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Data Integrity: Getting Back to Basics

Ensuring data integrity involves effort on an individual and global basis.

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I have been involved in the healthcare products industry for all of my professional life, more than 35 years in varied environments and operations in the United States, Europe, Asia, Australia, and Latin America. During that time, I have seen many changes in the manufacture and control of pharmaceutical and biopharmaceutical products.



Richard M. JohnsonSome changes are inherent in the newer products that have been introduced, but many of these changes have been technological: the advent of computerized systems; instruments and sensors to monitor and control machine function; increasingly sophisticated software; and the ability to communicate data via wire and wirelessly around the world.

One of the ways that we have applied these technologies is through the generation of volumes of data that were previously either not accessible or impractical to analyze. It is through the generation of data, and the review of these data by knowledgeable persons in comparison to specifications and standards, that we base our quality decisions. Even the least sophisticated operation today employs electronic systems for many applications: inventory control, analytical data capture and analysis, equipment control, and reporting. As these changes have occurred, there have been evolving changes in the regulatory focus--from quality control and an emphasis on testing quality--to quality assurance and process validation--to quality by design and lifecycle management.

The human element

But while electronic systems are becoming more widely used and generating ever larger amounts of data, it is also true that all of our operations depend on a network of people to perform a wide variety of functions, from material manufacturing, transportation, finished-product manufacturing, testing, distribution, regulatory filings, and controlling records that involve a combination of both electronic and paper-based records.

The global element

In addition, there is a growing globalization of the business and the dependence on partners from -outside the primary organization. Activities that used to be done within a single organization are more likely today to include a network of separate organizations that are interdependent on goods, services, and data exchange. Many of the healthcare products used by patients around the world involve manufacturers and suppliers from multiple continents who communicate in multiple languages.

The data element

A basic principle of assuring the quality of healthcare products is the review of data. Industry experts review data from their partners; independent quality groups review manufacturing and testing data; and regulators who are responsible for monitoring the products for the public review all data. The accuracy, trustworthiness, and the integrity of that data must not be in question, or all of the checks and balances, control measures, and quality agreements will not be effective. This is equally true of the traditional paper-based records and electronic data.

The recent emphasis on data integrity is not new, but it has never been more crucial. This principle should remind us of a basic tenet: All relationships are based on trust and evidence. If the integrity of one's data is questionable, the loss of trust will have severe consequences. We should all be committed to reinforcing the importance of data integrity.

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