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Quality Management System (QMS) and Product Lifecycle Management (PLM) are two proven disciplines that help companies improve quality and product profitability. Unfortunately, these highly complementary initiatives are typically owned by different departments and managed as separate processes — this leads to disparate QMS and PLM systems implemented with little integration. When companies bandage together silo'd systems, design processes are compromised and products suffer from serious costly quality errors. Does Quality Management belong in PLM?

Discover the answers in this eBook. Read the story of four Arena Solutions customers whose businesses benefitted significantly from having quality and product lifecycle management systems in a single solution. Tech-Clarity clearly demonstrates how an all-in-one Quality and PLM solution enables companies to better manage their quality management processes and regulatory requirements. They develop an accurate, cohesive view of the product and its history, and focus on their core competencies: delivering world-class products, on time and on budget vs battling complex third-party vendor integrations.

Tech-Clarity

Does Quality Management Belong in PLM?

Quality Management and PLM

The Value of Quality and PLM Overlap

Quality Management and Product Lifecycle Management (PLM) are both proven disciplines that help companies improve quality and product profitability. These two initiatives are highly complementary, but are typically owned by different departments and traditionally managed as separate processes.

This often leads to disparate Quality Management Systems (QMS) and PLM systems implemented with little integration supporting quality and product innovation.

There is significant overlap between the information and processes managed by PLM and QMS. This begs the question whether they should be separate systems, integrated systems, or a single system.

For many companies, the cost of implementing and maintaining multiple software systems is prohibitive. Further, our experience suggests that a single, integrated solution suite is more valuable than a collection of disconnected capabilities.

"Quality drove our PLM implementation. We wanted accurate BOMs and revision history. Then we quickly developed more in-depth quality processes."

— Rafael Leano, Applications Analyst, T.D. Williamson

Research Goals and Findings

Given the overlap and the importance of PLM to product innovation and product development, this eBook explores using PLM to manage quality processes and data. The research finds strong quality management capabilities in PLM related to:

- Product and Bill of Material (BOM) Centricity
- Business Process Focus
- Data Relationship Management
- Internal and Supply Chain Collaboration

Managing quality in PLM offers potential cost savings and the simplicity of a single system. It creates the opportunity to consolidate and integrate information. And, perhaps more importantly, it can provide the quality assurance, compliance, and customer safety manufacturers demand. Let's take a look.

Relying on a House Built of Paper

Paper Systems Have Limits
It would be nice to say that the status quo for most manufacturers includes well-defined processes and well-thought-out, integrated QMS and PLM implementations.

Unfortunately, that's simply not the case. Many companies, particularly smaller ones, have only one of these systems at best. They frequently try to manage without one or both of the systems and rely on manual processes. This results in tremendous inefficiency, unnecessary risk, and missed opportunities.

Many startups, for example, rely on paper-based quality systems, at least in the beginning. They couple formal, mandated processes with a manual compliance system.

Chris Hill, Director of Quality for Organ Recovery Systems, explains, "Paper systems work fine when you're a startup, but paper quickly becomes a disadvantage when the company starts growing." Paper simply can't scale efficiently beyond the simplest operations.

Of course "paper" might also include *digital* paper. Paper-based processes, even when electronically managed through scanning, capture information but make it difficult to retrieve it. Beyond the difficulty of finding a single piece of information, paper systems make it nearly impossible to manage crucial data relationships such as those between complaints, non-conformance reports, CAPAs, and ECRs. Paper-based approaches are even more challenging when working across a global supply chain.

So, paper systems typically evolve to spreadsheet-based systems, resulting in a new set of scalability issues.

> *"We always had an electronic record, but as soon as quantities picked up we realized spreadsheets weren't going to work. When more than one person needs to manage the spreadsheet, it starts to break, you get different versions, and two people editing at the same time causes issues."*
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> **— Derek Warmack, Project Engineer, Yukon Medical**

Surviving by Spreadsheets

Spreadsheets and Documents Introduce Risk

Most companies turn to spreadsheets, documents, email, and shared folders to manage quality when paper-based systems get stretched beyond their limits. But these informal data and process management approaches aren't effective across multiple people and departments.

They're certainly not effective working across the distributed supply chain, which may include component suppliers, design partners, manufacturing partners, test partners, and others.

Relying on spreadsheets and documents introduces inefficiency and risk because they're hard to share, lead to version control issues, and contain errors.

Related Research

Unfortunately, quality processes are often manual or rely on spreadsheets and are both poor at sharing information across the enterprise and inefficient.

-**Quality Risk Management in Life Sciences – Tech-Clarity**

The Digital Thread

The digital thread ties product information, decisions, and history together in a structured, integrated way.

It captures product knowledge throughout the product lifecycle.

Formal Data and Process Management

Implementing formal data and process management systems helps improve quality and avoid preventable, repeat errors. Digitally managing processes provides the ability to create valuable, reusable corporate knowledge in what's called the "digital thread." That's why many companies turn to formal systems like PLM and QMS.

Tech-Clarity's experience shows that PLM systems are well suited for quality management and some leading PLM providers have added rich QMS capabilities into a single solution. We'll explore using PLM to improve performance and escape the status quo.

Quality is Product-Centric

Benefits of Integrating Product and Quality Data

The heart of a manufacturing business is the product as defined by specifications, BOMs, and a host of other product-related information. Together this information creates the product record.

Today's product record is more complicated due to the shift to mechatronic devices combining mechanical, electrical, and software elements.

Quality management is product-centric and requires a trusted product record. It's crucial to maintain revision and configuration history and associate it with quality activity. This lets companies manage the quality history of a product in the context of the product. For example, exceptions often apply to a subset of product revisions or may be related to a specific supplier. BOM-centric information is crucial to root cause analysis and corrective action and is already managed in PLM.

One of the most important benefits of integrated product and quality data is the ability to easily develop an accurate, cohesive view of the product and its history.

"A big part of the advantage of managing quality in PLM is linking it to the Bill of Material. It's helpful not having one software for Quality and different software for everyone else."

— Chris Hill, Director of Quality, Organ Recovery Systems

Documenting quality issues and resolutions with the product also increases the chance that resolutions will persist in new revisions and new products and prevents old quality problems from recurring.

Connecting quality and product history is valuable for more than audits – it promotes continuous improvement and captures corporate knowledge and knowhow. PLM helps companies effectively incorporate quality history as an integral part of the product's digital thread.

Quality is Business Process Oriented

Quality Management is Inherently Process Oriented

Quality management best practices such as CAPA, NCMR, Root Cause Analysis, 8D, and others are well known and proven. In fact, these practices are often dictated by standards such as ISO 9001 and ISO 13485. Poor process management often results in warning letters or failed audits that lead to significant business disruption.

Digital workflows help by enforcing the right standard operating procedures (SOPs), helping people know when they need to act, ensuring the right reviews and approvals, and providing an easily accessible audit trail.

One of the highest priority processes implemented in PLM is engineering change management (ECM). Effective ECM is critical to quality management. Getting engineering change under control allows companies to evolve products more rapidly so they can improve quality and meet market needs with greater confidence.

Digital processes like ECM are much more valuable when workflows are executed in the context of product data. For example an engineer reviewing an engineering change request (ECR) in PLM can easily see the underlying issue, like a customer complaint, alongside the design decisions to mitigate the issue.

"We realized that associating quality processes directly to our product data had significant value, so we decided to implement PLM quality tools to improve our Quality Management System. PLM workflows also allow you to provide users with assignments so they can work on the right process steps."

— Rafael Leano, Applications Analyst, T.D. Williamson

Quality Management in PLM

Leading companies are implementing quality processes directly in PLM, including formal processes like CAPA and FMEA that help make sure downstream exceptions are documented and used as design and validation requirements.

Today's leading PLM systems should be able to support these and other processes. For example, Organ Recovery Systems automated product sterility monitoring in PLM by creating a workflow to help remind them of critical tasks and deadlines.

Quality Requires Actionable Data in Context

PLM Manages Content in Context

Managing quality requires timely, accurate data. But it has to be the right data. Having information helps companies understand quality issues and allows them to drill down to investigate root causes. But, documents are not data. Information stored in documents is unavailable for effective search and reporting.

As Tech-Clarity's Science Lifecycle Management in the Enterprise Ecosystem points out, "Most companies have utilized 'paper on glass,' taking the same process they had on paper and executing it electronically." PLM, on the other hand, makes quality data simple to search and report on by making it easy to access and highly visible to the right people.

Beyond making data accessible, PLM manages the relationships between various pieces of information and provides an integrated view of quality. It creates a cohesive picture that includes product data, supply chain information, manufacturing history, training records, and process data including complaints, deviations, non-conformance, and more.

Linking data contextually, for example tying an ECR back to a NCMR and/or CAPA, helps improve productivity and enables people to make better decisions. Managing data in a product context also creates the opportunity to gain better product quality insights through analytics. Business Intelligence (BI) extends the value of PLM by creating visual representations and deeper insights so people can better interpret information, look for trends, identify anomalies, and discover counterintuitive relationships between data points.

For example, companies can infer associations between complaints and process control data to identify problems. This is not possible unless you effectively manage data.

> *"There are so many relationships between part numbers, documents, change orders, and more. With paper, you lose the ability to accurately cross-reference between documents so knowing how accurate your DMR is becomes almost impossible. Then you lose your DHF."*
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> **— Document Control Admin, Medical Device Company**

Tech-Clarity

Quality is a Collaborative Process

PLM Helps Companies Collaborate

Quality management is collaborative by nature, requiring cross-functional people to work closely together. Without collaboration, issues get lost in the gaps between people, departments, and supply chain partners. As Tech-Clarity's Quality Risk Management in Life Sciences explains, "Information on potential issues is spread across the organization, with different departments holding different pieces to the puzzle." Collaboration helps companies improve quality by sharing the deep knowledge embedded across their business.

Effective collaboration is critical in today's distributed, global environment. Companies typically rely on a supply chain including contract engineering firms, embedded software developers, component or subsystem suppliers, and potentially, regulatory bodies. All have valuable input and roles to play.

Collaboration brings their different experiences and insights together for problem solving, helping companies find and correct root causes and design higher quality products through processes like DFM or FMEA. As Derek Warmack, Project Engineer at Yukon Medical explains, "PLM helps us collaborate with vendors. It's highly valuable to collect data in one place and collaborate with suppliers from a quality standpoint."

> *"One of the biggest features is the ability to collaborate internally and with suppliers and partners. PLM allows you to give a supplier visibility or perform a role in the process, like approving a document change or developing a plan of action for an issue."*
>
> **— Derek Warmack, Project Engineer, Yukon Medical**

The Status Quo Isn't Good Enough

The status quo today is ineffective. It includes ad-hoc communication and document sharing that fails to capture corporate know-how. PLM provides the collaboration platform to involve the right people through subscriptions, workflows, and roles. For example, companies can loop issue resolutions back to design so issues don't persist.

PLM takes collaboration out of email, phone, and water cooler conversations to capture collaborative input, opinions, and decisions. PLM retains knowledge as a part of the product's digital thread and contributes to corporate knowledge.

Why Quality Belongs in PLM

Single and Consistent Source of Product Data

PLM and QMS are both valuable solutions, but together can result in significant data and process duplication. The most practical way for most companies to get a single, rationalized quality management and PLM solution is to leverage PLM to support quality along with product innovation, product development, and engineering processes.

PLM is ideally suited to manage quality because it's a collaborative system, spans the enterprise, and is built to connect the supply chain. Some leading PLM vendors have extended PLM to manage quality processes and put quality and product data into a unified, connected product record. This makes it easy to find information, develop insights using BI, and meet product documentation needs such as DMR and DHF.

Beyond data, PLM supports quality processes to integrate data, procedures, and people. These capabilities make PLM a natural fit for those that want to improve quality and reduce risk. Companies looking for quality management capabilities should consider PLM a strong option, particularly if they value a single solution.

"We looked at cost over three years between PLM and other QMS software packages. There was a cost savings for PLM, but the capabilities and the linkage to the BOM led us to PLM even without the cost savings. Since then we've improved complaint investigation duration and timeliness of CAPAs through process improvement supported by PLM."

— Chris Hill, Director of Quality, Organ Recovery Systems

Related Research

"Top Performers are 2.7 times more likely to manage quality processes in their PLM systems than other, poorer performing companies."

- **PLM Beyond Managing CAD – Tech-Clarity**

Top Ten PLM Requirements to Manage Quality

1. Effective BOM management
2. Ability to manage product-centric data relationships
3. Strong business process management
4. Efficient search capabilities
5. Support for quality processes (CAPA, NCMR, etc.) and product-centric processes (ECR, ECO, etc.)
6. Collaborative capabilities that create real-time, reusable corporate knowledge
7. Business intelligence for product and quality data
8. Granular security model and electronic signatures (21 CFR Part 11)
9. History of trouble-free validation (if needed)
10. Ease of use and ease of implementation

Quality in PLM Drives Business Value

"It was the right decision to implement quality in our PLM. There is significant value in having one system that does it all and one source of data instead of using different systems. The obvious benefit is that it saves a lot of time."

— Rafael Leano, Applications Analyst, T.D. Williamson

"The turnaround time on our ECOs went from over a week to two or three days and we improved our metric on clearing non-conforming items. We couldn't have done that without PLM."

— HW Quality Engineer, Medical Device Company

www.tech-clarity.com

clarityonplm.com

@jim_techclarity

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About the Author

Jim Brown is the President of Tech-Clarity, an independent research and consulting firm that specializes in analyzing the business value of software technology and services. Jim has over 20 years of experience in software for the manufacturing industries. He has a broad background including roles in industry, management consulting, the software industry, and research.

Jim's experience spans enterprise applications including PLM, ERP, quality management, service lifecycle management, manufacturing, supply chain management, and more. Jim is passionate about improving product innovation, product development, and engineering performance through the use of software technology.

Jim is an experienced researcher, author, and public speaker and enjoys the opportunity to speak at conferences or anywhere he can engage with people with a passion to improve business performance through software technology.

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