The Role of Quality Assurance within the Pharmaceutical Quality System

by Dr. Bernd Renger

The pharmaceutical entrepreneur bears the responsibility for establishing an effective Pharmaceutical Quality System (PQS), defining and communicating duties and responsibilities and providing adequate resources for the system.

Both the EU GMP Guide, Part I, revised Chapter 1 and 21 CFR, Parts 210 and 211 of the FDA mention (and demand!) only one quality organizational unit in any given company. Both of these regulatory works call for this unit, which is referred to as Quality (Control) Unit, to be totally independent of production. Nevertheless, current industry practice generally divides the responsibilities of the Quality Control Unit (QCU) between Quality Control (QC) and Quality Assurance (QA) functions.

If a pharmaceutical company decides to divide the duties of the quality function into a control and an assurance function, the duties and responsibilities must be clearly defined to ensure that all individual aspects are correctly covered, and that no counterproductive redundancies and conflicts occur.

Quality Assurance as caretaker of the Pharmaceutical Quality System (PQS)

The obvious assumption would be that the establishment of an effective PQS belongs to the duties of a QA department or a QA Unit. However, even though many of the required elements are considered to be central duties of quality assurance, others can only be implemented through a networked organization that fully incorporates the appropriate specialized departments; they may even be handled completely under the auspices of other functions. Therefore, the most feasible way appears to be through a Quality Unit or a QA Department as a staff unit or global function with a direct line of reporting to the executive level or to senior management (see figure 1). In this case, the task of QA would be focused on providing the appropriate systems and defining them in higher-level instructions and SOP’s, and vice versa, on providing appropriate information and key figures for senior management).

![Figure 1: Possible organisational structure with a QA staff unit](http://www.gmp-publishing.com)
Quality assurance preparing the groundwork for certification by the Qualified Person

It is also possible to understand and shape the function of a QA department or unit with far more emphasis on operational aspects. It may be helpful to regard the function of quality assurance as consisting in the preparation of data for the Qualified Person for the certification and batch release. In this model it would then be the task of a QA organisation to generate portions of these batch-related data, to make them available through appropriate reporting systems and parallel to that to ensure the functionality of the classic quality systems. The division of labour between the Heads of Production, QC and QA entails a hierarchical equivalency of these areas (line function) (see figure 2).

![Figure 2: Possible organisational structure within an “operational” QA](image)

Quality on the Floor

Especially in larger, highly specialised organisations with long connecting pathways, it can make sense to break down the central function of a QA Unit (regardless of whether it is a staff function or a line function) and to delegate employees on the spot into other operational departments, particularly into Production. They would then be available around the clock as contact persons for quality on the floor. For this purpose the Quality employees must be provided with appropriate decision-making authority, thus ensuring short decision routes. In order for Quality managers and the managers of operational units to be partners on equal footing, Quality employees must possess well-founded special knowledge of the workflows in the operational unit.

Selecting the Organisational Form

The size and complexity of the company determines the structure of the pharmaceutical quality system as well as the layout of quality management. Whether or not the QA would then be implemented as an operational line function or a staff function lies within the discretion of the pharmaceutical entrepreneur. No supervisory function of QA over other Quality departments can be derived from any of the European or American regulatory works.

A detailed analysis of this issue can be found in our GMP MANUAL (Update 18), Chapter 19 A Quality Assurance Duties.

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