



Implementing a Quality Management System

In today's highly competitive marketplace, it is critical that organizations have a strategy to differentiate their product offering from their competition. Of course, we all know that if your product is differentiated by its features and offerings, that satisfy a customer needs, you've got a winning recipe.

However, one concept, that most times gets unnoticed, is that the **Quality** of your product, is something that differentiates your product from the competition. Not only in the short term, but much needed for long term success.

Consider this, even if your product has differentiated product features, yet it has a poor quality reputation and record, do you think it will be a long term success? As consumers, we can all answer this question with a resounding "NO".

So how does a company build a **Quality Management System**, that ensures quality products and long term successful product launches?

Start by designing success metrics from two perspectives. First, the external viewpoint achieved from Customer Satisfaction Ratings and Independent Product Rating agencies. Second, from the organization's internal quality metrics, such as, service incident rates, etc.

So what is a good approach to setting up a **Quality Management System** for your company? We use a three pronged approach:

1. **Design the Quality In** - The development process needs to build the quality into the product and process.
2. **Critical Parameter Management** - Build a manufacturing process, that incorporates the use of critical parameters, that need to be controlled and monitored for

the success of the product quality.

3. **Corrective and Preventive Action (CAPA)** - Development of a closed loop Corrective and Preventive Action (CAPA) system with built in Audit capabilities.

1. Design the Quality In

In order to design the quality into the product development process, organizations need to embrace and embed the use of:

- ◆ **Configuration Management**—Keep a "record" of the truth through changes in the Design (Digital) and the Verification (Physical) through the product development process.
- ◆ **Simulation Tools and Techniques**— This needs to include simulation for both the mechanical and electronic component development of the product.
- ◆ **Failure Mode Effect Analysis (FMEA)** A step-by-step approach for identifying all possible failures in the design and manufacturing of the product. Create a true relationship with multiple interactions and conversations between your organization and customers.
- ◆ **Design Verification Plan and Report**— Plan the testing needed to validate the product through each phase of the product development process, then document the testing and results using a closed loop resolution system.

2. Critical Parameter Management

Is a proven method that co-ordinates the needs of marketing, engineering, and manufacturing to ensure the new product offering meets the needs and expectations of the end consumer while aligning a common language for all disciplines.

Focusing on these critical parameters, allows integration from design into manufacturing and the extended supply base.

3. Closed Loop Corrective and Preventive Action (CAPA) System

A closed loop corrective and preventive action system needs to incorporate 5 key components.

1. A controlled documentation process that provides configuration control of documents.
2. A documented "Root Cause" methodology to investigate non-conformances that are reported.
3. Establishing an "Action Plan" for resolution of each non-conformance.
4. Follow-through of the "Action Plan" and monitoring it through its execution.
5. Evaluating the effectiveness of the "Action Plan" to ensure the desired outcome is achieved.
6. Continuous improvement of the CAPA process,

From our perspective, the development of a Strategic Quality Management System, is something that is essential to the long-term growth and longevity of your organization.

The impact of poor quality has devastating results. It damages your brand reputation and equity. It adds enormous cost to your product offering and operations. It becomes a barrier to your company's ability to fund new product development projects.

We have the experience and expertise to help you Design, Build and Implement a Strategic Quality Management Solution.

Coming in April: DRIVEN-4 News— Upcoming Conferences and Exhibits

