



Good Distribution Practice for Medical Device (GDPMD)

An Introduction

GDPMD at its core

GDPMD is all about ensuring that medical devices are handled, stored, and transported properly - from the manufacturer to the end-user; and that they remain safe and effective throughout their lifecycle.

It's a requirement that double down to protect patient by assuring the safety and quality of medical devices to be conserved within the supply chains. Ultimately, this is to ensure that medical devices can be used for their intended purpose as declared by the manufacturer.



Requirement of GDPMD

- ✔ Establishing a solid quality management system - ensure regulatory adherence and fulfill regulatory expectations.
- ✔ Employing trained, qualified personnel who understand their responsibilities, and competent to undertake the tasks required.
- ✔ Maintaining suitable premises and equipment for medical device storage and handling
- ✔ Maintaining accurate and complete records as required by regulation.
- ✔ Following established SOP for procurement, storage, and distribution.
- ✔ Ensuring that outsourced activities are performed by competent, reliable partners.
- ✔ Conducting internal audits and management reviews to ensure compliance with regulatory requirements
- ✔ Implementing robust post-market surveillance and vigilance system - monitor the safety and performance of devices - after placement has been made
- ✔ Maintaining medical devices traceability to facilitate recalls



Rational of the requirement

Making sure medical devices are safe and effective, and indirectly safeguarding patients from unreliable devices. Failure to thoroughly follow GDPMD requirements may lead to complications and placement of substandard, unsafe, and non-conforming medical devices

By following GDPMD requirements, establishments should be able to minimize the risk of errors and lapses, thus preventing the distribution of non-conforming, substandard or unsafe products, and respond quickly to any issues that may arise due to deviation from the requirements.