



**Sparta Systems**

# Quality Management in the Complex Manufacturing Environment

WHITE PAPER

The number and value of merger and acquisition (M&A) transactions in the consumer packaged goods (CPG) industry has steadily increased over the last 30 years. That activity is likely to accelerate, according to Deloitte, LLP, as larger corporations take advantage of sizable cash reserves, low interest rates and easy access to credit to increase exposure to faster-growing markets, consumer segments and product categories, and to integrate vertically and optimize supply chain operations and routes to market.

At the same time, CPG manufacturers are trying to advance toward a lean and standardized manufacturing process in order to enhance production flexibility and better manage industry compliance standards. These efficiencies are particularly effective when applied to global supply chains, business networks, service initiatives, and production activities. The result can vastly improve the entire manufacturing process. Important to note, integrating new acquisitions while moving to a standardized manufacturing process often increases the complexity of operations. Complexity often affects quality.

## Getting to a Lean, Standardized Manufacturing Process That Drives Quality

By establishing a standardized process, organizations are better able to identify standards that are not being adhered to or adopted, as well as when and where to take corrective action. To get there, CPG manufacturers need to take advantage of an enterprise quality management solution (EQMS) that coordinates business processes and IT infrastructure with operational processes. Such a system simplifies and consolidates these critical processes to provide real-time insight across plants, geographic regions, and suppliers. That insight can inform quality assurance issues, support compliance with legislative and regulatory requirements, and can help merge business processes and systems between companies and balance the functionality of new capabilities. Manufacturers that have instituted EQMS have found these benefits:

**Simplified change management** – EQMS streamlines Corrective and Preventative Actions (CAPA) Management, helping to prevent and quickly resolve any non-conformances.

**Centralized audit management** – EQMS makes real-time audits possible, to help make the identification and resolution of issues more efficient across a global manufacturing operation.

**Effective supplier quality management** – EQMS delivers visibility into upstream operations to help manufacturers to effectively collaborate with partners and suppliers.

**Powerful enterprise integration** – EQMS web-based integration architecture can seamlessly integrate with a manufacturer's Service Oriented Architecture as well as Enterprise Resource Planning (ERP), Laboratory Information Management Systems (LIMS), and Manufacturing Execution Systems (MES).

**Streamlined compliance achievement** – EQMS efficiently provides insight into compliance by integrating related events and actions, automating workflow, and facilitating trending and reporting across systems.

By leveraging EQMS for a collaborative and standardized manufacturing process, CPG manufacturers are finding that they can achieve operational excellence and enhance speed-to-market. In addition, software-enabled quality management makes the CPG manufacturer's Quality Assurance Department 35 percent more efficient, according to customer data gathered by Sparta Systems. This efficiency translates into faster and more accurate record closures (e.g., as measured by Reduction in Record Closure Cycle Time, On Time Record Closure, and Record Closed Right the First Time). This, in turn, frees up quality assurance resources to proactively work on the business (e.g., more audits as opposed to CAPAs).

The value of data that results from an EQMS—a record of operating environment, people and system interactions—can touch every Standard Operating Procedure in the CPG manufacturer's business. If mined correctly with proper reporting tools like big data analytics solutions, this information can streamline reporting and enhance compliance, as well as help senior executives within CPG organizations quickly identify errors and make fast, effective, business-critical decisions. In addition, this data provides a record of how the business continually improves on its journey toward maximizing the true measures of success, which are the Lean Manufacturing Measures (See table 1)

Table 1: Lean Manufacturing Measures

PROCESS FLOW METRICS				
1	Process Throughput	PT	Jobs per Hour ↑	Process output rate per hour of sellable product.
2	Line Efficiency	LE	Percent (%) ↑	Ratio of actual process Throughput to the theoretical ideal throughput based on the pace and cycle time at the bottleneck station.
3	Total Manufacturing Lead time	TML	Hours ↓	Total time from receipt of raw material to shipping of the final product.
4	Processing time quotient	PTQ	Percent (%) ↑	Ratio of value added processing time to total manufacturing lead time (TML).
5	Material Handling time quotient	MHTQ	Percent (%) ↓	Ratio of material handling time to total manufacturing lead time (TML).
6	Setup Time quotient	STQ	Percent (%) ↓	Ratio of setup time to total manufacturing lead time (TML).
7	Equipment & Personnel Waiting time quotient	EPWQ	Percent (%) ↓	Ratio of equipment and personnel queuing and waiting time to total manufacturing lead time (TML).
8	Materials Waiting Time quotient	MWTQ	Percent (%) ↓	Ratio of waiting time for materials to total manufacturing lead time (TML).
9	Information Waiting Time quotient	IWTQ	Percent (%) ↓	Ratio of waiting time for information to total manufacturing lead time (TML).
QUALITY METRICS				
10	Scrap Rate	SR	Percent (%) ↓	Percentage of units starting as raw material that are lost as scrap from all steps in the process.
11	Rework Rate	RR	Percent (%) ↓	Percentage of units starting as raw material that have to be reworked at least once in the process.
FINANCIAL METRICS				
12	Cost per Part	CPP	\$/Unit ↓	Total cost per unit for raw materials, processing and indirect overhead.
13	Inventory Level	IL	Units ↓	Inventory level of raw materials, work in process and finished goods.
14	Inventory Cost	IC	\$/Month ↓	Holding cost per month for raw material, work in process and finished goods inventory.
PRODUCTIVITY METRICS				
15	Labor Productivity	LP	Percent (%) ↑	Ratio of monthly product value shipped to monthly labor expenditures.
16	Capital Productivity	CP	Percent (%) ↑	Ratio of monthly product value shipped to monthly capital charges (for tools, equipment and facilities) depreciation and direct expenditures.
17	Setup Intensity	SI	Percent (%) ↓	Ratio of setup time to scheduled plant operating time.

## Supplier Remediation Supported by EQMS

Once supplier issues are identified, organizations typically resolve issues in one of three ways. They can bring suppliers in-house, which is a strategic solution if the supplier provides a unique service or technology that delivers competitive advantage. Manufacturers can also change suppliers which is an easy solution if the supplier is a low value-add partner or a commodity supplier. Or, a manufacturer can help the supplier improve through a well-planned remediation plan.

If a supplier remediation plan is necessary, an EQMS can streamline the process and make remediation more effective. An EQMS can identify supply chain failures, such as suppliers or contract manufacturers causing quality problems, and provide the data necessary to develop a strategic remediation plan that includes action items, key performance indicators and bench marks. Once a plan is outlined, EQMS continues to add value through the remediation program by capturing and reporting data that helps managers monitor and course-correct performance.

## Driving Quality Through Visibility Into Supplier and Contractor Deliverables

Making investments in quality assurance-related personnel, processes and technologies to more efficiently and effectively create predictable outcomes within manufacturing systems is a great start. In fact, these investments in internal quality assurance are paying dividends by driving down internal manufacturing costs and risks, as evidenced by Ely Lily's public claim that EQMS has added 2 – 3 percent to the organization's gross margin. However, organizations are still exposed to a great deal of risk as a result of poor quality being delivered by suppliers and contract manufacturers.

This is because, in an ever-changing economic climate, organizations have outsourced a great deal of work to contractors that have core competencies in particular areas and can deliver product inputs at a lower cost. According to recent data from Ernst & Young, 51 percent of supply chain business partners agree the biggest risk to the supply chain is the lack of visibility into how those contractors are manufacturing deliverables .

In addition, 85 percent of CFOs agree that data and analytics are key to building more collaborative partnerships that help drive performance measures.

Coupled with a lack of visibility into the quality process of contractors, CPG manufacturers often use unsecure or inefficient means to gather supplier quality data, efficiently notify suppliers about quality issues and work through remediation. (See sidebar: Supplier Remediation Supported by EQMS)

## Keys to Improved Quality Across the Manufacturing Environment

Quality is dependent upon the type of work done across the manufacturing enterprise. As M&A activity accelerates and CPG manufacturers advance standardized processes, quality management must also evolve, with the goal of continuous improvement of key business processes. To get there, organizations should:

- Work to get on one manufacturing process. This will drive consistent manufacturing outputs across the enterprise and help squeeze out inefficiencies at scale. Consider using an Enterprise Quality Management solution to achieve this goal.
- Commit to achieving consistent quality across the entire manufacturing process. This will strengthen an organized, compliant business foundation that efficiently gathers data and reports on quality, which can build successful partnerships with regulatory bodies.
- Focus on getting rich and detailed supplier and contract manufacturing data in order to get the full picture of what is happening in manufacturing environment. This will allow systematic and objective management of contractor relationships.
- Overlay supplier quality data with an analytics solution to get VPs and CFOs on the same page, and facts to drive formality around management of suppliers and contract manufacturers.

To learn more about this topic and how Sparta Systems can help, visit [www.spartasystems.com](http://www.spartasystems.com)

Sparta Systems, an industry pioneer and leading provider of enterprise quality management software (EQMS) solutions, enables businesses to safely and efficiently deliver their products to market. Its TrackWise® EQMS, a trusted standard among highly regulated industries, is used by quality, manufacturing and regulatory affairs professionals to manage compliance, reduce risk and improve safety across the global enterprise. Headquartered in New Jersey and with locations across Europe and Asia, Sparta Systems maintains an extensive install base in the pharmaceutical and biotechnology, medical device, electronics manufacturing and consumer products markets.

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