Leaning Into Six Sigma

Integrating Lean Six Sigma and a manufacturing execution system can help meet regulatory compliance goals. This exclusive report shows how such integration can increase return on investment without compromising quality or efficiency.

AT A GLANCE [1]
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&#149Lean Six Sigma defined
&#149 Problems with ERP technology
&#149 Advantages to MES and MCP
&#149 The ideal system examined

Plant managers have concluded that ERP helps the business but hurts operational productivity because it lacks real-time quality information, process analysis, and the granularity required to make faster and better decisions.A manufacturing compliance platform connects businesses and provides enterprise-wide control, visibility, and real-time analysis of manufacturing operations, while providing an infrastructure within the plant that ties together disparate data sources and tracks all manufacturing activity.

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By Joseph Vinhais

Lean Six Sigma, the union of lean manufacturing and Six Sigma, has provided manufacturers with an unprecedented tool for generating the lowest cost, highest quality product on time. Lean Six Sigma's potential has not been realized in the life sciences industry, although several industries, including the aerospace, electronics, and automotive industries, use Lean Six Sigma with great success.

Safety and efficacy are key variables in the life sciences, and the industry has been disinclined to trust automation with regulatory compliance initiatives. Accordingly,

the industry conventionally has reinforced technological advances with paper records, thereby increasing cycle time and production costs. To address these issues, a multifaceted model must integrate successfully a third key player, regulatory compliance, into the proven Lean Six Sigma model.

Six Sigma typically is discussed in defective parts per million or DPPM. DPPM can be equated in life sciences to the number of opportunities for non-compliance. The concept addresses error rates within one standard deviation (i.e., 1 sigma) of the mean (i.e., the average). Operating within &#1771 sigma translates to the consumption of resources or "cost of compliance" of approximately 65 percent of sales revenue. Optimal operation at &#1776 sigma results in 99.9997 percent compliance (about 3.4 DPPM) or consuming less than 10 percent of sales revenue for the cost of compliance. Few companies operate at this rate. Most top companies operate closer to a 99 percent error free rate or &#1773 sigma. That sounds pretty good, but what does that really mean from a cost of compliance standpoint? Table 1 offers a breakdown for each scenario.

Activities that cause the end customer's critical-to-quality (CTQ) issues and create the largest time delays in any process offer the greatest opportunity for improvement in cost, quality, capital, and lead-time. Lean Six Sigma maximizes shareholder value by achieving the fastest rate of improvement in customer satisfaction, cost, quality, process speed, and invested capital; however, lean manufacturing alone cannot bring a process under statistical control, and Six Sigma alone cannot improve dramatically process speed or reduce invested capital. Neither, alone, offers solutions to meet the demands of life sciences within regulatory compliance.

The solution exists in the institution of a manufacturing compliance infrastructure and focuses on the following three goals.

1. Aligning the three most influential disciplines for manufacturing output: regulatory compliance/affairs, quality control/assurance, and manufacturing/operations as illustrated in Figure 1
2. Aligning the three major initiatives of variability reduction, cycle-time reduction, and risk mitigation into a combined, focused corporate effort
3. Leveraging a risk-based approach model utilizing and aligning efforts of failure modes effects analysis (FMEA), failure modes effects criticality analysis (FMECA), and critical-to-quality (CTQ) characteristics

These three key goals provide a thought process that combines variation control and speed control with risk exposure/mitigation and effectiveness while considering customer's needs, design control, and manufacturability.

Why is this effort so important? It's called the "single version of the truth," a phrase coined by Roddy Martin, an industry analyst at AMR. It exposes the many systems and subsystems that contain different and sometimes replicated data about production, quality, lab information, and engineering. These silos of information expose organizations to desperate decisions and, in most cases, conflicting analysis. According to Martin, "regulatory compliance is the license to be in business, which requires linking a manufacturing compliance platform to supply chain capabilities."

The most fundamental challenge of aligning resources and improving communications, with regards to production, is understanding "what is the system of record associated with output." It's argued that with so many systems and subsystems in existence, there are typically several systems of records&#151again

exposing the fundamental issue of multiple versions of the truth.

Current Technology

Enterprise resource planning (ERP) is predominantly the current system of record for manufacturers. ERP technology provides a single, logical view of the enterprise and facilitates standardized business processes, as well as planned orders and production, while providing rolled up financials. Typically, however, ERP benefits do not include production reality and real-time feedback. At the data and compliance level, granular tracking below the order level is necessary, but most ERP systems track at the order level without such functionalities of granular, detailed history and genealogy. In addition, most ERP systems have no real-time operations information, and operations managers need immediate information. Finally, ERP systems use static BOMs and routings, which limit control over the product and process. Manufacturers need dynamic toolsets to reflect the real-world conditions of dynamic decision making within production.

Surveyed plant managers have concluded that ERP helps the business but hurts operational productivity because it lacks real-time quality information, process analysis, and the granularity required to make faster and better decisions. After ERP, managers still depend on spreadsheets to run the plant; consequently, ERP has turned supervisors into data collectors while pulling IT resources out of the plants. Many plant managers find ERP manufacturing functionality difficult to use and thus use plant resources to fill ERP gaps. Paper travelers have become device and batch history records, causing significant delays in product release because of back-tracking non-recorded events and missing information.
Companies use multiple software and paper systems to manage business processes from the ground up in a layered fashion. Real-time control functions at the ground level control automation and specifications for process and equipment management. At the top, ERP functions in plant operations and, ultimately, customer order fulfillment. A manufacturing compliance platform effectively connects ground and high-level functions. Ideally, this central layer coexists and capitalizes on data investments already made, without replication, so that the data may be associated to the final electronic device history record and/or batch record.

A Centralized Solution

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A manufacturing compliance platform provides enterprise-wide control, visibility, and real-time analysis of manufacturing operations, while creating an infrastructure within the plant that ties together disparate data sources and tracks all activity. Execution solutions, such as a manufacturing execution system (MES), fill in the gaps between basic shop functions and customer order fulfillment. They "information-enable" manufacturing operations and provide real-time feedback to ERP and other planning and scheduling systems. MES differentiation enables manufacturers to compete in multiple dimensions. Production excellence drives

financial advantage while response and control drives higher margins by improving customer satisfaction and loyalty as well as product speed-to-market. This facilitates shifts to new businesses in addition to new business or operating models.

The ideal system includes the following functionalities, all of which enhance Lean Six Sigma by eliminating wasteful activities and by providing reliable and immediate quality control.
&#149 Personnel management such as records of education, training, and experience
&#149 Designcontrol and development planning, purchase, and acceptance such as raw materialreceipts and supplier quality ratings
&#149 Material control including qualityassurance and document control such as electronic signature revision enforcementand tracking
&#149 Equipment and facilities functions such as equipment and resourcestatus verification
&#149 Production and process controls including equipmentcertification
&#149 Statistical process control encompassing quality parametricdata collection and quality analysis
&#149 Corrective and preventative actions(CAPA) for failed acceptance criteria tracking and CAPA generation, preventativeaction implementation, and tracking
&#149 Identification and tracing ability usingunique control numbers, lot splits, and lot combines
&#149Device and batch history record with full genealogy and traceability with a trueunderstanding of "as-designed," "as-built," and "as-maintained"
&#149 Servicefeatures such as complaint management, RMA, repair, warranty, and field services
MES features detailed tracking of product genealogy throughout the manufacturing process including resource utilization and graphical setup of detailed workflows. It also models dynamic workflows and conditional routings. In addition, MES collects and tracks parametric data tied to work-in-progress and is built for high availability, 24 hours a day, and supports shop-floor activity and transactions with real-time in seconds.
MES also provides automatic data collection from external sources and a seamless Web-based graphical user interface that ties in work instructions, operator interface, work order sequencing, product drawings, and statistical process controls. Tracking "as built" configuration for product specification through manufacturing processes is integrated with real-time visibility into single or multi-plant workflows, resulting in real-time feedback on raw material consumption and tracking of quality performance within manufacturing. Tracking of actual cycle times and resource utilization within manufacturing allows for detailed inventory tracking on the plant floor. It is a closed loop. Non-conformity, customer complaints, and CAPAs are integrated with electronic device and batch history records.

Manufacturing Compliance Platform

A manufacturing compliance platform (MCP) connects businesses and provides enterprise-wide control, visibility, and real-time analysis of manufacturing operations, while providing an infrastructure within the plant that ties together

disparate data sources and tracks all activity. By utilizing a systemic approach and leveraging the established Lean Six Sigma methodology with regulatory compliance and manufacturing execution systems technologies, life sciences manufacturers can trust automation to answer its operations, quality, and compliance needs. Automated systems efficiently utilize statistics and variables to document and validate data, thereby decreasing the number of checks and balances necessary to maintain safety and efficacy. The integration of regulatory compliance technology facilitates using the Lean Six Sigma tool in the life sciences manufacturing industry, ultimately increasing return on investment while meeting regulatory compliance goals without compromising quality or efficiency.

Ultimately, the goal is to produce products at the lowest cost and with the highest quality, delivering them on time and ensuring their safety and effectiveness&#151the holy grail of life science manufacturing.

Medical Device Example

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Implementing Lean Six Sigma can have a dramatic impact on a company's operations.Below is an example of how it could help a manufacturing company improve operationsand its bottom line.

Sample company's characteristics
&#149 Medical device division
&#149 Averaging 13.9 percent operating growth annually
&#149 Three manufacturing sites
&#149 Early adopter of lean manufacturing in transition to make-to-order (MTO), which could not be supported with current technologies and processes

Company's critical issues

&#149 Need for data collection, full genealogy, and reporting to support FDA compliance
&#149 Need to bring new product to market faster and utilize MTO demand model to stay ahead of competition
&#149 Need to manage production lines to optimize efficiency and improve quality trend

Benefits of lean manufacturing, Six Sigma, and compliance alignment

&#149Reduced cycle time through better and quicker decisions through common platform, portals, data interchange, and reporting
&#149 Improved yield by tightly coupling MES, SPC, and machine controls
&#149 Reduced cost-of-compliance reporting by 25 percent through electronic device history records

&#149 Common manufacturing architecture across three generations of manufacturing operations

Results of Lean Six Sigma and compliance

&#149Yield improvement of 5 percent
&#149 Net present value: $3.2 million
&#149 Internal rate of return: 41 percent
&#149 IT support costs lowered by 22 percent

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