Quality Assurance (QA) and Quality Control (QC) for Manufacturers

Quality assurance and quality control both play vital and distinct roles in manufacturing organizations. Understanding those roles can help your organization master each to deliver the best products possible.

Quality Assurance vs. Quality Control: 5 Differences

Quality assurance (QA) are actions taken to design and manufacture a safe and effective product by building quality controls into the product life cycle.

Quality control (QC) are test procedures used to verify that a product is safe and effective after manufacturing is done. Both QA and QC are necessary.

1. Proactive (QA) vs. Reactive (QC)

Effective quality assurance is proactive. It aims to prevent defects before they occur through process design. QC is reactive and exists to identify defects after they have happened.

QA involves the design of processes, such as documenting standard operating procedures (SOPs). A safe, effective product should be the result every time processes are followed. QC involves the testing of products to ensure they meet standards for safety and efficacy. If QC testing uncovers quality issues, it should result in reactive steps to prevent an unsafe product from being shipped and distributed.

Ideally, QC issues should also spark a QA review. Non-conforming test results should result in corrective and preventive action (CAPA) investigation to determine the root cause of quality issues and update processes to prevent the problem from happening in the future.

2. Process (QA) vs. Product (QC)

QA is process-oriented, and it focuses on preventing quality issues. QC is product-oriented and focused on identifying quality issues in manufactured products. Another way to understand this distinction is actions vs. results. QA involves the actions which create the product, while QC is focused on the resulting product. Several examples of each type of activity are detailed below.

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QA Processes:

- Documentation
- Audits
- Supplier management
- Personnel training
- Change control
- Investigation procedures

QC Procedures:

- Batch inspection
- Product sampling
- Validation testing
- Laboratory testing
- New call-to-action

3. System (QA) vs. Parts (QC)

Quality assurance control systems are the methods and procedures which are used to safeguard quality standards. Quality control systems measure parts, including the outputs of the system.

QC efforts may also be focused on parts used to create the final product, such as raw materials from a supplier. The QA system for quality management may dictate various activities to make sure inputs are consistently safe and effective, such as auditing suppliers and batch sampling raw materials.

4. Creation (QA) vs. Verification (QC)

The result of QA activities is a roadmap for creating high-quality products. It involves defining standards for product design, manufacture, packaging, distribution, marketing, and sales.

QC involves verification of products post-manufacture and before distribution, or confirming safety and efficacy.

5. Entire Team (QA) vs. Dedicated Personnel (QC)

Quality assurance activities involve the entire team. Every member of a manufacturing organization is responsible for QA activities by following SOPs. While the quality management system (QMS) is generally the responsibility of the quality unit and the leadership team, QA activities involve standards for training, documentation, and review across the workforce.

QC is generally the responsibility of certain personnel within the organization whose duties include following SOPs for product testing. QC staff follow SOPs for quality control and document their findings based on standardized procedures for product testing and process validation.

The Role of an eQMS in Quality Assurance and Quality Control

QC and QA are better together, and they're best when both are incorporated into an enterprise quality management system (eQMS) for end-to-end quality processes. A QMS can integrate processes for assuring and controlling quality through document control and training, CAPA management and complaint handling throughout the product life cycle.

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