Quality vs. Regulatory – Key Similarities and Differences

Quality and Regulatory Affairs (RA) are critical functions within an organization. With that said; however, how are they similar? How are they different? What is Quality Assurance (QA) as opposed to Quality Control (QC)?

This White Paper provides a discussion on fundamentals of Regulatory Affairs as well as Quality, including QA vs QC. This will help to define key similarities and differences between the functions, as well as how certain roles can be considered both QA and RA.

What Is Regulatory Affairs and the Regulatory Profession?

The professional organization, Regulatory Affairs Professionals Society (RAPS), provides the following description of the regulatory function:

> *The regulatory function is vital in making safe and effective healthcare products available worldwide. Individuals who ensure regulatory compliance and prepare submissions, as well as those whose main job function is clinical affairs or quality assurance are all considered regulatory professionals.*
>
> *Regulatory professionals are employed in industry, government and academia and are involved with a wide range of products including:*
>
> - *Pharmaceuticals*
> - *Medical devices*
> - *In vitro diagnostics*
> - *Biologics and biotechnology*
> - *Nutritional products*
> - *Cosmetics*
> - *Veterinary products*
>
> *The regulatory professional's roles and responsibilities often begin in the research and development phases, moving into clinical trials and extending through premarket approvals, manufacturing, labeling and advertising, and postmarket surveillance.*

What Is Quality (Including QA vs QC)?

RAPS publication, Fundamentals of US Regulatory Affairs, has provided a discussion on this topic:

> *Drug Good Manufacturing Practices (GMPs) describe the "quality control unit" (21 CFR 211.22). However, in most companies, the responsibilities described in this section of the regulations are assigned to the QA group. Regulatory affairs professionals should understand that the term "quality control unit" as used in the drug GMPs is much broader than the term "quality control" as generally used in industry. Quality control is the process through which actual quality performance is measured and compared to standards, and any differences or similarities are acted upon. Quality assurance is the activity of providing evidence required to establish confidence that the quality function is being performed adequately. Quality control is actually controlling the product. Quality assurance, which is broader than quality control, involves developing confidence that the product will perform as expected and that quality control is doing its job properly. Quality control alone is not enough. The specific terms used to describe QA versus QC functions within a company are not important for GMP compliance. What is important is that the critical quality control unit functions described in the regulations are being executed and are independent from manufacturing or other units that might pose a conflict of interest with the QA/QC function.*

> *The production staff tries to produce the most goods, in the least time and space, at the lowest cost. QA/QC personnel are trying to certify high-quality goods.*

Practical Application

To illustrate the application of the above concepts, the following practical and basic examples are provided:

Regulatory Affairs (RA)

The Regulatory Affairs role within an organization may be responsible for performing regulatory assessments for new products or changes to existing products. This may include updates to device listings and/or registrations, as applicable. It may also include regulatory submissions such as Premarket Approval

(PMA), 510k, etc. This also applies to products intended for international distribution and may include additional submission requirements such as Technical Files, Design Dossiers, etc. These submissions may incorporate product information such as Indications For Use, materials, drawings, test data, etc. They may also include details relative to clinical trials, manufacturing, labeling, postmarket surveillance methods, etc.

Quality Assurance (QA)

The Quality Assurance role within an organization may be responsible for implementation of Quality Management Systems. This includes procedural requirements for multiple aspects relating to Quality and is implemented on the front end (pre-production initiation). Quality Assurance provides the inspection / test detail to be executed by the Quality Control function and aids in assurance that the product will perform as expected. Quality Assurance may provide oversight to Quality Control functions.

Quality Control (QC)

The Quality Control role within an organization may be responsible for conducting product inspection / test against the specification criteria (accept / reject) established by Quality Assurance. Quality Control activities are implemented on the back end (post-production initiation) to ensure that product meets applicable acceptance criteria at appropriate production phases and prior to product release.

QA and QC roles require management empowerment to carry out their responsibilities. Neither QA nor QC should report to individuals responsible for product manufacture due to a potential conflict of interest. Production personnel goals are established by quantity, where Quality personnel goals are established by quality.

Quality Assurance / Regulatory Affairs (QA/RA)

Often times, organizations recognize the interrelationship between Quality Assurance and Regulatory Affairs. QA and RA functions can go hand in hand. This may result in the establishment of a QA/RA role which manages the requirements of both Quality Assurance and Regulatory Affairs functions. This is also aligned with the RAPS description of the regulatory function which includes:

> *Individuals who ensure regulatory compliance and prepare submissions, as well as those whose main job function is clinical affairs or quality assurance are all considered regulatory professionals.*

Summary

Quality and Regulatory Affairs (RA) are important functions within an organization. Although there are key elements within Regulatory Affairs, Quality Assurance and Quality Control functions, there is also an interrelationship between these. Specific terminology for QA / QC is noncritical as long as functions described within the regulations are being executed appropriately and are independent from potential conflict of interest. Alignment of Quality Assurance and Regulatory Affairs responsibilities to allow for the performance of required activities by a single role (QA/RA) is allowable and may be appropriate based upon organizational needs.

About the Author: Nola Benstog is a diversified professional with a thorough knowledge of Quality Management Systems. She has over sixteen years of experience in the areas of Quality Assurance, Quality Control, Regulatory Affairs, Validation and Sterilization in both industry and consulting roles. She has worked in the medical device, pharmaceutical, combination product and nutritional supplement industries with experience ranging from start-ups to Fortune 100 and 500 companies. She began her career as a Technician in a Microbiology Lab and has held various positions up to the Executive Management level throughout her career. Nola received a Bachelor of Science in Microbiology from Weber State University and a Master of Business Administration from Utah State University. She has been an American Society for Quality (ASQ) Certified Quality Auditor (CQA) since 2007.