



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

14 – 16 November 2017
Phnom Penh, Cambodia



Introduction

The Centre of Regulatory Excellence (CoRE) at Duke-NUS Medical School, with the support of the Asian Development Bank (ADB), was pleased to conduct a training workshop on medical device regulation in Cambodia from 14 – 16 November 2017.

The training programme was designed to support Cambodia's efforts to implement the ASEAN Medical Device Direction (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

28 participants attended the workshop, including 20 from the Department of Drugs and Food (DDF) and 8 from hospitals and public health programmes, including the National Center for Parasitology, Entomology and Malaria Control (CNM).

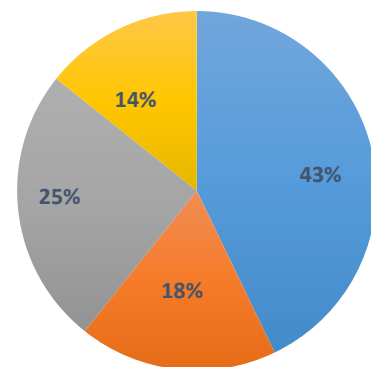
The workshop faculty consisted of three subject matter experts including Ms. Adena Lim from the Health Sciences Authority (HSA) of Singapore, Ms. Deliana Aboka from the Uppsala Monitoring Centre (UMC), and Dr. Jean-Christophe Delumeau from Bayer Southeast Asia and the International Society of Pharmacovigilance (ISoP).

The workshop objectives were to:

1. Outline the risk-based approach and regulatory controls that apply to medical devices, including how they are different from drug regulation, e.g., the use of risk classification and the Essential Principles of Safety and Performance.
2. Explain why medical device surveillance and vigilance activities are essential to medical device regulation.
3. Discuss and identify key next steps to be taken towards the implementation of regulatory controls for medical devices in Cambodia.

Breakdown of Participants by Workplace

Workplaces of Participants



- Regulatory Authority: Central Office
- Hospital
- Ministry of Health
- Others (Public Health)

Opening Address by Dr. Heng Bunkiet



Dr. Heng Bunkiet, Director General of the Department of Drugs and Food (DDF), Ministry of Health, Cambodia, delivered the opening address of the workshop. He highlighted that the medical device sector presented opportunities for economic growth, such as attracting foreign investment. Dr. Bunkiet also emphasised that there was much to do to complete the implementation of medical device regulatory controls, as well as the urgent need for training to build regulatory capability.

Workshop Sessions

The workshop was divided into five sessions. The first four sessions addressed four priority areas in medical device regulation, including the need for an integrated approach throughout the product life cycle, the application of a risk-based approach, the use of the Essential Principles of Safety and Performance to assess medical devices, and the crucial role of post-market activities. The fifth and final session focused on facilitated discussions to identify next steps for implementing regulatory controls in Cambodia.

Session 1: Overview of Medical Device Regulatory Controls

Laying the foundation for the workshop, Session 1 reviewed the medical device product life cycle and the regulatory controls applicable at each stage, highlighting the rationale for different regulatory controls and decision-making processes between medical devices and drugs. Pre-reading materials focused on the safety and product life cycle of medical devices, as well as the roles and responsibilities of various stakeholders in medical device regulation.

Session 2: Applying a Risk-Based Approach to Implementing Regulatory Controls

The aim of Session 2 was to enable participants to apply a risk-based approach to regulating medical devices, whereby the risk class assigned to a medical device determines the regulatory controls that should be applied to it. Pre-reading materials provided a review of key definitions and the basic principles of risk classification.

Session 3: Assessing Medical Devices for Safety and Performance

Session 3 explained how to assess medical devices using the Essential Principles of Safety and Performance, which specify the fundamental requirements for medical devices. The fulfillment of these requirements provides assurance that the medical device is safe and performs to its specification throughout its life cycle.

Session 4: Medical Device Surveillance and Vigilance

This session focused on post-market activities for medical device regulation including adverse event (AE) reporting and other requirements unique to medical devices, such as Field Safety Corrective Action (FSCA). Post-market surveillance is crucial for medical device regulation because possible device failures and other unanticipated problems may arise during actual use of the device. Pre-reading materials highlighted the importance of post-market activities to protect patient safety and public health, and the role of the national regulatory authority with respect to maintaining oversight on these activities in its own country.

Session 5: Developing an Action Plan for Cambodia

The final session aimed to discuss the current status of medical device regulation in Cambodia and to define next steps for implementation and strengthening of medical device regulatory controls. The pre-reading material focused on the importance and benefits of applying Good Regulatory Practices, highlighting that sound and effective regulation of medical products can have a positive impact on public health, the national economy and relationships with stakeholders within the country and in the region.

Feedback

The post-workshop survey yielded very positive feedback. 89% of participants agreed that the workshop had met its stated objectives and found the topics relevant. Further, 95% of participants felt that they had gained new knowledge and skills, and 85% believed that they could apply learnings from the workshop to their own work.

95%

**Gained New Knowledge
and Skills**

89%

**Found the Topics
Relevant**

85%

**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, appropriate policy amendments to achieve alignment with the AMDD, and increased collaboration with stakeholders and other regulatory agencies.