PEER REVIEWED

Data Integrity and Preservation in Pharmaceutical Manufacturing:

Technology's Role in Safeguarding Compliance Throughout a Drug's Entire Life Cycle

The life sciences' relationship with technology has come a long way since Deloitte's 2015 global life sciences outlook, describing it as 'operating in an era of significant transformation.' Since the report was published, most in the industry have re-evaluated traditional methods of operations, put to bed (or at least put a plan in place to deal with) ineffective, costly, and disjointed systems and practices, and are embracing the positive change innovative technology can bring.

The market is full of technology-based solutions that promise to deliver a compelling return on investment. From scheduling systems that work with real-time data to accurately forecast drug demand and identify potential gaps in supply, to automated production lines and temperature management devices that drive efficiency and promote safer and more profitable operations. In 2018, whatever process-based headache you're experiencing, chances are there's an 'app for that'.

Equally, the way we now access this technology is changing. The advent, and gradual acceptance, of the cloud is also transforming how we work. It is making sophisticated software more accessible – both financially (with monthly software-as-a-service subscriptions replacing the need for substantial upfront investment) and in terms of the ability to securely access these systems remotely. However, a common thread that weaves all of this technology together is that without data (without good, trustworthy data) the technology is rendered redundant. Without full confidence in the integrity of data, the whole point of the exercise (make drugs, help patients, be a trusted organisation, make profit) is compromised.

Pharmaceutical manufacturing organisations face a set of specific challenges relating to the documents and data they produce and store. And as more data is generated each day, as businesses consider replacement of legacy systems in favour of these more advanced alternatives, and as commercial factors dictate a need to migrate data from one system to another – or hold historical data for compliance purposes on an acquired system – the need to manage this process and safeguard compliance throughout a drug's entire life cycle, and beyond, becomes a pressing one. But how should manufacturers best approach this task? What are the pitfalls to be wary of? How can technology help achieve best practices around data integrity? And, how can legacy data be preserved long into the future so that compliance is championed at every stage of a drug's life cycle?

Getting Compliant, Staying Compliant

Before exploring the role data preservation can play in removing risk, it's important to understand why data matters in the first place. The reason we should invest so heavily in protecting the integrity of the data is that this underpins each and every pharmaceutical manufacturing operation.

Data integrity refers to maintaining the accuracy and consistency of data over its entire life cycle – from creation to deletion to preservation and everything in between. It is the bedrock of GLP, GCP and GMP; and is viewed by the FDA, as well as all other regulators, as 'an important component of the industry's responsibility to ensure the safety, efficacy, and quality of drugs, and of the FDA's ability to protect the public health.'[1]

Technology is simplifying the process of collecting, monitoring and analysing data; and making it quicker and easier for quality professionals to demonstrate compliance. Indeed, regulators recommend that 'firms should implement meaningful and effective strategies to manage their data integrity risks based upon their process understanding and knowledge management of technologies and business models'[2].

Knowing what data integrity best practice looks like is relatively straightforward. And, there are plenty of innovative applications, such as electronic quality management software (EQMS) available on the market to support it once systems and processes are established. The challenge is in the transition, the identification of current risks, understanding the data held within multiple disjointed systems, and migrating this information to more robust repositories.

Manufacturing Data Challenges

There are numerous data-related challenges that face life science manufacturers. Many of these challenges relate to managing the correct ownership of records with the current licence holder. Several common scenarios can present themselves here, such as a change of ownership because of merger and acquisition activity, the individual sale of a drug licence or facility, the closure or consolidation of facilities, or moving manufacturing operations to different parts of the manufacturing supply chain.

All of these scenarios demand appropriate, and compliant, data archiving. They also demand that manufactures effectively identify and migrate relevant drug data from their own systems to the new owners of the licence or facility. It's also worth considering that multiple organisations may need to access historical records and deal with regulatory, quality, and knowledge transfer demands to make processes such as the preparation of product quality review reports as efficient and effective as possible.

Moving data from one site to another will quite often mean that it is being moved to an environment where the standard quality management system is different. The receiving party, themselves, will then face challenges relating to the legacy system's validation status.

A further risk to data integrity for manufacturers, and the life science sector in general, results from the abundance of new technology-based solutions now on offer. The pace of technological advancement means older legacy systems are unsuccessfully competing with more modern, advanced, intuitive and affordable alternatives. These older systems are quickly becoming obsolete and unsupported by vendors; meanwhile, document formats are becoming incompatible with newer versions of software. All of these factors risk the integrity of digital information becoming compromised (readability and traceability required for regulatory demands) or lost entirely.

This poses a problem for the data housed within the legacy software. According to a leading IT analyst firm, legal and regulatory requirements relating to document preservation often prevent retirement of legacy systems. This, in turn, can result in up to 80 per cent of IT budgets being spent on multiple archaic systems that add no additional value to the business. The knock-on effect of this is that life science manufacturers become hostages to their data. It becomes a headache to manage, rather than a resource to exploit.

The need to retain and maintain data sets varies in scale and timeframe from business to business. Whereas clinical data needs to be kept during the entire time a drug is in circulation, manufacturing batch data need only be kept for the shelf life plus one or two additional years. Given these varying demands, where different sections of the same organisations may have changing requirements, flexible and robust archiving solutions are invaluable to meeting those needs and keeping the whole business compliant.

One specific area of archiving functionality that can prove incredibly beneficial is the automatic destruction of data in a controlled and recordable manner. There are very few businesses willing, or even able, to store information for longer than they must. So, the ability to rely on a system which will only maintain the data it absolutely has to, can provide both peace of mind and significant cost savings for an organisation.

Migrating Data with Cost and Compliance in Mind

The solution to this is to retire unsupported legacy systems and migrate the data contained within them to a robust, singular and centralised, long-term electronic data preservation system. Utilising a manageable, system-agnostic and hosted solution to automate aspects of the data migration process, will facilitate quick, efficient, and precise data transfers.

Retrieving documents from a series of systems and formats, collating, recording and migrating them into a centralised archiving system is not only achievable, but essential. With experts estimating that by 2020, 50 per cent of all current applications in the data centre will be retired, it's clear to identify the wider trend and acknowledge the need to take action.

Realising you need to take action is one thing. Knowing what precise action to take is another. A good place to start is by adopting an industry standard method such as OAIS, PAIMAS or ISO. These will give a route to proven conversion paths and accepted terminology. It is essential to ensure any storage system can then store both the native object and preservation object along with any associated metadata.

The onus is on life science businesses to embrace a best practice approach to future-proofed, compliant, efficient and cost-effective document preservation. Overcoming the perceived barriers of retiring legacy systems and migrating data can be supported by tools that automate parts of the process. By doing so, migration activity can be sped up, validation activity reduced, and potential areas of risk surrounding human error can be avoided.

Systems that are able to preserve data in formats that are widely used today (CSV, TXT, PDF/A, TIFF), while also harnessing the metadata, stored as XML, so the original relationship between documents and the context in which they were created is preserved, will also add significant value and support both reduced compliance risk and IT overheads.

Embracing Technology Today to Preserve Data for Tomorrow

Implementing a data preservation system will provide manufacturers with enhanced confidence over the current and continued integrity of data. It will demonstrate compliance by facilitating improved access controls and audit history for digital records, as well as for all data that has been migrated in from multiple systems. This in turn will remove the challenges that legacy systems present relating to security and access controls failing to meet current requirements of CFR21 Part 11/Annex 11. It will also remove the cost and complexity of maintaining legacy systems, as there will be no further need to retain expertise or resource to maintain, run and manage information requests from the legacy system. A preservation system will also remove the need for hybrid systems, where master records are partially retained as paper documents.

Once preservation systems are in place, they can be used to run periodic audits in an incredibly efficient manner. These audits can verify whether or not files have been altered since ingestion. If a file has been altered, these systems will quickly identify the 'needle in the haystack' and flag the issue. This can then be investigated to determine: if there was a legitimate reason for the file change and that it has been appropriately recorded; if the information relating to the reason for change is not fully defined; if the original file has been corrupted; or if there has been deliberate or accidental alteration to data. With this information available instantly, manufacturers are empowered to

take appropriate and immediate action to safeguard data integrity and compliance.

With an abundance of technology on offer, preservation systems represent a single way of maintaining controlled records and data, and making that control simpler to manage, explain, and demonstrate both to internal teams and auditors. They also provide a simple platform to allow for bulk migration of additional records into the archive. These systems can also be used to demonstrate business-critical risk reduction. For example, enabling the use of failover redundancy – also known as mirrored backup – between hosted environments that protects the data and guarantees availability.

Understanding the role technology can play in managing records appropriately and preserving documents and data in secure, future-proofed repositories (while maintaining the integrity of data to bolster quality functions) should be considered a business-critical task. Not only does this technology provide a mechanism for more streamlined workflows and reduced IT spend, it provides regulated companies with a single way of controlling all electronic data, using a platform and model that meets the best practice associated with data integrity around the world.

As manufacturing protocols become more complex and regulatory requirements show no signs of abating, the pressure is on to sit up, take note and act.

REFERENCES

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