The Crossroads of Compliance, Audit Readiness, Profitability, and Data Integrity

True compliance and audit readiness starts with a well thought out, holistic, structured approach that aligns with an organization's business and quality objectives. Profitably and safely managing a batch production facility while maintaining the compliance and quality of the product and production facility is a challenge that every pharmaceutical and biotech company faces.

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Many organizations struggle with prioritizing changes that can effectively improve profitability, safety, and compliance, which are often seen as competing goals. Yet there is one place where these goals can be met together – reducing the variability in manufacturing and associated business processes. Data integrity is front and center in this overall battle.

Understanding and detecting sources of variability before and using this information to prevent deviations is essential to running an operationally excellent facility. There are several ways to reduce variability. Mistake-proofing processes, eliminating sources of controllable variability, and knowing how to respond to the remaining sources of variability are all important methods to consider.

One of the most effective means of reducing variability is automating production and business processes. Automation is a solution that enables predictability, detection of variability, and the ability to appropriately respond to remaining variability. Compliance ready systems along with a structured project approach are keys to ensuring the data integrity of these types of solutions.

The right people with the right experiences and skills, adequate planning, and appropriate technology are necessary for an appropriately designed intersection of compliance, audit readiness, profitability, and data integrity.

Involving experienced, knowledgeable people in the process

When embarking on an operational excellence journey, including an individual who understands manufacturing and business processes is important. Yet it is equally as important that the internal resource or an external consultant have a breadth of experience working with many companies in the industry to take advantage of best practices, incorporate a view of where the industry as a whole is heading, and know what automation solutions are available. It is also important for this individual or team to be able to show the alignment of solutions to a company's business and quality objectives.

Often, companies do not have the time and resources available to develop a holistic, structured approach to operational excellence. For this reason, it can be helpful to look outside of the organization to find a suitable partner.

Appropriate technology

Integration of manufacturing control systems with day to day business needs is a difficult problem to solve. Because the needs and benchmarks for success can differ so greatly between the plant floor and the enterprise, finding commonality between solutions requires experience and careful planning.

The ISA S95 standard of automation can help develop consistency between all levels of business when implementing automation systems. At every level of the enterprise, ISA S95 provides guidelines that help organizations develop best in class solutions for integrating automation at all levels.

The right partners, who have a breadth of knowledge and experience developing systems that integrate business and manufacturing needs, will be able to develop a complete compliance wrapper that sets the standards for ensuring that a project is developed to meet all

regulations while keeping each layer of the ISA S95 standard in mind.

Layer 1

Layer 1 of the ISA standard considers the manufacturing floor. At this layer, the focus is on properly sensing and manipulating the production process. The primary concern for level 1 is standards adherence: equipment must comply with and enforce quality regulations.

The complete compliance wrapper focuses on implementing monitoring devices that are accurate and reliable for the long-haul. Not only is it essential to select the right instruments and right control valves for the right applications, but these devices must also deliver data that can be used in higher levels of the ISA S95 architecture.

Knowing that the right sensors are reporting the correct information at all times means reducing variability in product. For example, Emerson's field devices offer the scalability and flexibility needed to meet the monitoring needs of today and the future. It is important to select intelligent sensors that enable prediction of downtime and reduce process variability by keeping devices and instruments performing at their best.

Additionally it is important to select the best in class smart field devices that are delivered pre-calibrated with documentation and certification to ensure that regulatory standards are met, building compliance into the architecture. Integration specialists can help tie these sensors back to the control system, developing sophisticated alarms that notify operators of variability and faults in manufacturing.

Layer 2

At layer 2 of the ISA standard, the focus shifts to monitoring processes, providing supervisory and automated control of the production process.

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With proper automation, organizations can limit variability, which means simplifying compliance.

Batch manufacturing requires sophisticated sequencing across a plant, while at the same time ensuring that only the correct equipment is used, while in the correct state. Defining the process specific requirements and using best in class process control systems (PCS) are keys to success at this layer.

Emerson's DeltaV distributed control system, delivered 21 CFR part 11 compliant, is a key part of the compliance wrapper's integration of systems. Equipped with simple to use yet powerful applications for recipe configuration and management, the PCS is designed to ensure that product quality is the same on every single batch. In addition, DeltaV Batch Historian automatically collects and displays detailed recipe execution and process management event data. After capture, this data can be examined locally or remotely through a web interface using the History Analysis application.

Using class-based and S-88 recipe management to automate manufacturing lines means ensuring that every stage of the production process is completed and verified. This not only means improving product quality and yields, but also being able to continuously verify that critical process parameters are controlled properly with data available at any time, such as when an audit occurs. Appropriate use of an overall compliance and quality plan that includes risk based validation approaches can help any user get the most out of the class-based, S-88 approach for the project and the life of the system by minimizing validation costs while maintaining compliance.

Layer 3

Layer 3 of ISA S95 connects the concepts of the organizational management system (ERP) to the activity taking place on the production floor.

Because the operational needs and requirements of the business and management office are often very different from those of manufacturing and production, operating without a data integrity plan often results in production managers trying to connect isolated islands of process, quality, operations and logistics data by paper, databases, and other mechanisms which may incidentally cause a data integrity issue.

As part of the compliance wrapper around these solutions, key personnel on a project with multi-layered and cross-company experience help organizations select the right Manufacturing Execution System (MES), such as Emerson's Syncade smart operations management suite, for order, resource, master batch record, batch execution, and document management. An MES solution can be used to help minimize paper-based traps with electronic verifications of equipment and recipes to reduce variability and deviations, reducing errors associated with these activities. When properly integrated with the PCS and asset and machinery management, the MES provides access at time of use, ensuring all production records can be easily produced, stored, and approved with electronic signatures. Additionally, as errors are reduced and all the processing data including the remaining manual steps is now more readily available, the need for war-room investigations of paper batch records can be virtually eliminated.

The MES can also be integrated with ERP systems to allow for tracking of materials, manufacturing orders, inventory transactions and more. Syncade's functionality can eliminate manual, error-prone data transactions, resolving inventory and production discrepancies.

Layer 4

Layer 4 is the level at which business planning and logistics happen. At this level, planners develop the basic plant schedule, monitor material use, track ordering/delivery, and schedule shipping of product.

Inventory control and shipping schedules are directly tied to production ability on the plant floor. If production and materials use records don't correlate with inventory and delivery records, an organization can find itself producing too little product, or having to store excess inventory that simply sits around.

Conclusion

Organizational excellence experts can help promote data integrity by ensuring that technology and practices are coordinated between the layers of the ISA S95 model. Working through a conceptual design, these experts help organizations develop future state requirements. The result is a road map that includes automation standards to meet the most pressing business and quality needs, encompassing both process qualification and process verification, as well as implementing change control and deviation procedures for long-term stability. Up front planning means less rework both during and after the project. As organizations have the most control over costs at project inception, this can mean substantial savings of both money and time.

Thinking downstream, these experts can also help an organization prepare for transition to market. As a company moves from research to clinical manufacturing, and from clinical to commercial manufacturing, procedures must be established to ensure that operators have the right recipes, have all the critical process parameters and attributes identified, and are prepared to transfer the information from one part of the organization to another without data loss. Drawing on best practice knowledge and extensive field experience, these experts can make this process as simple and efficient as possible. ■

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