Bridging the gap between compliance and innovation

ENOVIA PLM solutions for life sciences

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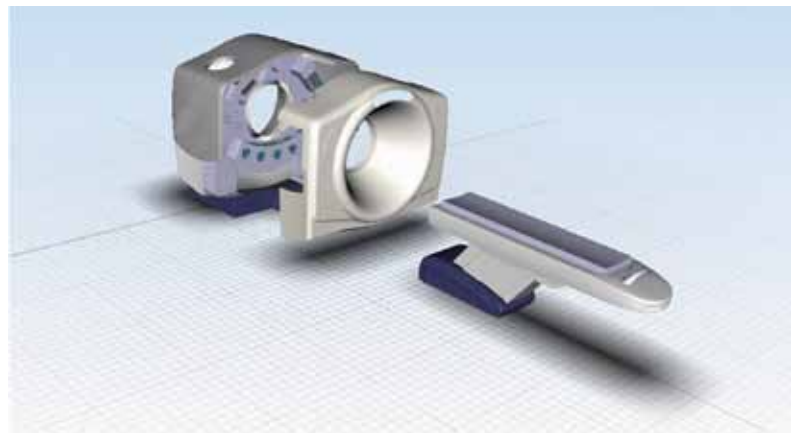
Executive summary

Success in medical device manufacturing requires continual innovation in order to deliver improvements in the quality of patient care. This in turn drives business revenue and profits. At the same time, device manufacturers need to comply with the extensive quality systems regulations as issued by the Food and Drug Administration (FDA) and other regulatory bodies and standards organizations.

Today, product development and regulatory compliance functions are usually conducted by different organizations in silos, using multiple information systems and manual processes. These critical functions often consume excessive amounts of time, and deliver less than optimal results because of the difficulty in exchanging information and a mutual lack of coordination. The ENOVIA® product lifecycle management (PLM) solutions for life sciences, is a major leap forward. It offers an end-to-end solution within a single environment, spanning the entire product development process as well as most of the quality systems processes. Contributors within the different groups of product development and quality systems can easily access the information they need, regardless of who created it or currently owns it. Workflows can be developed within both product development and regulatory compliance, bridging the gap between the two. This enables the automation of many currently manual processes.

The result is a dramatic improvement in both product development and regulatory compliance. Information that is captured in the regulatory compliance process can be automatically used as an input into product development, accelerating innovation. Aligning regulatory compliance concerns with product development allows for the faster identification of problems so that these can be resolved before they become compliance issues. By automating a wide range of business processes, dramatic time-savings can be achieved and errors reduced. Compliance and innovation become complementary rather than conflicting processes, to their mutual advantage.

Figure 1: Continual innovation needed for success in medical manufacturing

Integrating compliance and innovation: a critical business challenge

A number of manufacturers have implemented business systems designed to improve the performance of their critical product development and quality systems processes. However, almost all still implement these business systems incrementally as point solutions, typically department by department, to address a specific need. For example: one department fielding complaints might enter them into a call management system; a second might enter the same complaints into a different system that formats them for reporting to the FDA; a third might use yet another method in order to identify trends in the data, with a further system to track and resolve corrective and preventative actions (CAPAs).

It is almost universally the case that the separation of product design information and quality systems creates a natural barrier between quality and engineering. The product development process often involves similar technology silos and manual processes. Nearly every medical device manufacturer uses a computer-aided design (CAD) system to define the design of their products electronically. Many use a product data management (PDM) system to preserve product structure and document integrity. Yet change orders (COs) and other similar business processes are typically manually executed, with the required documentation being emailed or carried by hand from reviewer to reviewer. The evaluation and approval of COs, product structures and documents can easily be held up when a reviewer is out of the office or has mislaid some information. Users of design data such as manufacturing, purchasing, quality control and suppliers usually have to access it manually.
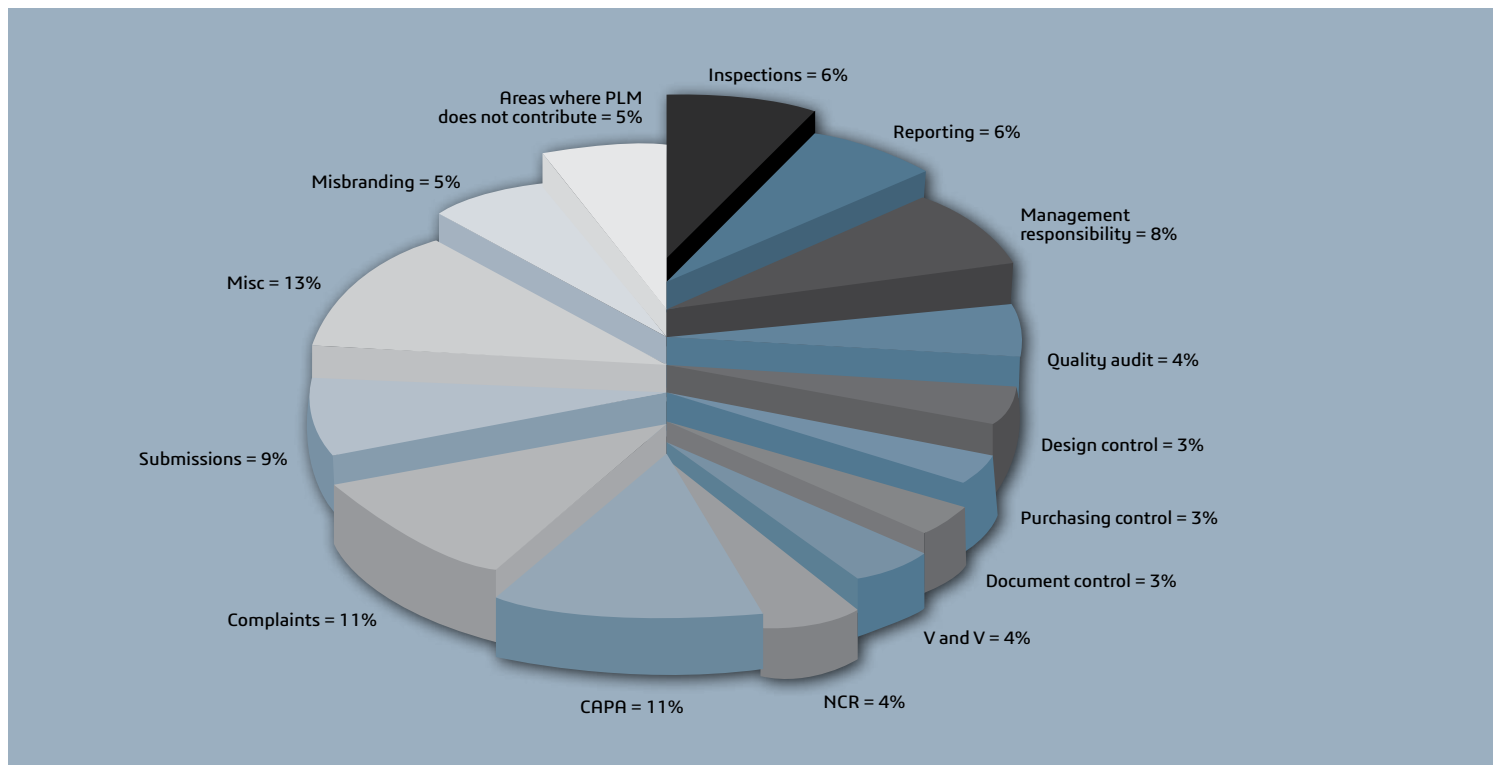

Figure 2: Documented causes of FDA warning letters

Time wasted interfacing between different functions

A major problem with this approach is that contributors in every area of the organization spend far too much time performing manual processes that do not add value, whether manually transferring data from one system to another or seeking out information owned by a different function. For example, a design engineer developing a new version of a product might have to spend considerable time tracking down complaints, non-conformances and CAPAs to be sure that they are addressed in the new version. The engineer might have to go to multiple quality systems departments in order to get information on, say, complaints, CAPAs and clinical trials, at each stage running the risk that important information might be missed. Similarly, the person in the quality systems department involved in tracking a complaint tied to a particular product may have to spend significant time tracking down the status of the CO raised to resolve the complaint.

Such interactions between quality systems and product development can involve a substantial time element. In one documented customer example, an R&D professional was timed as he walked across the building to get a document from the quality control group. Not only had he to wait 15 minutes for the document, he was interrupted during his journey and consequently was away from his desk for a full hour.

Contributors in all departments often end up wasting time by working with outdated versions of information. They admit they do not take the time or effort to ensure they are working from the correct data or, worse, are unaware of information that may be key to their decision-making process. Some companies have implemented PLM or quality systems suites in order to address these problems.

The basic issue with nearly all of today's solutions is that while they focus heavily either on product data or on quality systems, they ignore the critical interactions between these two functions. PLM systems may successfully focus on product data and design control but typically solve less than 10 percent of regulatory compliance requirements. Quality systems suites are frequently concerned with quality process workflows and trends and are typically designed to solve approximately 30 percent of regulatory requirements. Largely only capable of superficial product information management, they fail to get to the level of detail that companies need to drive intelligent decisions. They ignore product data details that are essential for closed-loop problem solving and ignore many enterprise functions and the extended value chain.

An end-to-end solution for product development and quality issues management

The ENOVIA PLM solution for life sciences overcomes these challenges by providing an end-to-end solution that commands all elements of a medical device company's quality system regulatory compliance and ISO-regulated design control. This flexible solution manages all quality issues including product complaints, non-conformance reporting (NCRs), audits and CAPAs, through a single, global, online system. It thus avoids compliance risk, improves productivity and drives innovation in product development. By integrating easily with all aspects of the product lifecycle, quality processes can reach directly into those practices they seek to improve, whether inspections, reporting, purchasing, verification and validation, submissions or misbranding.

The Enovia PLM solution for life sciences breaks down the technology silos that limit interaction between those who design, build and sell products and those who manage the regulatory compliance process. Collaborating teams can easily access relevant data and participate in automated business processes. A common platform enables seamless integration of all processes related to the product lifecycle and to regulatory compliance.

The solution offers industry best practices to quality issue management. It is configurable to specific business needs through a business modeling studio. Users may also configure the interface to fit the way they work. The ENOVIA PLM solution for life sciences is highly scalable and suited to all organizations, whatever their size. It has the ability to be adopted within very large single-core enterprises with unique divisional configurations and a broad geographic scope. Unlike multiple point solutions, it can be implemented at a much lower cost of ownership across multiple divisions.
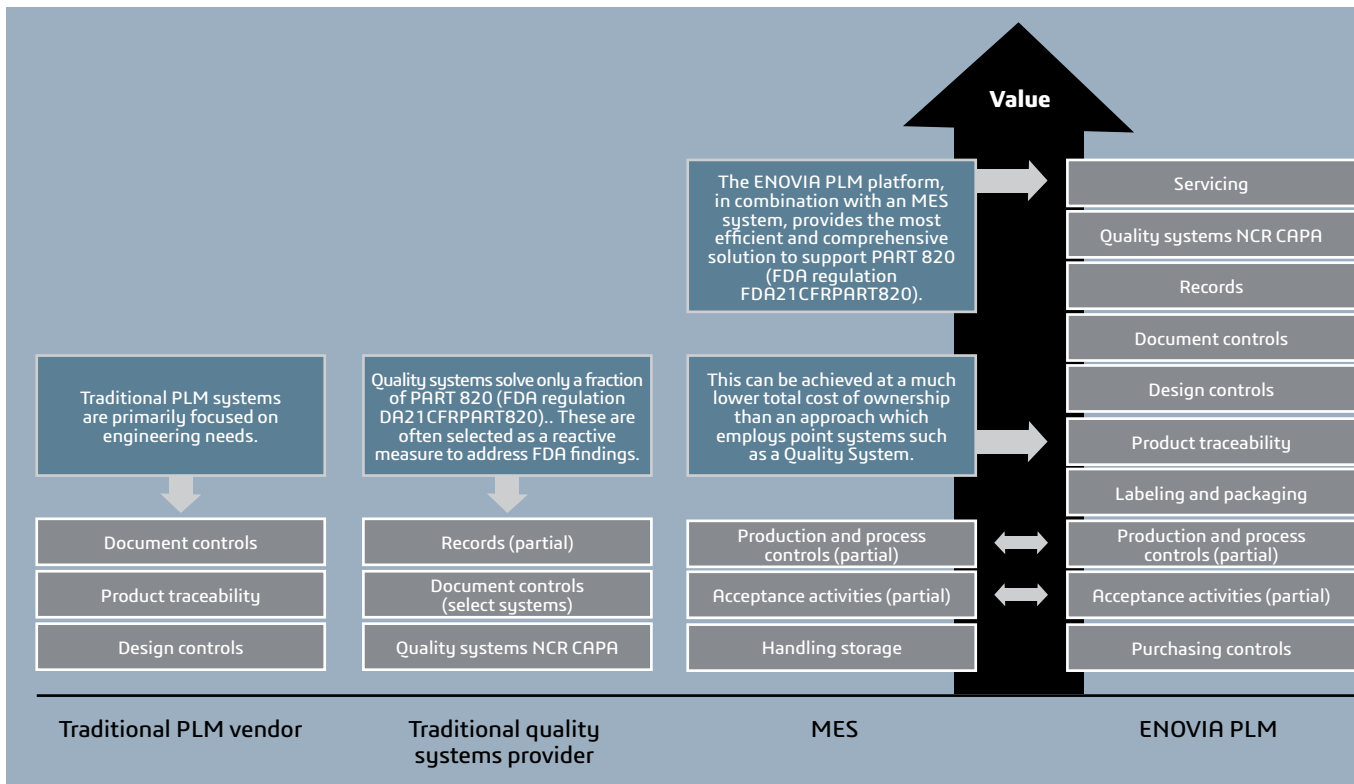

Figure 3: Integration between engineering and quality is a critical challenge in medical device manufacturing

Product development solutions

ENOVIA software provides a collaborative mechanism to capture all product information centrally and drive product-related business processes such as design control, manufacturing and sourcing from a single system. It promotes innovation by providing physical designs with the means for tracing market needs. Quality data can be captured in real time and tied to product design information. Designs can be reviewed with the market throughout the design process. The contributions of every product design discipline, including mechanical design, electrical design, electronics design and software design, are combined into a single product record that facilitates interaction during the product development process.

ENOVIA makes it easy to manage complex, multi-level product engineering bills of material (BOMs) and manufacturing BOM structures, including part versions, part revisions, alternate parts and spare parts. The solution tracks precise details of the product's makeup as it evolves across the lifecycle, for example as-designed, as-manufactured or as-maintained. All elements of the device master record (DMR) can be run from a single integrated source to eliminate discrepant information and reduce compliance risk. Other PLM processes and enterprise applications such as enterprise resource planning (ERP) can be integrated, giving all collaborators a rich knowledge network across a product's lifecycle. By defining a rigorous but flexible engineering change order (ECO) process, the collection of all required information, assessments and approvals is enforced, together with a preset approval process and status visibility. Change planning, approval and instantiation are automated in order to tightly control the evolution of BOMs and other product and quality systems documents throughout their lifecycle. The ability to enforce different sets of requirements according to change risk level allows fast processing of risk-free editorial revisions and also ensures the correct rigor for high risk changes. Reference documents and files are connected to give immediate visibility to all pertinent information regarding the change. Reporting capabilities show the status of changes and help identify bottlenecks.

Quality systems solutions

The CAPA solution, as part of the ENOVIA PLM solution for life sciences, provides capabilities to ensure complete resolution of systemic quality issues. This solution provides a request phase, where the CAPA site leader can determine if the CAPA request is in fact a CAPA or should be handled by a different process such as a CO. Once a CAPA is instantiated, an investigation is conducted which considers risk factors and root cause analysis. Depending on the results, workflow events maybe initiated automatically or manually set up by the investigator. The action plan is then reviewed and agreed by appropriate personnel. Once the CAPA is approved it is executed, which may result in the implementation of other processes such as a project or CO. When the action plan is completed, the CAPA is moved into the effectivity stage where its status is tracked.
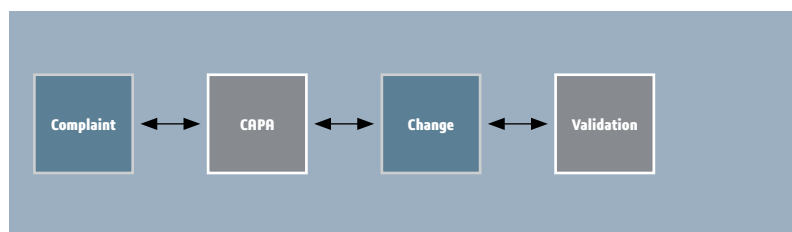

Figure 4: Interfaces between quality systems functions

This solution enables medical device manufacturers to track, investigate and process field complaints, product inquiries and service requests. The complaints capability includes management of complaints, equipment service requests and inquiries. Problems may be escalated up and down between these categories. The complaint process enables users to gather the information necessary to process the complaint adequately, handle contacts and correspondence, and determine risk, impact and reportability. Once reportability has been determined and internally approved, the complaint solution prepares the DMR form ready for submission through printed or direct electronic transmission to the FDA. Other regulatory body submissions, such as European Union and Canada, are included. Complaints can be configured to integrate directly with CAPA, change, BOM and many other ENOVIA PLM processes.

The NCR solution within the suite of solutions automates the control and disposition process by identifying issues and tracking the review, monitoring and reporting of follow-up actions. NCR runs both product and process non-conformances. The system manages product disposition including approval and verification. It includes assignable cause analysis and immediate corrections.

Similarly it can be configured to integrate with other PLM processes. For example, it may be necessary to escalate the non-conformance into a CAPA request. The Quality Issues solution for Audits allows users to track auditors' requests and provide responses. These responses can be automatically linked to the relevant data in the PLM system such as a manufacturing procedure. Any audit findings may be documented, triggering other processes in the ENOVIA system such as CAPAs, projects or COs.
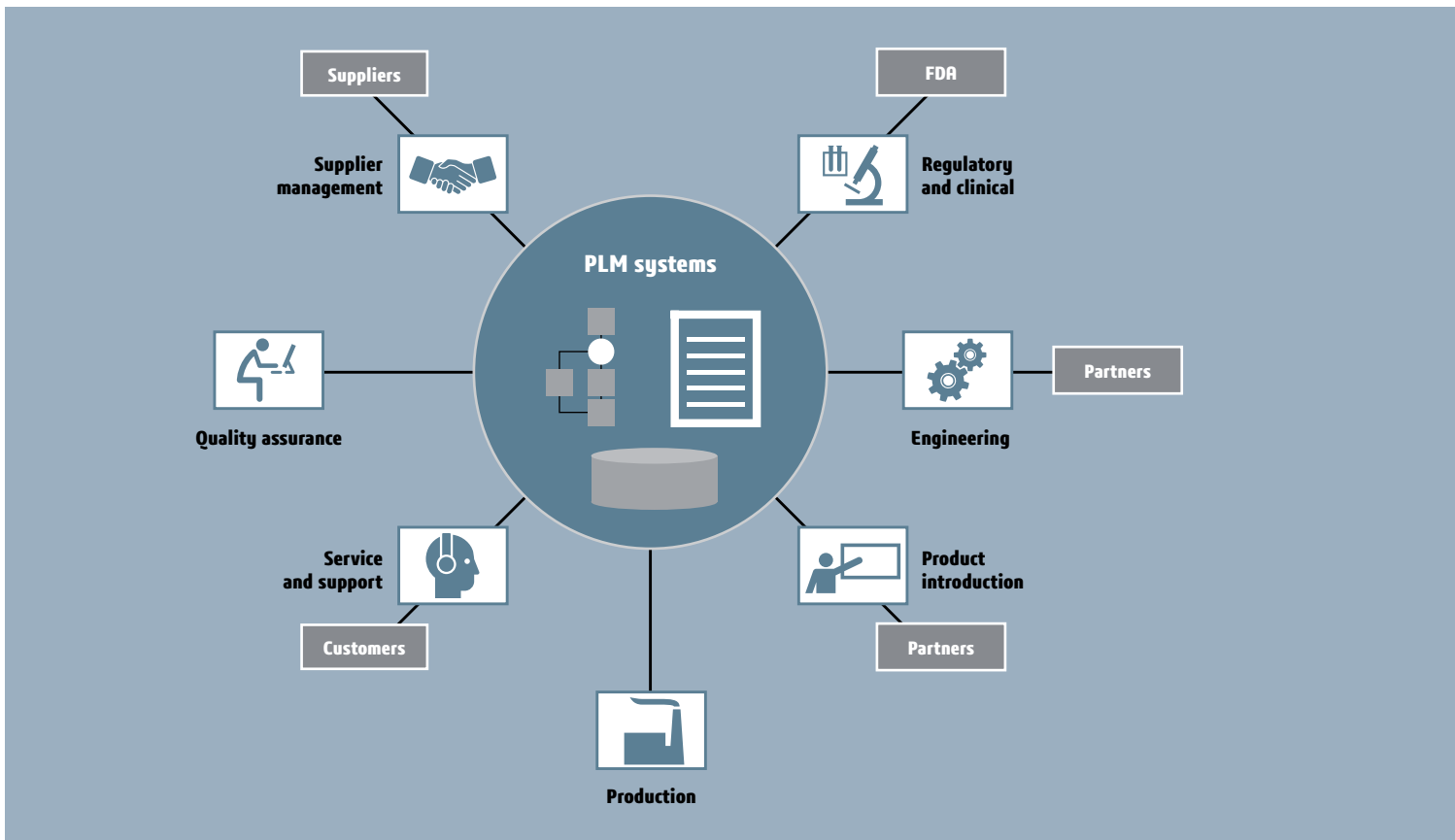

Figure 5: Integrated PLM and quality systems solution enables teams to easily access relevant data and participate in automated workflows

The Audits solution allows users to develop an audit schedule to track and plan internal, supplier and external audits. The tool tracks all details including audit lead, audit participants, risk management, type, areas of investigation and findings, and provides management and trending reports of audit results and conclusions.

Driving both innovation and compliance

By integrating product development and quality systems processes, the ENOVIA PLM solution substantially improves innovation and regulatory compliance while reducing costs. Quality issues and products are easily linked together. For example, when a user creates a complaint it is simple to link it to the relevant part in the bill of materials. Later, when a CO is developed to address the complaint, it can be tied back to the complaint and CAPA. Product designers working to address the problem have instantaneous access to each individual complaint as well as information on the complete compliance process. Quality systems personnel working on the compliance process can easily access product information such as the design geometry and the status of COs intended to address the problem. When making a change in response to an NCR, an engineer simply references it, rather than copying the problem report information from another system.

Providing all contributors with instantaneous access to information saves considerable amounts of time and ensures everyone is working with the latest data. Product development teams can now pull together multiple sources of ideas during new product development. For example, design engineers working on a new iteration of a sub-assembly of a product can easily access any quality issue relating to that sub-assembly, including audit findings, CAPAs, non-conformances, complaints, field service requests and inquiries from the product's release period. These issues can be collectively reviewed and decided upon, addressing future product iterations. In traditional environments, on the other hand, quality issues are typically only summarized quarterly and may not even make their way back to the product development teams.
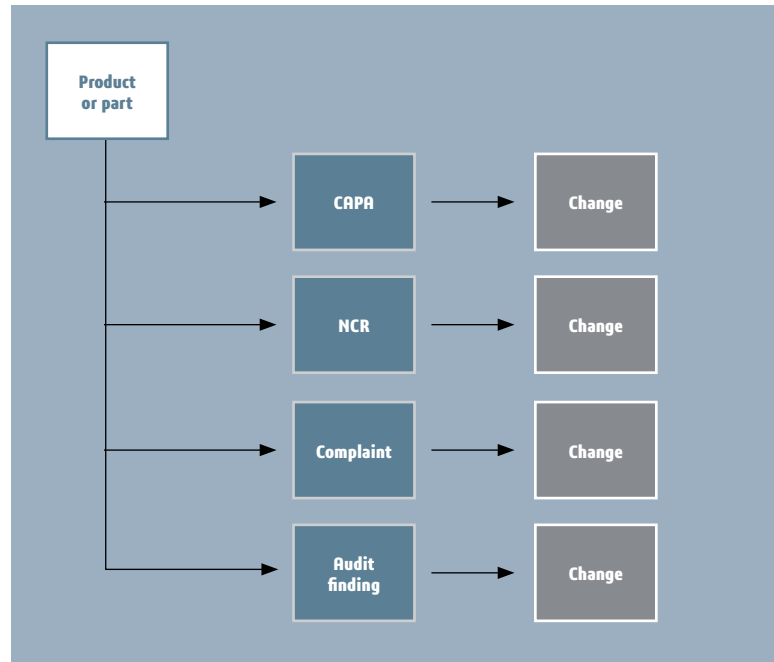

Figure 6: Links between qulaity and product engineering data

Audits may be executed much more efficiently. The Audits solution makes it much easier to track the audit process and locate information that the auditor is likely to request, such as complaints, CAPAs and design history files (DHFs). Companies implementing ENOVIA software solutions have seen a 33 percent decrease in compliance costs and a reduction in time taken to respond to DHF requests from days to minutes. Substantial time savings and improvements in accuracy can be achieved by developing workflows that cross the boundary between product development and quality systems.

These dramatic time-savings and improvements in data accuracy can be seen by the following example: when a complaint is initiated against the product, a risk analysis is performed and determines that the complaint is serious enough to be escalated to a CAPA. This is achieved simply by changing its status – no additional data entry is required. Several NCRs are noted as possibly related so they are associated to the CAPA. Audit findings are also determined to be connected to the same issue and then linked to the CAPA. A CO is generated to address the CAPA
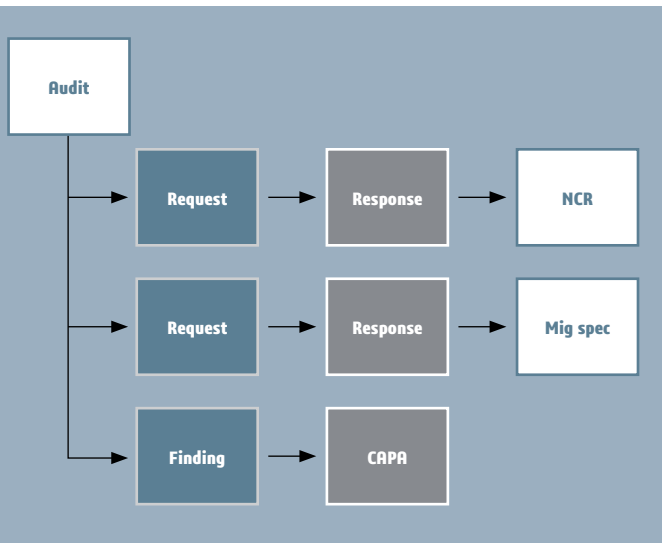
Figure 7: Workflows bridge gap between quality and engineering

and is linked to the CAPA, NCRs and audit findings. The change is validated, with protocols and reports approved through a workflow process. When the change is complete it is released to manufacturing. In many cases, one of the root causes of complaint is poor supplier performance. The supplier is consequently downgraded and the CAPA is linked to demonstrate the reason. A lack of an efficient audits solution would commonly result in lost links, missed actions, wasted time, warning letters (CAPA being the main source) and even product recalls.

In another cross-boundary workflow example, the CAPA can be configured to launch a CO automatically. The system can be set to prevent the CAPA from reaching a state of effectivity monitoring until that change has been fully validated and approved. In turn the CO cannot be considered complete until the BOM has been updated to conform to the CAPA action plan.

Conclusion

The ENOVIA PLM solution for life sciences bridges the gap between compliance and innovation to drive operational efficiency, improve product quality, enhance innovation and accelerate time to market. The ENOVIA collaborative platform automatically and seamlessly integrates product development with quality systems to encourage innovation while ensuring regulatory compliance. Through this solution the generally conflicting objectives of compliance and innovation become complimentary, by harnessing knowledge gained from executing quality issue processes, new product development or design iteration process. Process quality and consistency is also increased. This improves overall conformance and drives innovation by consistently tracking quality issues. Medical device manufacturers that have utilized this solution have achieved the following results:

- 10 percent reduction in product recalls
- 33 percent reduction in cost of compliance
- 45 percent reduction in time spent responding to information requests
- 60 percent reduction in document approval and processing times
- 98 percent reduction in product information retrieval times
- 75 percent reduction in floor space utilization in the document center
- 65 percent reduction in engineering change throughput
- 30 percent increase in item master accuracy to 99.998% accuracy
- 60 percent reduction in time searching for data
- 50 to 75 percent acceleration in product development speed
- 30 percent reduction in cost of prototypes, including iterations
- 20 percent time reduction in authoring designs.

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