

Whitepaper

Avoid the High Cost of Quality Failure

*Reduce Failures 50%
Embed QMS in Your PLM*

Bad News Travels Fast

In today's social media world, news of a negative product review on the web can be spread around the globe before your damage-control team gets their boots on; because of this, manufacturers are focused now more than ever on preventing quality issues from slipping to market.

The reality is a quality failure can occur anywhere in the value chain. And once it's out the door, the cost to rectify it increases.

The ability to proactively monitor errors and product failures with enterprise-wide visibility is only possible with a holistic approach to quality. When a Quality Management System (QMS) is one with design and development systems, supply chain oversights, employee missteps and product design errors can be dramatically reduced.

Unfortunately, precious few companies have aligned supply chain stakeholders, manufacturing processes and solution capabilities to achieve this deeply embedded 'best practices' level of standards.



What's Inside

In this whitepaper, Arena highlights the pertinent best practices for, and benefits of, managing quality as an integrated part of your business to build a culture of collaboration and innovation. Topics covered:

- Cost of Quality Failure
- Advantages of a Holistic Approach to Quality
- Financial Benefits of Integrating QMS with PLM
- Value of Centralizing Quality Data
- Why a PLM-based Quality Solution?

Cost of Quality Failure

In today's fiercely competitive marketplace, more companies, ranging from medical device to electronics, understand the painful costs of quality failure and the brand-damaging hangover that persists long after the issue has been remediated. A recent LNS Research Quality Management Survey concluded that reducing the cost of quality was the number one objective for electronics (46%) while reducing non-conformances in manufacturing was the top objective for industrial equipment (35%) and medical devices (28%). (1)

The "cost of quality failure" discussion can be thought of in terms of both "internal" and "external" costs. In general, internal costs, such as scrap, rework, and shipping delays are less damaging than external failures — e.g., expensive product recalls, returns and the brand diminution caused by negative product reviews.

So how can companies prevent internal product failures from becoming costly external nightmares?

One word: "collaboration".

A company's ability to foster collaboration across the enterprise is key to successfully managing quality. The problem is that too often cash-strapped startups rely on folders, email and spreadsheets to jury-rig a CAPA system; equally as bad, many large companies frequently use specialized third-party quality tools that are disconnected from other departments. Neither of these tactics fosters the cross-functional collaboration and visibility necessary to sustain successful quality management across the product lifecycle.

Organizations with disparate quality management systems face these challenges:

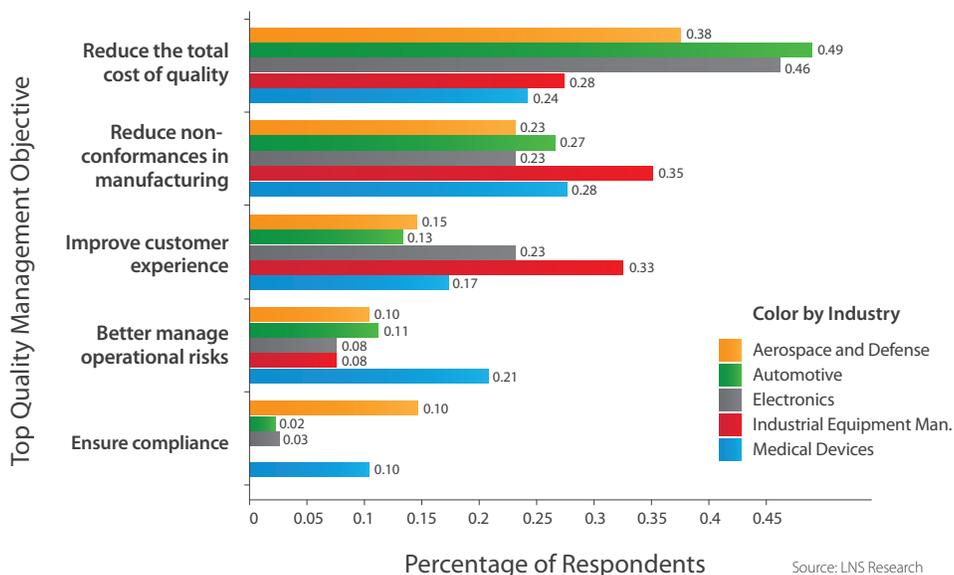
- Product Delays** — Without a centralized quality system, tracking quality progress and completing a corrective or preventive action can be difficult. When you can't find documents, processes become inefficient.
- Scrap and Rework** — Companies with disparate quality systems tend to have higher rework rates and more often repeat errors due to lapses in manual processes and poor documentation of prior effort's root causes,
- Increased Risk of Quality Failure** — Absent a holistic solution, a lack of visibility leads to miscommunication, thus increasing the risk of a repeat quality issue.



Credit: Aaron Bacall

One of the big problems of relying on multiple disparate systems is the ability to retrieve recorded notes; because of this, reports and prior corrective actions become increasingly more difficult to true-up. Quality Digest discovered that up to “80% of quality issues are repeat issues for which a corrective action has already been identified but does not persist.” (2)

Top Quality Management Objectives



Unfortunately, many companies fail to realize the importance of formally documenting records, such as corrective actions, and providing team members easy access to them. A QMS solution's ability to track records — as rudimentary as it may seem — can reduce quality issues dramatically.

Advantages of a Holistic Approach to Quality

When a QMS is linked to the product record, product development processes and other business systems, everyone across the company can participate in the quality process; this empowers teams to better identify quality issues early on and orchestrate the appropriate remediation before the problems escalate.

By combining quality processes with PLM, a holistic solution is created to support continuous improvement. According to an Aberdeen Group report, PLM and QMS interoperability can help reduce internal and external failure costs by more than 50% and reduce the total cost of quality by 8%. (3)

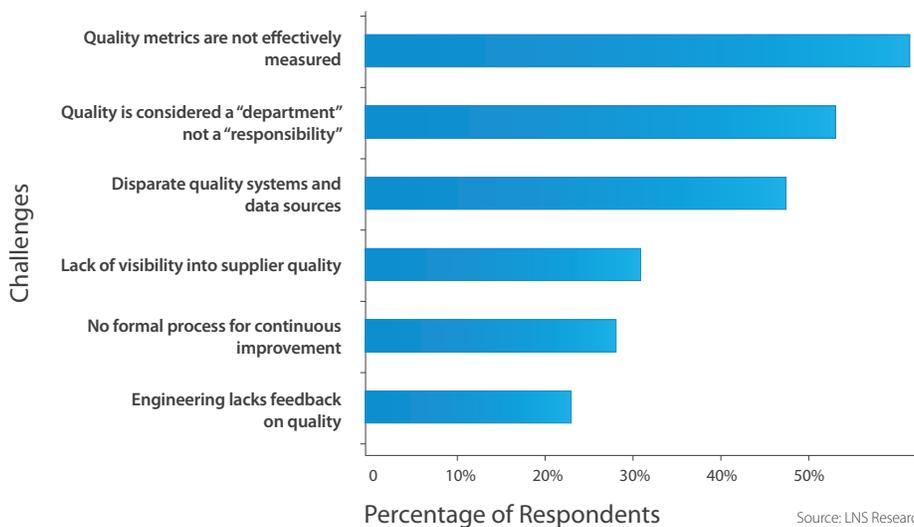
In short, interoperability can turn a feedback loop into a collaborative circle of trust that ensures product quality.

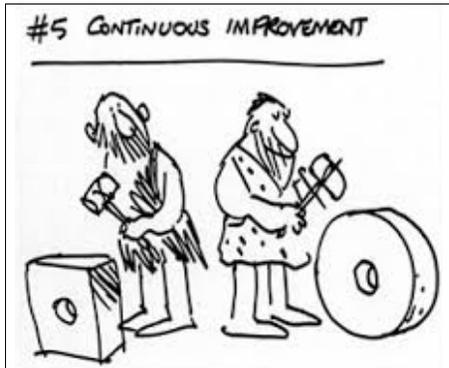
Because of existing investments in engineering, many companies are implementing QMS and associated functionalities, such as CAPA, as an extension of PLM. For engineering-intensive organizations, this not only helps to interconnect quality processes during the design process, it also enables quality integration with new product development processes and business operations. Extending CAPA and other QMS functionalities with PLM strengthens the feedback loop, thereby allowing critical information to be utilized earlier in the value chain, especially in the design phase.



Credit: Aaron Bacall

Top Quality Management Challenges





When a boat leaves the harbor, just a few degrees of difference in the rudder's heading will make a vast difference in where it ends up the further it travels from port. The same can be said for QMS. The earlier an organization infuses quality management processes with engineering and product development processes, the more effective it will be at managing quality for the long haul. A holistic integrated approach to quality, which starts with design and continues to a product's end of life, is the most efficient approach to preventing quality snafus from happening early and even more maddening...from appearing again later.

Financial Benefits of Integrating QMS with PLM

Because quality is an organizational issue, more companies are focused on implementing end-to-end business processes that extend across the supply chain. With a PLM-based quality solution, processes are connected with enterprise business systems and other external data sources through in-context links. Integrating product and quality processes can provide the following business benefits:

- Lower the cost of quality by **up to 3X** by switching from correction to prevention⁴
- Increase operating margin **25%** and reduce failure costs **29%** with integrated PLM and quality tools⁵
- Reduce cost of poor quality (COPQ) to increase earnings **10 – 15%** with consistent, integrated quality best practices⁶

By integrating QMS with PLM, links within the quality process permit users to navigate to related parts, changes, requests, projects, files and connected systems. This allows users to drill into quality process details and understand the entire quality issue at a glance, without losing context with other components in the product record.

Value of Centralizing Quality Data

Linking QMS with PLM in a centralized system offers companies a complete quality picture for maximum business results.

When quality, product and project data are all visible in a single globally-accessible centralized system, collaboration, management and documentation processes are facilitated. By ensuring teams are working from the latest document versions, employee errors, scrap and rework costs are reduced.

A centralized system should additionally provide teams a connection to parts, engineering changes and other business processes thereby allowing users to quickly find relevant data in the context of their critical tasks. By removing the tedious need to forensically investigate errors in spreadsheets, emails and old paper files, the ability to identify opportunities for improvement becomes an easy part of the day-to-day process.

Why a PLM-Based Quality Solution?

In product development work here at Arena Solutions, we've engaged in deep conversations with companies as they built their successful quality cultures for well over a decade. Companies tackling CAPA, CAR and SCAR or other remediation requirements have been quoted as saying:

- “We need everyone in our product team to know about quality issues and to take them seriously so we don't repeat mistakes.”
- “If we can just get engineers, quality teams and suppliers to all record the issues and solutions in the same place, then we could find issues, see trends and know where to focus our efforts to have the largest impact.”
- “We need to report on quality efforts across the board, so everyone can see why these initiatives matter and can understand how we are doing against our company-wide goals!”

Use of a single, tightly woven, collaborative PLM and quality solution allows frictionless flow of information between teams. Communication of actions taken by all relevant parties prevents disjointed and duplicated efforts. This facilitates company-wide collaboration to address product improvements. The result is a focused understanding of quality's value, the pride in continuous growth and knowledge that each individual's contributions will drive company success. The resulting business benefits include:

- **Improved Time to Market** — Operations, manufacturing, quality and engineering collaborate to include quality processes proactively in the development cycle, addressing feedback up front to speed time to market.
- **Higher Product Quality** — Teams build better product in a culture of continuous improvement, where they are alerted to new issues in real time, and can learn from a documented library of past challenges as well as the precise steps taken for remediation.
- **Reduced Costs and Higher Margins** — Quality process improvements in operations, manufacturing and development reduce scrap, rework and labor to improve product margins and maximize return on investment.
- **Increased Innovation** — By leveraging all stakeholders, companies capitalize on the expertise throughout their workforce to create state of the art solutions to meet customer needs.



QMS Embedded in PLM Maximizes Results

Arena Quality is a cloud-based, PLM-drive quality solution. It's designed to bring visibility, team collaboration and long-term tracking of quality resolutions across engineering and manufacturing teams alike. Specifically, Arena Quality enables companies to better meet ISO standards, 21 CFR Part 11, 21 CFR Part 820, FDA quality system regulations and a spectrum of product quality business processes, such as NCMR, CAPA and 8D.

The quality module is embedded into Arena PLM to ensure your engineers, manufacturing, quality and supply chain teams have in-context visibility to all quality issues and improvements as they design, review, improve and build your products.

A PLM-based solution connecting quality with the fundamental product development processes will deliver higher-quality products. With this holistic, end-to-end view of quality management, Arena Quality is helping companies deliver higher-quality products more efficiently for a competitive edge.



Bibliography:

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- 2) Quality Digest
- 3) <http://aberdeen.com>
- 4) International Journal of Management
- 5) <http://aberdeen.com>
- 6) <http://www.mckinsey.com>

About Arena

Arena invented cloud-based PLM. For over a decade, Arena has been redefining PLM with a suite of cloud applications that enable engineering, manufacturing and their extended supply chains to work better together—from first prototype to full-scale production. Arena helps innovative manufacturers bring better products to market faster with cloud PLM offerings that speed prototyping, reduce scrap and help manufacturers collaborate on product changes with strategic partners worldwide. Based in Foster City, California, Arena has been ranked as a Top 10 PLM solution, Top 5 Supply Chain Collaboration application and also holds a spot on the *San Francisco Business Times*' Best Places to Work List for 2013.

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