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Automation Challenges for a modern plant

The purpose of this document is to outline the challenges that GPN SMEs have come across in the design and review of automation systems for modern Pharma plants. These challenges are becoming more important as companies are driving for increased automation and the regulatory authorities are increasing their understanding and subsequently their validation and control requirements on these systems.

Strategy:
Before purchasing automation system for a process or a portion of a plant the company should take a strategic view of automation on site. This is not always possible but at the very least should be developed in conjunction with the development of the automated system currently under review. The key challenges to be addressed in the strategy are:

1. How automated will our plant eventually be?
2. Will we want all of these systems to interact with one another?
3. What IS systems will we want the automation to interface with (warehouse management, ERP, DMS, LIMs etc)
4. How automated do we want to make the batch documentation and what information will the automation systems provide?
5. What are our change control policies on Batch Manufacturing Records and recipes?
6. How much standardisation do we want between systems within the plant and what levels of expertise do we or will we need to carry?
7. How often will systems need to be upgraded and how will interconnectivity be impacted by this?
8. How will we manage non-GMP and GMP systems in the one environment and will this impact on automation?
9. What is the level of resilience and disaster recovery planning that we require?

Lifecycle approach:
As can be seen from the challenges above the purchase and development of an automated system in today's world is not an isolated project and to ensure that the company obtains the maximum quality, control and ROI from the system it needs to be integrated into the overall plan for the site.

In order to ensure that the automation system is developed correctly a lifecycle approach should always be taken. This will ensure that for the system in question all design requirements including ongoing maintenance, upgrade and replacement will be considered as part of the design and development.

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A common pitfall when purchasing equipment that includes the control system is to treat the software/control system as just a simple part of the vendor package. When in reality due to current validation requirements as outlined in GAMP the software/control system is the area requiring the most design, specification and documentation. As a result a lot of companies fail to clearly define their documentation requirements until the vendor has presented the system on site for installation and commissioning. A lifecycle approach will prevent this as the company's validation and subsequent documentation requirements will be designed into the overall development lifecycle from project launch. Before commencing any form of automation purchase a company should have a clearly documented policy on validation and in particular software validation. The documentation required to successfully meet these policies and management cycle should be documented as part of the User Requirements Specification for the system being purchased. These should then be included as deliverables in the project plan and agreed with the vendor. The ability of the vendor to develop and manage the required documentation should be an integral part of the vendor assessment process. Quite often the standard documentation from vendors will not meet a Pharma company's requirements so it is important to be clear on the requirements at the start of a project before the purchase order is placed.

When this type of lifecycle approach is taken it ensures that all the relevant disciplines are involved (engineering, purchasing, QA, validation etc) from the start and it ensures that the vendor is working to meet the company's validation requirements from the start of the project. This creates an environment where it is possible for the plant to leverage the vendor's testing as part of the validation cycle, and this in turn can minimise the level of repeat testing that needs to be carried out on site.

Electronic Records and Electronic Signatures, including 21 CFR Part 11 and EU Part 11 requirements (collectively called Part 11 below)
All Automation vendors have their own view on what Part 11 compliance means and how their system adheres to it. The most important thing for any company today is that they have documented their interpretation of what Part 11 compliance means on their site and their philosophy for compliance. It is this that the vendor has to meet in the design. When Part 11 compliance is discussed it is quite often that a company will say it is not an issue because the BMR is paper based. This is where the site IT strategy comes into play because the site may want to have electronic BMRs in the future (2/3 years). Typically it is better to include these future requirements in the project from the start so that they are taken into consideration in the design. Failure to do so will typically mean recoding in the future and re-validation. There is great potential to minimise these costs when taking a Lifecycle approach and including the IT strategy.

Technical Issues
There are numerous technical issues that must be addressed as part of the design process and here again the strategy and Lifecycle approach provide a firm basis for the design and development of automated systems.
From a design perspective, there are a number of issues relating to standardisation of components, which while obvious, are sometimes overlooked. These issues include:

- Hardware Standardisation
  - What type of PLC to use? (e.g. Siemens S7-300 / S7-400 or different make)

  - What modules will we standardise on? (CPU, Comms Cards, IO etc (can reduce spares holding))
  - What communications and infrastructure will be select? (Ethernet, Profibus etc.)
  - How should operator displays be handled? (SCADA PC, OP-17 etc.)
- Software Standardisation
  - Should we use a SCADA or PLC platform?
  - What programming language will we select? (STL, Ladder, Function Block etc)
  - What coding standards do we wish to apply? (naming conventions, device standards, etc.)
- What standards will be applied in presenting the information to the user? (Colour conventions, layouts, alarm handling etc)
- Use of Technology
  - What technology will we use? (e.g. Fieldbus technologies → Profibus, Foundation Fieldbus, AS-I, etc),
  - Should we utilise skid-mounted systems? Use of Skid mounted Remote I/O (can I/O be mounted on the skid?) means there is a minimum of disconnection of I/O wiring between factory & site but may require cleaning to be specified in the specification (GMP/Cleaning issues with regard to panel type/location).

By considering these issues as part of the overall design a company can ensure that the interfacing of multiple systems becomes easier and more reliable. It also means that the ongoing management and validation of the systems is easier to control. It also means that the ongoing cost of maintaining the systems is controlled i.e. common spares, one system to learn and maintain, less vendors do deal with etc.