

Medical Device Single Audit Program

Training Brochure



Medical Device Single Audit Program

INTRODUCTION

The Medical Device Single Audit Program (MDSAP) was an initiative from the International Medical Device Regulators Forum (IMDRF). Developed to enhance the auditing and monitoring approach of medical devices manufacturing globally, MDSAP went through a 3-year pilot project from 1st January 2014 until 31st December 2016 and became a full program from 1st January 2017.

This MDSAP training provides a comprehensive introduction to the Medical Device Single Audit Program and its regulatory purpose. The course explains the MDSAP framework, audit model, and key requirements, including how MDSAP supports compliance with the regulatory authorities of participating countries. Participants will gain practical insight into audit expectations, preparation strategies, and how to maintain ongoing compliance.

COURSE OBJECTIVES

After participating in the training, you will be able to:

- Learn the structure and purpose of Medical Device Single Audit Program (MDSAP).
- Gain a good understanding of the seven processes in MDSAP and their interlinkages.
- Learn the MDSAP audit approach.
- Understand the MDSAP certification process.

COURSE OUTLINE

1. Background of the MDSAP
2. MDSAP members, official observers, and affiliate members
3. The seven processes in MDSAP
4. Chapter 1 – Management
5. Chapter 2 – Device Marketing Authorization and Facility Registration
6. Chapter 3 – Measurement, Analysis and Improvement
7. Chapter 4 – Medical Device Adverse Events and Advisory Notices Reporting
8. Chapter 5 – Design and Development
9. Chapter 6 – Production and Service Controls
10. Chapter 7 – Purchasing
11. Auditing Organization (AO) and MDSAP certification
12. The MDSAP audit approach and audit time determination

DURATION

Two (2) full days

Medical Device Single Audit Program

MODE OF TRAINING

Remote Online Training or Classroom Training

COURSE AGENDA

Day	Time	Details
1	9.00 am – 12.30 pm	Background of the MDSAP MDSAP members, official observers, and affiliate members The seven processes in MDSAP Chapter 1 – Management Chapter 2 – Device Marketing Authorization and Facility Registration Chapter 3 – Measurement, Analysis and Improvement
	12.30 pm – 1.45 pm	Lunch break
	1.45 pm – 5.15 pm	Chapter 4 – Medical Device Adverse Events and Advisory Notices Reporting Chapter 5 – Design and Development
2	9.00 am – 12.30 pm	Chapter 6 – Production and Service Controls
	12.30 pm – 1.45 pm	Lunch break
	1.45 pm – 5.15 pm	Chapter 7 – Purchasing Auditing Organization (AO) and MDSAP certification The MDSAP audit approach and audit time determination

CONTACT

For enquiries, please email to Medsociate Sdn Bhd

Authorised training provider of AMMI

Email: learning@ammi.com.my / admin@medsociate.com

Tel: +6012 539 4194