



www.qtimeconsult.com  
info@qtimeconsult.com



CONSULTING



INHOUSE TRAINING



PUBLIC TRAINING

# Risk Management Improvement Program

(ISO 14971 Harmonized Standard for Medical Devices)

โปรแกรมการพัฒนากระบวนการบริหารความเสี่ยง ตามมาตรฐาน ISO14971

## Introduction

The introduction of risk assessment for Medical Devices manufacturer is corresponded to **the ISO13485, U.S., European Union, FDA and Health Canada requirements, the essential requirement.** Quality Management that has been revised to include aspects of quality risk management within the quality system framework. Therefore risk management becomes **an integral part of a manufacturer's quality system.**

Quality risk management is a systemic process for the **assessment, control, communication, and review of the risks** to the quality of medical devices product throughout the product life cycle.

outlines the risk management requirements to:

- Review a product's intended use
- Identify and quantify any potential hazards during the design and development process
- Mitigate risks to a acceptable level and affirm the acceptability of risk prior to marketing a device.
- Establish processes to monitor products post market
- take action if risks are greater than expected or new risks arise.



## Consulting & Improvement Program

Our Program will help to improve, manage, and reduce Risk for Medical device at all stages, from the design process, to production and commercialization, Post market etc..

### Improvement Step ;

- 1) Refresh by Training and Coaching
  - ✓ Overview of Risk Management and its use in the product development lifecycle
  - ✓ Risk Management Planning,
  - ✓ Risk Identification, Determining how to approach, and hazards
  - ✓ Risk Analysis Tools and Technique
  - ✓ Risk Monitoring and Control
  - ✓ Workshop
- 2) Review & Survey the company QMS and related
- 3) Identification and Evaluation of Risk updating, root cause analysis, control method
- 4) Response plan development, Monitoring Program improvement ;- select management strategy, perform capabilities, develop metrics, prepare and implement treatment activities
- 5) Creating a Risk reduction method, continuous improvement. Updating

Do Not hesitate to contact us @ Hotline : 081-713-3450  
68/858 Moo 8 , Bangkrasor, Muang, Nonthaburi 11000 • info@qtimeconsult.com • 0-2965-5181