AMMI
ASSOCIATION OF MALAYSIAN MEDICAL INDUSTRIES
PERSATUAN INDUSTRI PERUBATAN MALAYSIA
Medtech Malaysia

Medsociate
Authorised Training Provider

Industry Expert Training Series * HRDCorp SBL-Khas Scheme Claimable

US FDA 21 CFR Part 820 – Quality System Regulation

Training Brochure

US FDA 21 CFR Part 820 - Quality System Regulation

INTRODUCTION

The US FDA 21 CFR Part 820 – Quality System Regulation was developed and published to regulate and monitor medical devices and their life-cycle activities. The US FDA 21 CFR Part 820 outlines the current good manufacturing practice (cGMP) guidelines for the manufacturers and other relevant organizations to ensure the efficacy and safety of the medical devices.

Compliance with the regulatory requirements is crucial to ensure constant device supply and benefits to the users. A thorough understanding of the regulatory requirements is necessary to ensure effective implementation and continuous compliance. It will also elevate the confidence level in the manufacturers to prepare and host periodic FDA inspections.

COURSE OBJECTIVES

This course aims to help delegates to understand the UD FDA 21 CFR Part 820 requirements and get themselves ready for the FDA inspection. The consultant will also share practical examples to help delegates to understand the content better and guide them on effective implementation of the requirements.

The course content outlined is to provide delegates with:

- Understanding on the role and responsibilities of the US Food and Drug Administration (FDA)
- Knowledge and interpretation of the 21 CFR Part 820 requirements
- Simple practical implementation examples
- Readiness for the US FDA inspection

COURSE OUTLINE

- Opening & Introduction
- The US Food and Drug Administration
- The Federal Food, Drug, and Cosmetic Act (FD&C Act)
- The Code of Federal Regulations
- 21 CFR Part 820 (Subpart A-O)
- FDA Inspection – The Expectation and Preparation
- The FDA inspection outcomes
- Summary

COURSE BENEFITS

Upon completion of this training, delegates will: -

1. Have a good understanding of the US FDA CFR Part 820 requirements
2. Be able to put the requirements into effective implementation
3. Understand the FDA inspection process and the expectation

DURATION

4 half-day course (4 hours per session)

MODE OF TRAINING

Remote Online Training

TARGET AUDIENCE

This programme is designed for ALL functions and levels of an organization who need to gain understanding of the FDA 21 CFR Part 820 requirements, especially organizations that has embarked on the journey and plan to expand their market reach to the United States of America.

This programme is particularly useful to those managing the quality management system, process owners and internal auditors.

TRAINER'S PROFILE

Kenny Chong is the General Manager at Quintas Consulting Sdn Bhd where his role also includes maintaining top quality training, consultancy and coaching service for Medical Device & other regulated industries.

He has been involved in the Medical Device Industry for the past 14 years, working with Straits Orthopaedics, Symmetry Medical, Neville-Clarke as well as BSI Services. In this time, his experience throughout the entire product lifecycle and all 3 medical device regulatory stages has enabled him to gain qualification on all medical device technology scopes.

He is a trained CQI & IRCA Lead Auditor of ISO 9001:2015, ISO 14001:2015, OHSAS 18001:2007 as well as ISO13485:2016.

PAYMENT AND CONFIRMATION OF REGISTRATION

Option 1: HRDCorp Claim under SBL-Khas Scheme

A quotation together with course outlines and course agenda will be sent to you for HRDCorp grant application upon confirmation of the training. Please send us the grant application number for our record upon submission.

Option 2: Self-paying

2a) Direct Bank-in or via E-Banking

An invoice will be sent to you within 3 working days upon your registration. Please note that any Early Bird Discounts (for registration within validity period) will be reflected in the invoice. Please email us (admin@medsociate.com) the bank-in slip / remittance slip once the payment is made.

Please refer the following bank account details:
Beneficiary Name: Medsociate Sdn Bhd
Bank Account Number: 230-302-078-2
Bank: UOB Bank
Swift Code: UOVBMYKL
For Government Sector - A Local Order (LO) or letter of approval to participate must be submitted before your registration can be confirmed.

2b) Direct Online Payment

You may choose to make credit card payment via Paypal. An invoice with payment link will be sent to your email address separately when you choose this option.

CANCELLATION / REFUND POLICY

The organisers, AMMI/ Medsociate Sdn Bhd reserves the right to cancel or postpone any training or event but with due notice to the registered participants / company(s). Any payment made will be refunded in full if the cancellation is made by AMMI/ Medsociate Sdn Bhd. No shows and cancellations made by participants/ companies within the specified period will incur the specified costs as per below schedule.

Prior to Training Date	Cancellation Charges
30 days or more	No charges
15-29 days	25% of training course fee
8 - 14 days	50% of training course fee
0 - 7 days	100% of training course fee

SUBSTITUTION

Replacement of participant is allowed at no additional cost if you are unable to attend. Please inform us of the replacement in writing at least 3 working days before the training date.

CONTACT

For enquiries, please email to Medsociate Sdn Bhd
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