

**Medical Device  
Change Control**  
Training Brochure



## Medical Device Change Control

### COURSE OBJECTIVES

This course provides quality systems professionals, manufacturing engineers, and process development engineers with the knowledge and skills to implement change control for medical devices.

### COURSE OUTLINE

1. Introduction to medical devices change control
2. Change control - Deep dive into regulatory requirements
3. Navigating medical devices change control process
4. Integrating medical devices change control and risk management
5. Integrating quality management system (QMS) with change control process
6. Implementing medical devices change control process
7. Change control - Good Documentation Practices

### DURATION

Two (2) full days

### MODE OF TRAINING

Classroom Training

### COURSE AGENDA

Day	Time	Details
1	9.00 am – 12.30 pm	Introduction to medical devices change control Change control - Deep dive into regulatory requirements
	12.30 pm – 1.45 pm	Lunch break
	1.45 pm – 5.15 pm	Navigating medical devices change control process Integrating medical devices change control and risk management
2	9.00 am – 12.30 pm	Integrating QMS with change control process
	12.30 pm – 1.45 pm	Lunch break
	1.45 pm – 5.15 pm	Implementing medical devices change control process Change control - Good Documentation Practices

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### **CONTACT**

For enquiries, please email to Medsociate Sdn Bhd

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