Quality Lifecycle Management

Managing quality, reliability, and risk throughout the product lifecycle

Introduction

Assuring quality, reliability, and safety is an integral part of product development. But companies often address product quality too late, using disjoint processes with inadequate cross-functional communication. Not managing quality in an integrated way throughout the product lifecycle is costly to companies, both in profitability and reputation.

Achieving product quality is a multidimensional challenge for discrete manufacturers. With an increasingly global workforce, a widespread network of contractors and suppliers, technically complex products to deliver, and a highly competitive marketplace, quality is often sacrificed in the name of globalization, profitability, or time to market–sometimes with disastrous results.

To be most effective, quality should be managed early in the product development lifecycle and consistently throughout the entire process, using cross-functional, collaborative methods so that the quality information obtained in one lifecycle stage is available to relevant processes in other lifecycle stages. What's more, quality information must be highly visible throughout an organization to ensure that any and all decisions that may require quality data or impact product quality are informed in a timely, efficient, and accurate fashion.

Quality Lifecycle Management, or QLM, provides a formalized, systematic solution to manage all aspects of product quality, reliability, and risk using methods that are fully integrated into the product development lifecycle and highly visible to all personnel with a stake in product quality.

Why manage product quality?

In a perfect world, manufacturers would have a complete, accurate picture of product quality as it develops and matures throughout the lifecycle. This information would:

- Unite the quality-related development activities occurring throughout the product lifecycle
- Serve as a "single source of truth" to provide insight for all stakeholders into the current state of product quality at any time in the lifecycle
- Connect top management with the critical information they need to make decisions that impact product quality, reliability, and risk
- Help personnel across the product development lifecycle understand the quality impact of their development activities

Quality management should encompass and connect quality- related activities across all lifecycle stages, including quality planning; early insight into quality, reliability, and risk; cost planning; and the communication and reuse of lessons learned.

Quality Planning

The ability to identify all functional needs of the product ahead of time and incorporate this information into each stage in the product development lifecycle is key to ensuring product quality. With all functional requirements of the product identified from every potential source – including customer feedback – all product characteristics that are necessary to support these requirements may be identified and tracked across product development to ensure they are being fulfilled.

For example, design engineers will have criteria defining which parts to select in support of these requirements; test engineers will know which characteristics to test for and what their minimum performance must be; manufacturing will know which aspects of the product to control during production to ensure product safety and performance; and service technicians will know which aspects of product performance to address during routine maintenance or repairs.

Early Insight into Product Quality, Reliability, and Risk

Early reliability and risk analysis can identify how well a product performs its anticipated function, and how safe it is, as early as the design stage – before a prototype is ever built. The earlier companies can determine these aspects of product quality, the less costly product changes will be. Conversely, the later in the development lifecycle changes are needed –after testing, manufacture, or, worse, after products have gone to market –the costlier they will be.

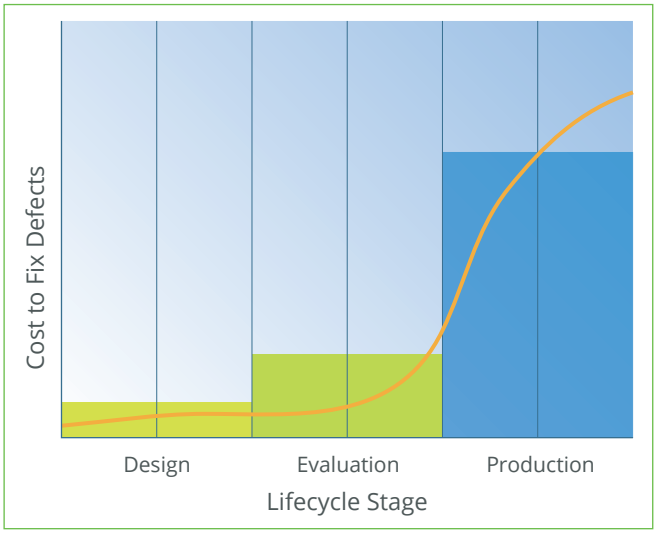


Figure 1. The cost of addressing quality issues increases as the product development lifecycle progresses.

Cost Planning

With a clear picture early on of a product's expected reliability, its post-production maintenance or servicing needs, and a well-documented trail of every effort taken to mitigate product risks, companies save money. When products are sent to market that exhibit poor quality, the repercussions for companies can be devastating. The high costs of not addressing product quality include catastrophic product failures, cancelled programs, reduced profits, lowered consumer confidence, extensive product recalls and repairs, high numbers of warranty claims, and even legal liabilities. Yet high-performing, reliable, and safe products not only boost a company's reputation, they save money in repair, replacement, maintenance, warranty, and other expensive post-market services.

Quality Digest has found that "Eighty percent of all quality issues are repeat issues".

Communication and Reuse of Lessons Learned

Quality Digest has found that "Eighty percent of all quality is- sues are repeat issues" and, what's more, a majority of quality issues are experienced with conforming products. This means that, not only are lessons learned not being communicated and reused, the root causes of issues are not being investigated and corrected across the product development lifecycle. Ensuring issues are communicated to the teams responsible for investigating and correcting them, and enabling best practices to be reused to prevent the repetition of mistakes, requires the systematic capture, analysis, and correction of product failures, and the automated dissemination of this information to essential teams throughout the lifecycle with a stake in product quality.

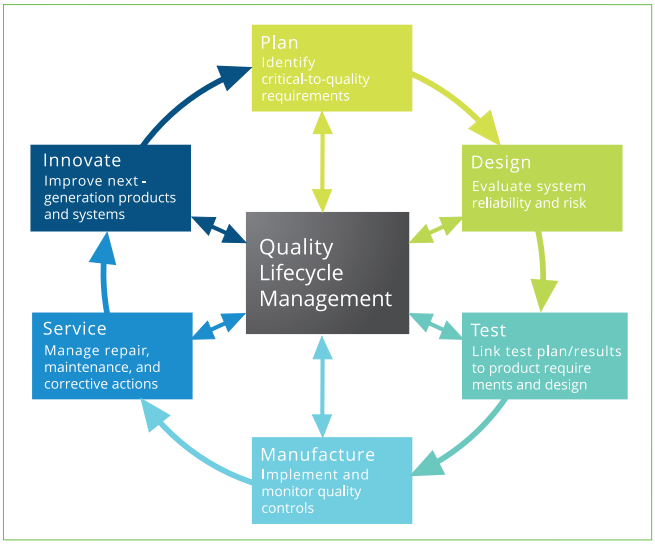


Figure 2. Quality Lifecycle Management, or QLM, unites the quality-related activities of each stage in the product lifecycle through a single database platform.

What is QLM?

Quality Lifecycle Management is an enterprise-wide, cross- functional solution to ensure product performance, reliability, and safety are aligned with the requirements set for them over the course of a product's life. QLM is used to build quality, reliability, and risk planning into every part of the product lifecycle by aligning functional needs with product requirements, ensuring these requirements are met by specific characteristics, and tracking these characteristics systematically throughout development, testing, manufacture, fielded use, and service to ensure the product requirements are met at every lifecycle stage.

Outputs from each lifecycle stage, including analysis results, product failures, corrective actions, lessons learned, and best practices, are compiled within a single database platform using QLM. They are made accessible to other relevant lifecycle stages using automated software processes. This ensures the continuous improvement of products both over the course of development and during next-generation product design.

QLM links together the quality, reliability, and safety activities that take place across every stage of the product development lifecycle. Through QLM, one lifecycle stage informs the next, and feedback from each stage is automatically fed into the other stages to which it relates, creating a unified, holistic view of overall product quality.

With numerous quality, reliability, and safety processes united within a single software platform, QLM enables:

- A highly structured solution automating the work-flow of quality information and feedback between product lifecycle stages
- Cross-functional collaboration across multiple departments and teams responsible for product quality, safety, and reliability
- Functional links between product requirements, product characteristics, and quality activities at each lifecycle stage
- Complete management visibility into key dimensions of product safety and reliability at any lifecycle stage
- A fully documented history of product development from a quality perspective

Overcoming quality challenges with QLM

Quality information about a product is frequently disjointed, informal, and undocumented, making it difficult to locate the information, integrate it with other quality information about a product, and translate it into an easily digestible format for use in high-level decisions. Quality information exists primarily in tacit form, in personal communications, or in incompatible formats like email, documents, spreadsheets, and multiple databases among which information cannot be immediately shared.

QLM overcomes the common challenges to managing product quality, including the definition of quality for a specific product, the accessibility of timely, easily digestible quality information, the integration of quality-related activities, and the reuse of lessons learned to improve product quality.

Quality Must First Be Defined

The challenge of managing quality begins with its highly nebulous nature: does "quality" mean a high degree of safety, proven product reliability, stand-out performance over the lifetime of a product, exceptional value to a customer, or the unique ability to meet a specific need? Quality can reside in each of these characteristics, and, more importantly, within the complex interactions among them. The challenge of de- signing a product for exceptional quality is complicated by the fact that any of these priorities may contradict one another as the product lifecycle progresses.

- QLM begins by identifying the requirements set for product quality and defining how a product should work in order to meet its various functional needs. Requirements are then mapped to specific characteristics that are tracked throughout the product lifecycle, providing the means to determine whether or not a product meets its requirements at any given point in its development or use.

Quality Is Addressed Too Late

The way most companies implement quality checks can best be described as "too little, too late." Without a clearly defined method to track a product's quality against its requirements throughout product development, quality checks happen too late in the development process to be effective. This means error-prone or unsafe products are shipped, expensive rework is required, product launch is delayed, or, in some cases, an entire program must be scrapped. The cost of not managing quality early, and often, is high.

- QLM ensures the early, integrated analysis of product quality from the planning and design phases through test, manufacture, and service to proactively address quality issues before they are manifest in prototype or fielded products.

Quality Information Is Not Easily Accessible

Many companies implement multiple concurrent tools to manage product quality. These are often highly specialized, proprietary "point solutions" that are limited to a single department or team. They may reside in complicated, one-off database or spread-sheet applications and require extra time and effort to set up and maintain, even though their range is limited to a single, narrow analysis activity. When the time comes to make management-level decisions in which this information is critical, it often cannot be easily obtained or effectively used. And, what's worse, when the individual with the specialized knowledge necessary to use the resource leaves, the resource often disappears, too.

- QLM provides a single software platform on which to perform the full range of quality, reliability, and safety-related analyses and output comprehensive, high-level product quality information in order to provide complete management visibility into product performance at every lifecycle stage.

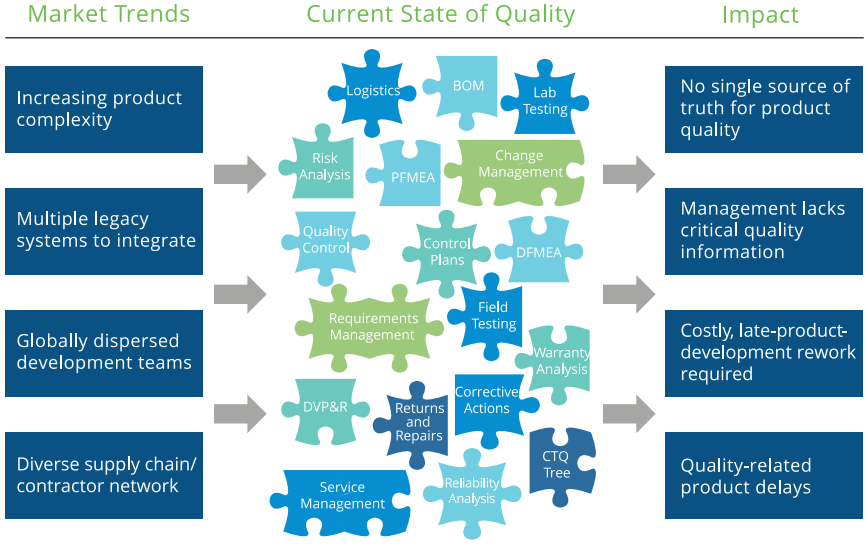


Figure 3. Due to emerging market trends and business realities, addressing quality is too often the work of disparate "point solutions" that do not communicate well or foster the collaboration and visibility necessary for successful quality management across the product lifecycle.

Quality Processes Do Not Work Together

With many point solutions in place throughout an organization and used at various times during product development, the problem is compounded. Because of their limited scope and proprietary nature, these processes seldom communicate with one another. This can cause the time-consuming task of data entry to be replicated across several departments, resulting in a tedious, error-prone process. And when the output from one resource is needed as input for another, the ability to extract the necessary data and communicate it efficiently relies upon the time and efforts of a single person or team, thereby slowing productivity, impeding innovation, and creating costly, inefficient workflow steps.

- In QLM, quality processes are united in one software tool where each analysis integrates seamlessly with the next, enabling cross-functional collaboration and creating a "single source of truth" for product quality information across the organization.

"Lessons Learned" Are Seldom Reused

Research indicates that up to 80% of quality issues are re- peat issues for which a corrective action has already been identified but does not persist. This can be due to the corrective action not being formally recorded, or not being accessible in the right context, at the right time, or in the right format. Manufacturers need a systematic way to record, store, and disseminate past experiences and lessons learned related to product quality. And because lessons learned can be accumulated at any point in the product lifecycle, and may apply to other lifecycle stages, this system must be inherently cross-functional and collaborative, spanning lifecycle stages and integrating their work seamlessly. An efficient, centralized method to acquire, communicate, and reuse lessons learned at each stage in the product development lifecycle can enable companies to leverage prior corrective actions as design improvements and best practices that effectively inform future generations of products.

- QLM provides a structured, systematic solution to compile and retrieve product information from within a centralized, cross-functional solution in order to unite core quality processes: including design and manufacture, risk analysis and testing, service and next-generation product development, and so on.

Enabling QLM at each product lifecycle stage

QLM enables the integration of all lifecycle processes used to ensure product quality, as summarized here:

- Planning: QLM begins in the earliest planning phases of product development with a quality plan in which product requirements for performance, reliability, and safety are clearly defined. Other elements of the product development lifecycle are accountable to the standards set in the quality plan.
- Design/Development: During system design, specialized risk and reliability analyses are used to predict system performance and eliminate or mitigate product risks. This is done before the more expensive phases of prototype and manufacture have even begun.
- Testing: When optimal system design has been achieved, a comprehensive test plan is created using both the outputs from reliability analysis and the predefined product requirements to optimize testing activities. Prototype testing against the quality plan verifies and validates system design and early reliability and risk analyses.
- Manufacture: After the design has been validated through testing, critical-to-quality work instructions are generated that define and implement manufacturing control measures to ensure product quality is protected throughout the manufacturing stage.
- Service/Use: Service planning identifies the best methods to sustain product quality throughout fielded use, enabling the optimization of cost drivers such as preventive maintenance schedules, spares, and prioritized troubleshooting guides. The service and use phases produce valuable feedback from product failures and other incidents that arise. These are recorded and passed on to the appropriate personnel for root cause analysis and corrective action: the essential components of product improvement in current and next-generation designs.
- Innovation: Product failure and performance data is collected from products in the field, and combined with lessons learned throughout all phases of product development, to contribute to a common database of best practices. This database is then leveraged to drive innovation by providing a single source of truth through which further product development activities are filtered during next-generation product design.

The QLM solution at each lifecycle stage, including the essential connectivity among all of the stages, is described in full below.

Plan: Identify Critical-to-Quality (CTQ) Requirements

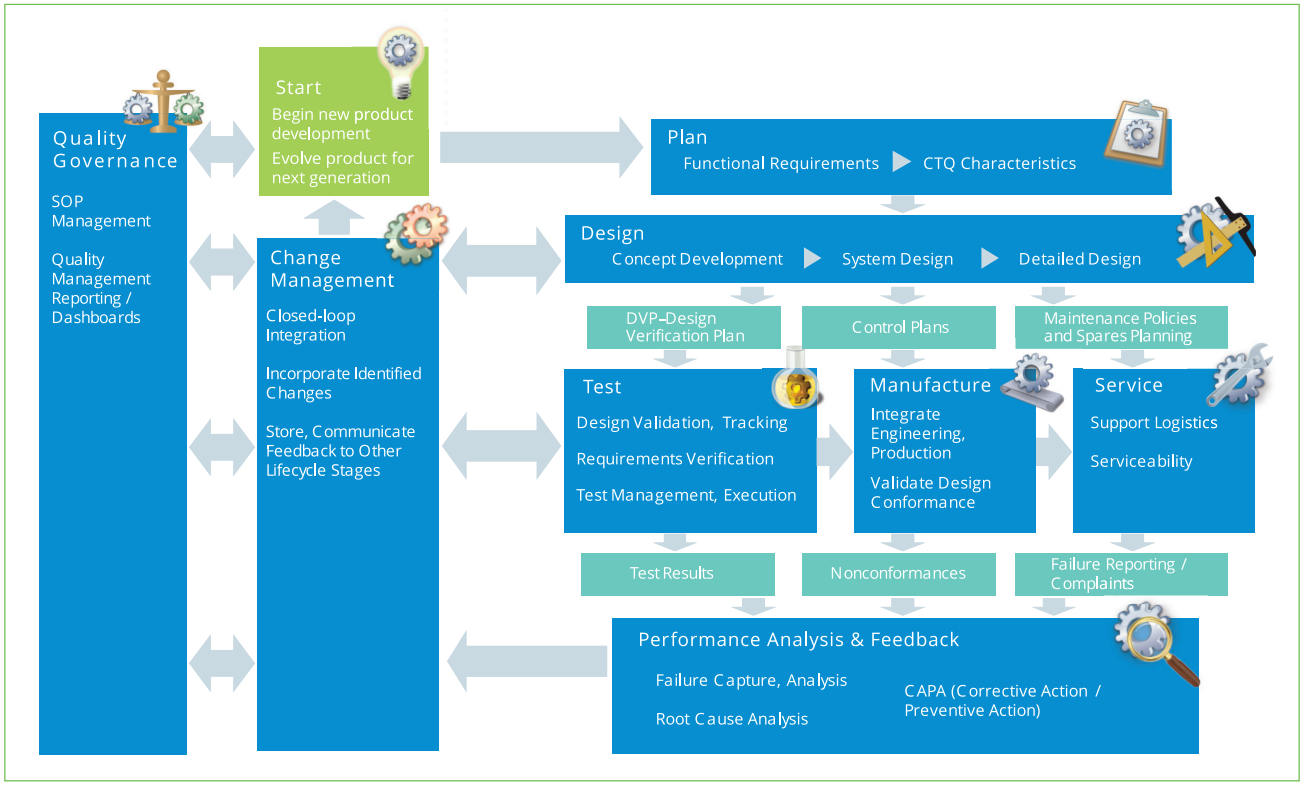
During the early planning stages of product development, quality, reliability, and safety requirements for the product are defined. These may be gathered from customer feedback, previous lessons learned, functional requirements of the product, government and industry standards, contractual specifications, and the like. The quality planning stage is essential because it will define the standards to which the remainder of the steps in product development will be held.

By defining the essential functional, safety, and performance requirements of the product, this phase identifies an overall plan for product quality, which will drive the remaining activities in the product lifecycle: prioritizing design changes based on quality, assigning test activities based on these requirements, and identifying manufacturing controls and service planning needs to realize and sustain these characteristics in the finished product.

Design/Develop: Evaluate System Reliability and Risk

The process of product design and development assigns the specific parts and systems–via a bill-of-material, or BOM– that will make up the product. In working to define the components and subsystems that will make up the final product, a number of reliability and risk analysis techniques are used early on–before a prototype is ever built–that define how safe and reliable the final product will be. Weak areas may be identified, trade-off studies can be performed to identify better parts or subsystems, and alternate system designs can be compared to ensure the safest, most reliable system is designed, all while holding the process accountable to both quality requirements and budgetary constraints.

If risks to product safety and performance are identified and mitigated early–before the product enters the prototype or manufacturing phases–fixes can be made in a much more cost effective, timely manner. Risk analysis considers system design, manufacturing risks, product/human interactions, and human process risks. It ensures that product safety is considered before the potential risks are "built into" the product via prototype or manufacture and must be discovered and changed through



Fiigure 4. QLM is a closed loop solution to ensure that quality, reliability, and risk planning influence every stage of the product development lifecycle; information flows freely from one stage to the next; and corrective actions are captured and reused to improve next-generation products.

expensive product recalls, rework, or program realignment.

During the design and development stage, the quality plan acts as a standard to which the parts and systems of a product must be compared in order to determine whether they meet specific requirements for safety and performance. The design and development stage impacts product testing, during which predicted results must be validated in real-life prototypes, as well as manufacture, service, and use, during which it must be verified that anticipated risks have been properly controlled. What's more, service planning can begin as early as the design stage using optimization tools that calculate preventive maintenance and service needs based upon the functional requirements set forth in the initial quality plan.

Test: Link Test Plan to Requirements and Design

With the best system design for product performance and safety identified, product prototyping and testing can begin. For testing to be effective in supporting quality, it must be driven by the requirements established during quality planning. In addition, tests must be performed to validate the predicted reliability of the components and subsystems assigned in the BOM during design and development, and to identify any real-life disparities between system design and prototype product.

Product testing determines how the prototype product will measure up against the predefined quality standards and requirements assigned during the quality planning stage. To test for quality, the product characteristics necessary to meet the predefined quality requirements must be identified, along with how to test for them, the required outcomes of the tests, and the necessary testing resources (materials, personnel, facilities, etc).

For effective quality lifecycle management, test results must be directed back to product design via automated processes so results can effectively inform design changes that may be necessary to support the initial quality plan. This feedback loop must in turn be tightly integrated with additional proto- type testing, to ensure that design changes do not negatively affect the quality of other product components or systems.

Manufacture: Implement and Monitor Quality Controls

After system design has been validated through testing, critical-to-quality work instructions are specified to ensure manufacturing adheres to the strict quality guidelines established during the previous lifecycle phases. These may include machining tolerances, assembly procedures, and tests of safety or performance that must be completed before finished products are shipped.

Critical-to-quality work instructions are managed in documents known as control plans, which are linked to the quality planning, design, and testing activities that came before. The quality plan helps to define the critical-to-quality characteristics that must be controlled throughout product manufacture, while design and testing define which components contribute to these functional requirements, what their tolerances and expected performance goals must be, and how manufacturing can best meet these goals.

Manufacturing also provides important feedback that may yield design changes and should be considered by other lifecycle stages–including, in some instances, design and testing–either before manufacturing can continue, before product is shipped, or in the future, during next-generation design iterations. This information is communicated to the necessary personnel in other lifecycle stages.

> "Companies can minimize lifecycle costs by comparing failure costs to solution costs for better reliability, serviceability, diagnosis, and detection."
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> ISSAT

Service/Use: Manage Maintenance and Corrective Actions

Service planning can take place as early as design and development and throughout the product life-cycle up to and including the service phase. Service planning ensures the optimization of critical cost drivers such as preventive maintenance schedules, spare parts needs, and service resources like personnel and maintenance costs. Earlier quality lifecycle processes such as risk analysis, design, and testing also provide input for prioritized trouble-shooting guides used during the servicing phase to help sustain critical-to-quality characteristics.

Not only is it essential to link quality planning, design, and testing information to service information in order to ensure the highest quality service is delivered, but detailed feedback from service experience and use–including return, repair, and warranty claims–assists in identifying quality issues, initiating root cause analysis, implementing corrective actions, and incorporating changes into next-generation product design.

One of the central functions of QLM is to investigate the correlation between field failures and manufacturing, component, or design defects. QLM provides a closed loop system to relay quality issues experienced during service and use back to quality planning, design, testing, and manufacture in order to record and retain lessons learned and improve next-generation products. Service and use are therefore essential sources of feedback about the real-life quality and safety issues experienced by customers or service technicians, including previously unforeseen contributors to reduced product quality.

Innovate: Improve Next-Generation Products and Systems

When the time comes for next-generation product design, QLM provides a structured method to filter new product life- cycle activities through the aggregated best practices and les- sons learned acquired at each stage in the product lifecycle. Through QLM, innovation is made more efficient: rather than starting from scratch, the quality planning process is already equipped with a wealth of lessons learned and best practices already proven successful in establishing and sustaining product quality.

Feedback in the form of lessons learned is essential to supporting quality throughout next-generation product design. Through QLM, best practices and lessons learned identified during risk and reliability analysis, product testing, design modifications, manufacturing controls, service, and fielded use can be amassed in a centralized information portal and subsequently used to "filter" a future product BOM. Automated software processes can associate lessons learned with components, systems, failure modes, risk controls, and the like. These are then compared with the new product BOM throughout reliability analysis, service planning, and test development, saving time and supporting efficient, affordable innovation by automatically leveraging past experiences.

What's more, because innovation in the way of continuous product improvement occurs concurrently with product development throughout the lifecycle stages, more dramatic innovation is possible when it comes time to design next-generation products. Larger strides in innovation can be made during new product development because smaller steps toward quality were continuously made during the development of previous generation products.

Quality Governance

Quality governance is the process of establishing and documenting process quality guidelines and standards. It also requires the management and auditing of these standards, to ensure they are being implemented correctly throughout the organization. Because product quality is closely linked to process quality, many companies seek not only to identify and correct product nonconformances stemming from internal and external sources, but also to establish processes that track, monitor, audit, and manage these internal and external nonconformances and the corrective actions used to address them.

Very often, these process guidelines and standards conform to internal quality initiatives – like ISO 9000, Six Sigma, APQP, and CMMI –or externally-imposed quality standards, like those found in the medical device industry through directives like ISO14971, ISO 13485, and 21 CFR Part 820. In addition to providing for the intake, recording, and resolution of internal and external nonconformances, Quality governance provides a structured, automated, and repeatable internal process to advance these issues through a Corrective Action/ Preventive Action (CAPA) workflow to ensure they are addressed, corrected, and prevented in current and future designs. CAPAs may be tracked against the product BOM, advanced through management review steps, documented to establish an audit trail and/or meet compliance requirements, and advanced throughout the organization for supplier and training management.

Figure 5. The QLM solution covers each stage of the product lifecycle and ties together quality, reliability, and risk management processes.

The tools of QLM

Several methodologies are commonly used to complete quality, reliability, and safety-related analyses throughout the product development lifecycle. These are all available and tightly integrated in Windchill Risk and Reliability within a single database platform to enable QLM most efficiently.

System Modeling

Analytics

Used early during the product design stage to calculate the probable failure rates of components and systems, Windchill Risk and Reliability's Analytics module helps engineers determine whether product performance under anticipated conditions will match the goals established for it. Windchill Risk and Reliability is used to assess product reliability early in the design process, identify leading contributors to system failure, measure the impact of environment and stress on a system, and perform design trade- off studies to compare the effects of design changes on system reliability.

Reliability Prediction begins as design engineers create or import a bill-of-material (BOM) and use the software to identify the expected reliability of parts in the BOM. The reliability of each part in a system–or, the probability of a part not failing under expected operating conditions–is combined to calculate overall system reliability. By considering alternate system designs, engineers can identify more reliable systems, subsystems, and components in order to better meet system objectives as defined in the requirements definition and quality planning stages of the product lifecycle. With a working system model, system reliability can be calculated for various operating conditions, and parts can be easily changed out to consider alternate designs without the need to build expensive prototypes.

Optimization and Simulation

Windchill Risk and Reliability's optimization and simulation technology combined with intuitive reliability block diagrams enables design engineers to create more sophisticated product models using a variety of advanced techniques: including series systems, redundant systems, parallel redundancy, load sharing redundancy, and hot/warm/cold standby operating conditions. These techniques help improve product reliability during the design stage of product development–before prototype products are ever tested or built–as well as compute key system metrics including system availability, reliability, cost, and service needs

such as projected repair/replacement periods or required preventive maintenance activities.

Improved product reliability translates into reduced costs downstream by preventing issues like warranty claims, re- pair, recall, and replacement. And the ability to proactively identify maintenance needs, forecast personnel and spares resources, and create more reliable products before a prototype is built all contribute to lower-cost, more efficient processes throughout the product lifecycle.

Risk & Reliability Analysis

FMEA (Failure Mode and Effects Analysis)

Windchill Risk and Reliability's Failure Mode and Effects Analysis (FMEA) module is used to systematically identify all of the potential failures throughout a system and develop controls to minimize or prevent their occurrence or effects. FMEA is a bottom-up analysis technique that identifies each failure mode beginning with the lowest-level components in the system, and examines the effects of their failures on higher levels of the system. It uses system hierarchy to trace the effects of failures up through the system in order to identify and categorize negative effects at the subassembly, assembly, and system levels.

FMEA is an extremely flexible analysis tool that is used starting in the design stage of products and systems to identify and prevent or mitigate sources of safety risks and product failures. However, its reach also extends to the testing and manufacturing stages of product development due to its various types as well as to its powerful outputs.

Various types of FMEAs are used in QLM to identify failure modes, causes, and controls in light of the various functional requirements of the product, according to the specific components and assemblies in the system design, and in consideration of the product risks that could arise from manufacturing procedures.

> "Process FMEA proved itself as a design tool that can help identify and mitigate assembly errors before they ever occur."
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> ASME

- A Functional or System FMEA focuses on the functions or requirements that a product is designed to fulfill. It identifies the required functions of the product, the ways in which the product could fail to meet these requirements–also known as failure modes –and the causes of each failure mode. This type of FMEA is used in the design stage of products and systems, is essential to quality planning, and is a key link to product testing due to its output–the Design Verification Plan or DVP (defined below).
- A Design or Component FMEA, also known as a piece- part FMEA, is focused on part risk and reliability. It identifies the components, subassemblies, and assemblies that make up a system in order to consider the ways in which they can fail and the effects that each of these failures can have on product operation. A Design FMEA can map to functional requirements indicated in the Functional or System FMEA, making it a powerful tool in an overall QLM solution because it connects product requirements with the parts that sustain them, the possible ways in which those parts can fail, and therefore the ways in which the product can fail to meet its requirements. A Design FMEA can also analyze the effectiveness of controls introduced to prevent part and functional failure. Important outputs from the Design FMEA are the DVP and, less frequently, Control Plans.
- A Process FMEA or PFMEA examines the ways in which manufacturing processes can affect device operation and product quality. It may also be applied to the way in which the tool is used, systematically identifying the consequences of improper use on device failure and/or potential hazards. In QLM, the PFMEA is used to identify risks to part quality, and therefore product quality, that could be caused by the manufacturing process. The output of a PFMEA that is most commonly used in QLM is the Control Plan.

- A Design Verification Plan, or DVP, is a test plan which may be output from a Functional FMEA or a Design FMEA. A DVP is used to validate the requirements of a system, and is linked to the design requirements specified in the FMEA to show whether or not that requirement has been met. It includes information about how the functional or component requirement will be met, including the specific tests, when they will be run and by whom, benchmarks for passing/failing the test, the test results, and whether the test was passed or failed.
- A Control Plan is most commonly output by the Process FMEA, but because controls are implemented as part of the Design FMEA, it may occasionally be an output from the Design FMEA, as well. Control Plans are used to specify and implement controls that prevent or mitigate the risks to product quality that may arise during manufacturing, as identified in the Process FMEA. For example, a Control Plan can define specific methods used to identify and minimize variations caused by the manufacturing process, ensure process control during manufacturing, and test or measure products prior to shipping to ensure specific requirements are met. The Control Plan is a living document that can be modified during manufacturing so that necessary feedback can be communicated to design or testing. This feedback can include manufacturing realities such as process limitations, machine tolerances, etc., or it may include best practices identified by manufacturing to support product quality.

Fault Three Analysis

Windchill Risk and Reliability's Fault Tree Analysis (FTA) module quantifies system risk and reliability to enable targeted decisions about design, maintenance, and controls that can reduce the likelihood of system failure. During Fault Tree analysis, a graphical representation of a product's critical safety/failure issues is constructed in order to identify all possible causes and contributing factors.

In contrast to FMEA, which is a bottom-up method starting with the lowest-level functions or parts and examining their effects on higher-level system failure or risk, Fault Tree is a top-down analysis method. In Fault Tree Analysis, the undesirable end event is identified first, and then the lower-level factors or events that contribute to the undesirable top-level event are identified.

In Windchill Risk and Reliability, Fault Tree and FMEA technologies may be used together. A FMEA may be generated from the lower-level failures that have been attributed to a high- level end event in a Fault Tree. That FMEA is used to identify other effects that the lower-level failures could have throughout the system. Similarly, when a FMEA process has identified system-level failures caused by failures in lower levels of the system, a Fault Tree analysis can be performed to identify other causes that may contribute to the same system-level failure.

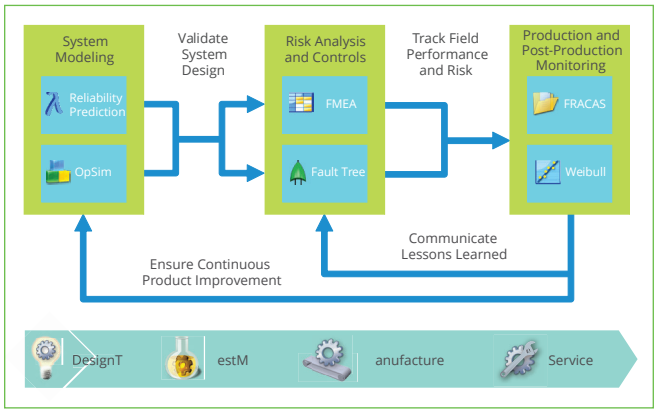

Figure 6. The Windchill Risk and Reliability modules integrate seamlessly to enable QLM.

Closed Loop Corrective Action System

FRACAS (Failure Reporting, Analysis, and Corrective Action System)

When errors occur during testing or fielded use, FRACAS captures failure data and facilitates the implementation of closed loop corrective action processes. FRACAS is used in QLM as early as the testing phase of the product lifecycle and throughout fielded service and use. By providing widely-accessible, web-based forms for failure or incident reporting, FRACAS ensures a standardized format for all errors or incidents reported. And with customizable workflow capabilities, FRACAS electronically advances each reported issue through the stages of root cause analysis, corrective action, review, and close-out using automated workflows and alerts, ensuring that every recorded issue is addressed.

Because it resides on the Windchill Risk and Reliability platform with other analysis methodologies, Windchill's FRACAS capability is tightly integrated with the QLM tools used throughout the product lifecycle. For example, due to the tight functional integration between the Windchill Risk and Reliability modules, FMEA records, including DVPs, may be tied to FRACAS incidents. That way, as issues are found during product testing, they may be communicated back to design engineers to ensure they are evaluated and corrected in light of product requirements to minimize found risks.

In addition, any failure modes found, recorded, and corrected during fielded use via a FRACAS–including those found during product repair, service, or return–can be output to FMEA for the design of risk controls, tests to verify the effectiveness of these controls, and a broader analysis of their impact on the system. And because this information is stored within the same software database, it can easily be recalled later, during next-generation product design or when considering alternate system configurations. Windchill Risk and Reliability can automatically populate the new analysis with lessons learned and best practices related to the particular system, component, failure mode, or cause under consideration.

Finally, data gathered in FRACAS from either testing or fielded use can be analyzed using Windchill's Weibull to determine the characteristic failure behavior of products or of their component parts and assemblies. This information can be used to validate early reliability prediction analyses that took place during design and development, and feed real- world product data into new product designs through function- al links between the Windchill Risk and Reliability modules.

Quality Governance

Nonconformance

Windchill Risk and Reliability's Nonconformance module facilitates the management of all activities associated with nonconformance handling in a regulated environment. Leveraging valuable internal information related to quality–including test results, manufacturing inspections, and supplier lots–Windchill Nonconformance enables initiation, evaluation, assignment, monitoring, and review of each nonconformance to ensure it is addressed in a closed-loop manner. Seamless integration with CAPA ensures that all reported nonconformances are addressed with corrective/preventive actions in a timely manner as part of a closed-loop, enterprise-wide quality management process.

Handling Customer Complaints

Windchill Risk and Reliability's Customer Complaints module provides for the intake, evaluation, and investigation of customer feedback for fielded products in a regulated environment. With the ability to generate and electronically submit regulatory reports for the medical device field, and seamless integration with CAPA, Windchill Risk and Reliability's Customer Complaints ensures that every re- corded item is addressed with closed-loop functionality that is highly structured, automated, and repeatable.

CAPA

Windchill Risk and Reliability's CAPA (Corrective Action/Preventive Action) module enables a closed loop corrective action workflow to address the root cause analysis, corrective or preventive action identification, and resolution of product or process quality issues identified from internal or external sources. In addition to providing for the role-based workflow and management review of CAPAs, Windchill Risk and Reliability enables the monitoring, tracking, review, and audit of system-wide CAPAs, providing a single view into the safety, manufacturing, and performance trends covering the lifespan of a product.

The Windchill Risk and Reliability modules are tightly integrated within a single database platform to enable QLM most efficiently.

The characteristics of a successful QLM solution

A successful QLM solution requires the seamless integration of analysis methodologies to enable cross-functional quality activities, enterprise-level accessibility to support personnel collaboration, and structured workflow tools to implement closed loop quality processes: all of which are realized in the Windchill Risk and Reliability software suite.

Integration

- Windchill Risk and Reliability encompasses a single software platform facilitating a full range of quality-related activities and analyses
- Windchill Risk and Reliability enables the easy, automatic output of data from one analysis type to the next
- Windchill Risk and Reliability implements functional links between key quality-related lifecycle activities

Accessibility

- Windchill Risk and Reliability provides enterprise-wide access via a web-based platform for all quality-related personnel, regardless of location
- Windchill Risk and Reliability supports the efficient reporting of high-level quality information for use by top management personnel

Structure

- Windchill Risk and Reliability facilitates a standardized methodology to capture quality issues found during any stage in product development
- Windchill Risk and Reliability offers highly structured workflow tools to ensure the communication of quality issues to responsible personnel
- Windchill Risk and Reliability supplies built-in tools to automate the reuse of lessons learned captured in any product lifecycle stage