GDPMD Accredited Certification
Supporting the Role of Regulators

Due to aging population and increasing health concern, the demand of medical services increases by double digit in the past few years, which leads to an increasing demand on medical device. The huge business opportunity arisen from the medical device industry attracts many organizations in extending their business into the manufacturing or distribution of medical devices. Nevertheless, there are stringent requirements on medical devices manufacturing and distribution process, in order to ensure their safety and efficiency. Some of the countries are either in the process of drafting the regulations or implementing their mandatory regulations on medical device. For example, Singapore has imposed regulation to monitor medical device distribution in 2007.

Worldwide, many countries including Europe, America, Australia, Canada and Japan have already established medical device related regulations, while many Asian countries such as China, Philippines, Indonesia, South Korea, Thailand, Singapore and Malaysia are now regulating medical devices distribution. Any device that does not fulfill corresponding local requirements shall not be authorized to be distributed to the market.

Good Distribution Practice for Medical Devices (GDPMD) is a set of documented requirements governing various procedures during the processes of distribution. Organizations could follow GDPMD to establish a safe and effective best practice.

Since Pakistan is one of the largest importer of medical devices (more than 90%), the Drug Regulatory Authority of Pakistan (DRAP) has established and implemented a regulatory requirements for medical device safety and performance (Guidelines on Good Distribution Practice for Medical Devices, MDB/GD No. 2 under Medical Device Rules 2015 and DRAP Act 2012) to govern the local and foreign medical device distribution procedures.

Different from general products, the quality of medical devices directly affects the users' safety and health. The users of medical device are mainly patients, elderly, disabled and medical professionals who are more vulnerable to diseases. Medical devices may also be used in high risk surgical procedures, while improper uses may cause server casualty or even death.

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GDPMD can enhance the safety and effectiveness of medical device during the distribution procedures, and to well define the responsibility of distributors. Medical device distributors are responsible to support the adverse incident reporting procedures when there are nonconformities during the design, manufacturing, import or retail processes.

To conclude, GDPMD possesses the following advantages: (1) Improve the traceability of medical devices; (2) Systemize the control and maintenance of records and documents; (3) Standardize the overall distribution procedures of medical devices; (4) Strengthen the consistency of the distribution activities like customer order handling, procurement, warehouse management, devices delivery to maintenance; (5) Optimize warehouse management and equipment maintenance; (6) Effectively implement the procedures to recall nonconforming products, issue advisory notice, build up effective communication channels with regulatory bodies and users, handle customer complaints; (7) Effective storage conditions, etc.

Pakistan National Accreditation Council (PNAC) has launched the GDPMD Accreditation Scheme. Certification Services Pakistan (CeSP) is the First CB Accredited by PNAC for GDPMD Scheme (MDB/GD No.2) **applicable to Importers, Suppliers, Distributors, Supply Chain Agents and Service providers for Medical Devices** under DRAP Act 2012 and Medical Device Rules 2015. **CeSP endeavors to strengthen the role of Regulators** i.e. DRAP for ensuring safe, secure, persistent and traceable use of quality medical devices, by its Accredited GDPMD Certification Scheme.