Medtronic

Engineering the extraordinary

An overview of medical devices

Fatemeh Razjouyan

Director, Regulatory Policy, International and Harmonization

Steve Kipkoti

Sr. Regulatory Affairs Specialist, ESA & Delve markets

August 23, 2023

Nairobi, Kenya

Agenda

1 Differences between medical devices and pharmaceuticals

2 Definitions of medical devices

3 IMDRF classification of medical devices

4 Steps to birng a new device to market

Medtronic

Though both are vital to healthcare, the medical device and pharmaceutical industries are distinctly different

Two different worlds in one health setting

	Innovation	Technology Lifecycle	Nature	Product Diversity	Compliance	Outcome	Adverse Event
MEDTECH (more than 2,000,000 different products- 6700 Categories)	Physicians Engineering IT	Rapid and iterative	Mostly Mechanical w/ inert effect on body	Diverse product sets	Higher compliance based on professional use	Depends on surgeons' skills & training and patient's response	Adverse events most often local in nature
PHARMA (20,000 Prescription Drugs)	Pharmacology Chemistry Biotechnology Genetics	13 years for patent protection	Chemical Interacts actively w/ body	Limited products and therapeutic areas	Compliance dependent on patient use	Dependent on patient response to therapy	Patient system toxicity

Medtronic

Drugs yesterday, today and tomorrow

Medtronic

As simple as a tongue depressor or a thermometer

As complex as robotic surgery devices

Medtronic

Intended use

is a significant factor

in determining whether a

product is regulated as a

medical device

Unregulated

Intended for fitness

and general wellness

Regulated

Intended for

diagnosing medical

conditions

Heart rate measurement device

Medtronic

IMDRF definition of “Medical Device”

Medical Device means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of or compensa-tion for an injury
- investigation, replacement, modification, or support of the anatomy or of a physiological process
- supporting or sustaining life
- control of conception
- disinfection of medical devices
- providing info by means of in vitro examination of specimens derived from human body

and does not achieve its primary intended action by pharmacological, immunological, or metabolic means, in or on the human body, but may be assisted in its intended function by such means

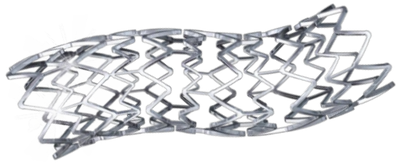
Variability Across Jurisdictions:

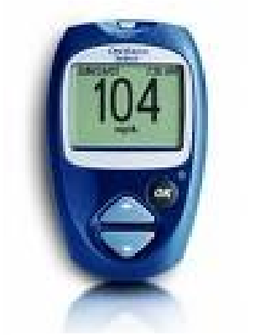
- disinfection substances
- aids for persons with disabilities
- devices incorporating animal and/or human tissues
- devices for in-vitro fertilization or assisted reproduction technologies

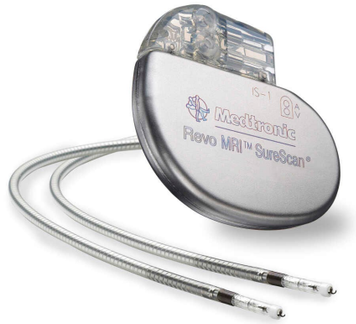
https://www.imdrf.org/sites/default/files/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n071-2012-definition-of-terms-120516.pdf

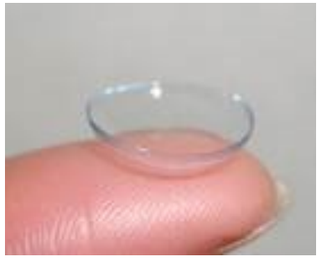
Medtronic

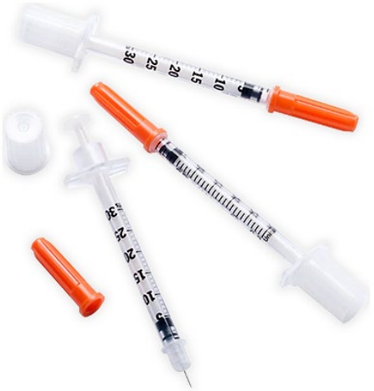
Examples of medical devices





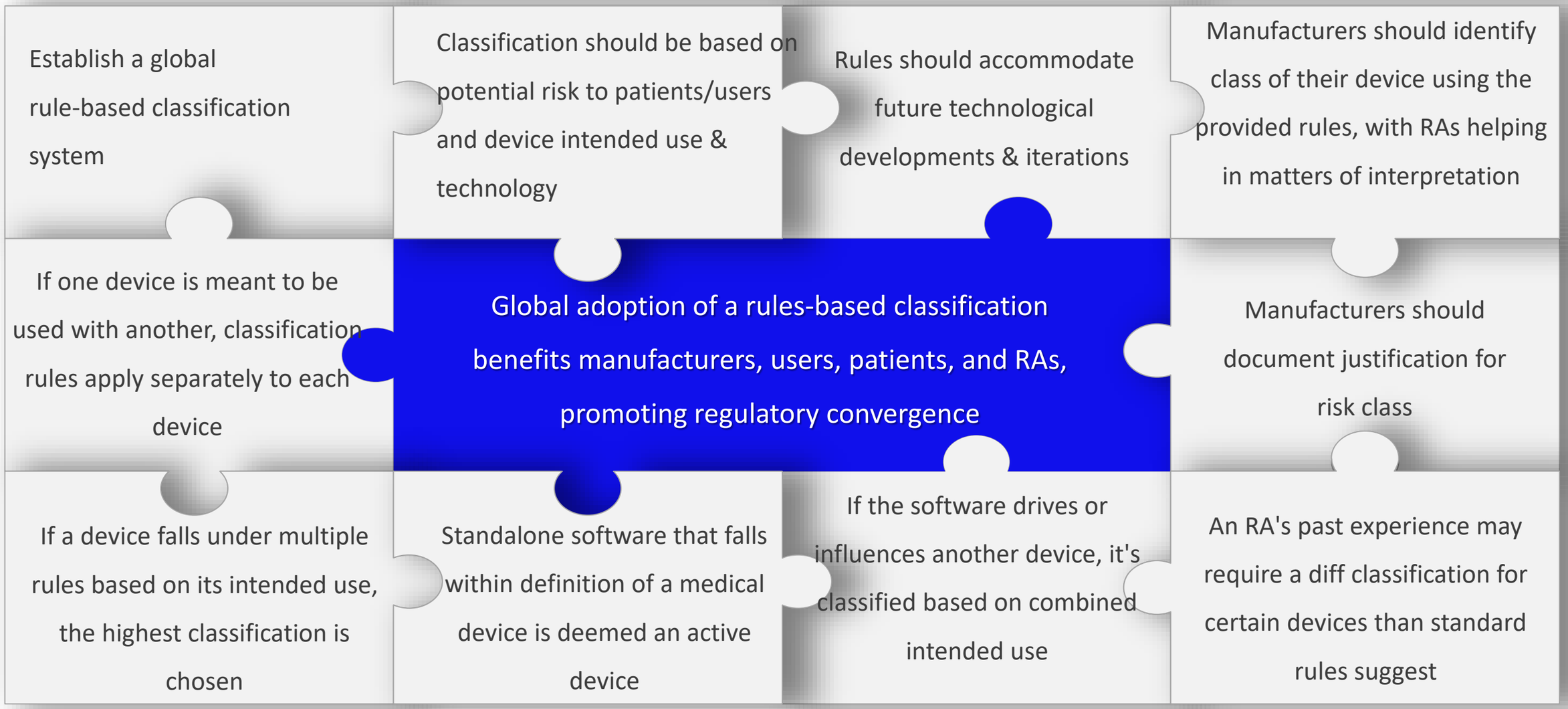






Medtronic

IMDRF classification recommendation for medical devices



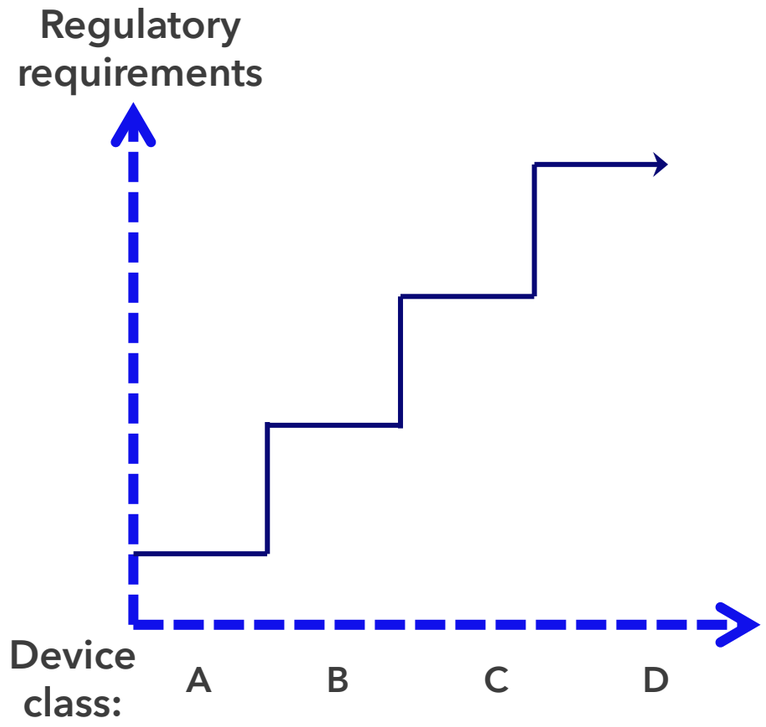
https://www.imdrf.org/sites/default/files/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n77-2012-principles-medical-devices-classification-121102.pdf

Medtronic

IMDRF proposed classification system for medical devices

WHO also recommends the IMDRF classification

Class	Level	Device examples
D	High risk	Heart valves, implantable defibrillator
C	Moderate-high Risk	Lung ventilator, bone fixation plate
B	Low-moderate risk	Hypodermic Needles, suction equipment
A	Low risk	Surgical retractors, tongue depressors



https://www.imdrf.org/sites/default/files/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n77-2012-principles-medical-devices-classification-121102.pdf

https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-wng64.pdf

Medtronic

Steps to bring a new device to market

Identify classification & regulatory pathway

Classification can inform regulatory pathway and level of evidence needed

Develop valid scientific evidence [1]

Clinical data, bench testing and/or animal studies appropriate to the potential risk of the product

Prepare premarket submission

Each type has own process, law and regulation, review times and evidence requirements

Verify that product is a medical device

Establish product

Identify intended use, indications for use, duration of use & target patient population

1 https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-181031-grrp-essential-principles-n47.pdf

https://www.who.int/publications/m/item/who-global-model-regulatory-framework-for-medical-devices-including-in-vitro-diagnostic-medical-devices--annex-3

Medtronic

“Safety doesn’t happen by accident”

Medtronic

Regulators and manufacturers are committed to timely patient access to safe, effective, and quality medical devices

Medtronic

Ensuring Safety & Efficacy of Medical devices

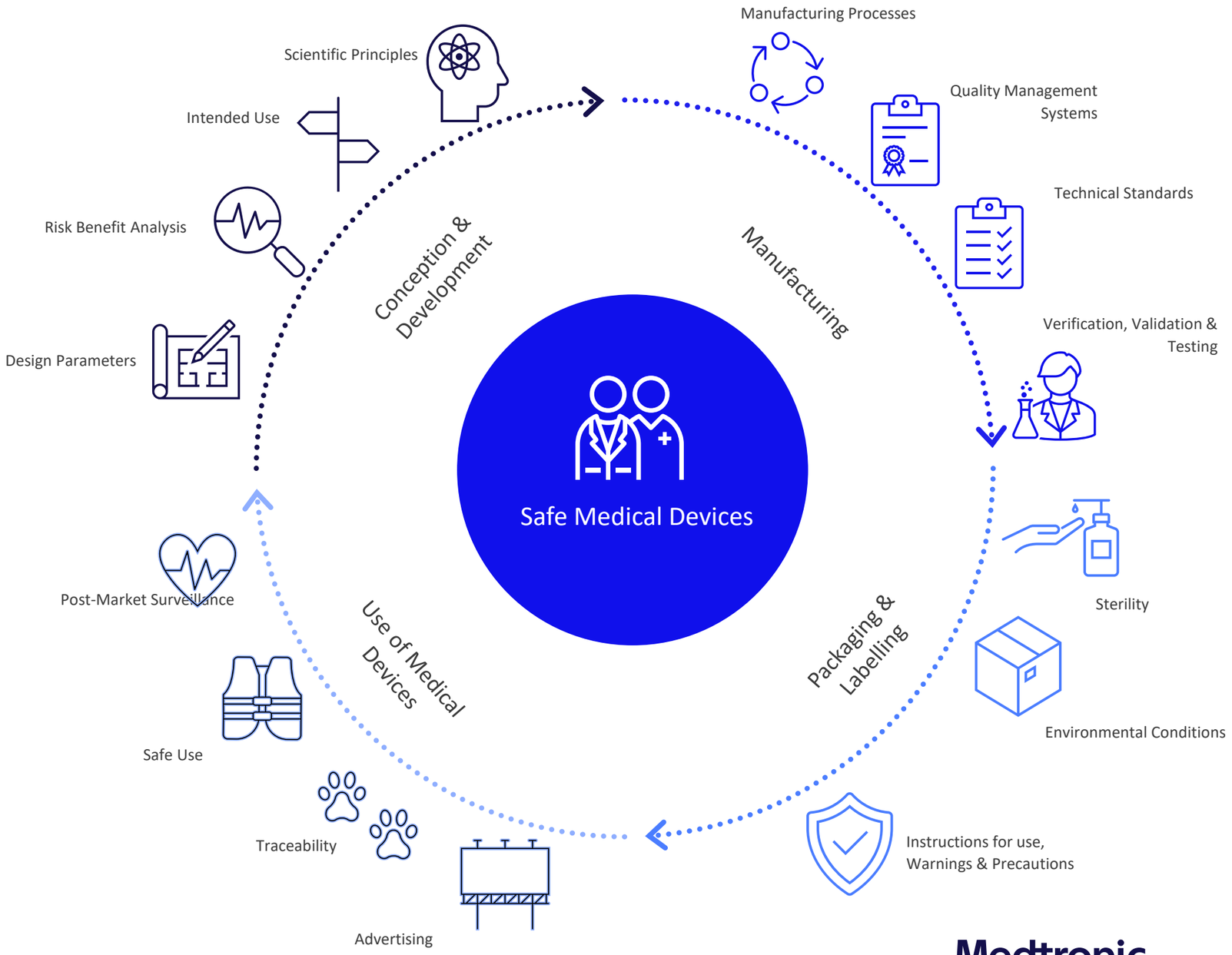
Shared Responsibility

Governments:

- Establish policies and regulations to ensure timely access to medical devices that are both safe and effective, with periodic revisions to accommodate technological advancements
- Drive healthy cooperation and transparency with stakeholders to ensure regulations are streamlined and practical

Manufacturers:

- Ensure products manufactured and maintained to meet or exceed required standards for safety and performance



Medtronic

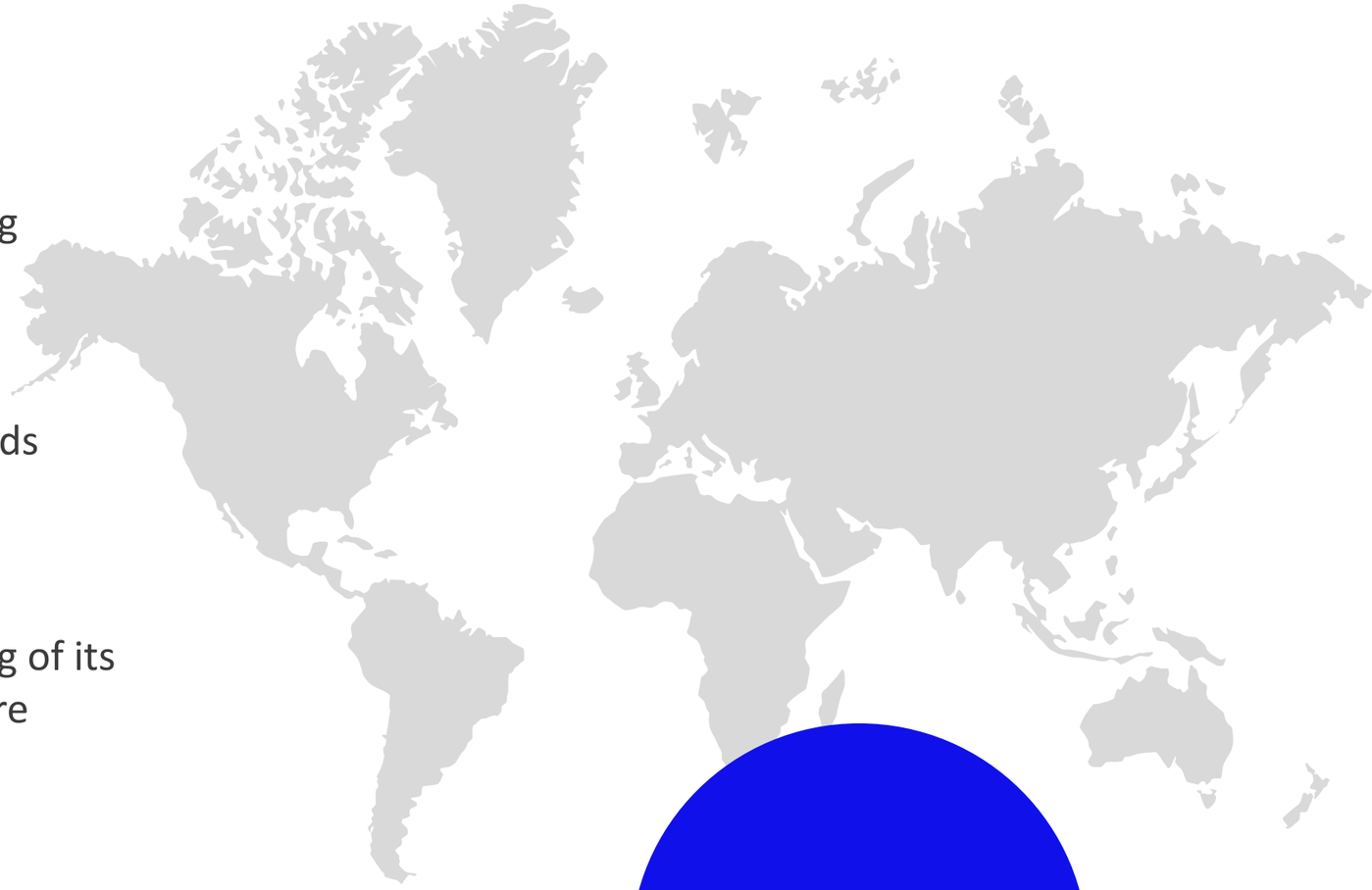
The global landscape and driving force

Drivers for regulating MedTech

Accelerated ageing population and increasing prevalence of chronic disease

Rapid innovation in MedTech to address needs in healthcare systems

Governments interest in promoting well-being of its people and mitigating healthcare cost pressure



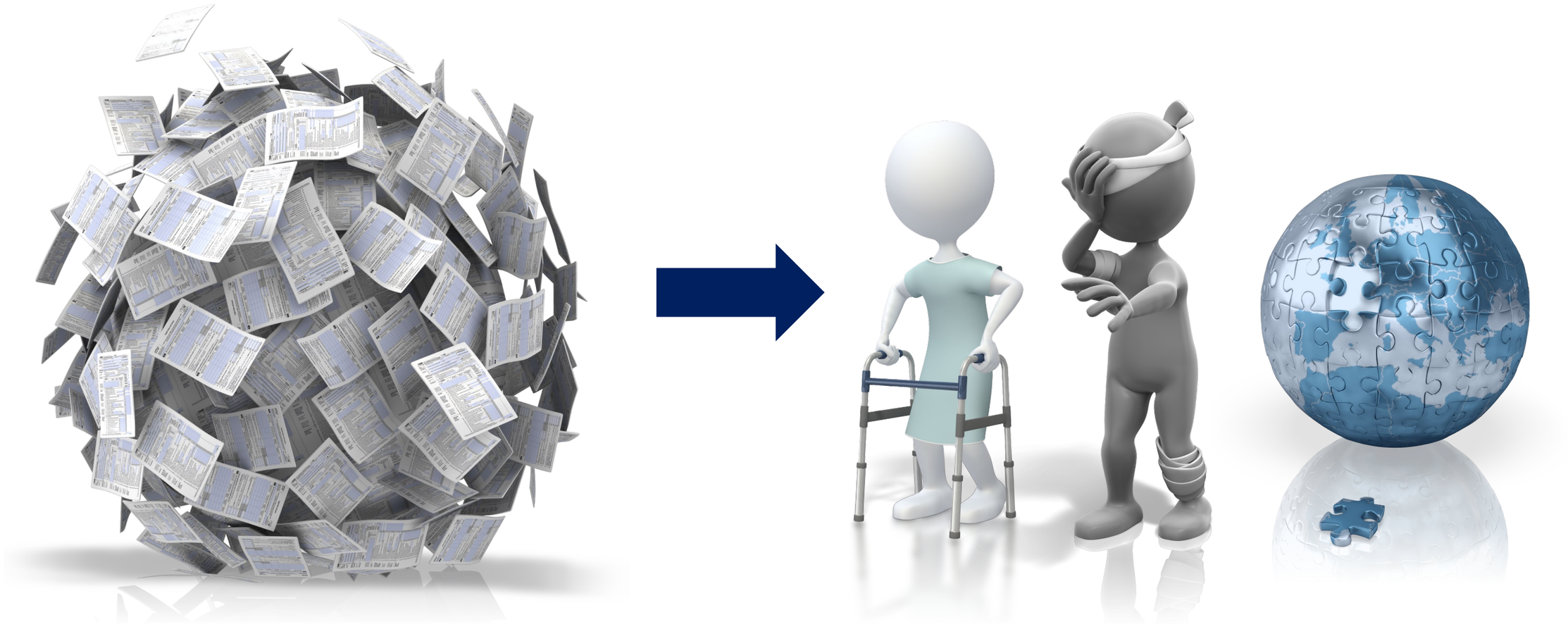
Governments takes on a big responsibility to facilitate **safe** and **timely** access to innovative technologies

84+

Medical Devices regulatory Agency around the world

Medtronic

Lack of common regulatory framework and regulators' resource challenges **hinder patient access** and manufacturers' ability to introduce innovative and life-saving medical devices to market



Medtronic

The call for regulatory convergence and reliance for all regulators

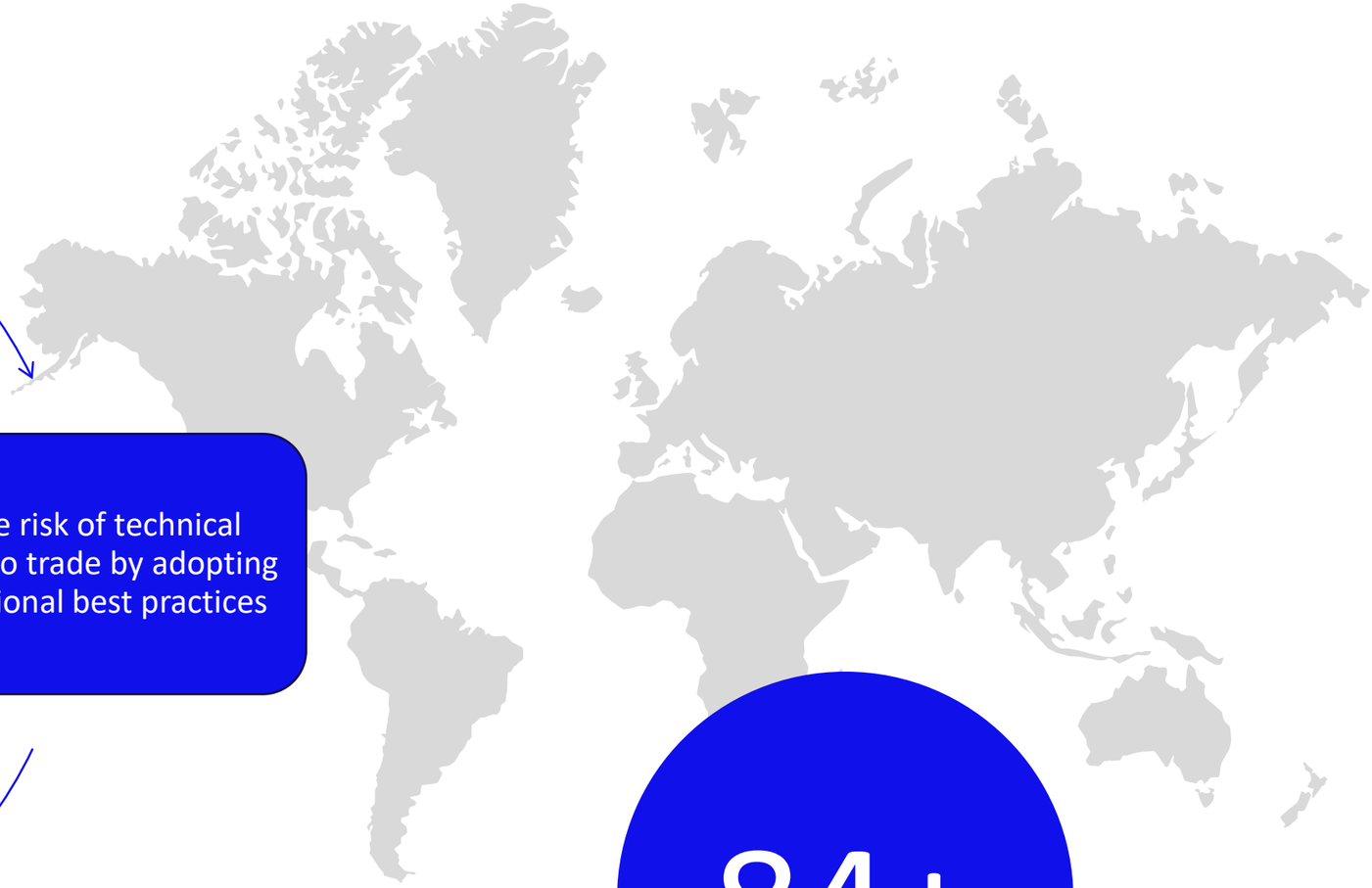
Around the globe

Enhance government efficiency through collaborative regulation: share audits, exchange info & leverage experiences

Reduce risk of technical barriers to trade by adopting international best practices

Reduce cost and time to market

Increase patient access to innovative medical devices



84+

Medical Devices regulatory Agency around the world

Medtronic

Up next …

IVD overview

Medtronic