The Future is “Cloudy” for Data Integrity

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Managing the integrity of manufacturing data is becoming ever more challenging, particularly as more and more critical manufacturing functions are outsourced, thus limiting the amount of oversight a pharmaceutical company can provide. Per ICH Q10, “the pharmaceutical company is ultimately responsible to ensure processes are in place to assure the control of outsourced activities and quality of purchased materials” (1). Further, the U.S. FDA holds “the owner’s quality unit ultimately responsible for approving and rejecting drug product manufactured by the contract manufacturer” (2).

Life science companies need to demonstrate control over their data—whether internally or externally generated. FDA officials indicate that “data that are not valid and trustworthy is a sign that an entire operation or facility is out of control and cannot assure the quality of its medicines” (3). Without accurate data, companies are less equipped to ensure the safety, effectiveness and quality of their products.

FDA Scrutiny Intensifies

As data integrity issues continue to surface during plant inspections, FDA leaders continue to lead the push for manufacturers to clean up data operations (4). In fact, standalone, raw data-generating systems, business processes and interfaced business and production control systems that formerly received only cursory reviews, are now under increasing scrutiny (5). The concern is that these companies’ products cannot be trusted due to the absence of credible data. The FDA has subjected many global companies to import alerts, refusing entry of their products into the United States (6).

Gap Between Systems and Processes

Quality processes now span internal and external parties, however, many supporting systems were designed to operate only within a company's four walls. In addition, many of these applications do not work well together—often existing in silos. Significant, manual overhead is necessary to bridge the gap between all parties and applications in order to stitch together a continuous process—providing many opportunities for data issues.

Having the quality team review the data from manufacturing sites is a great first step. Communication, however, still often occurs via email, or another uncontrolled method in a non-validated environment, which could lead to an observation or warning letter. In fact, according to the FDA’s recent draft guidance, “Workflow, such as creation of an electronic master production and control record, is an intended use of a computer system to be checked through validation. If you validate the computer system, but you do not validate it for its intended use, you cannot know if your workflow runs correctly” (7). As outsourcing grows, there is greater scrutiny of the review of the batch production and control records that support the batch release process—a common concern even without factoring in outsourcing. Companies currently use a combination of email and filesharing sites, making it almost impossible to provide a clear, consolidated audit trail, and to demonstrate chain-of-custody for the controlled data or documents.

DI Forecast: “Cloudy” Skies Ahead

Using cloud-based technology to orchestrate drug development and manufacturing enables all parties to be incorporated into the process from end-to-end. Every move is controlled and can be overseen. This reduces the risk of data being manipulated or lost amidst fragmented processes and disparate systems.

The cloud gives life science companies the ability to extend data integrity across all parts of the value chain, while at the same time enabling partners to access information they need to provide valuable services. Raw material suppliers, CROs, CMOs, brokers, and distributors can interact simultaneously under very controlled conditions to ensure that accurate, up-to-date information is always available to those that need it—whenever, wherever, or however (8).
Reviewing information from manufacturing sites helps detect data integrity issues, however, problems are typically more difficult to detect—and the impact greater—near the end of a process. Moving upstream and providing the quality team with direct access to the quality management system allows issues to be detected earlier and accelerates downstream decision-making. The quality team can review in-process deviations and results of the investigation so problems can be resolved proactively and approvals streamlined for improved efficiency. Providing all stakeholders with access to up-to-date, accurate data and content in a single, authoritative system instills greater confidence that operations are being executed with compliance.

As regulators require greater access to manufacturing data, having a solution that directly incorporates all parties into end-to-end processes will be essential to ensuring data quality and integrity.

**There’s Only One Direction to Look**
The industry must stop looking within, and start looking for solutions elsewhere. The best place to look is up—to the cloud. Cloud solutions that manage quality content and processes bring together all stakeholders on one platform and ensure an auditable trail of all activities with partners. Ultimately, the cloud offers a way to externalize and maintain internal control of quality.

**References**
1. ICH Q10, International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use.
7. Guidance for Industry: Data Integrity and Compliance with cGMP, U.S. FDA, April 2016 tinyurl.com/htj4xff

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