

# HOW TO REGULATE WITH EXCELLENCE: ACHIEVING REGULATORY EXCELLENCE

*by Dr. Muralitharan Paramasua, Chief Executive, MDA*

# Regulatory Landscape for Medical Devices



## Regulatory Governance

NRAs derive their mandate, scope of operations and governance mechanisms from national laws. NRAs established within ministries of health perform the full extent of the regulatory functions



## Performance of Regulatory Function



### Market Entry

- a) Marketing authorization or registration
- b) Licensing of establishments
- c) Conduct of oversight of clinical trials



### Continuing quality assurance

- a) Good manufacturing practices (ISO 13485)
- b) Quality control laboratories
- c) Market surveillance & control
- d) Vigilance



### Market Exit

- a) Recall & market withdrawal

## Impact of Non-Compliance

- a) Market Withdrawal and Recalls
- b) Legal Penalties
- c) Loss of Market Access

- d) Damage to Reputation
- e) Public/Patient Safety Risks

# 1. Strategic Focus on Regulatory Governance in Medical Devices



The **medical devices sector** has been identified as a **priority growth area** with a gradual shift towards the manufacture of higher-value medical devices such as orthopaedic products, surgical instruments & diagnostic radiographic equipment.



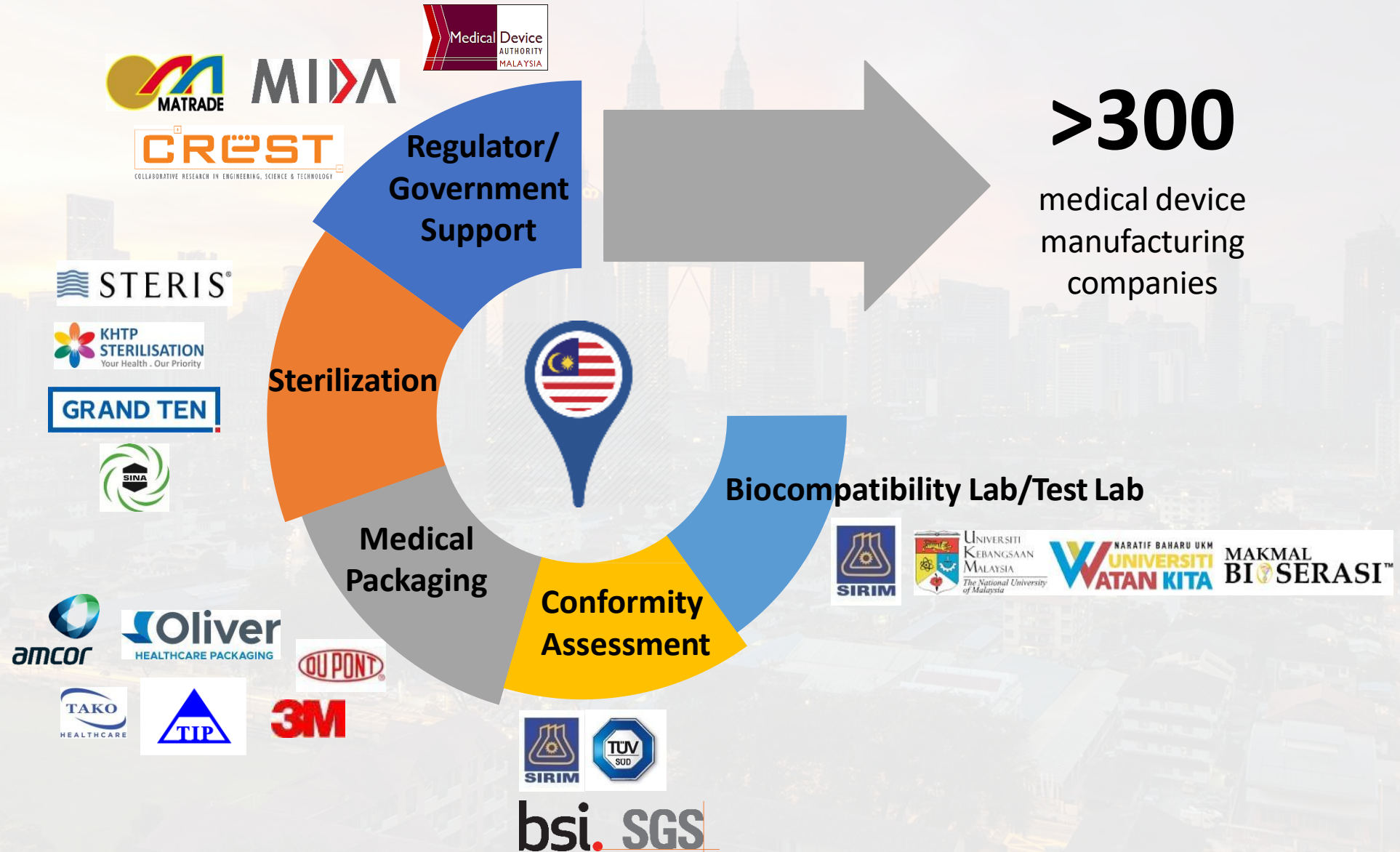
The **medical devices sector** was mentioned as one of the **strategic and high impact** industries in the 12<sup>th</sup> Malaysian Plan.



Table 1.1: Sectors Covered in NIMP 2030

Sectors	Industry	Relevant Sector-specific Policies
Priority Sectors	<ol style="list-style-type: none"><li>1. Aerospace</li><li>2. Chemical</li><li>3. Electrical and Electronics (E&amp;E)</li><li>4. Pharmaceutical</li><li>5. Medical Devices</li></ol>	<ol style="list-style-type: none"><li>1. Aerospace Industry Blueprint 2010</li><li>2. Chemical Industry Roadmap 2030</li><li>3. Malaysia Plastics Sustainability Roadmap 2021-2030</li><li>4. E&amp;E Roadmap 2021-2030</li><li>5. Malaysian National Medicines Policy</li></ol>

# 2. Government Role in Strengthening Medical Device Ecosystem



# 2. Government Support, Infrastructure & Ecosystem : Incentives

## INCENTIVES – MEDICAL DEVICES : Promoted Activities under Promotion Investment Act (1986)

### GENERAL INCENTIVE

*Manufacture of professional, medical, scientific and measuring devices/parts*

“Medical, surgical, dental or veterinary devices or equipment and parts or components/ accessories thereof”

#### Pioneer Status

**70%** Income tax exemption from the statutory income for **5 years**.



#### Investment Tax Allowance

**60%** of Investment Tax Allowance on qualifying capital expenditure incurred within a period of **5 years** to be offset **up to 70%** of statutory income.



OR

### HIGH TECHNOLOGY INCENTIVE

*Design, development and manufacture of*

“Medical, surgical, dental or veterinary devices or equipment and parts or components/ accessories thereof”

#### Pioneer Status

**100%** Income tax exemption from the statutory income for **5 years**.



#### Investment Tax Allowance

**60%** Tax Allowance on qualifying capital expenditure incurred within a period of **5 years** to be offset **up to 100%** of statutory income.



#### 2 ADDITIONAL CONDITIONS FOR HIGH TECH INCENTIVE:-

Science & Technical staffs (degree OR diploma min 5 years experience) **at least 15%** of total manpower;

Annual R&D expenditure **at least 1%** from annual gross sales

# 2. Government Support, Infrastructure & Ecosystem: Building Manufacturing Hub

Malaysia is One of the Global Offshore Manufacturing Hubs for Medical Devices



Malaysia has the highest concentration of medical device MNCs' manufacturing sites in ASEAN

A horizontal banner displaying logos of various medical device MNCs. The logos are arranged in three rows. The first row includes Abbott, Alcon, Ambu, Ansell, amcor, B. BRAUN, Boston Scientific, BD, Bactiguard, Biocon, CardinalHealth, Cochlear, and flex. The second row includes Dexcom, FRESINIUS MEDICAL CARE, HAEMONETICS, ITL, Integer, Intersurgical, Insulet, JABIL, JLL, KLS martin, Menicon, and Mölnlycke. The third row includes Masimo, MEDIPRO, OWEN MUMFORD, Paramit, TECAN, MeHow, ResMed, Smith+Nephew, SteriPack, SANMINA, Teleflex, TECOMET, TOP, PLEXUS, and VISCO.

# 2. Government Support, Infrastructure & Ecosystem: Talent Development in Innovation

Malaysia ranks #33 in World Talent Ranking

IMD World Talent Ranking 2022

Annual Graduates: 224,000 (2022: All fields)

Courses Available in Malaysia:

Bio-Medical Engineering Programme

Medical Equipment Engineering Programme



Private Higher Learning Institution

INTI College

Monash University

Cyberjaya University College of Medical Science

Asia Pacific University of Technology & Innovation

University Southampton Malaysia

UCSI University

Vision College

Perdana University



Government Higher Learning Institution

UPM

UTHM

UTM

UM

UTAR

13 Universities & Higher Learning Institutions

# 3. Building a Strong Medical Device Ecosystem

## RAW MATERIALS

### Consumables

- Biomaterials
- Latex (Natural/Synthetic)
- Plastics

### Surgical instruments, Implants & Clinical Devices

- Titanium
- Stainless Steel
- Biomaterials
- Ceramic Polymer

### Healthcare Equipment & Components

- Stainless Steel
- Plastics
- Electronic Modules

## TECHNOLOGY

### Latex/Plastic

### Metal

### Machining

### Electronics

### Furniture

## PRODUCTS

Medical Gloves, Contraceptives, Catheters, Woundcare, Syringes, IVD, SUD, Blood Collection Tubes

Pacemakers, AED, Orthopedics, Bone Grafts, Dental Implants, Surgical Instruments, Intraocular Lens, Contact Lens

Electronic Modules, Pulse Oximeters, Blood Management Devices, Ultrasound, Life Sciences Instruments, Hospital Beds, Dental Chairs

## MAJOR PLAYERS



## END USERS

Government Hospitals

Private Hospitals

Clinics

Medical Wellness Centers

## NEW/EMERGING MEDICAL DEVICES

Convergence of Technologies (e.g. Medical Devices-Pharmaceutical/ Electronics/ ICT/ IoT/ 3-D Printing (Additive Manufacturing)/ 4-D Diagnostic Equipment)

## SUPPORTING INFRASTRUCTURE

Medical Packaging

Electronic Manufacturing Services

Machiner & Engineering Support

Testing

Sterilisation

Education Training

Industry Association  
-AMMI, PERANTIM

## ENABLERS





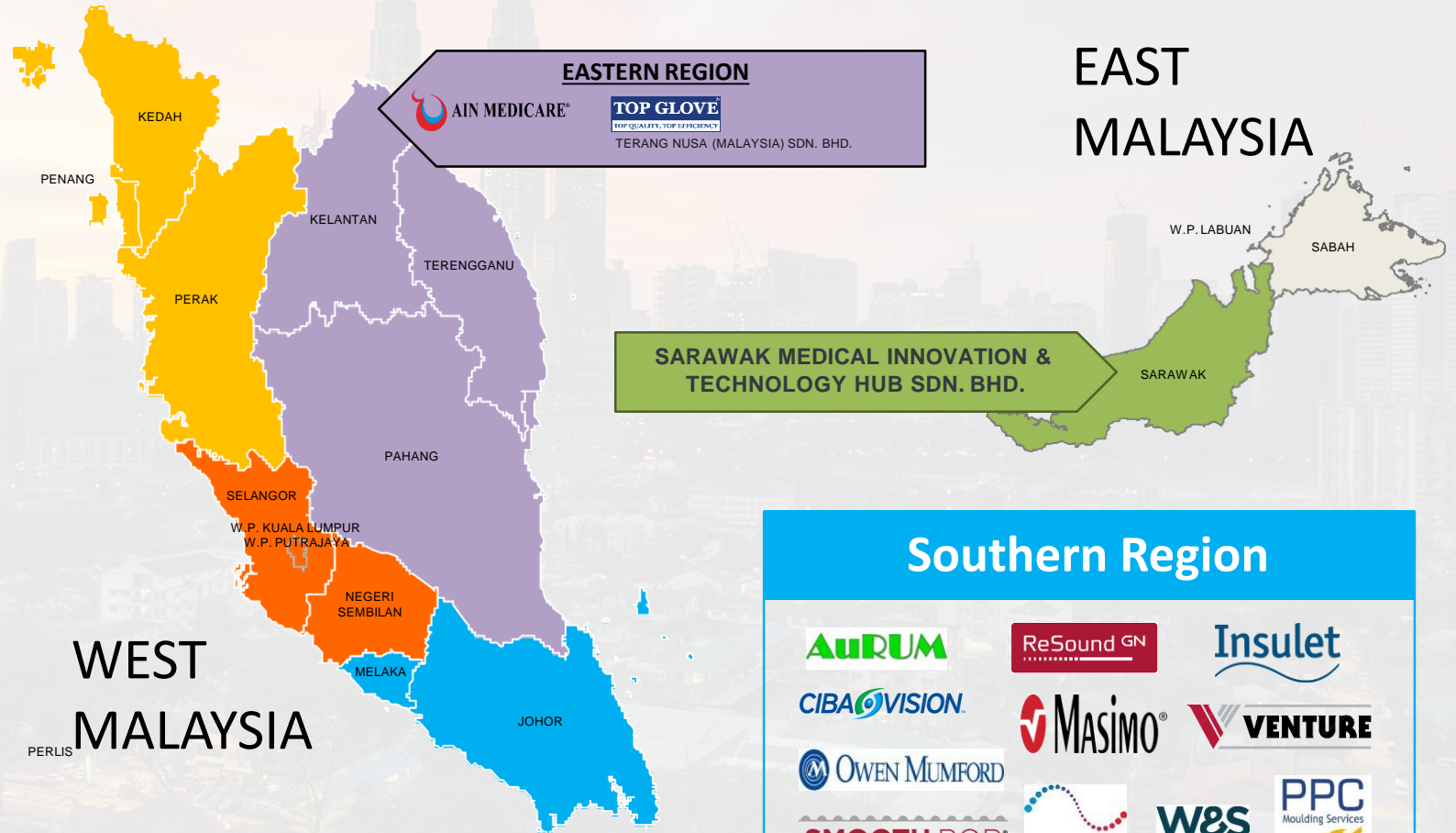
# 3. Building a Strong Medical Device Ecosystem

## GEOGRAPHICAL DISTRIBUTION

### Northern Region



### Central Region



### Southern Region



# 4. Adapting and Strengthening the Regulatory Framework

Basic level controls and enforcement		
Pre-market	Placing on the market	Post-market
Publish law including definitions and regulations with transition period	Registration of establishments	Establish a system for reporting adverse events and incidents
Establish medical device classification for regulatory purposes	Listing of medical devices	Require mandatory notification by the manufacturer of field safety corrective actions
Establish Essential Principles of safety and performance	Import controls	Establish a procedure to cancel market authorization for products that no longer meet quality, safety or performance requirements
Establish basis for reliance and recognition		Establish a procedure to issue safety alerts to users
Establish requirements for Declaration of Conformity		Undertake market surveillance
Establish requirement for manufacturers for a Quality Management System		
Establish requirements for labels and labelling		
Prohibit deceptive, misleading and false advertising		
Establish provisions for exceptional pre-market situations		

Expanded level controls and enforcement		
Pre-market	Placing on the market	Post-market
Create oversight of clinical investigation	Perform in-country quality management systems audits	Establish processes for review of manufacturer's post-market surveillance
Appoint and have oversight of conformity assessment bodies (CAB)	Perform review of submissions for compliance with Essential Principles	Require mandatory and timely reporting of adverse events and incidents by manufacturers
Adopt standards		Inspection of registered establishments
Adopt medical device nomenclature system		Provide for testing laboratories
Control advertising and promotion		

# 4. Adapting and Strengthening the Regulatory Framework: Current Trends

**Innovative/  
Advanced Medical  
Device Industry**

**Harmonization, Convergence  
and reliance**

**Unique Device  
Identifier (UDI)**

**Artificial Intelligence in  
Medical Devices:  
Regulatory Consideration**

**Data privacy,  
security and  
protection**

**E-labeling**

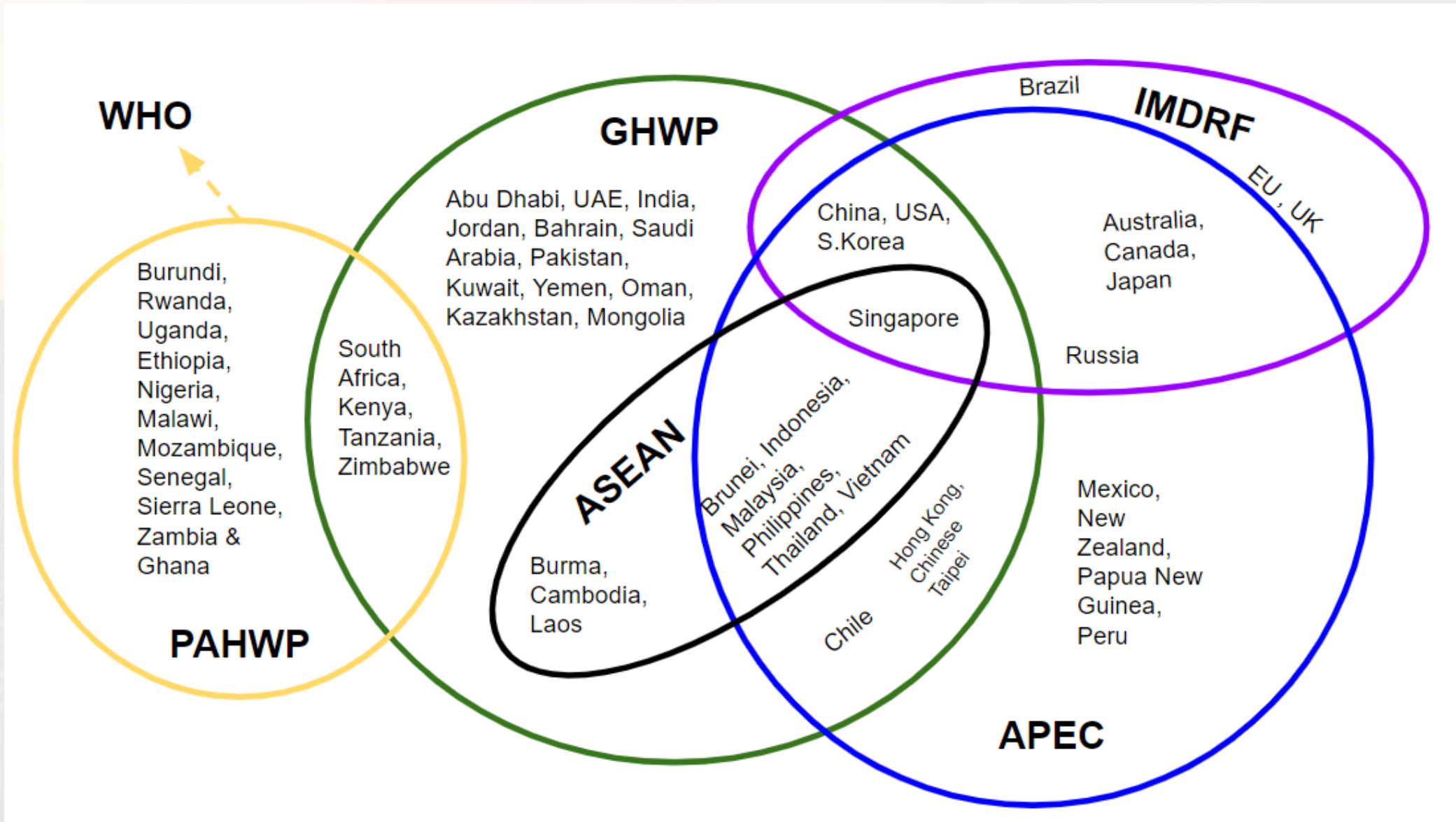
**Evolution of Software as a  
Medical Device (SaMD)**

**Cybersecurity**

**Real World Data /  
Real World Evidence**

**Post-Market Surveillance: National  
Competent Authority Report**

# 5. GLOBAL REGULATORY CONVERGENCE/ HARMONISATION INITIATIVE



# 5. GLOBAL REGULATORY RELIANCE/ CONVERGENCE/ HARMONISATION INITIATIVE



World Health  
Organization

## Promoting Good Regulatory and Reliance Practices

### Good regulatory practices

Set of principles and practices applied to the development, implementation and review of regulatory instruments in order to achieve a public health policy objectives in the most efficient way



Addressing responses to **common gaps in regulatory practices** identified during benchmarking of national regulatory systems



**Relevant to all regulators**, irrespective of resources, maturity or regulatory models (national, supranational and multiple institutions)

- **Good reliance practices**

- The act whereby the regulatory authority in one jurisdiction takes into account and gives significant weight to assessments performed by another regulatory authority or trusted institution, or to any other authoritative information in reaching its own decision.



Importance of **international cooperation** to ensure the safety, quality and efficacy or performance of locally used medical products



**Make best use of available resources and expertise**, avoid duplication and concentrate regulatory efforts and resources where most needed

# 6. Future Regulatory Facilitation: Advancing Malaysia's Medical Device Industry Milestones

**1980s**

## Rubber-based Products (Gloves)

- HIV/AIDS epidemics
- Surge in global demand
- Major producer of natural rubber latex
- **Product: Medical gloves**

**1990s**

## Consumable Products

- CAGR growing at 15-20% annually
- Identified as high value-added activities under IMP3 (2006-2020)
- Malaysian companies striving to be exporters – self-regulated
- **Product: Syringes, catheters, condoms and medical gloves**

**2010s**

## Advanced Medical Device Products



- Reinforced in RMK-11 (2016-2020), as a high-growth sector
- The NIMP 2021-2030 will include the development of 21 industry sectors including medical device
- Establishment of Medical Device Authority and Medical Device Act
- Export > 90%, majority contributed by rubber based consumables, gloves & catheters
- **Product: Orthopaedics, implants, laryngeal mask, headgear for sleep apnea, digital radiography system, hemodialysis solutions, intraocular lenses, surgical instruments**

**Future**



## Convergence Medical Technologies

- Exploring to non-invasive or minimally invasive solutions using micro-components and high precision devices
- To increase the export of premium and advanced medical devices
- **Product: Continuous glucose monitoring, robotic surgical system and bio medical engineering, intervention products, advanced surgical visualisation**

# 7. Economic Impact of Medical Device Investment: Medical Device Investments Over the Past 5 Years

Description	Medical Devices Sector 	Pharmaceutical Sector 
Total Approved Investments (2019-2023)	<b>RM28.1 billion</b>	RM1.2 billion
New Job Opportunities (2019-2023)	<b>45,166</b>	1,136



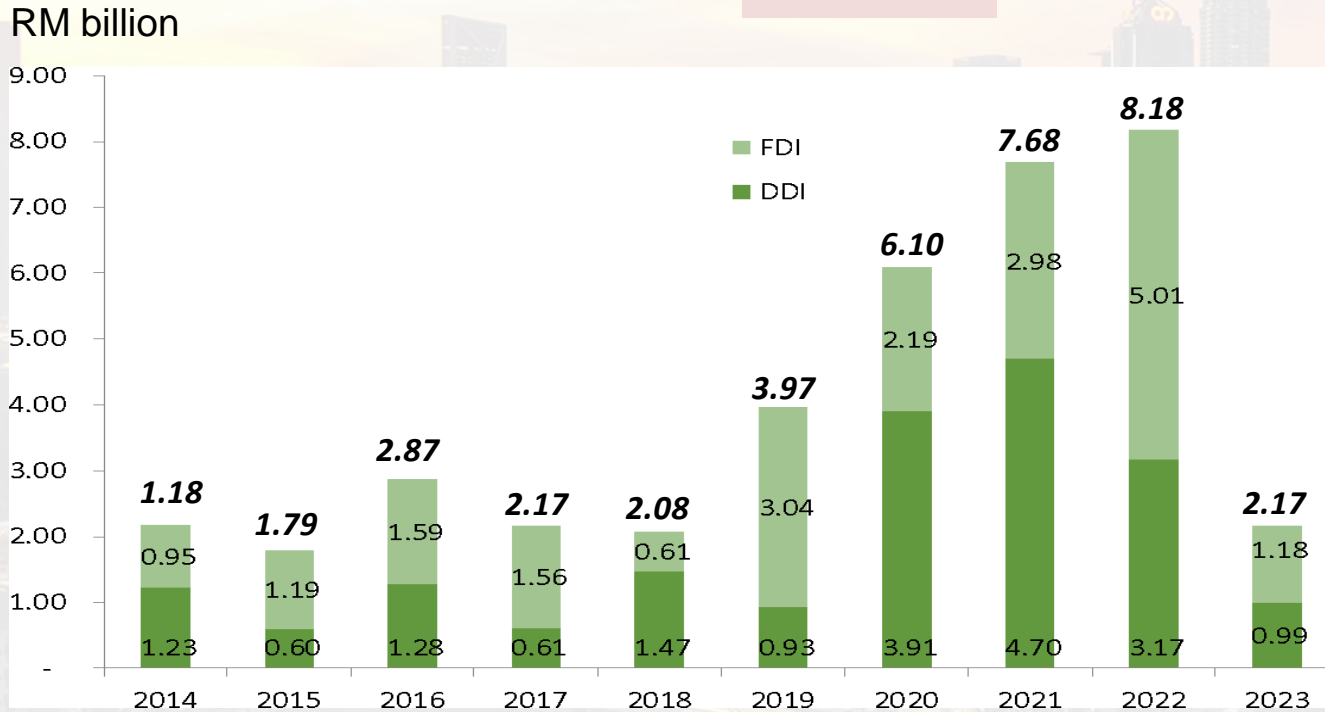
Approved Investments  
 **23x bigger** 

New job opportunities  
 **39x bigger** 

# 7. Economic Impact of Medical Device Investment: Malaysia

## Approved Investment from 2014-2023

FDI : 52%  
DI : 48%



Source: Malaysian Investment Development Authority (MIDA)

**TOTAL INVESTMENT  
APPROVED RM48.34 BILLION**

**POTENTIAL JOBS CREATION  
97,324**

**TOTAL PROJECTS APPROVED  
412**



An aerial photograph of a city skyline at sunset. The sky is filled with vibrant orange, red, and purple clouds. In the foreground, a residential area with various buildings and a green field is visible. The city skyline in the background features numerous skyscrapers, with the Petronas Twin Towers being the most prominent. A semi-transparent white banner is overlaid across the middle of the image, containing the text "THE END" and "THANK YOU" in bold, black, sans-serif font.

**THE END**  
**THANK YOU**