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What Your Organizational Design Says About Your Commitment To Data Integrity

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Data integrity is developed over the course of executing business operations rather than delivered as a solution after the fact. That is to say that the evolution of data integrity is the direct result of the maturation of quality systems and related processes. Often, we see this evolution occur in the establishment of new business operations and, simultaneously, with the product development life cycle. As a new business launches in support of the development of a new product asset, we have seen data integrity develop positively where management understands the value of data integrity and communicates that value throughout the enterprise.

Health authorities expect "the role of management with executive responsibility to create a quality culture where employees understand that data integrity is an organizational core value."[1] Even where the new business is small (e.g., only a handful of senior executives in a virtual startup), we have seen positive results in strong data integrity when a quality culture is adopted early in the product development life cycle. We have seen the positive effects of management support of a quality culture when data verification results in the confirmation of development data that will inform regulatory filings and make the downstream activities related to auditing conformance to file before submission more efficient.

Quality Is Everyone's Responsibility

Management support is vital in establishing a positive quality culture that results in robust data integrity. That support often begins with an understanding that everyone in the organization has an impact on the quality culture – that it is not simply the responsibility of the quality function. Without such an understanding and "in the absence of management support of a quality culture, quality systems can break down and lead to CGMP noncompliance"[1] or worse (e.g., negative impact to consumers or patients).

The assessment and measurement of an organization's quality culture includes both objective and subjective interpretation. There are quantitative measurements that may be assumed to correlate (e.g., deviation aging, number of product recalls, repeat human errors), but we have found that these measurements alone cannot accurately indicate the quality culture of an organization. Qualitative measurements must also be added for consideration, such as the result of stakeholder interviews, detailed review of investigations, and evaluation of the content (not simply the completion list) in personnel training records. In short, we find that measuring an organization's quality culture requires as much art as it does science.

Organizational design is one quantitative measurement that we have seen inform an assessor's or investigator's impression of management commitment to the responsibility for quality culture. These measurements are very simple to capture through review of organizational charts or staff directories. The total number of staff in each of the functional areas as compared to the total number of staff in the quality function may be interpreted to inform an opinion, fairly or not, of the management commitment to quality (which informs robust data integrity).

Quality Staff In The Numerator

We have often seen established companies develop some level of staffing algorithm or formula that commonly includes a ratio of quality staff to (for example) the number of manufacturing sites, operational staff, or products. These established companies frequently have the advantage of many years (sometimes decades) of historical staffing and operational data that may inform organizational design down to the functional level, including quality.

Startup or virtual companies typically do not have the same advantage. Even when led by experienced executives, the new business venture often presents a unique or innovative solution that requires prospective consideration of the organizational design. A common misconception that we've seen in the establishment of these companies is the thought that fewer qualify function staff are required when manufacturing is performed by a contract organization. That is to suggest that when operations are outsourced, staffing is reduced (including quality staff). While this is generally accurate, we find that oversight of completely virtualized operations requires sufficient quality staff to ensure that quality standards are met and maintained. The values, principles, and cultures of a virtual company are not significantly different from those of a traditional business; however, a virtual company has greater challenges

presented by (among other things) the various contract organizations for operations. We have seen this point lost on some executives who bring the traditional staffing algorithm or formula from their previous jobs to their current responsibilities in the new business venture.

To see how organizational design may be interpreted to inform impressions of quality culture and, therefore, commitment to data integrity, consider the following examples. Imagine a 500-person firm with virtual laboratory and manufacturing operations that support one commercial product and more candidates in the pipeline in various stages of clinical study. Of the 500 employees, less than 3 percent of the total staff are dedicated to the quality function (both quality assurance and quality control). Compare that to the more than 22 percent that make up the combined support functions of information technology, finance, and legal, and the difference may lead to an impression of a lack of commitment to quality culture.

In another example, the information technology (IT) department of a 400-person company is staffed at nine times the number of computer system validation (CSV) staff. This company also had one commercial product and more candidates in the pipeline in various stages of clinical study. The disparity between CSV and IT staff could be interpreted as the company having a greater commitment to laptop computer support for sales staff than quality support for technology that is critical to laboratory operations and manufacturing automation.

In summary, it is critically important to be cognizant of your responsibilities for or contributions to quality culture and to be aware of the related impact on the evolution of data integrity. Understanding how to be appropriately staffed and being prepared to explain any perception of inequity could mean the difference between success and failure of appropriate data integrity in both regulatory compliance and product support.

References:

1. FDA (2018), Data Integrity and Compliance with Drug CGMP: Questions and Answers Guidance for Industry (U.S. FDA, December 2018).

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