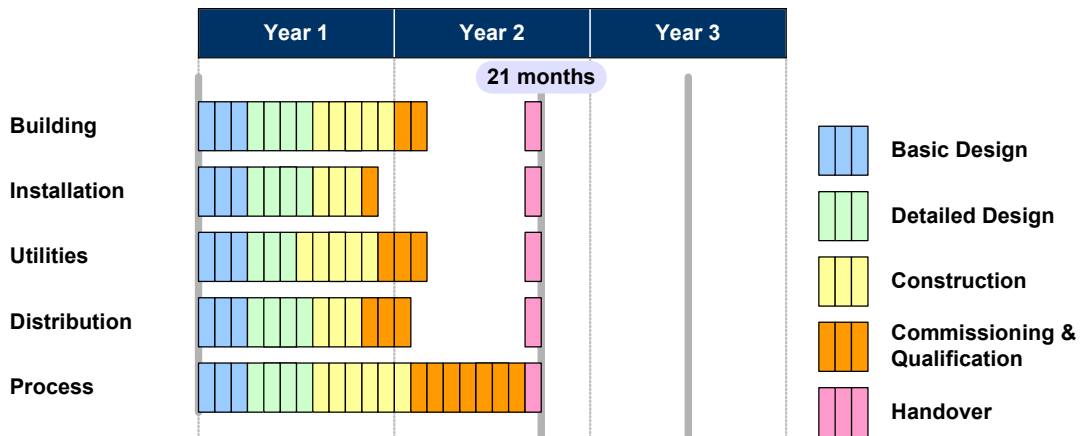
- Independent engineering: a project framework should be established that allows choosing different engineering partners for different modules.
- Be multi-disciplinary: The same supplier provides process, mechanical, electrical and automation engineering as well as validation.
- Physical independence of the construction site: modules should be made off-site.
- Concurrent engineering, construction, and test of the different parts of the plant.

An engineering framework that allows these things will bring flexibility into the project execution that will allow significantly faster projects. Two major parts of the framework is: Design Basis, that states the common basis for the modularization and for all modules and that also outlines all the physical and logical interfaces between the modules and the Validation planning that outlines how the Validation of the project is to be made and how this is to be build into the actual design phase (and documents produced) of the project. Risk associated with the project will also be reduced because of the fewer dependencies in the project.

The following time schedule is typical for conventional projects. The necessity of completing commissioning and qualification in dependant steps postpones project completion. The schedule is based on a recently completed pharmaceutical processing facility.



With a modular approach this schedule may be compressed significantly as dependencies are broken and activities are executed concurrently. The following schedule is taken from a facility presently under construction where modularization is key to project execution.

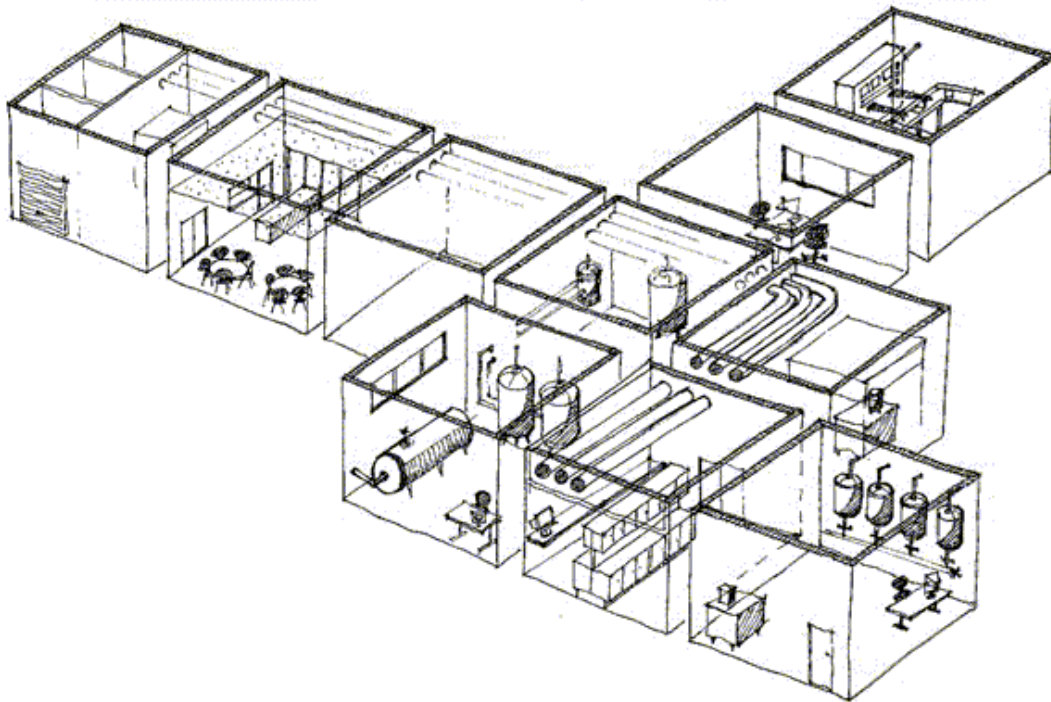


In this project it is possible to start construction earlier. Sections that previously were waiting for completion of other sections are not delayed. In the shown schedules 9 months have been cut. This increased control of speed is a competitive advantage to a pharmaceutical company.

When the modularization is implemented in full including a higher level of planning for the validation, it is expected that it will be possible to cut out further time especially on Detailed Design and Commissioning & Qualification and thereby be able to execute projects within a time frame as short as 1 year.

If modularization is adopted more widely then specialized suppliers may eventually produce modules in series. This will mean that the most qualified people do the work where they live when they have time rather than the people available where the plant is and in a tight schedule. If this maturity can be reached then costs will also fall.

This evolution will only be possible if the traditional suppliers of equipment will take a broader responsibility and acquire the knowledge that is necessary for this.



## PROCESS MODULES

Now modularization is in no way a new thing – particular for automation engineers working in the batch processing industries. S88 is widely adopted as the standard guideline for breaking down applications.

The granularity of modularization may depend. The important issue is that the granularity supports the previously outlined goals of independency, multi-disciplinary, off-site construction and concurrency. These objectives may only be achieved if the interfaces between modules are as simple as possible. This may lead some to conclude that these modules are process units, and others may argue they are process cells. To avoid this discussion the term *process module* will be used here.

A process module should support the previous modularization goals and:

- Only have simple standardized interfaces to the rest of the plant.
- Complexity should be encapsulated inside the modules.
- Together with other modules, form the facility – ideally with no “glue” in-between.
- Consist of one or more process units - this means that a process module will be batch aware.
- A process module can not contain more than a Process Cell, but a Process Cell may contain more than one process module.

These rules apply the building and mechanical aspects as well as automation.

## **SKIDS**

There are many companies that produce skids for a variety of applications: bioreactors, chromatographic systems, filtration systems, CIP-stations, etc. Automation on the skids may be based on loop controllers, PLC's, or PC based software.

The most mature of these can, in some cases be seen as process modules. In most cases the skids are not supported with the necessary automation and validation, and they typically don't address integration: all the engineering necessary to glue the skid together with the rest of the plant.

The automation system supplied with a skid is usually not S88 compliant in a sense that the software application is described in S88 terms - it may have recipes, but there are rarely any description of operations, phases, and equipment modules. As the software application is a significant and complex part of the skid, this should not be accepted.

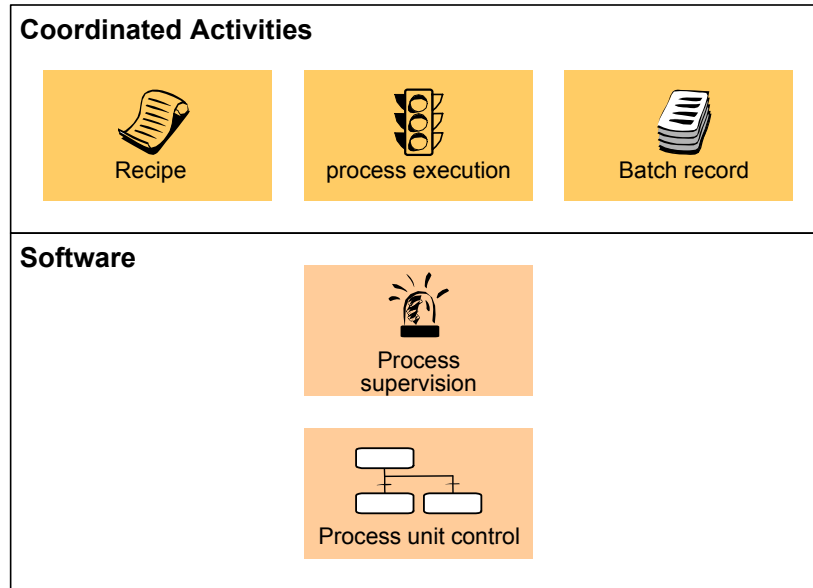
If skid automation was built according to S88 then integration would be easier. The growth of OPC is rapidly changing the problems of integration. Previously wires and protocols were critical issues. In the future interface specifications will concentrate on functionality. The present development in S88.02, and the various OPC extensions will gradually ease the effort and improve the functionality of these interfaces. To stimulate this development it should be a general requirement to the skid vendors that they produce an OPC interface.

## **INTEGRATED AUTOMATION**

If the plant is pieced together by a series of different suppliers then their collaboration may not be able to produce the integrated automation systems that many companies favor. The integrated systems have a series of key benefits that should not be jeopardized:

- I. MES-functionality/coordinated plant activities: plant-wide systems for recipes, user access, execution, reporting, as well as material management, material tracking, local inventory, scheduling, etc.
- II. One/few suppliers of systems: few interfaces, upgrades in packages, reduced validation effort.
- III. Easy maintenance.

Automation systems in the pharmaceutical industry must comply with regulatory requirements. These dictate substantial quality assurance activities (validation, GMP, GAMP, 21 CFR Part 11), which increases for every automation system that is introduced.

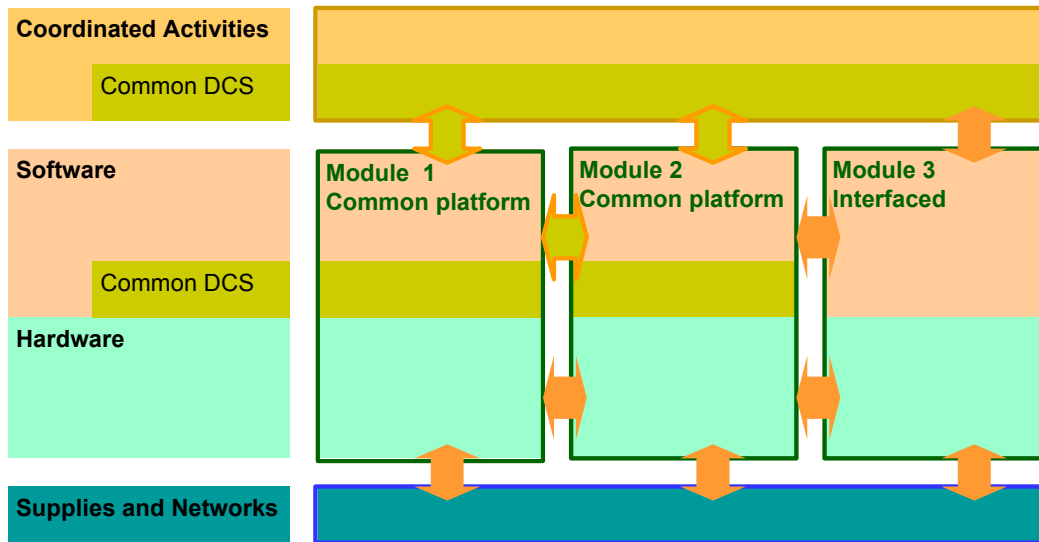


Basically the integrated system may be produced in two ways that does not exclude each other:

1. **Interfaced Systems:** Suppliers can choose their preferred platform if they conform to standard interface conventions. Process modules that are interfaced are integrated islands. Whether the systems/islands are PLC's or DCS systems dedicated to the module is not that relevant in the present discussion.
2. **Common Platform:** One particular automation system is selected for the facility and all suppliers of process modules must produce applications for this system.

A mixed approach will typically be employed – it is not a question of one or the other, but rather being able to manage both types. Some process modules may use one strategy whereas others use the other.

The following figure shows how the different types of modules will be integrated with coordinated plant activities and infrastructure.



The following table compares the two strategies:

|              | Interfaced Systems  | Common Platform  |
|--------------|---|--|
| Integration  | Difficult to achieve integration benefits                             | Support the integration benefits for a particular project                |
| Dependencies | Limited to interfaces   | Depend on a particular supplier as well as common engineering standards  |
| Timing       | Should be less time consuming because of re-use and less dependencies | If not slower then this strategy may increase risks for delays.          |
| Costs        | Applications may be (partially) re-used thereby reducing costs        | In practice applications will often be custom engineered and more costly |

In short the interfaced approach is favored for fast projects and reducing invested capital. However this may jeopardize integration benefits (MES activities and maintenance). If these requirements are essential then it would a common platform approach should be chosen.

On the regulatory side especially the FDA rulings for Electronic Records and Electronic Signatures (21 CFR Part 11) raises a number of questions for both the Common Platform as well as the Interfaced Systems, where the actual count of different systems holding Electronic Records or using Electronic Signatures is significant, and may lead to a reduction in the count of systems in a plant, and thus may favor the Common Platform vs. the Integrated Systems. The solution is although not

that simple, as a proper corporate decision for managing ER and ES can benefit the Integrated Systems solution.

The interfaced systems are currently chosen in many pharmaceutical facilities for the above reasons. In some cases this choice is combined with a reduced automation level compared to the more established facilities.

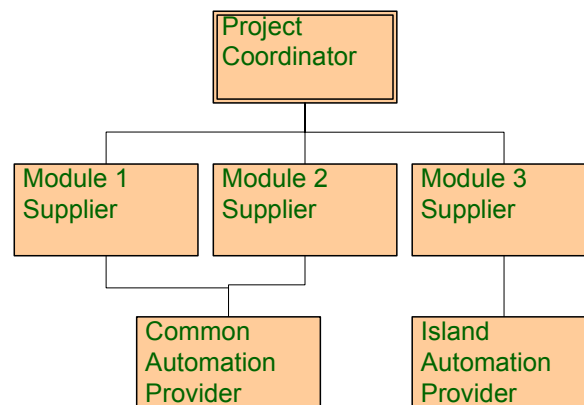
It is a challenge to the automation community to deliver automation systems that can be employed in modularized pharmaceutical projects – and at the same time support increasing levels of automation and increased regulatory requirements.

## ACCELERATED WITH A COMMON PLATFORM

To accommodate a common automation platform in an accelerated project it is necessary to make the process module suppliers responsible for the automation within their respective modules. This means that module suppliers will have to bring automation competence to their delivery:

- a. On their own
- b. With the platform supplier
- c. With a 3<sup>rd</sup> part supplier

As the overall objective is speed and reduced risk it may be beneficial to dictate the same partner to all module providers. This will facilitate use of standards and support successful integration. The following organizational diagram depicts how different automation providers may refer to process module suppliers.



If a common partner is not found, then it is necessary that there will be a comprehensive engineering package that describes standards that must be employed across the different modules. Otherwise the

benefits of a common platform may be significantly reduced, because of a varying standard of the software for the different process modules.

Configuration management (e.g. how the application software is maintained in the system) is currently a hot issue in the pharmaceutical industry – and system vendors are adding functionality in this area to their systems. With modular engineering there will be several suppliers of the application. This requires that the software from different modules/suppliers can be clearly separated through configuration management functionality.

## **ACCELERATED WITH INTERFACED SYSTEMS**

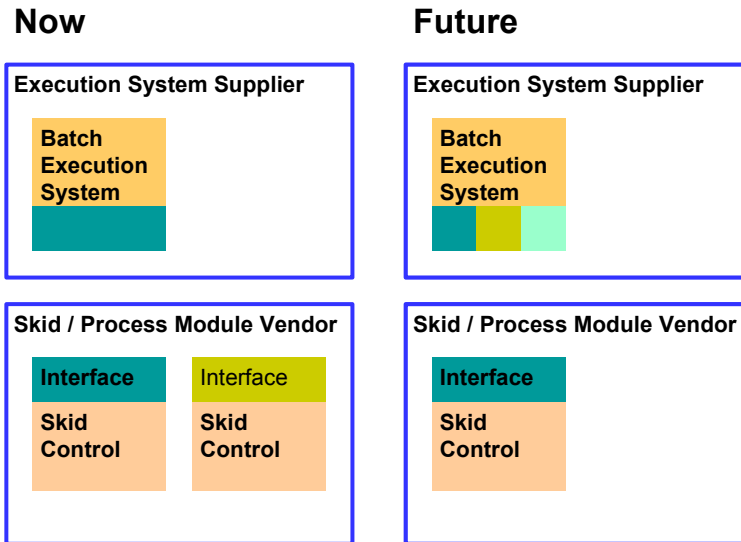
With this strategy the automation associated with a process module consists of two levels:

- 1) Process control associated with the process module
- 2) Automation associated with coordinate activities

What belong to which level and how they are interfaced may be an endless discussion. Where does the batch execution system ideally reside? In both levels? Skid vendors must have a standard to work from.

The most common interface today is that between a batch package and a PLC – the OpenBatch paradigm. This is an interface that has its origin in different hardware platforms, and a mapping of phases across this. DCS's with batch capability typically have an internal interface on this level. A whole lot of work has been put into interfacing at this level.

However the interfaces are in no way standardized. The batch packages have different interfaces, and they may expect phases to support different states. Today a PLC will be programmed to a particular batch package. This is not acceptable to the skid vendor. In stead the batch execution systems must be equipped with a series of phase interfaces to choose from. Most DCS vendors are willing to supply such interfaces as an addition to their main system (e.g. mimic other batch execution systems).



Interfacing at this level leaves recipes, batch execution, and reporting on the coordinated activities level. A plant MES or DCS will address them.

It also isolates the time-consuming activities inside the process modules. These are in particular functional design, application programming, hardware installation, and testing of hardware as well as software.

The user interface must also be a part of the module as it is a time consuming activity and necessary for testing. It may be necessary to specify user interface conventions to get at uniform operating environment.

What the interface systems do not accommodate is a centralized user access (a common user database in the plant), a common configuration database, and common material management.

## CONCLUSIONS

The automation community is currently challenged by the requirements of the pharmaceutical industry as a consequence of the competitive situation as well as regulatory requirements. Automation system construction demands more flexible organizations consisting of several companies. This collaboration must be supported by the automation systems functionality as well as standards in the community. Suppliers of skids will start supplying associated automation. Their solutions should be met with standardized requirements from customers.