Quality Qorner

Lingo Lesson

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There are too many quality terms flying around out there. So many, in fact, that we are all prone to using them interchangeably, assuming they all mean the same thing. The cold fact is that quality terms have specific definitions and we need to learn the words and their respective meanings and how to use the words correctly when writing laboratory requirements, delivering educational programs, and publishing laboratory literature.

I consider the International Organization for Standardization (ISO) as the "mother of all quality management system documents." ISO is a worldwide federation of national standards bodies; our U.S. national standards body is the American National Standards Institute (ANSI). One very important document—ISO 9000[1]—provides the fundamentals and vocabulary for quality management systems and it's the glossary in this document I always turn to when I need the "official" definition of a quality term.

Here are some quality terms that are often used interchangeably—incorrectly—by presenters and accreditors alike: quality plan, quality planning, and quality program. Let me explain why, using the quality glossary published by the international experts.

A *quality plan* is a document specifying which processes, procedures, and associated resources will be applied by whom and when to a specific project, process, or product.[1] Examples include when blood samples are collected in plastic versus glass tubes (change in process); when your laboratory installs a new instrument for a specified set of laboratory tests (new project); and when your blood supplier decides to provide "Red Blood Cells, Leukocyte Reduced" for most, if not all, routine blood transfusions (new product). In each of the changes described above, a documented quality plan specifies how the implementation will unfold. In the instrument example, your laboratory would have a written quality plan for how the acquisition will occur; when specified activities in the installation, verification (or validation), and initial calibration will happen; and who is responsible for which activities.

One very effective way to prepare a quality plan is to use the 12 Quality System Essentials (QSEs) as a checklist for considering all the activities that need to take place and all the documents that need preparation. In the instrument example, you would go through each of the 12 QSEs, asking questions such as: Do we have the necessary floor space and environmental conditions for this new instrument? (QSE: Facilities and Safety.) Who will be responsible for setting up the orders for purchasing reagents, controls, and calibrators? (QSE: Purchasing and Inventory.) What is the validation (or verification) plan for these new analytes? (QSE: Process Control.) What proficiency testing needs to be ordered and when? (QSE: Assessments.) Gantt and PERT charts are additional project management tools that provide a visual representation of a quality plan. Think of a quality plan as a roadmap for all the myriad activities that need coordination for ensuring the success of such events. With the quality plan as a specific document that describes a single new or changed laboratory activity, a given laboratory would have several documented quality plans across time—one for each specific new or changed project, process, or product.

Quality planning is not the same thing as a quality plan. Quality planning is a management activity that focuses on setting quality objectives and specifying necessary operational processes and related resources to fulfill the quality objectives.[1] At least once a year, your laboratory's management team should come together and set quality objectives for each clinical discipline for the coming year and discuss how the respective laboratory sections intend to achieve the proposed objectives. For example, your laboratory's sample receiving area sets a quality objective to reduce the number of data entry errors by 50% within six months and the automated testing areas set a quality objective of delivering at least 95% of routine morning test results before the published turnaround time. Each area needs to specify *how* these objectives will be accomplished; that is, what new or changed processes or procedures will be needed, what improvements to the workflow will be made, etc. It's likely that the outcome of the quality planning session will be that you'll need some documented quality plans!

Neither a quality plan nor quality planning is the same as your laboratory's *quality program*. A documented quality program describes how quality activities are organized in your laboratory. For example, your laboratory might state that it has developed policies, processes, and procedures for managing each of the 12 QSEs and that these documents are contained in the laboratory's quality manual. It might also state that documented processes and procedures for the preanalytic, analytic, and postanalytic activities in the laboratory's path of workflow are located in section-specific manuals where the work is performed.

All those quality words flying around like buzzing bees! Well, we've captured a few here but there will probably be more lingo lessons, with the confusion between quality control, quality assurance, and quality management. Please don't think they are the same!

1. ISO. ANSI/ISO/ASQ Q9000–2005 Standard: Quality management systems—Fundamentals and vocabulary. Milwaukee: American Society for Quality Press; 2005.

This Month's Quality Quote:

"Zounds! I was never so bethumped with words…."
—*Shakespeare, King John*

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