TECHNOLOGY | **MERGERS & ACQUISITIONS**

Information Management Strategies To Improve Data Integrity During M&As

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Merger and acquisition integration presents great challenges to maintaining business continuity, transferring appropriate knowledge, and transferring information assets in a timely and effective manner. By starting with the end in mind and engaging the entire integration team early (i.e., before the contract closure), the change-management activities and education/maturation of information management practices will greatly reduce these risks and challenges, and will significantly increase the probability of successful business continuity during and after M&A.

The FDA has long been concerned about data integrity. From the advent of 21 CFR Part 11 in 1996 to the most recent FDA Draft Guidance on Data Integrity, the accuracy and consistency of data used in life sciences has been a focus of regulation and related inspection both in the U.S. and most other major biopharmaceutical markets.

As business strategies are defined and implemented with the inclusion of M&As, which seem to be only increasing in recent years, data integrity represents a critical risk to the probability of successful M&A. Due diligence for M&A is rarely sufficient to uncover operational-level risks that present real threats to (for example) integration of manufacturing operations, business continuity, and continuous supply of life-saving therapies.

In one recent M&A-related project, manufacturing operations of a top-10 biopharmaceutical company were potentially threatened by complications in identifying all regions where recently acquired assets were registered for commercial market. While both the acquiring and the acquired companies managed their regulatory data effectively, the disparity in information technology systems,

roles and responsibilities for information, and data definitions presented sufficient differences that caused confusion and (at a minimum) minor delays in product release while details were sorted out. While this is not unusual during the initial months (and in some cases, years) after "Day 1" of a merger, the challenges can be reduced and the risks mitigated with increased effort on data integrity in the early days of M&A discussion, strategy, planning, and integration.

Too often we see IT systems and related data discounted to a few line items on a due diligence report or integration plan. It is very common to behave in a reactive mode during M&A, where the deal is done and the attention to data integrity applied too little and too late to make an effective and efficient difference to the final company integration. Underestimating the resources required inevitably compounds the resources assigned to perform data verification and cleanup activities after "Day 1," but it doesn't have to be this way.

AN OUNCE OF PREVENTION

Data integrity involves much more than information tech-

nology systems and data definitions. Data integrity starts with a culture of understanding information as a vital company asset. Only by truly understanding the quality culture of an organization can we plan appropriately for the integration of cultures and information during M&A.

By making a disciplined and intentional assessment of how a culture manages its data early in the M&A life cycle, much confusion and risk can be avoided. Leaders in business development should take a look at information priorities between the acquiring and the target companies as early as possible and engage functional areas like regulatory, QA, and legal during the early due diligence stage. It is far less disruptive to make adjustments in perspective, priority, and management of information before IT system integration begins, than to wait until integration starts and pass that responsibility on to the resources who are tasked with merging great amounts of disparate data.

By engaging the entire M&A integration team early to

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align expectations for knowledge transfer and data/document transfer, the probability of successful business continuity is significantly increased. Use tools like process mapping, data diagrams, and information models early to help key employees understand how and when data is created and managed. In doing so, disparities may be identified and resolved long before the IT systems begin to merge. In some cases, cultural change is necessary to (for example) shift responsibilities for data management from one level or one department to another. Modifying the operations even before the IT systems are merged can ensure better understanding, integration and adoption, and uninterrupted business operations.

DATA INTEGRITY IS ABOUT CULTURE
Strong data integrity is the result of a cultural norm that identifies information as a vital company asset — and permeates every operation in the organization. From document control, to management of raw analytical data, to the execution of batch records on the manufacturing floor, data integrity is elevated through a strong quality culture.

Assessing this early in M&A activities ensures better preparation for mitigating risks when (not if) issues arise.

The biopharma companies that exhibit the strongest data integrity have taken the culture seriously enough to implement offices of Information Governance under IT. These groups are sometimes organizationally aligned with IT departments and other times integrated in business functions. Regardless of the organizational location, they are always most successful when the members of these groups represent cross-functional, cross-divisional interests. As members of these groups learn the operations of the functional areas that they represent and become trusted advisers of, and advocates for, these areas, value is realized in reduced confusion, less information conflict, and improved operational efficiencies (e.g., by reducing defects in data transactions from function to function).

Personnel management and personal development also involve critical success factors for strong data integrity during M&A. Very understandably, the personnel of an acquired company may feel anxious about their future and very insecure in their roles and responsibilities. For this reason, a proactive effort is needed to identify early on the information owners and critical stakeholders in the acquired company and to engage them in the planning of, and activities for, integration. This early effort results in a much more successful transfer of information assets and alignment of operations. Likewise, adding data integrity-related topics and continued education to the job descriptions, role curriculum, and personal development plans of information owners and critical stakeholders has resulted in great improvements in data integrity. Results have included reduction in the number and severity of deviations, improved clarity and efficiency in processes, and increased adherence to supply chain plans (to name a few).

When data integrity concepts are successfully embedded at every level of an organization, the business matures to a level of strategic alignment that produces self-correcting results and ensures a greater avoidance of risk. While these results may improve integration of the acquiring and acquired company operations and ensure business continuity during M&A, they also ensure the highest probability of meeting demands for patient therapies and increasing shareholder value. Ⓛ

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