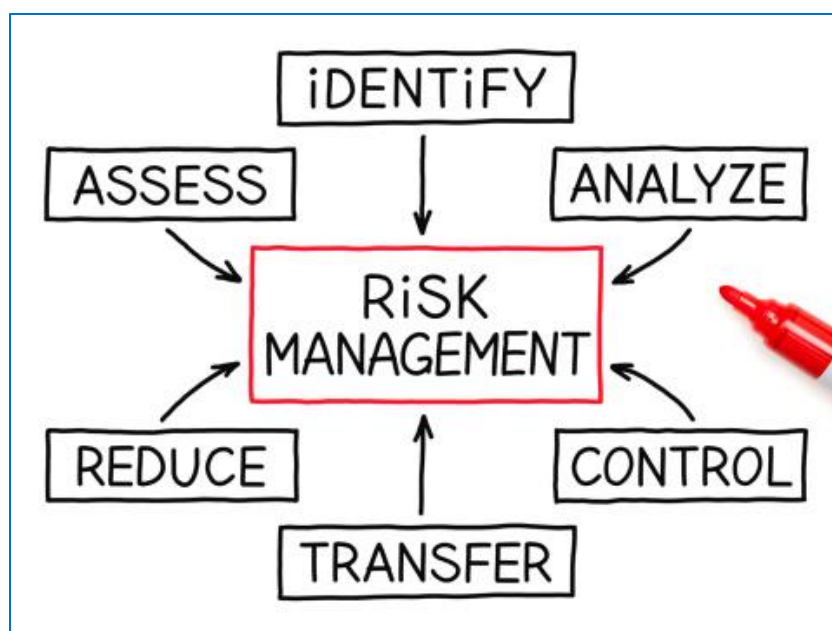




TM290: Quality Risk Management

Training Description:

Quality risk management is the process that involves understanding and managing the risks that are associated with any business or institution of service. In all organizations and sectors of the nation, there are always risks associated with them. Therefore, having the knowledge and understanding of control or mitigating such risks within an establishment cannot be undermined. Therefore, quality risk management is the systematic procedure of assessing, mitigating, communicating and evaluating the risk associated with pharmaceutical products.

This intensive training course aims to provide the trainee with the complete and standard rules of quality risk management within the medical space. We will empower you with the skills necessary for carrying out swift decisions in terms of your medical field professionally. The quality risk management training is set to enable you to understand risk management standards effectively.

Training Objectives:

How can you be involved in risk management?

Attendees would be equipped with the major tenets and applications as they apply to ICH (International Conference of Harmonization) Q9 and ISO (International Organization of Standardization) 14971 standards and be well introduced to the necessary tools, techniques, and skills for the effective implementation of risk management. Quality Risk Management training will also help adherence to the regulations of ISO 13485: 2017.

Finally, we will discuss the commonly used Failure Mode Effect Analysis (FMEA), Hazard Analysis, and Critical Control Point.

Why you should attend the training?

It has become essential that every firm or organization has some degree of risk management as a core determinant of the patient and production management since the risk is a part of the business life. Also, since ICH Q9 has become vital within the health industry, decision-makers responsible for managing risk should be trained to gain risk management and control assets. The training will also provide attendees with tools that would ease their decision-making, making them competent and efficient in the right use of resources.

In line with the ICH and ISO regulation, the training session has the following critical objectives:

- ✓ Learn how and when to utilize the supporting facilitation and systematic tools
- ✓ Understand how to apply ICH Q9 according to need in times of crisis in their sectors
- ✓ Use decision-making analysis tools such as HACCP (Hazard Analysis Critical Control Point) and FMEA
- ✓ Identify roles and responsibilities in quality risk management
- ✓ Get equipped with tools and resources for risk evaluation and control

Training Designed for:

Quality risk management is appropriate for firms in the health sector or individuals with medical devices and professionals in the medical field.

This course is intended for:

- ✓ *Professionals* seeking to improve their knowledge in risk management
- ✓ *Employees* that are responsible for the management and control of risk

- ✓ *Senior management officials* are responsible for the decision that may arise to risk assessment and management
- ✓ *Professionals* that are looking to become risk management consultants
- ✓ *Companies* that are patient-related and want to enhance or give more quality services to their clients

Training Requirement:

“Hand’s on practical sessions, equipment and software will be applied during the course if required and as per the client’s request.”

Contents can be adapted to your specific wishes. It is therefore possible to focus on specific modules of the training course as per client’s learning needs and objectives. Further, it should be forwarded to us a month prior to the course dates.

Training Program:

FIVE DAYS:

- ❖ **Module 1: Risk and Hazard**
 - What is a Hazard?
 - What is a Risk?
 - What is Risk Management?
- ❖ **Module 2: Types of Risks**
 - Operational Risks
 - Interest Rate Risks
 - Business Risks
 - Strategic Risks
 - Market Risks
 - Liquidity Risks
 - Legal Risks
 - Political Risks
 - Financial/Investment Risks
- ❖ **Module 3: Risk Prevention and Assessment**
 - Foreshadowing risks
 - Risk detection and identification
 - Identifying potential victim
 - Actions/Precautions to protect the target
 - Risk control
 - Scaling risk impact
 - Consequence Scale
 - Tools of risk assessment
- ❖ **Module 4: Risk Assessment Methods**
 - Event tree
 - FTA – Fault tree analysis
 - What-if analysis
 - Incident Bow-Tie

- HAZOP – Hazard operability analysis
- FMEA – Failure mode event analysis
- ❖ **Module 5: Methodical**
 - Risk Monitoring
 - Risk Analysis
 - Risk Precautions
 - Decision Analysis tree
- ❖ **Module 6: Tracking and Updating Control Measures**
 - What is Control Measure?
 - Procedures
 - Training
 - Supervision
 - Updating and Maintaining
- ❖ **Module 7: Risk Management Techniques**
 - Reduce the Risk
 - Transfer the Risk
 - Avoid the Risk
 - Accept the Risk
 - Manage the Risk
 - Avoid Repeat
 - Fishbone Diagram
- ❖ **Module 8: General Office Safety and Reporting**
 - Accident Reports
 - Accident Response Plan
 - Emergency Action Plan
 - Training and Education
- ❖ **Module 9: Business Impact Analysis**
 - Gather Information
 - Identify Vulnerabilities
 - Analyse Information
 - Implement Recommendations
- ❖ **Module 10: Recovery Plan**
 - Risk and hazard control plan
 - Plan Implementation
 - Evaluation of control plan
- ❖ **Module 11: Summary of Risk Assessment**
 - FMEA and HACCP
 - What are the hazards?
 - Who might be harmed?
 - Are existing control measures sufficient?
- ❖ **Module 12: Concluding**
 - Lessons Learned
 - Completion of Action Plans and Evaluations
- ❖ Course Conclusion
- ❖ POST-TEST and EVALUATION

Training Methodology:

This interactive training course includes the following training methodologies as a percentage of the total tuition hours:

- 30% Lectures, Concepts, Role Play
- 70% Workshops & Work Presentations, Techniques, Based on Case Studies & Practical Exercises, Gamification, Software & General Discussions
- Pre and Post Test

Training Certificate(s):

CMCT Internationally recognized certificate(s) will be issued to each participant who completed the course.

Training Fees:

TBA as per the course location - This rate includes participant's manual, hand-outs, buffet lunch, coffee/tea on arrival, morning & afternoon of each day.

Note: The 5% VAT (Value Added Tax), will be effective starting 01st of January 2018 as per the new regulation from the UAE Government. The VAT applies for all quotation both for local and abroad.

Training Timings:

Daily Timings:

07:45 - 08:00	Morning Coffee / Tea
08:00 - 10:00	First Session
10:00 - 10:20	Recess (Coffee/Tea/Snacks)
10:20 - 12:20	Second Session
12:20 - 13:00	Recess (Prayer Break & Lunch)
13:00 - 14:00	Last Session

For training registrations or in-house enquiries, please contact:

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