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TO UNDERSTAND THE RESPONSIBILITY OF QUALITY ASSURANCE AND QUALITY CONTROL DEPARTMENT IN PHARMACEUTICAL INDUSTRY

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1. ABSTRACT

The terms "quality" are used interchangeably in the medical radiology professions due to the historical and current evolution of practice, technology, terminology, and programs related to quality. Quality Control (QC), Quality Assurance (QA), and Management (QM) in colloquial terms. The purpose of this White Paper is to clarify QM, QA, and QC in the context of medical physics and to offer guidance on the proper usage of these terms in the American College of Radiology (ACR) Practice Parameters and Techni-call Standards, which can be applied to other guidance initiatives. The explanation of these complex terms in nuclear medicine, radiology, and radiation oncology environments will not only make the Medical Physics Technical Standards and Practice Parameters easier to understand and use, but they will also give ACR's clinical physician-led Practice Parameters—which also use these crucial terms for monitoring equipment performance for safety and quality—a foundation and clarity. Additionally, by offering a common framework that differentiates the different kinds of responsibilities carried out by medical physicists and others in the medical radiological environment this will support the continued development of the professional practice of clinical medical physics. Examples of how QM, QA, and QC can be used in relation to ACR Practice Parameters and Technical Standards are given.

- **KEYWORDS:** medical physics, quality assurance, quality control, quality management.

2. INTRODUCTION

Maximizing the patient's clinical benefit is a cornerstone of medical practice, while mini-minimizing risks that are related to the patient and their caregivers. Applying this principle in the various fields of radiology, radiation oncology, nuclear medicine and molecular imaging, medical physics, and different imaging-guided medical procedures may entail maximizing therapeutic gain, diagnostic image quality, and/or image guidance accuracy (relevant to treatment planning or performing medical procedures).

These The objectives of the American College of Radiology (ACR) clearly highlight the vital significance of quality and safety programs. The ACR Commission on Quality and Safety oversees and manages all radiology quality and safety initiatives and programs, including Practice National Radiology Data, Appropriateness Criteria®, accreditation programs, centers of excellence, parameters and technical standards, and quality measurements Imaging-RADS, RADPEERTM, and Registry.

The terms Quality Management (QM), Quality Assurance (QA), and Quality Control (QC) are interchangeable in the vernacular due to the historical and current evolution of the practice, technology, terminology, and implementation of programs related to quality in the radiological sciences. A well-structured and comprehensive discussion of QM, QA, and QC was presented in AAPM Report 283 (Task Group 100)2. This discussion was combined with risk analysis techniques and applied with remarkable detail for Intensity Modulated Radiation Therapy (IMRT).

This White Paper's two main goals are (a) to recapitulate the usage of these three terms and (b) to offer instances of the general application of QM, QA, and QC in medical physics, with a focus on ACR's Practice Parameters and Technical Standards. Under the direction of ACR's

3. QA DEFINATON

Pharmaceutical product safety, effectiveness, and dependability are all dependent on quality assurance (QA). It is a thorough framework of guidelines, practices, and initiatives intended to incorporate quality into each phase of the creation and manufacturing of pharmaceuticals. QA's main goal is to strengthen systems and procedures in order to prevent errors in addition to finding them.

Good Manufacturing Practices (GMP), process validation, instrument calibration, documentation control, supplier qualification, auditing, and employee training are just a few of the components that make up quality assurance.

It guarantees that all processes, from the acquisition of raw materials to the release of the finished product, are carried out in compliance with established quality standards and legal requirements. Documentation, sometimes known as "If it isn't written, it didn't happen," is another essential component of quality assurance. Traceability and accountability are ensured by appropriate documentation in batch records, SOPs, deviation reports, and change controls. Internal audits, which assist in finding gaps and putting corrective and preventive measures (CAPA) into place, are also managed by QA.

Pharmaceutical companies maintain consistent product quality, adhere to regulatory requirements, prevent manufacturing errors, and guarantee patient safety through the use of strong quality assurance systems. In the end, by ensuring high standards of quality and dependability, QA fosters trust between the manufacturer, regulatory bodies, and patients.

- **QUALITY ASSURANCE**

Fig. No. 1

- **Role of QA in the Pharmaceutical Industry**

Fig. No. 2

1. Establishing Quality Systems

QA designs and maintains key systems such as Good Manufacturing Practices (GMP), Standard Operating Procedures (SOPs), and quality policies.

2. Documentation Control

QA ensures proper documentation including Batch Manufacturing Records (BMR), deviation reports, change controls, and SOPs. Good documentation is considered "*the backbone of GMP*.

3. Validation and Qualification

QA oversees equipment qualification, process validation, cleaning validation, and method validation to maintain reliability and reproducibility of processes.

4. In-Process Quality Control

QA reviews in-process checks to confirm that each step of manufacturing follows predefined specifications.

5. Change Control & Deviation Management

Any change in procedure, equipment, or materials must be evaluated by QA to ensure quality is not compromised.

6. CAPA (Corrective and Preventive Action)

QA implements CAPA to eliminate root causes of deviations and prevent recurrence.

7. Internal Audits

Regular audits ensure compliance with regulatory requirements and continuous quality improvement.

8. Product Release

QA gives the final approval for batch release after verifying all test results and documentation.

4. Responsibilities of Quality Assurance (QA) and Quality Control (QC)

1) Quality Assurance (QA)

1. Develop quality policies and procedures: Establish and maintain quality standards, guidelines, and procedures to ensure compliance with regulatory requirements.
2. Ensure compliance with regulatory requirements: Ensure that all aspects of the manufacturing process comply with relevant regulations, guidelines, and standards.
3. Conduct audits and inspections: Conduct regular audits and inspections to ensure compliance with quality standards and regulatory requirements.
4. Provide training and support: Provide training and support to ensure that personnel are aware of and comply with quality standards and procedures.
5. Monitor and improve processes: Continuously monitor and improve processes to ensure that they are effective and efficient.
6. Change control: Ensure that changes to processes, equipment, or materials are properly evaluated, approved, and implemented.
7. Risk management: Identify and mitigate risks associated with the manufacturing process.

2) Quality Control (QC)

1. Test and inspect products: Conduct tests and inspections to ensure that products required quality standards.
2. Release products to market: Release products to market only after they have been tested and meet required quality standards.
3. Detect and prevent defects: Detect and prevent defects or irregularities in products.
4. Investigate deviations and complaints: Investigate deviations, complaints, and adverse events, and take corrective action.
5. Maintain quality records: Maintain accurate and complete quality records, including test results, inspection reports, and certificates of analysis.
6. Stability testing: Conduct stability testing to ensure that products remain stable and effective throughout their shelf life.

7. Validate processes and methods: Validate processes and methods to ensure that they are effective and reliable.

3) Key Differences

1. Focus: QA focuses on preventing defects, while QC focuses on detecting defects.
2. Approach: QA is proactive, while QC is reactive.
3. Scope: QA covers the entire product lifecycle, while QC is typically focused on the manufacturing process.

- **Importance**

1. Patient safety: QA and QC ensure that pharmaceutical products are safe and effective.
2. Regulatory compliance: QA and QC help companies comply with regulatory requirements.
3. Product quality: QA and QC ensure that products meet required quality standards.

Fig. No. 3

#	Quality Assurance	Quality Control
1	Aims to prevent defects	Aims to identify and fix defects
2	Is a preventive technique	Is a corrective technique
3	Defines standards and procedures that need to be adhered to in order to meet customer requirements	Ensures that standards are followed while working on the product
4	Helps build processes	Helps implement the existing processes
5	Activities are determined before production work begins and performed while the product is being developed	Activities are performed after the product is developed
6	Is a managerial tool	Is a corrective tool
7	It is the duty of the complete project team	It is only the duty of the testing team
8	Comes under the category of verification.	Comes under the category of validation
9	Is a process oriented exercise	Is a product oriented exercise
10	Prevents the occurrence of issues, bugs or defects in the application	Detects, corrects, and reports the bugs or defects in the application
11	Does not involve executing the program or code	Involves executing the program or code
12	Done before Quality Control	Done only after Quality Assurance
13	Human-based checking of documents or files.	Computer-based execution of program or code
14	Is generally not a time-consuming activity	Is generally a time-consuming activity
15	Makes sure quality team is doing the right things in the right way	Makes sure that whatever the quality team has done is as per the requirement
16	Processes are planned to prevent defects	Processes are planned to discover defects and fix them

Fig. No. 4

5. Quality Control (QC) Responsibilities

A] Quality Control

1. The quality of the inventory is monitored and managed during its creation through a system of routine technical tasks known as quality control.
2. The quality control system's objective is to
3. To guarantee the accuracy, completeness, and integrity of the data, conduct regular, standard tests.
4. Find and correct mistakes and omissions.
5. Keep track of all Quality Control actions and record and preserve inventory items.

- **Quality Control (QC) Responsibilities**

Inspection & Testing: Performing physical checks, inspections, and measurements on raw materials, in-process steps, and finished products.

- **Verification**

1. Verifying that products adhere to certain standards and requirements.
2. Data Generation: Giving management and QA data to prove compliance
3. Defect Identification: Recognizing mistakes or deviations as they arise

- **Key Differences & Interplay**

1. Focus: QA is process-oriented (prevention); QC is product-oriented (detection).
2. Timing: QA is proactive (before production); QC is often reactive (during/after production).
3. Goal: QA provides confidence; QC verifies conformance.
4. Roles: QA sets the framework; QC executes checks within that framework.

Fig. No. 5

B] Application of quality control

Quality control is applied in various industries to ensure that products meet required quality standards.

- **Industry Applications**

1. Pharmaceutical industry: Ensures pharmaceutical products are safe, effective, and meet regulatory standards.
2. Food industry: Ensures food products are safe for consumption and meet quality standards.
3. Automotive industry: Ensures automotive parts and vehicles meet quality standards and are

reliable.

4. Aerospace industry: Ensures aircraft and spacecraft meet quality standards and are safe.

- **Key Applications**

1. Product inspection: Inspecting products to detect defects or irregularities.
2. Process control: Monitoring and controlling processes to ensure they operate within specified limits.
3. Testing and calibration: Conducting tests and calibrating equipment to ensure accuracy and reliability.
4. Supplier quality management: Managing supplier quality to ensure raw materials and components meet quality standards.

- **Benefits**

1. Improved quality: Ensures products meet required quality standards.
2. Increased customer satisfaction: Helps increase customer satisfaction by ensuring products are reliable and meet their needs.
3. Reduced costs: Helps reduce costs by detecting defects early and preventing waste.

6. Application of quality Assurance

Quality Assurance (QA) is a systematic process designed to ensure that products or services meet specific requirements and standards. Here are some detailed applications of QA:

1. Software Development

- Ensuring software meets requirements and is reliable
- Identifying and fixing bugs and defects
- Improving software development processes and methodologies (e.g., Agile, Scrum)

2. Manufacturing

- Improving production processes and product quality
- Reducing defects and waste
- Implementing quality control measures (e.g., Six Sigma, Lean)
- Conducting audits and inspections
- Ensuring compliance with regulatory standards (e.g., ISO 9001)

3. **Pharmaceuticals**

- Ensuring drug safety and efficacy
- Conducting clinical trials and testing
- Validating manufacturing processes
- Ensuring compliance with Good Manufacturing Practices (GMP)
- Monitoring and reporting adverse events

4. **Healthcare**

- Enhancing patient care and safety
- Improving clinical processes and outcomes
- Conducting medical audits and reviews
- Ensuring compliance with regulatory standards (e.g., HIPAA)
- Implementing electronic health records (EHRs)

5. **Aerospace**

- Ensuring safety and reliability of aircraft and spacecraft
- Conducting safety audits and inspections
- Implementing quality control measures (e.g., AS9100)
- Ensuring compliance with regulatory standards (e.g., FAA, EASA)
- Testing and validating aircraft systems

6. **Food Industry**

- Ensuring food safety and quality
- Conducting food safety audits and inspections
- Implementing quality control measures (e.g., HACCP, ISO 22000)
- Ensuring compliance with regulatory standards (e.g., FDA, FSSAI)
- Monitoring and controlling food production processes

7. **Automotive**

- Improving vehicle safety and performance
- Conducting quality audits and inspections
- Implementing quality control measures (e.g., IATA, ISO/TS 16949)
- Ensuring compliance with regulatory standards (e.g., ISO 26262)
- Testing and validating vehicle systems

7. CONCLUSION

In summary, QA and QC are essential components of the pharmaceutical industry, ensuring that products are safe, effective, and meet regulatory standards. QA focuses on preventing defects, while QC focuses on detecting defects. By working together, QA and QC professionals help ensure the quality and integrity of pharmaceutical products. Quality Control and Quality Assurance are two essential pillars of the pharmaceutical industry that work together to ensure the safety, purity, effectiveness, and reliability of medicines.

Quality Assurance focuses on building a strong system, implementing procedures, and preventing errors, while **Quality Control** ensures that every product meets predefined quality standards through testing, inspection, and verification. Together, QA and QC ensure that medicines are consistently produced and controlled according to regulatory requirements such as GMP (Good Manufacturing Practices). Their combined effort helps maintain customer trust, reduce risk of product failure, and support the overall goal of delivering high-quality and safe pharmaceutical products to patients.

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