



# Centre of Regulatory Excellence In-Country Training on Medical Device Regulation

17 – 19 April 2018  
Hanoi, Vietnam

# Introduction

The Centre of Regulatory Excellence (CoRE) at Duke-NUS Medical School was pleased to conduct a training workshop on medical device regulation in Hanoi, Vietnam, from 17 – 19 April 2018.

The training programme was designed to support efforts to strengthen Vietnam's medical device regulatory systems and implement the ASEAN Medical Device Directive (AMDD), by enhancing critical skills required in the regulatory assessment of medical devices, supporting the implementation of a robust and efficient medical devices regulatory system, and encouraging regional regulatory collaboration.

## Participants & Faculty

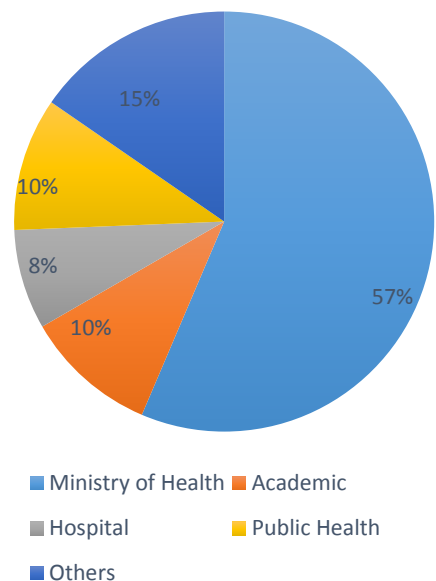
39 participants attended the workshop, including 22 participants from the Ministry of Health (including the Department of Medical Equipment and Construction, or DMEC) as well as representatives from other government agencies, academia and healthcare institutions.

The workshop faculty consisted of four subject matter experts, including Mr Michael Gropp (former Chair of the Regulatory Affairs Professionals Society Global Advisory Council) who served as the lead workshop facilitator, Dr Sethuraman Rama (Acting Director, Medical Device Branch of Singapore's Health Sciences Authority, HSA), Dr Yow Soh Zeom (Senior Regulatory Specialist at HSA) and Mrs Joanna Koh (former Director of the HSA Medical Device Branch).

### The workshop objectives were to:

1. Enhance critical thinking and decision-making skills to assess the safety, quality and performance of medical devices, including in vitro diagnostic (IVD) medical devices.
2. Explain why medical device surveillance and vigilance activities are essential to medical device regulation.
3. Encourage regional regulatory collaboration and the use of reliance practices to increase efficiency and optimise the use of available resources.

### Breakdown of Participants by Workplace



## Opening Address by Mr Nguyen Minh Tuan



Mr Nguyen Minh Tuan, Director General of the DMEC, Ministry of Health Vietnam, delivered the opening address at the workshop. Speaking of recent legislation that were being implemented, DG Tuan reminded participants of the aim to bring medical device regulation into alignment with the AMDD, as well as to protect public health and support economic development by promoting the domestic production of medical devices. He encouraged active participation and engagement among the faculty and participants during the workshop, underlining the importance of applying learnings from the workshop to their work.

# Workshop Sessions

The workshop was divided into four sessions, covering pre-market to post-market regulatory activities for medical devices, as well as discussions on the regulation of IVD medical devices and opportunities to enhance regulatory decision-making and processes.



**Mr Michael Gropp**  
Former Chair  
RAPS  
Global Advisory  
Council

**Dr Sethuraman Rama**  
Deputy Director  
Medical Device Branch  
Health Sciences  
Authority  
Singapore

## Session 1: Ensuring Medical Device Safety and Performance (Pre-Market)

Session 1 addressed the pre-market requirements for medical devices and covered topics such as the Definition and Risk Classification of Medical Devices, Evidence Requirements and Procedures for Dossier Evaluation, Essential Principles of Safety and Performance in Medical Device Evaluation, Examples of General Medical Device Registration Dossiers, and Applying Data Towards Robust Regulatory Decision-Making.



**Mrs Joanna Koh**  
Principal Consultant  
MDNet.Regulatory  
Consultants

## Session 2: Post-Market Activities in Medical Device Regulation

Session 2 moved on to post-market requirements and covered topics such as The Crucial Role of Post-Market Activities in Medical Device Regulation, and Post-Market Reporting and Controls. The session featured a team problem-solving exercise on Field Safety Notices and Field Safety Corrective Actions, and a discussion on opportunities for post-market regulation of medical devices in Vietnam.

## Session 3: Regulation of In Vitro Diagnostic Medical Devices

Session 3 focused on the regulation of IVD medical devices, reviewing the key concepts and going through examples of registration dossiers. The session also discussed opportunities to enhance the regulation of IVD medical devices in Vietnam.

## Session 4: Enhancing Regulatory Decision-Making and Processes

Session 4 touched on topics such as Clinical Evidence for Medical Devices and Optimising Resource Use Through Reliance Practices. The workshop concluded with discussions on further opportunities for regulatory systems strengthening.



**Dr Yow Soh Zeom**  
Senior Regulatory  
Specialist  
Medical Device Branch,  
Health Sciences  
Authority  
Singapore

# Feedback

The post-workshop survey yielded overwhelming positive feedback. All participants agreed that the workshop had met its stated objectives and found the topics relevant. Further, all participants felt that they had gained new knowledge and skills, and believed that they could apply learnings from the workshop to their own work.

**100%**  
Gained New  
Knowledge and Skills

**100%**  
Found the Topics  
Relevant

**100%**  
Can Apply Learnings  
To Work

The faculty and participants discussed several possible next steps to continue strengthening the medical device regulatory system, including continued efforts to enhance regulatory capability and capacity, further training on the regulation of IVD medical devices, and increased collaboration with stakeholders and other regulatory agencies.