



Prinsip Mahir Sdn Bhd

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ISO 13485 LEAD ASSESSOR

Introduction

Today medical devices safety is a global concern. Pressure from user, patients, and legislative bodies affected the whole chain of medical devices. While we are considering our medical device are safe. Several profile cases had underlined the potential danger of devices to users, patients and brand value. For this reason manufacturers, distributors and service providers are now concerned more about the safety of the devices ever before.

With the increase in the number of different medical device schemes, developed at Regional level, national level, by trade associations, medical device distributors, service providers and manufacturers all requiring implementation and certification to ISO 13485:2003 Medical Devices- Quality Management Systems to demonstrate devices safety.

In 2003 the International Organization for Standardization (ISO) has published ISO 13485:2003 Medical Devices- Quality Management Systems. This system had been developed to aid harmonization of approach to managing medical devices safety for all type of organizations that could impact on the safety of devices covering from Pre-market, Replacement on Market and Post Market phases of the device.

Course objective

In February 2005, a decision was made by the Malaysia Government to regulate medical devices in Malaysia. The Ministry of Health Malaysia is responsible to develop and implement a regulatory framework for the control of medical devices. The aims of the medical devices regulation are;

- to protect public health and safety
- to allow patients for earlier access to new technology for early detection, diagnosis and treatment
- to facilitate trade and to invigorate the medical devices industry

Voluntary Registration of Medical Devices Establishments (MeDVER) registration of establishments and their medical devices is considered to be the most basis level of regulatory control of devices in the market. It will identify the devices, the responsible party and will facilitate any regulatory activity.

This training is designed for all medical devices parties to gain a better understanding on ISO 13485:2003 with regards to National / International requirements to demonstrate devices safety. In addition, the concept of application of risk management to medical devices is introduced and how it adds value to the organization. Internal Audit skills will be taught with reference to ISO 19011:2002 to ensure system conformance to ISO 13485:2003 and National / International requirements. Upon completion of this training, individual will be able to exercise enforcement on devices safety through effective auditing from designing, to manufacturing and until distributing.



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Course content

The scope of the medical devices auditing will apply to the whole life cycle of the device ranging from the pre-market phase, the placement-on-market phase and the post-market phase. Regulation activities to be covered are design and manufacturing, labeling, advertising and sales, use, maintenance and disposal.

- Introduction to Quality Management System
- ISO 13485 guidance and conformance standard
- Recognize Malaysia Medical Devices Regulation and estimate future inquiries
- Application of ISO 14971:2001 principles and method
- Introduction to Quality Management System (QMS) audit
- Auditor qualities and responsibilities
- Audit planning and preparation
- Managing an audit
- Conducting the audit
- Reporting the audit findings with non conformities categorization
- Examination