propharma

case study

ensure data integrity compliance and patient safety with a data governance framework

Using Trustworthy Data for Accurate Decision Making

By using a data governance framework that applies behavioral, procedural, and technical controls to improve data reliability, ProPharma successfully helped a client mitigate data integrity problems.

As a result, their data became trustworthy (complete, consistent, and accurate) and their stakeholders were able to make better decisions.

Procedural controls were put in place to ensure all parties involved received the latest accurate information. In turn, this resulted in compliance and ultimately ensured patient safety.

Even though the right mindset is the start of data integrity compliance, that alone is not enough to demonstrate compliance. In today's world, every business revolves around data. If your data is trustworthy, you will be able to make better decisions, thus resulting in improved patient safety.

challenge

Data is collected throughout the product lifecycle; including research data, clinical data, manufacturing data, and product data, to name a few. The data documents contain quality data and proof efficacy of the product. For our client, an auditor observed that updates of Summary of Product Characteristics (SmPC), e.g. **an indication, were not properly communicated to stakeholders.** This meant that actual SmPC data were not available to all parties involved. This was a problem because they were making safety decisions based upon obsolete information.

The audit also unveiled that old emails containing SmPC updates were not legible, due to a change in platforms, meaning that SmPC changes were not traceable, and the SmPC data could be modified by unauthorized persons. In terms of data integrity, these observations meant that SmPC data were not accurate, legible, contemporaneous, or enduring. These were serious data integrity violations about which the auditor was rightfully concerned.

In the SmPC scenario it became clear that certain work processes were not yet described, e.g. the process for email retention and the process for receiving updated SmPCs by the Marketing & Sales departments.

solution

We discovered that the flow of SmPC data did not stop at the Regulatory Affairs department, but continued to stakeholders. For a correct handling of the data lifecycle this meant that a confirmation of receipt by them was implemented, as well as providing them with an impact assessment of each update.

Our solution to mitigate the problems is to implement a data governance framework that applies behavioral, procedural, and technical controls to achieve data integrity compliance.

Behavioral controls, for example, aim to create a company culture that endorses data integrity. For management this means they should define data integrity priorities and provide appropriate resources; and, for employees, this means they should receive data integrity awareness training. In the context of the SmPC observations, this meant that employees learned about the importance of audit trails and their role in the end-to-end process.

The description of the procedures and the translation of the procedures into work instructions not only enabled the company to prove data integrity compliance, but also gave the company better insight into actual work processes.

results

Apart from describing work processes in instructions and procedures for data integrity compliance, it was important for the client to become aware of data flows and the lifecycle of data in their organization.

The primary added value of implementing the data governance framework is data integrity compliance. However, the implementation of this framework can do much more than that, because companies are forced to critically assess their work processes and the data flows through their organization.

By implementing behavioral changes within the data governance framework, one can improve data quality as well. Ultimately it is the quality of data produced during the production process that determines the upper limit of product quality that can be guaranteed by the company.

If your data is rubbish, one can expect troubles ahead ('garbage in, garbage out'). However, if your data is trustworthy (complete, consistent, and accurate) your management will be able to make better decisions. This will result in compliance, successful audit completion without fi findings, and ultimately, patient safety, which in turn lowers costs and improves revenue.

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