PTC®

the product development company®

Quality Lifecycle Management

MANAGE QUALITY, RELIABILITY, AND RISK THROUGHOUT THE PRODUCT LIFECYCLE

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.

Why manage product quality?

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

- Serve as a "single source of truth" providing insight for all stakeholders into the current state of product quality

- Connect top management and decision makers with critical information to make informed decisions that impact quality

- Help personnel across the product development lifecycle understand the quality impact of their development activities

- Unite the quality-related processes that occur throughout the product lifecycle

QLM meets the need for…

- Quality planning: Define functional needs ahead of time and link requirements with product characteristics

- Early insight into product quality, reliability, and risk: Identify how safe and reliable a product is during the design stage
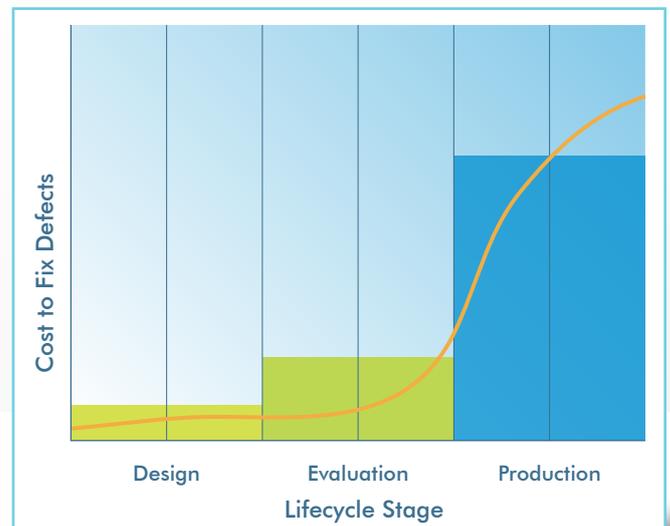
The cost of fixing defects increases as the product development lifecycle progresses. Cancelled programs, delayed launches, warranty claims, recalls, and aftermarket repairs all contribute to the high cost of not managing quality.

- Cost planning: Avoid the cost of poor product quality, boost company reputation, and save money with more reliable products

- Communication and reuse of lessons learned: Ensures corrective actions are communicated to improve products and services

What is QLM?

Quality Lifecycle Management, or QLM, 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 the entire lifecycle

- Align functional needs to product requirements

- Ensure requirements are met by specific product characteristics

- Track characteristics systematically throughout the lifecycle

- Identify quality issues and initiate corrective actions

- Communicate and reuse corrective actions to improve products
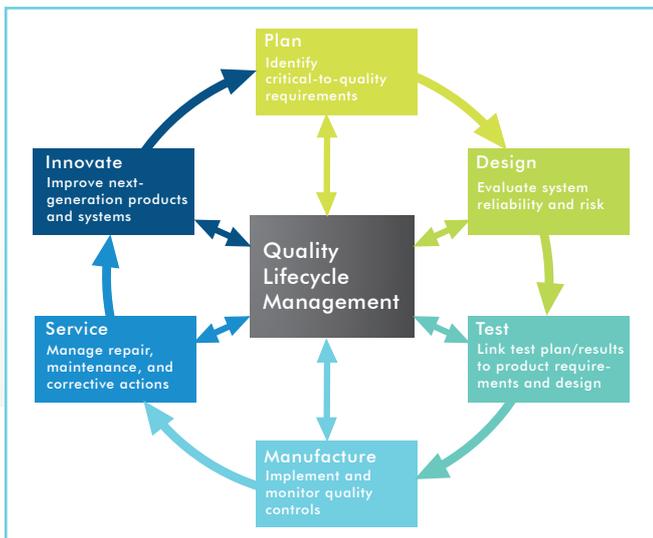
Quality Lifecycle Management, or QLM, unites the quality-related activities of each stage in the product lifecycle through a single database platform.

Benefits of QLM

QLM links together each of 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 other relevant stages, creating a unified, holistic model of overall product quality.

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

- A highly structured solution automating the workflow of quality information and feedback between product lifecycle stages

- Complete management visibility into key dimensions of product safety and reliability at any lifecycle stage

- 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

- A fully documented history of product development from a quality perspective

QLM at each product lifecycle stage

QLM enables the integration of all lifecycle processes used to ensure product quality, including:

- Planning: QLM begins 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 risks. This is done before the more expensive phases of prototyping and manufacture have 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 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 to define and implement manufacturing control measures that 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 reported for the initiation of root cause analysis and corrective actions essential to product improvement in current and next-generation designs.

- Innovate: Product failure and performance data is collected from the fielded use of products, and combined with lessons learned throughout all phases of product development, creating a common database of best practices. This database drives innovation by providing a single source of truth through which further product development activities are filtered during next-generation product design.

- 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.

Tools of QLM

System Modeling

Windchill Prediction

Reliability Prediction begins as design engineers create or import a bill-of-material (BOM) and use software to calculate the expected reliability of the parts, subsystems, and assemblies that make up the BOM.

Windchill OpSim

Windchill OpSim combines intuitive reliability block diagramming with optimization and simulation technology, enabling design engineers to create sophisticated product and system models, as well as to calculate key system metrics such as availability, reliability, and maintenance and spares optimization.
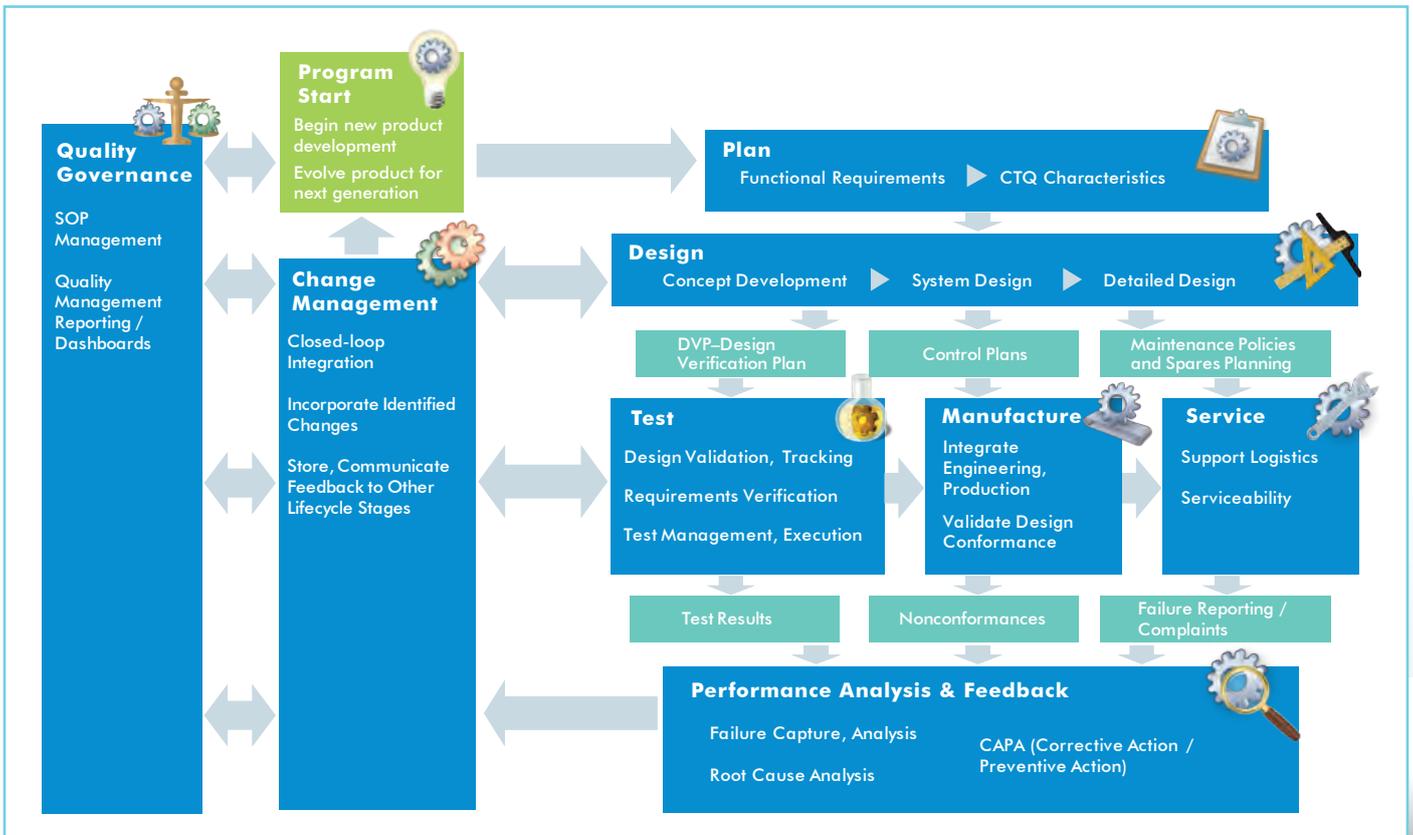
QLM is a closed loop solution to ensure that quality, reliability, and risk planning influence every stage of the product development lifecycle; information flows freely from one stage to the next; and corrective actions are captured and reused to improve next-generation products.

Reliability and Risk Analysis

Windchill FMEA (Failure Mode and Effects Analysis)

A 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.

The types of FMEAs used in QLM and their outputs are as follows:

- A Functional or System FMEA focuses on the functions or requirements that a product is designed to fulfill. It is used early on, in the design stage of products and systems.

- A Design or Component FMEA, also known as a piece-part FMEA, is focused on part risk and reliability. It identifies the component parts, subassemblies, and assemblies 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.

- A Process FMEA or PFMEA examines the ways in which manufacturing can affect device operation and product quality.

- 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.

- A Control Plan is most commonly output by the Process FMEA. Control Plans are used to specify and implement controls that will prevent or mitigate the risks to product quality that may arise during manufacturing, as identified by the Process FMEA. The Control Plan communicates feedback to design and testing.

Windchill FTA

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

Closed Loop Corrective Action System

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

When errors occur during testing or fielded use, Windchill FRACAS captures failure data and facilitates the implementation of closed loop corrective action processes. Windchill FRACAS is used in QLM as early as the testing phase of the product lifecycle and throughout service and use.

Quality Governance

Windchill Nonconformance

Windchill Nonconformance 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.

Windchill Customer Complaints

Windchill Customer Complaints 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 Windchill CAPA, Windchill Customer Complaints ensures that every recorded item is addressed with closed-loop functionality that is highly structured, automated, and repeatable.

Windchill CAPA

Windchill CAPA (Corrective Action / Preventive Action) 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 CAPA 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.

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 Quality Solutions software suite.

Integration

- Windchill Quality Solutions encompass a single software platform facilitating a full range of quality-related activities and analyses

- Windchill Quality Solutions enable the easy, automatic output of data from one analysis type to the next

- Windchill Quality Solutions implement functional links between key quality-related lifecycle activities

Accessibility

- Windchill Quality Solutions provide enterprise-wide access via a web-based platform for all quality-related personnel, regardless of location

- Windchill Quality Solutions support the efficient reporting of high-level quality information for use by top management personnel

Structure

- Windchill Quality Solutions facilitate a standardized methodology to capture quality issues found during any stage in product development

- Windchill Quality Solutions offer highly structured workflow tools to ensure the communication of quality issues to responsible personnel

- Windchill Quality Solutions supply built-in tools to automate the reuse of lessons learned captured in any product lifecycle stage

For more information

For more information on Windchill Quality Solutions, please visit: PTC.com/products/windchill/quality

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