WORKSHOP ON DESIGN CONTROL FOR MEDICAL DEVICES

(29TH & 30TH NOVEMBER 2018)

Design Control For Medical Devices: From Theory to Practice

Design Control or Design and Development Control is a systematic procedure of documenting activities that are carried out primarily to meet the standard and regulatory requirements during new product development or design change. In addition, it is also intended to meet the requirements of customer, user, product performance properties, safety and efficacy. It is an important part of US Quality System Regulations: 21CFR 820. Under the regulations, it applicable to all Class II and Class III medical devices and some Class I medical devices such as surgical gloves. Clause 7 of ISO 13485 on product realisation states that organisation is required to establish, implement and maintain the design and development control procedures for all medical devices. It also covers identifying, evaluating, analysing, assessing, and mitigating potential risks associated with the product at an early stage to reduce the risks of product recall and failure. In addition, design control is one of the common inspection targets during a quality audit. As such, a well-documented design history file based on well-established design control procedures is important in meeting the expectations of the quality auditor or inspector

This 2-day short course is intended to introduce the design control concept (theory) and to guide the participants systematically on how to practise the design control procedures for new product development or design change.

As new product development or design change activities normally involve R&D, Manufacturing, Sales and Marketing, Quality Assurance, Engineering, Legal, Regulatory Affairs, Finance departments, this course is suitable for these personnel to understand their roles and responsibilities in the implementation of design control procedures.

Open book test (optional): A simple objective open book test will be conducted to allow the participants to assess themselves their understanding on the course content. For each question, the participants will only need to choose either “True” or “False” as the answer.

Trainer profile: Dr Eng Aik Hwee has more than 30 years of experience in Latex and Rubber Research. He was instrumental in commercialising several medical gloves over a period of 15 years, including Class III medical gloves, where he was an R&D technical leader. He is currently an advisor and technical trainer on medical gloves.

REGISTRATION

Fees

Member – RM 1200 per person
Non-Member – RM 1300 per person
Group Registration (2 or more persons per organisation) – RM 1100 per person

Foreign – US$ 350 per person
Foreign Group (2 or more persons per organisation) – US $ 300 per person

Payment MUST accompany registration to secure your seat at the workshop.

Please make cheque payable to **THE PLASTICS & RUBBER INSTITUTE MALAYSIA.**
Alternatively, please bank in direct into our current account below and fax/email the transaction slip to us

Our Banker: PUBLIC BANK BHD
KAMPUNG BARU SUBANG BRANCH
Account No.: 314 916 2131
Swift Code: PBBEMYKL

Registration Fee includes workshop materials, morning tea, lunch and afternoon tea for both days.

DATE & TIME:

29th (Thursday) & 30th (Friday) November 2018

9.00 am to 5.00 pm

VENUE:

Lee Foundation Hall, PRIM Building
20, Jalan Utarid U5/28
Mah Sing Integrated Industrial Park
40150 Shah Alam
Selangor
Malaysia

CONTACT DETAILS:

Telephone: +603-7847 1034
Fax: +603-7847 1610
Email: primy@prim.org.my

Person-in-charge: Mr. Aru and En. Ab'Llah

REGISTRATION FORM:

NAME OF PARTICIPANT: _____SALUTATION:_____

ORGANISATION: _____

POSITION: _____

ADDRESS: _____

_____

TELEPHONE NO: _____ EMAIL: _____

SIGNATURE OF PARTICIPANT: _____

For Company-Sponsored Participant:

Approved by: _____

Designation: _____

Signature: _____

Date: _____

Company Stamp: