AN INTRODUCTION TO PRODUCT DEVELOPMENT AND QUALITY MANAGEMENT SYSTEMS FOR HEALTH/MEDTECH INNOVATIONS

Course Code: GMS_BD1DPD

This 1-day workshop focuses on the product realization phase of a health technology innovation. The workshop will guide participants through the approach for taking a health technology innovation beyond idea/prototype towards product development. Participants will learn of the required medical device product development process, the importance of a properly established quality management system (QMS) and how both of these closely relate to each other to help innovation teams better plan and derisk their product development plan, in preparation for clinical testing and regulatory approvals.

This course is catered towards gearing individuals, project teams and potential spin-off teams who are in their POC or POV phase towards product realization. We also welcome medtech innovators who wish to learn the various considerations that goes into a QMS and product development cycle.

DATE & TIME
RUN 1
Monday, 06 Sep 2021
9:00am - 6:00pm

RUN 2
Monday, 07 Mar 2022
9:00am - 6:00pm

COURSE FEES
inclusive of GST

Original Price: SGD 1,016.50

After Subsidy*
SC < 40yo & SPRs: SGD 304.95
SC ≥ 40yo & Enhanced training support for SMEs: SGD 114.95

How to register?
Simply scan the QR Code and search for the course name as a self-sponsored participant! Refer to our registration guide here: https://bit.ly/SB_RegistrationGuide

If your company is sponsoring your participation upfront, please email us at sbenquiry@hq.a-star.edu.sg for registration instructions.
Understand the different strategies pertinent to product development and design control for innovations targeting a medical application.

Appreciate and apply knowledge on how to conduct a robust risk analysis and design failure mode and effect analysis (DFMEA) and how they relate to the design requirements of a medical/healthtech product.

Understand the importance of establishing a QMS, the steps required to set up a QMS for medical devices, the lifecycle stages and associated challenges.

Participants are expected to:

- Understand the different strategies pertinent to product development and design control for innovations targeting a medical application.
- Appreciate and apply knowledge on how to conduct a robust risk analysis and design failure mode and effect analysis (DFMEA) and how they relate to the design requirements of a medical/healthtech product.
- Understand the importance of establishing a QMS, the steps required to set up a QMS for medical devices, the lifecycle stages and associated challenges.

**Course Agenda (Tentative)**

- **0900H - 0910H** Introduction to the Session and the Approach
- **0910H - 0940H** Overview and Structure of Quality Management System
- **0940H - 1000H** Product Development Process & Design Controls: Concept Phase
- **1000H - 1015H** Tea Break
- **1015H - 1100H** Product Development Process & Design Controls: D&D and V&V Phases
- **1100H - 1200H** Requirement Specifications: User Needs and Design Inputs
- **1200H - 1300H** Lunch
- **1300H - 1400H** Risk Management Plan
- **1400H - 1500H** Risk Hazard Analysis and Risk Controls Exercise on Ventilator
- **1500H - 1515H** Coffee Break
- **1515H - 1530H** Components of Design History File
- **1530H - 1600H** Preparation for Audits and What Happens, Timeline for Setting up QMS and Expectation
- **1600H - 1700H** Q&A and Discussion
RUN 1: 4 Oct 2021 - 5 Oct 2021
RUN 2: 4 Apr 2022 - 5 Apr 2022
GMS_BD2DDTHI Design Thinking for Healthcare Innovation: Focusing on Identifying and Inventing for the Unmet Need (2 days)

RUN 1: 1 Nov - 3 Nov 2021
GMS_BD3DBMI Business Model Innovation for Healthcare Innovations (3 days)

RUN 1: 26 Nov 2021
GMS_BD1DFFHI Fundraising Fundamentals for Healthcare Innovations (1 day)

RUN 1: 13 Dec 2021 - 14 Dec 2021
GMS_BD2DBIHMT Business Implementation for Health/MedTech: Project to Market Overview (2 days)

RUN 2: 17 Jan 2021
GMS_BD1DDT Design Thinking for Healthcare Innovation: An Overview (1 day)

RUN 2: 14 Feb 2022 - 18 Feb 2022
GMS_BD5DBC Biodesign Bootcamp: Deep Dive Into HealthTech Innovation With An End in Mind (5 days)

To find out more,
EMAIL: SBEnquiry@hq.a-star.edu.sg
WEB: https://www.a-star.edu.sg/sb