SINGAPORE BIODESIGN



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

Date & Time

Run 1

Monday 02 October 2023 09:00 am - 05:30 pm

Run 2

Friday 02 February 2024 9:00 am - 05:30 pm

Location

To be informed upon confirmation

Course Fees

(Inclusive of GST)

Original Price SGD 1026

After SSG Subsidies SC < 40yo & SPRs SGD 307.80

SC ≥ 40yo & Enhanced training support for SMEs SGD 117.80

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.

or click **here**

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.

COURSE AGENDA

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

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

Programme Highlights:

| 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 | | | |
| 1630H - 1700H | timeline vs doing the documentation | | | |
| | 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.

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Biodesign Bootcamp: Deep Dive into HealthTech Innovation

with an End in Mind

Run 1: 31 July - 04 August 2023

Run 2: 26 February - 01 March 2024

Design Thinking for Healthcare Innovation:

An Overview

Run 1: 11 September 2023

Run 2: 15 January 2024

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

Run 1: 02 October 2023 Run 2: 02 February 2024

Business Model Innovation for Healthcare Innovations

Run 1: 01 - 03 November 2023

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

Run 1: 14 - 15 November 2023 Run 2: 25 - 26 March 2024

Business Implementation for Health and MedTech: Project to

edTech: Project to Run 1: 04 - 05 December 2023 Market Overview

Health and MedTech Project Management +

Run 1: 08 January 2024

Contact Us For More Information:





