Overcoming Data Management Challenges in Pharmaceutical Laboratories

Overcoming Data Management Challenges in Pharma Laboratories — WESTBOURNE

Businesses are becoming increasingly data-driven, and the pharmaceutical industry is no different. Data is driving change in all areas of business, from manufacturing and quality control to marketing and R&D. Industry 5.0 technologies, strategies, and best practices exist to facilitate the changes that pharmaceutical organisations need to make, but there are challenges to overcome, including the challenges of data management.

The data management challenges that exist are particularly acute in operational aspects of pharmaceutical businesses, including on production lines and in laboratories.

All of the challenges can be overcome, but the first step is to understand them, so they can be addressed holistically and comprehensively.

Data Management Challenges

Integration

There are many reasons for the lack of systems and equipment integration in pharmaceutical organisations, including the prevalence of legacy systems, the use of solutions from multiple vendors, and the distinctive gap between IT and OT (operational technologies).

This lack of integration results in data being lost. Where data is retained, it is often fragmented and frequently exists in silos. So, even where the data exists, it is not possible to fully utilise it because of unconnected and, sometimes, inaccessible systems.

The solution is to increase integration across all platforms and systems not just in the laboratory and on manufacturing lines, but across all parts of the business – sales, marketing, customer service, finance, HR, etc. Deepening levels of integration in the supply chain is also beneficial.

Manual Processing

Many pharmaceutical manufacturers continue to rely on manual data processing. This doesn't just involve pen-and-paper manual processing, but also where the manual processing is carried out using digital systems. Entering a value on a spreadsheet is a good example, or manually recording a reading from a piece of laboratory equipment into a software application.

Pharmaceutical manufacturers should implement solutions that eliminate the need for manual data processing. Moving away from manual data processing as much as possible improves accuracy, eliminates errors, prevents data manipulation, and ensures record keeping is contemporaneous.

Data Integrity

Pharmaceutical manufacturers have equipment and processes that produce large amounts of data, but that data is often unstructured, so it lacks consistency. This lack of structure, standardisation, and consistency makes it impossible to fully use the data or extract meaningful insights.

Therefore, establishing effective data governance is just as important as integration and automated data processing, where data across all systems and platforms is standardised.

The aim should be to have data that follows ALCOA+ principles. This means data should be:

- Attributable
- Legible
- Contemporaneous
- Original
- Accurate
- Complete
- Consistent
- Enduring
- Available

ALCOA+ Data Integrity — WESTBOURNE

Attributable	Legible	
Who, what, where, and when	Can be read and understood	
Contemporaneous	Original	Accurate
Recorded when the action or activity takes place	Original records and not copies or transcriptions	Error free with no editing of original information
Complete	Consistent	Enduring	Available
Nothing should be deleted or lost	Time and date stamped chronologically	Ensuring the data is available long after it's recorded	Data should be accessible for review & inspection

Cybersecurity

The existence and use of data in pharmaceutical organisations increases cybersecurity risks. This includes risks to business data and IP data, both of which are highly valuable. There are also operational risks if data is compromised, i.e., production could be slowed or stopped, or quality control data could be manipulated.

Pharmaceutical manufacturers can also have access to patient data which needs to be protected.

Any solution designed to improve the management and use of data in pharmaceutical organisations should have cybersecurity as a central consideration. This includes strong cybersecurity features in any technologies that are implemented, as well as robust cybersecurity procedures, protocols, and training programmes.

Skills availability

Pharmaceutical organisations often struggle to recruit and retain the skills required to integrate equipment and build the systems that make it possible to extract the full potential of data.

As with all the other points on this blog, this challenge also presents opportunities.

- The challenge of skills availability = the opportunity to partner with a solution provider that not only fills those skills gaps but offers additional expertise and experience.
- The challenge of cybersecurity = the opportunity to improve your organisation's understanding of cybersecurity risks and the mitigation steps that are needed.

- The challenge of data integrity = the opportunity to improve the quality of data in your organisation.
- The challenge of manual processing = the opportunity to automate processes and make better use of resources.
- The challenge of integration = the opportunity to increase connections that will drive productivity gains.

Overcoming Data Management Challenges: The Benefits

The benefits of addressing the data management challenges highlighted above are substantial, with data-driven decision-making being one of the main advantages. You will also have significantly better insights across the organisation. Examples include:

- Business insights – for example, more accurate, data-driven predictions about product demand and/or raw material availability.
- Quality control insights – for example, automatically identifying potential quality deviations so adjustments can be made before any manufactured batches are affected.
- Operational insights – for example, reducing unplanned downtime and improving OEE through predictive maintenance where maintenance work is based on data rather than generic, vendor-produced schedules.

To realise these benefits and take the next steps to overcome data management challenges in your organisation, get in touch with us at Westbourne IT. We have the technical capabilities in addition to extensive pharmaceutical, laboratory, and regulatory experience, enabling us to provide comprehensive consultancy advice and practical support. We can help you extract the full potential of data in your laboratory and wider operations.