propharma

case study

navigating QMS requirements from a medical device perspective

life science consulting

Learn how our QA team efficiently updated a medical device company's QMS for EU distribution of pharmaceutical products.

Our client is a major player in the medical device industry, supplying MD-classified utilities, and equipment to hospitals on a global scale. Their portfolio also includes a smaller number of pharmaceutical classified products.

This creates a challenge in EU as distribution and sales of MD products are under MDR while pharmaceuticals are under EU-GDP and require a wholesaler dealer authorization (WDA). By efficient support from our QA consultant, the client was able to update their QMS and meet current GDP requirements.

Contact us to learn how our experienced team can help ensure successful outcomes throughout the product lifecycle.
ProPharmaGroup.com, info@ProPharmaGroup.com

challenge

The challenge with distributing a product type in a company where that is not the core business is to keep the QMS up to date with the applicable changes in regulation.

For a medical device company, updates in pharma legislation are not a priority and will not be given the attention it requires. **This will create a gradual gap between the pharma QMS and the current regulations.**

The number of pharmaceutical subject matter experts is also limited in a medical device company.

solution

On short notice, ProPharma engaged one of our QA consultants, with expertise in GMP and GDP.

During a time period of 10 weeks, the QA consultant was able to review the QMS, suggest changes, and implement updates in the SOPs to meet current GDP guidelines.

The consultant also trained the client's staff in GDP regulations.

results

Through the partnership with ProPharma, the client was able to achieve a QMS in line with the current regulations for distribution and sales of pharmaceutical products.

As a direct result of this project, the client now has a system in place that will pass a health authority inspection, be compliant with current regulations, and safeguard the quality of the pharmaceutical products.

improve the health and safety of patients.

From early concept development through each clinical phase, product launch, and commercialization, we partner with pharmaceutical, biotechnology, and medical device clients to tackle complex challenges. We help to ensure regulatory goals are met, business objectives are achieved, and patient health and safety is improved.

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