

# Webinar Talk on ISO 13485:2016 Insights to the Role of an Engineer

BEM APPROVED CPD/PDP: 2 IEM22/HQ/073/T (W)

## SPEAKERS:

**Mr. MOHD FAUZI BIN MOHD IDRIS**  
&  
**Ir. SHAMILA ARIARATNAM**

**26 MARCH 2022**  
**SATURDAY**  
**11.30AM - 1.30PM**



# **SYNOPSIS**

**Safety and quality are non-negotiable in the medical devices industry. Regulatory requirements are stringent throughout the product's life cycle, including service and delivery. ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes requires engineers to understand the role they play in the life-cycle of the medical device. This is important as the engineer must know which regulatory requirements are applicable, their level of responsibility regarding safety of the device, reporting requirements and their commitment towards the quality management system (QMS).**

## **SPEAKER'S BIODATA**

**Mr. Fauzi graduated from Universiti Putra Malaysia in Bachelor of Science (Biomedical Sciences) in 2012 and received his Master Degree in Master of Science (Physiology) in 2017. Currently working as Head of Operations cum Auditor at Medivice Certification Sdn Bhd where he is responsible for managing and monitoring the operations as well as serving in the committee for certification decision for audits and conformity assessments. He is also the Management Representative for authority inspection or audit and accreditation audit.**

**Ir. Shamila graduated from Universiti Putra Malaysia (UPM) with a Bachelor's Degree (Hons) in Electrical/Electronics Engineering in 2000. She started her career with TriSystems Engineering Sdn Bhd in February 2001, as an Engineer and resigned as Project Engineer in 2004. Ir. Shamila was selected to represent Malaysia at the International Association of Traffic and Safety Sciences (IATSS) Forum, a 55-day leadership training program in Japan for young professionals from Asian countries hosted by Honda Motor Corporation, Japan. After she returned from IATSS Forum in 2004, she joined Matsushita Toshiba Picture Display (M) Sdn Bhd as the Safety and Health Engineer, a position which she held from August 2004 – March 2007. She completed and passed her Safety and Health Officer Training with NIOSH in October 2006. Concurrently, she pursued her Master of Business Administration from University of Strathclyde part-time and graduated in 2008. She joined Subang Jaya medical Centre in April 2007, now known as Ramsay Sime Darby Healthcare Hospitals as a Quality Executive. She rose through the ranks from an Engineer to Manager of the Biomedical Engineering Department before resigning to form her own company. Now she is self-employed under Armamentarium Consulting as a Freelance Healthcare & Biomedical Engineering Consultant, Trainer and Auditor.**