



MEDTECH TALENT & EMPLOYMENT PROGRAMME

Handbook for Participants
(Updated April 2015)

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1.0 ABOUT THE MEDTECH TALENT AND EMPLOYMENT PROGRAMME (MTEP)

This handbook is designed to give Participants an overview of the Medtech Talent and Employment Programme.

The Medtech Talent and Employment Programme is created to assimilate employees of AMMI member companies into the medical device industry through training and familiarisation programme.

This is in line with the objectives of AMMI to provide a single-minded approach to grow the medical device industry by focusing on strategic initiatives in promoting manufacturing and operational excellence, talent development, support market driven innovation and R&D processes and promote opportunities for developing shared services.

2.0 PROGRAMME OBJECTIVES

- 1) To CREATE knowledgeable employees
- 2) To ASSIMILATE new employees into the medical device industry through training / familiarisation Programme.
- 3) To BRIDGE the competency gap between tertiary education and industry requirements



3.0 ABOUT AMMI

Formed in 1989, the Association of Malaysian Medical Industries (AMMI) represents leading medical device manufacturing companies in the Malaysian medical technology industry. AMMI members share a common commitment to quality and are reputable international and local firms that strictly adhere to the quality management system codes laid down by governmental agencies.

The AMMI member companies continue to be the growth base of the medical device industry in Malaysia and consist of three main types of industry players: manufacturers, suppliers of raw materials and services to the medical devices manufacturing companies; importers and exporters of medical devices, all of whom employ a sizable workforce.

As of December 2014, AMMI represents 53 companies that collectively account for more than 40% of the total export revenue for Made in Malaysia medical devices



4.0 PROGRAMME STRUCTURE

The Medtech Talent and Employment Programme is a six (6)-month talent development Programme comprising of medical device technical training and “On-Job-Training (OJT)” for new recruits in participating AMMI member companies.

4.1 Training Modules and Duration

Module	Technical Subjects	Days
1	Medical Device Design Control	2
2	Process Validation for Medical Devices	5
3	Risk Management in Medical Device Manufacturing	2
4	Medical Device Sterilization	2
5	ISO 13485 Quality Management System	5
6	ISO 13485 Internal Auditing	2
7	CE Marking and EU Medical Device Directive	2
8	FDA Good Manufacturing Practice (21 CFR Part 820)	4
9	FDA Quality System Inspection Technique (QSIT)	2
10	Malaysian Good Distribution Practice for Medical Devices (GDPMD)	2
11	Medical Device Classification and Labelling	1
12	Post Market Surveillance, Vigilance and Adverse Event Investigation	1
13	Team Building	2
	Total Duration Each Batch	32

4.2 Programme Assessment

Each module comes with an assessment to gauge the understanding and competency of each participant.

4.3 On-Job-Training (OJT)

“On-Job-Training (OJT)” will be provided by participating AMMI member companies.

4.4 Location, Time and Meals

The medical device technical training sessions will be held at Northam Hotel, George Town, Penang and/or selected venues.

Training sessions start from 9.00am to 5.00pm. Two (2) tea breaks and lunch will be provided for participants.



5.0 ADMINISTRATIVE PROCEDURES

5.1 Training Schedule and Course Material

You will receive the Training Schedule together with Letter of Offer. The Training Schedule will be updated from time to time with email notification to you.

You will receive your course materials on the first day of each module.

5.2 Documentation

You are required to provide the following documents to AMMI within five (5) working days upon commencement of the Programme:

1. Letter of Undertaking
2. Identity Card (Photocopy front and back)
3. Academic Degree Certificate / Transcript

5.3 Attendance

Kindly ensure all attendance requirements are met and to sign the attendance sheet for classroom trainings. You will be considered 'absent' if you fail to do so. You are also expected to present a medical certificate (MC) or a valid reason should you be absent from any classroom training. In the event of an emergency, you can be excused from attending the training provided you have a legitimate reason validated by proper documents.

5.4 Withdrawal/Drop-Out

In the event that you withdraw for any reason whatsoever before the completion of the Programme, you are required to return all costs, ie the training grant amounted to RM15,000 to AMMI. You shall complete the full duration of Programme unless you have obtained AMMI's prior written consent to withdraw from Programme in acceptable circumstances.

5.5 Grievances

The AMMI is committed to provide high quality services to all its participants and Member Company and welcomes the opportunity to serve and respond positively to all issues. You can call or email the AMMI Person-in-Charge should you have any grievances that you wish to highlight.

6.0 CONTACT INFORMATION

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Disclaimer

AMMI wishes to emphasise that, while every effort is made to ensure accuracy, the material in this Handbook is subject to alteration or amendment by AMMI.



Prepared by

Medsociate

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Authorized Training Provider and Secretariat for the Association of Malaysian Medical Industries

AMMI
ASSOCIATION OF MALAYSIAN MEDICAL INDUSTRIES
PERSATUAN INDUSTRI PERUBATAN MALAYSIA

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