

Beginner Level

Medical Device

Single Audit Program (MDSAP)

Training Brochure



**HRDF
CLAIMABLE**

Medical Device Single Audit Program (MDSAP) for Beginner

INTRODUCTION

The Medical Device Single Audit Program (MDSAP) was the 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.

There are currently 5 MDSAP members and they are:

1. Therapeutic Goods Administration (TGA) of Australia
2. Brazil's Agência Nacional de Vigilância Sanitária (ANVISA)
3. Health Canada (HC)
4. Japan's Ministry of Health, Labour and Welfare, and the Japanese Pharmaceuticals and Medical Devices Agency (MHLW/PMDA)
5. U.S. Food and Drug Administration (FDA)

The MDSAP requirements are developed based on the 5 MDSAP members' country's regulated policies for medical devices with ISO 13485 Quality Management System requirements as the basis. MDSAP certification audit is performed by approved and authorized Auditing Organizations (AO) and the MDSAP certification is on a 3-year cycle.

COURSE OBJECTIVES

This course aims to give delegates an overview of the Medical Device Single Audit Program (MDSAP) and the course content outlined is to provide delegates with:

- Introductory knowledge on MDSAP
- Introduction of the 7 processes in MDSAP
- The advantages of MDSAP certification

COURSE OUTLINES

1. Development of Medical Device Single Audit Program (MDSAP)
2. The **overview** of 7 processes in the MDSAP
3. MDSAP Certification

COURSE BENEFITS

Upon completion of this training, delegates will: -

1. Be able to understand the structure and purpose of MDSAP
2. Be able to have some decisional pointers if the organization shall be MDSAP certified

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DURATION

2 half-day course running from 8.30am to 12.30pm **OR** 1.30pm to 5.30pm.

MODE OF TRAINING

Online Training

TARGET AUDIENCE

This program is useful to delegates (regardless of their job role and responsibilities) who are new to the Medical Device Single Audit Program (MDSAP). Top Management personnel are also encouraged to enroll to this program to understand the MDSAP at a high-level view.

TRAINER'S PROFILE

Kenny Chong is the General Manager at Quintas Consulting Sdn Bhd where his role also includes maintaining top quality training, consultancy and coaching service for Medical Device & other regulated industries.

He has been involved in the Medical Device Industry for the past 14 years, working with Straits Orthopaedics, Symmetry Medical, Neville-Clarke as well as BSI Services. In this time, his experience throughout the entire product lifecycle and all 3 medical device regulatory stages has enabled him to gain qualification on all medical device technology scopes.

He is a trained CQI & IRCA Lead Auditor of ISO 9001:2015, ISO 14001:2015, OHSAS 18001:2007 as well as ISO13485:2016. He has also attended and passed training on Conformity Assessment Procedures on Quality Management System & Post Market Surveillance by the Medical Device Authority, Malaysia.

PAYMENT AND CONFIRMATION OF REGISTRATION

Option 1 : Direct Bank-in or via E-Banking upon receipt of Invoice

An invoice will be sent to you within 3 working days upon your registration. Please note that any Early Bird Discounts (for registration within validity period) will be reflected in the invoice. Please email us (admin@medsociety.com) the bank-in slip / remittance slip once the payment is made.

Please refer the following bank account details:

Beneficiary Name: Medsociety Sdn Bhd

Bank Account Number: 230-302-078-2

Bank: UOB Bank

Swift Code: UOVBMYYL

For Government Sector - A Local Order (LO) or letter of approval to participate must be submitted before your registration can be confirmed.

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Option 2 : Direct Online Payment

You may choose to make credit card payment via Paypal. An invoice with payment link will be sent to your email address separately when you choose this option.

CANCELLATION / REFUND POLICY

The organisers, AMMI/ Medsociate Sdn Bhd reserves the right to cancel or postpone any training or event but with due notice to the registered participants / company(s). Any payment made will be refunded in full if the cancellation is made by AMMI/ Medsociate Sdn Bhd. No shows and cancellations made by participants/ companies within the specified period will incur the specified costs as per below schedule.

Prior to Training Date	Cancellation Charges
30 days or more	No charges
15-29 days	25% of training course fee
8 - 14 days	50% of training course fee
0 - 7 days	100% of training course fee

SUBSTITUTION

Replacement of participant is allowed at no additional cost if you are unable to attend. Please inform us of the replacement in writing at least 3 working days before the training date.

CONTACT

For enquiries, please email to Medsociate Sdn Bhd

Authorised training provider of AMMI

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