propharma

case study

ensure successful batch release and regulatory compliance with experienced qualified persons (QPs)

Our team of QPs deliver results with streamlined processes and an improved Quality Management System.

A contract manufacturing organization (CMO) needs to have a reliable quality management system in place to meet clients' needs and comply with Good Manufacturing Practice (GMP).

Additionally, in Europe, a Qualified Person (QP) is required to certify every batch before it can be released to the market. ProPharma understands what is required to be compliant at every step of the process. A GMP compliant, risk-based approach guarantees a validated quality process mitigating the risk of potential regulatory actions or warning letters. We supported the CMO with streamlining the manufacturing process to ensure that it GMP compliant for EU batch release and with and USA inspection readiness.

A CMO client with a manufacturing site supporting both US and EU customers sought quality improvements for GMP compliance and efficient processes. So, how can CMOs readily ensure appropriate documentation, frequent quality checks, and inspection readiness to keep the manufacturing site operational?

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challenge

A CMO supporting different clients has to adhere to the quality assurance requirements of these clients.

Furthermore, the CMO will require its own MIA license and QP for the manufacturing activities.

Our client provided secondary packaging activities of pharmaceuticals for both the EU and US market. The packaging activities required quality improvement, regulatory, and validation support.

The request to ProPharma was to provide a QP from our expansive network for batch release and to support the quality improvement activities and FDA inspection readiness.

It was important to the client that the challenges could be tackled by one partner, which was a challenge due to the diversity of the work.

solution

A team of QPs was assigned to the client to ensure continuous support for the batch release process. Furthermore, to improve the structure of the Batch Manufacturing Records (BMRs), our team of experts implemented Six Sigma methodology.

Through a yellow belt project, an analysis of the Batch Manufacturing Records was completed to identify opportunities for improvement. The changes made resulted in higher quality Batch Records resulting in increase in Right First Time data entering.

In addition to the Six Sigma project, and as a part of the day to day batch release process, we proactively performed a trend analysis on required corrections to the completed Batch records. The trend analysis identified repeating problems that required remediation, and our team provided GMP training for the customer with a specific section on Good Documentation Practice (GDP).

results

ProPharma led the yellow belt project. We provided **significant improvement to the BMRs which, streamlined the manufacturing process, and improved the documentation process.**

Additionally, we made improvements to the GDocP. The trend analysis was continued after the training and **showed a reduction in the number of corrections required** further reducing the time typically required to complete a BMR, creating a more streamlined and effective process.

Furthermore, our team of experts worked collaboratively with the clients' regulatory department to ensure the required registration was in place. We also added the required yearly renewal into their **QMS documentation to ensure continued regulatory compliance** for their clients.

Our successful collaboration with the client resulted in a new request for shipping lane validation for a specific product. Our Life Science Consulting team of experts and engineers are working hard to ensure compliance of the GDP regulations. This project is ongoing.

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