



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

 $SC \ge 40$ yo & 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 <u>Health and Medtech Innovation Skills and Competencies whitepaper</u>.

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

If your company is sponsoring your participation upfront, please email us at **sbenquiry@hq.astar.edu.sg** for registration instructions.



Course Agenda

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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-ofconcept prototypes, and determine what tests are required to derisk 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

Course Schedule (Tentative)

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
	Requirement Specifications: Design Input
1600H - 1630H	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



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or click here.

