



INSTITUT KIMIA  
MALAYSIA

# CHEMISTRY AND TECHNOLOGY INFORMATION SERIES 2025 (CATIS 2025)

## Introduction to Design Control: *Ensuring Quality, Safety & Compliance in New Medical Device Development*

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Moderator

Associate Prof. ChM.  
**Dr. Siti Nurul Ain Md  
Jamil**

Universiti Putra Malaysia  
(UPM) Serdang, Malaysia



Invited Speaker

**ChM. Dr. Eng Aik Hwee**

Technical Trainer and  
Consultant at K&W Training &  
Consulting, Malaysia.



**18 NOV 2025**

TUESDAY

10:30 AM – 12:00 PM



**Zoom Online & FB Live  
(Institut Kimia Malaysia).**

The link will be provided upon  
completion of registration.

**Organized by Division of Polymers and Materials Chemistry (DPMC),  
Institut Kimia Malaysia (IKM)**

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## **Introduction to Design Control**

Design Control, or Design and Development Control, is a systematic process of documenting activities carried out primarily to comply with standards and regulatory requirements during new product development or design changes. Design here means products or processes. It also ensures that customer and user needs, product performance, safety, and efficacy requirements are met.

In the United States, Design Control is a key component of the Quality System Regulations (21 CFR 820). These regulations apply to all Class II (medium risk) and Class III (highest risk) medical devices, as well as certain Class I (lowest risk) devices such as surgical gloves. Similarly, Clause 7 of ISO 13485 on product realisation requires organisations to establish, implement, and maintain design and development control procedures for all medical devices.

Design Control also encompasses identifying, evaluating, analysing, assessing, and mitigating potential risks at an early stage, thereby reducing the likelihood of product failure or recalls. Because it is one of the common areas of focus during quality audits, maintaining a well-documented design history file in line with established design control procedures is essential for meeting auditor or inspector expectations.

Many other products, particularly those involving complex engineering or safety-critical features, will implement a similar design process, though it may not be called "design control". This includes any product where consistency and adherence to specific design parameters are crucial for proper function and public safety.

This presentation is intended to provide an introduction to the concept of design control for professionals engaged in new product or process development, with a particular focus on medical devices.

## **About the Invited Speaker**

With a doctorate in Functional Material Engineering, the speaker has been engaged in latex, rubber, and rubber glove research since 1986, including contributions to the commercialisation of Class III medical gloves. As a recognised TTT Exempted Trainer by HRDC Malaysia, he has delivered over 500 hours of technical training through more than 100 modules to members of the rubber glove and the related industries since 2016. He is also a Fellow of the Institut Kimia Malaysia (IKM).