Implementing Design Control Requirements and Best Practices for Medical Devices

Schedule: 13th – 14th Sep 17 (Weds to Thurs), 9.30am – 5.30pm

Venue: Aspiration Theatre, Level 2M Matrix Building

Biopolis @ one-north

About the Design Control Presenter

Mr Scott S. Sardeson

RAC US/EU
International Regulatory and Quality Compliance Director
3M Health Care Business
St. Paul, MN U.S.A

Scott Sardeson has held various positions at start-up and multinational medical device companies in manufacturing, R&D, quality, regulatory, and auditing. He is currently working in 3M Company in the Health Care Business Group as the International Regulatory and Quality Compliance Director. 3M Health Care provides clinical solutions for infection prevention, skin and wound care, oral care, and food safety. Scott's role is to provide regulatory and quality guidance to over sixty 3M subsidiaries that globally import, manufacture, and/or design medical devices and pharmaceutical products.

Scott represents the U.S. Industry in various international venues to drive harmonized regulation for medical devices. The goal is to collaborate with health care agencies to support regulatory convergence for product approvals, good manufacturing practice (GMP) requirements, and product standards. His work as an U.S. industry expert in Asia Harmonization Working Party (AHWP), and ISO Convener of the Technical Committee 210 Working Group 1 – Quality Systems is to assure better patient access to health care products as well as facilitate trade.

Organized by: MTIG of SMF, Singapore Manufacturing Federation 新加坡制造商总会

An industry partnership with: jtc

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Make sure your design process is compliant so you can avoid costly deviations.

The FDA has identified design control as a key area in its QSIT top-down inspectional approach to compliance. Manufacturers must have robust design control processes to comply with the FDA regulations and to ensure a safe, effective finished product.

This 2-day course covers the practical application of design control requirements and how to control the design process to ensure that your organization's devices meet user needs. The program has been revised to include more hands-on exercises, additional "how-to" information on implementation of design control requirements, increased focus on life-cycle aspects of risk management, and more industry examples.

In-depth discussions and workshops cover design and development planning, sound design inputs and corresponding design outputs, design validation, control of design changes, design results, transferring the design to product manufacturing, and the design history file. Class exercises explore the interface of design control with other processes such as risk analysis and corrective and preventive action (CAPA).

COURSE OBJECTIVES

- Understand the reason for design control and the current problems facing medical device companies today.
- Review and compare design control in the QSR and ISO 13485.
- Understand the process model approach to design control.
- Understand the phases of the product life cycle and their relation to design control.
- Identify the fundamentals and key elements of the design control process.
- Develop the proper interface of design control with risk management and CAPA processes.
- Understand the individual elements of the design control process.
- Recognize and apply the proper use of postproduction information in design control.
- Learn expectations of the FDA and its QSIT approach to inspection in relation to design control.

TOPICS

- FDA, ISO, and design control
- Principles of the process model
- Product life cycle and design control
- Design control, risk management, and CAPA
- Overview of the design control process
- Building a compliant design history file (DHF)
- QSIT with design control

WHO SHOULD ATTEND

Anyone managing, developing, or engaging in the design of medical devices, including direct engineering functions, QA/QC, production management, and regulatory, as well as anyone else who has a role in building a robust regulatory compliant environment.

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REGISTRATION

Name (Dr/Mr/Ms/Mrs):		
NRIC / FIN:	**Age:**	**Gender:**
Designation:		
Highest Academic Qualification:		
ACRA of Company:		
Company Name in ACRA:		
Type of Company : ☐ **SME** ☐ **Non-SME**		
Company Address:		**Postal Code:**
Email:	**Mobile:**	**Office DID:**

Training Workshop Fee *(Fee inclusive of GST)*

Singaporean / Permanent Resident:
Payable Net Fee - S$856.00

Non-Singaporean / Unsubsidised Singaporean / Unsubsidised Permanent Resident:
Payable Net Fee - S$1,070.00

For companies who are interested to register as SMF members, please submit the SMF member registration form which can be requested for separately.

Signature (With Company Stamp):

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