

# An Introduction to Product Development and Quality Management Systems for Health and MedTech

Course Code: GMS\_BD1DPD

## Date & Time

### RUN 1

Monday  
03 October 2022  
09:00 am - 05:30 pm

## Workshop Location

A\*StartCentral Seminar Room  
79 Ayer Rajah Crescent, #05-03  
Singapore 139955

## Course Fees

(inclusive of GST)

### Original Price

SGD 1,016.50

### After SSG Subsidies

#### SC < 40yo & SPRs

SGD 304.95

SC ≥ 40yo & Enhanced training  
support for SMEs

SGD 114.95

This workshop aims to equip healthcare innovators, including healthcare professionals, researchers, engineers and budding healthcare entrepreneurs with knowledge relating to the product development competency (intermediate) under the [Health and Medtech Innovation Skills and Competencies whitepaper](#).

This workshop will provide learners with perspectives encompassing the development of a health and medtech product, de-risking innovation and implementing quality management systems.

By the end of the workshop, health and medtech innovators will be able to identify the different milestones to demonstrate medical device readiness from concept to a user-ready final device, apply a framework for risk assessment for early stage projects and apply best practices towards implementing initial quality management systems in early stage projects.



## 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](https://bit.ly/SB_RegistrationGuide)

If your company is sponsoring your participation upfront, please email us at [sbenquiry@hq.a-star.edu.sg](mailto:sbenquiry@hq.a-star.edu.sg) for registration instructions.

# An Introduction to Product Development and Quality Management Systems for Health and MedTech

## Course Agenda

### Learning Outcomes:

By the end of this module, you should be able to

- Analyse and articulate key design requirement specifications
- Assess technology to design and develop functional proof-of-concept prototypes, and determine what tests are required to de-risk the project
- Respond and manage potential product development risks, develop a mitigation plan and manage risks
- Collaborates with different internal stakeholders (e.g., engineers and scientists) to define product requirements, develop prototype and validate results
- Understands the required regulatory and quality requirements, i.e., guidance documents, standards for different kinds of innovation projects; Able to design and carry out necessary tests and documentation.
- Apply basic quality management standards to ensure adherence to ISO standards in the early product development stages

0900H - 0910H

Introduction

0910H - 0940H

Overview and Structure of Quality Management System

0940H - 1000H

Product Development Process & Design Controls: Concept Phase and D&P Phase

1000H - 1015H

Tea Break

1015H - 1100H

Product Development Process & Design Controls: D&D and V&V Phases

1100H - 1200H

Requirement Specifications: User Needs

1200H - 1230H

Risk Management: Hazard Analysis

1230H - 1330H

Lunch

1330H - 1515H

Hazard Analysis and Risk Controls Exercise on Ventilator [Case study]

1515H - 1530H

Coffee Break

1530H - 1600H

Risk Management: Product DFMEA

1600H - 1630H

Requirement Specifications: Design Input

Experiences in early stage projects - common pitfalls, mistakes, pushing for dev timeline vs doing the documentation

1630H - 1700H

Implementing a QMS post-spin-off

1700H - 1730H

Q&A and Discussion



## Upcoming Workshops

Our courses cover a wide range of topics in the HealthTech and MedTech industry and are designed for professionals looking to up-skill or re-skill themselves in the healthcare innovation space.

### **Design Thinking for Healthcare Innovation: An Overview**

RUN 1: 04 July 2022

RUN 2: 16 January 2023

### **Biodesign Bootcamp:**

#### **Deep Dive into HealthTech Innovation with an End in Mind**

RUN 1: 01 - 05 August 2022

RUN 2: 20 - 24 February 2023

### **An Introduction to Product Development and Quality**

#### **Management Systems for Health and MedTech**

RUN 1: 03 October 2022

RUN 2: 12 March 2023

### **Design Thinking for Healthcare Innovation: Focusing on Identifying and Inventing for the Unmet Need**

RUN 1: 17 - 18 October 2022

RUN 2: 03 - 04 April 2023

### **Business Model Innovation for Healthcare Innovations**

14 - 16 November 2022

### **Business Implementation for Health and MedTech:**

#### **Project to Market Overview**

01 - 02 December 2022

**Contact Us For  
More Information :**

 [www.a-star.edu.sg/sb](http://www.a-star.edu.sg/sb)

 [SBenquiry@hq.a-star.edu.sg](mailto:SBenquiry@hq.a-star.edu.sg)



or click [here](#).

