

# IVD Regulatory Challenges for Manufacturer's In Southeast Asia (SEA)

Presented by:  
Kate Qi (Dr)  
SG Diagnostics



1. Introduction
2. Product Registration in SEA
3. Current Challenge
4. Proposed Solution



# 1. Introduction

---

## SG Diagnostics Pte Ltd



1

### Background

- Based in Singapore
- Incorporated in Year 2020



2

### Qualifications

- Certified in IVDD (98/73/EC)
- Certified in ISO 13485



3

### Scope of Business

- Production, Secondary Assembly, Storage, Import and Distribution of IVD Test Kits for Infectious Immunology



4

### Manufactured Product

- SG Diagnostics Covid-19 Antigen Rapid Test Kit
- SG Diagnostics Immunity Rapid Test Kit etc..

**SG Diagnostics**  
Committed to Quality of Health



# 1. Introduction

---

## SG Diagnostics:

Access quality diagnostic tests wherever you are in the world.  
Recognised by international medical institutions.



Singapore



Philippines



Colombia



Peru



UAE



Italy



Hungary



Germany



Israel



Spain



Czechia



Portugal

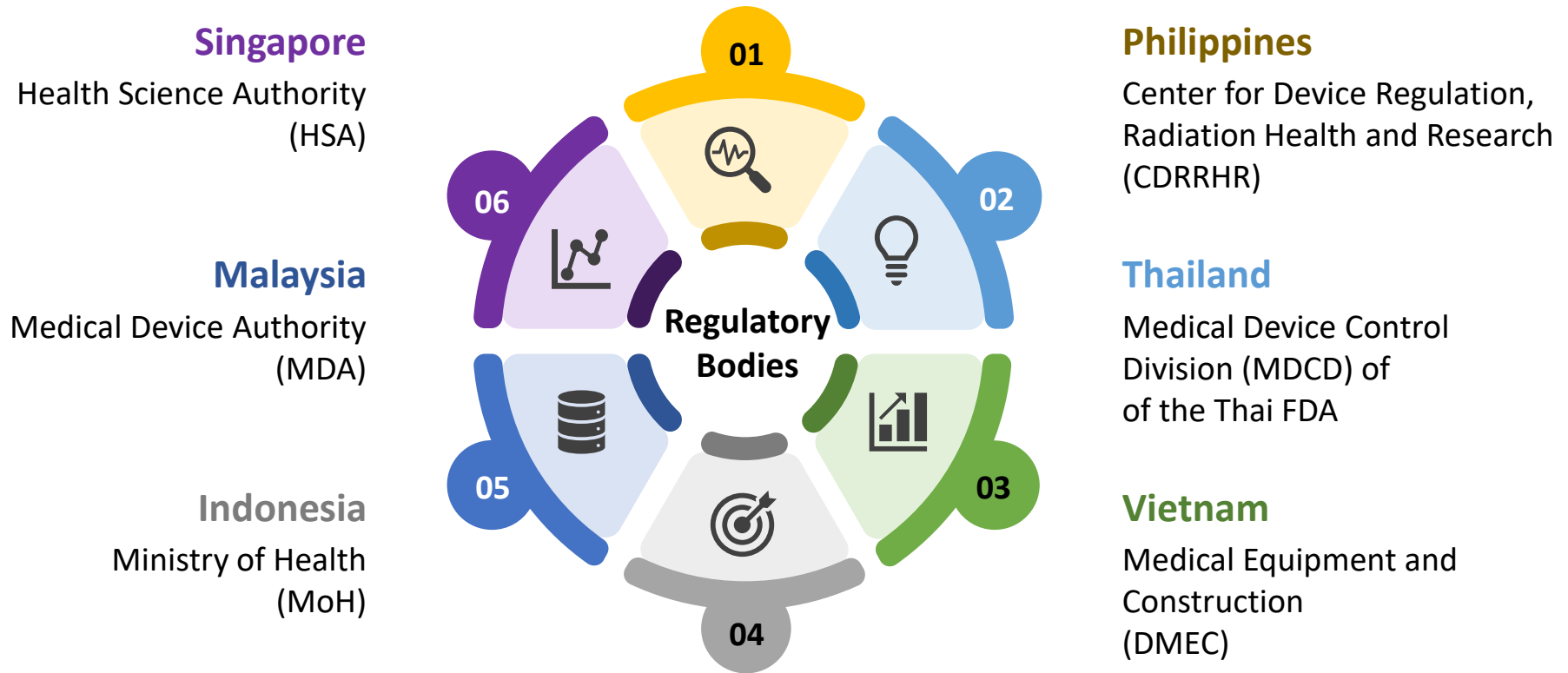


Mexico



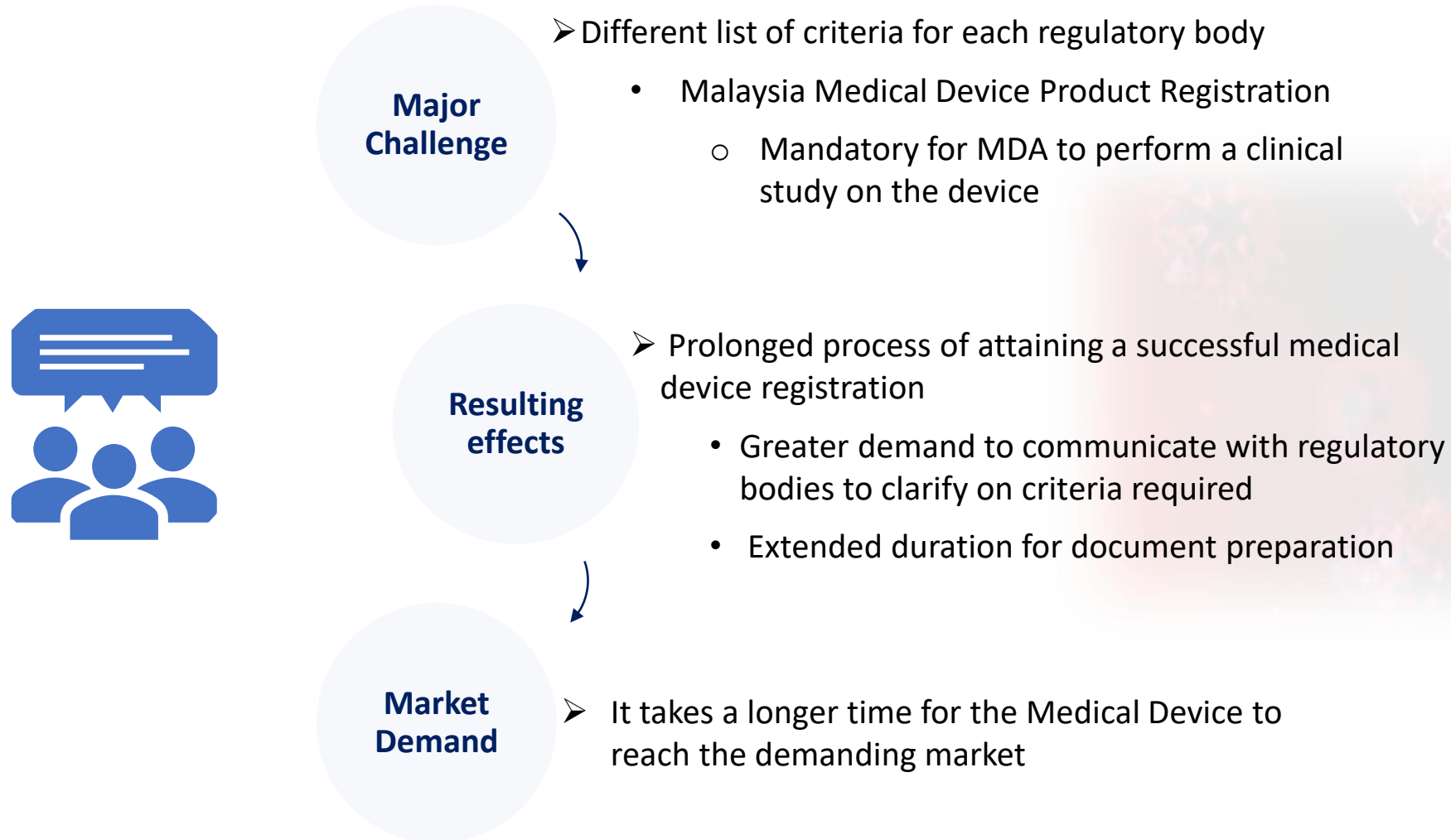
UK

### Regulatory Bodies responsible for Medical Device Registration



- Each Regulatory body has its individual list of criteria for Medical Device Product Registration

#### Regulatory updates for Covid Products:



## 4. Proposed Solution

---

### To establish a Harmonized Standard for Medical Device Product Registration

*A common List of Criteria used for Medical Device product registration*

#### ● Registration Process

- ✓ Simplify the process for product registration in SEA for manufacturers

#### ● Utilized Resources

- ✓ Reduce resources used for preparing Medical Device registration requirements

#### ● Communication

- ✓ Increase in effective communication between regulatory bodies



#### Quality ●

- ✓ Consistency of Medical Device quality in SEA Market

#### Time ●

- ✓ Duration for product registration is reduced without compromising on quality

**SG Diagnostics**

Committed to Quality of Health

*Thank you for your kind attention*

