propharma

case study

how to manage a drug product in a medical device environment

Learn how ProPharma effectively supported GMP and GDP compliance of a drug product ..... in a medical device environment.

A global medical device company asked ProPharma to assess the set-up of the entire supply chain of a drug product. We did so by reviewing the Global Quality Management System and we determined how it supported a drug product.

In addition we reviewed the entire supply chain and we made suggestions for improvement. This supply chain included the United States, EU, and Switzerland. The company implemented our suggestions for improvement and successfully passed inspections by the Swiss Health Authorities (Swissmedic) and EU Health Authorities. In conjunction, we executed more than 20 audits, resulting in further improvement.

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> Our expertise in medical devices and drug products, combined with our global presence made the difference for this company.

challenge

A US-based medical device company became a large global player due to a number of acquisitions. Obviously, the strategy focused on medical devices. All medical devices? Well, it appeared that one product was a drug product. The European headquarters in Switzerland called in ProPharma for help.

We started with an assessment of the Quality Management System. This system was indeed global, however for medical devices.

The challenge was that the Quality Assurance of medical devices is based upon ISO 13485 and inspection by notifying bodies, whereas drug products are inspected by local Health Authorities. And the latter became another challenge: product released in Switzerland does not automatically imply release into the EU.

Also, headquarters in Switzerland does not necessarily mean that product is physically imported into Switzerland.

Finally, an inspection by the Swiss Health Authorities (Swissmedic) was imminent.

solution

ProPharma started with a gap assessment where we reviewed how the current Quality Management System for Medical Devices supported the drug product.

In addition, we made visual the entire supply chain of the product in flow diagrams. This included all aspects such as manufacturing in the US, transportation and importation (batch certification) into the EU and Switzerland.

We presented the results to management and our suggestions included the preparation and revision of certain procedures, review of inter-company agreements, the internal audit program and the set-up of importation and product release into the EU and Switzerland.

It appeared that the expertise of ProPharma on both medical devices and drug products brought the added value that the company was looking for. Therefore, ProPharma was asked to execute the audit plan as well.

results

Taking the suggestions from ProPharma into account, the company successfully passed inspections by the Swiss Heath Authorities (Swissmedic) and EU Health Authorities.

In conjunction with the above, we executed more than 20 audits to cover the entire supply chain such as manufacturing, release, importation, and distribution.

In particular, we also paid attention to the role of local country organizations and how they relate to the European distribution center, e.g. with complaint handling and deviations.

Another advantage of the wide range of expertise and the global footprint of ProPharma was the ability to audit the organization of Medical Information, on a global scale. This included both the in-house organization of Medical Information and the outsourced organization, on two continents.

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.

Contact us to learn how our experienced team can help ensure successful outcomes throughout the product lifecycle

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