Data Integration Challenges and Solutions for Life Science Industry

n today's globalized world, identifying new markets, addressing the unmet demand, and delivering consistent business growth has become a top priority of business executives. The Life Sciences Industry, in both developed and especially in emerging markets, has a tremendous growth opportunity as unmet needs still abound and people around the world are waiting for new and better solutions.

Emerging markets are defining themselves in this growth place; however, they have a unique challenge of addressing wide customer profiles within highly cost sensitive markets. This wide customer spectrum along with changing economics of existing developed markets is applying new pressures on Pharmaceutical Manufacturers, including:

- Price reduction
- Diminishing profits
- Rising R&D cost
- Manufacturing process excellence / optimization

 Increased regulatory compliance
 These pressures are forcing the industry to drive manufacturing operational excellence through data integration across the business.

Within this new environment, challenges abound. Many plants are operated with many different systems that must either be updated manually or via integration of many different systems. Often, in these types of plants, the paper batch record is the glue that holds everything together. In this paradigm, these different levels of automation with the paper batch record do not provide optimal, efficient solutions for integrating business data and ensuring data integrity.

Data Integrity Challenges

- Mixed Levels of Automation
- Hybrid automation, a mix of manual and automated processes, forces plants to maintain elaborate SOPs and create manual records, increasing

compliance errors and data integrity challenges due to multiple places where the same data is captured or used.

- Managing product specific recipe elements while maintaining consistent operating philosophies can be timeconsuming and often increases overall batch cycle time. Lack of a central recipe library introduces errors and deviations, which can lead to material losses or delays in release.
- Partial automation addresses challenges of specific equipment; however, connecting data with the batch records still must be handled manually.
- Islands of automation on different
 platforms
- Multiple control systems cannot be designed based on plant-wide standards posing greater challenges for data integration.
- This lack of consistency can also be confusing to plant personnel and be a potential source of deviations.



Finding the resources to maintain the disparate systems can be challenging as well.

- Updating, modifying, or expanding several different automation systems requires extensive planning and is expensive.
- A mixed environment for managing the product specific recipe changes when producing the next SKU increases the overall batch cycle time due to resolution of errors and deviations associated with these activities.
- Manual and paper process
- Both manual processes and paper records enable more opportunities for manipulating the data and hence managing data integrity is a challenge. There is more opportunity for data to get out of synch or be revised inappropriately resulting in compliance issues.
- In the manual batch record and manual process world, information about batches in progress is not readily available, causing delays in decision making. Batch releases are delayed when an investigation requires review of data across several batches.
- There are more opportunities for errors including missing data, improper calculations, transposing of data, improper use of materials or equipment due to expiry dating or other mix-ups that are common when there is no electronic check.

Data management has serious implications on a plant's operations and productivity. Data from field devices must be communicated throughout the control systems, manufacturing execution systems, and enterprise business systems. If data is lost or blocked at any step in the data-chain, the plant's profitability will suffer. If data mapping is too difficult and requires too much maintenance, the lifecycle costs balloon. Without effective data management systems, companies face recurring issues in proving compliance, turning data into actionable information, and easily preparing for inspections and audits.

Save Time and Effort with Standards-Based Data Connections

"Digital Smart Field" is a common term used to illustrate field device diagnostic intelligence. These digital smart field devices are not only responsible for measuring process parameters with required accuracy but also have the capability to share diagnostic information over the same wires. Leveraging this diagnostic information with the control system allows the diagnostic information reach the Operator, Maintenance, Production, and Enterprise levels.

Emerson's DeltaV distributed control system makes it easy to connect data in the field. At the device level, the



DeltaV system provides plug-and-play capability for runtime and diagnostics in a variety of standard protocols: WirelessHART, HART, FOUNDATION fieldbus, DeviceNet, and Profibus DP. DeltaV SIS, although a separate architecture, integrates seamlessly with the DeltaV system to provide process safety that is managed from the same engineering, operations, and maintenance tools.

The DeltaV system makes it easy to connect to enterprise business systems. Industry standard OPC along with SOA web services have been built-in to provide connections to Emerson's MES, Syncade Suite, and other production level systems anywhere on the network.

Data integration with the DeltaV system links data between the field and business systems with minimal setup time. Decision makers at every level in the plant - from engineering, operations, and production - can get the critical data they need, reliably, securely, and in real time. With Syncade, integration to existing SCADA systems or PLCs as well as integration with the DeltaV system is easy.

Top process industry manufacturers are transitioning from paper-based to electronically executed manufacturing operations in order to increase production efficiency and quality. Configurable solutions that manage process plant production, quality and maintenance activities are delivering desired results. Emerson's Syncade software manages process manufacturing operations, providing solutions for material tracking, order management, manufacturing procedure workflow, systems integration and data visualization, and document management.

By delivering technology at levels 1-3 of the ISA95 architecture and designing tight integration between the



Figure 2: Emerson Manufacturing Digital Integration Solution

levels, Emerson delivers an optimized architecture for vertical data integration. From smart field devices at level one to process control at level two and asset management and operations management at level three, the data from your technology investment is delivered to the right people to enable quick and effective decision making.

Benefits of Vertical Data Integration

Share Real-Time Process Updates With All Decision Makers: Using the standard OPC protocol and robust Web Services, the DeltaV system connects to any layer of the manufacturing environment. Updates from processing data can be sent to decision makers responsible for production. Data integration provides complete visibility into the state of the plant to those who need to know.

With Syncade, the batch record information is readily available. Information about a given batch is available at any given moment – what equipment is used, where the batch currently is in the process, etc.

Eliminate Manual Data-Mapping

Errors: The DeltaV system's plug-andplay design with field devices allows operating and diagnostic data to start flowing with minimal configuration. The system removes the data-mapping step and connects the controllers directly to the equipment. This reduces costly data-entry errors during start-up and maintenance activities.

Mapping the product specific set points based on a recipe become even simpler when you add Syncade as part of the overall solution. With change control capabilities, you can manage the product specific parameters to produce many SKUs with one parameterized recipe.

Streamline Business Processes:

The DeltaV and Syncade systems allow management teams to react to changing market demands and modify order information by sending a request

within the business system. The system • can interpret the request and make the • appropriate adjustments to planned • orders. All this is implemented with easy-to-use human-machine interfaces.

Less waste and rework

- Higher quality at lower cost
- Improved compliance

Summary

Finally, plants can expect improved compliance and better plant-wide visibility to production status. With electronic manufacturing operations management, manufacturers experience:

- Reduced operator errors
- Better production coordination
- Improved inventory management
- Faster cycle times
- Increased productivity
- Higher capacity utilization
- Reduced working capital
- Improved right first time rates

In summary, standardized, consistent automation enables better data integrity and solutions for the business that can result in overall business profitability through reduction of errors, streamlined business processes, and constancy throughout the plant. Emerson's Syncade and DeltaV systems, effective process control, equipment management, materials management, and batch record management enable these business benefits. ■ **Contact:** michalle.adkins@emerson.com ritesh.patil@emerson.com



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