AMMI

ASSOCIATION OF MALAYSIAN MEDICAL INDUSTRIES
PERSATUAN INDUSTRI PERUBATAN MALAYSIA

Medtech Malaysia

Industry Expert Training Series
HRDF SBL Scheme Claimable

MEDICAL DEVICE DESIGN CONTROL

Training Brochure

Managed by Medsociate

HRDF MALAYSIA

CLAIMABLE

MEDICAL DEVICE DESIGN CONTROL

INTRODUCTION

Design Control is a substantial element of Quality System Regulation FDA 21 CFR Part 820 and ISO 13485 standards for medical device industries. Manufacturers must establish a robust design control processes to ensure develop a safe and effective finished product thus complies to regulatory requirements. This interactive course engages the participants with in-depth discussion of industry best practices to learn how industry leaders address design control challenges.

COURSE OUTLINE

1. Regulatory/QMS Compliance

1.1. QSR-21 CFR Part 820/EU MDR 2017/745

1.2. ISO 13485:2016, GHTF.SG3.N99-9

2. Introduction to Design Control

2.1. What is Medical Device Design Control Process

2.2. Application of Design Control-Waterfall Design Process

3. Medical Device Classification

3.1. European Medical Device Classification

3.2. US FDA Device Classification

4. Implementing Design Control

4.1 Design & Development planning [21 CFR 820.30 (b)]

4.2 Design Inputs [21 CFR 820.30 (c)]

4.3 Design Outputs [21 CFR 820.30 (d)]

4.4 Design Reviews [21 CFR 820.30 (e)]

4.5 Design Verification [21 CFR 820.30 (f)]

4.6 Design Validation [21 CFR 820.30 (g)]

4.7 Design Transfer [21 CFR 820.30 (h)]

4.8 Design Changes [21 CFR 820.30 (i)

4.9 Design History file [21 CFR 820.30 (j)]

5. Principles of Risk Management for Medical Device Design

5.1 Integration of risk management into the design and development lifecycle

5.2 Integration of risk assessment/risk management/ per ISO 14971:2019

6. Design Control and Usability Engineering

6.1 Application of usability engineering in medical device design

7. Design Control – Quality System Inspection Technique

7.1 QSIT inspection techniques for Design control

8. Design Control Case Studies

8.1 Design control scenarios

TARGET AUDIENCE

- ✓ Regulatory Personnel
- ✓ Quality Engineers
- ✓ Quality System Auditors
- ✓ Management representatives
- ✓ R & D staff
- ✓ Risk Management Team members

PRE-REQUISITES

Basic knowledge of medical devices and quality systems would be beneficial.

TRAINER'S PROFILE

Mr. Gobu Devarajan possesses Master Degree in Electrical and Electronic Engineering and Certified Manager of Quality/Organizational Excellence (CMQ/OE, Certified Quality Auditor (CQA) from American Society of Quality (ASQ). Certified Six Sigma Green Belt.

He has more than twenty five years of working experience with extensive knowledge in the field of Quality Engineering, Statistical Analysis and Quality System Requirements. He possesses excellent communication and presentation skills. He is capable of designing, conducting training programs and perform gap analysis according to QSR (21 CFR Part 820), ISO 13485, ISO 9001, ISO 16949 and ISO 14971. MDD 93/42/EEC, CMDCAS and JPAL

PAYMENT AND CONFIRMATION OF REGISTRATION

All payment is due immediately upon receipt of invoice. Please note that a confirmation letter for HRDF submission will only be issued upon receipt of payment.

Option 1 : Direct Bank-in or via E-Banking upon receipt of Invoice

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.

A confirmation letter for your HRDF submission will be issued to you upon receipt of payment.

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.

Option 2 : Direct Online Payment

You may choose to make direct online payment, via Paypal or your credit/ debit card. A tax invoice and confirmation letter will be sent to your email address within 3 working days, when you choose this option.

CANCELLATION / REFUND POLICY

AMMI 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. 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

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