

# WHO global model regulatory framework for medical devices including in-vitro diagnostics

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# Main features of the GMRF

## Table of contents

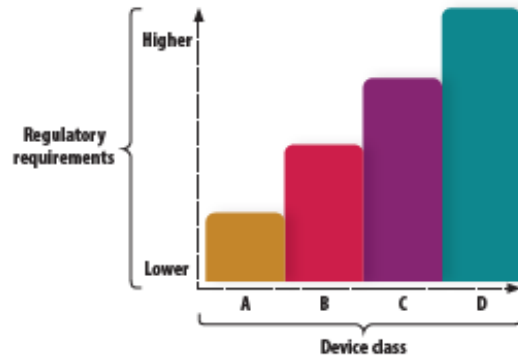
- Chapter 1-3. Introduction, purpose, scope and terminology
- Chapter 4. Definition, classification, essential principles, and conformity assessment of medical devices
- Chapter 5. Enabling conditions for effective regulation of medical devices including IVDs
- Chapter 6. Establishing a stepwise approach to regulating medical devices
- Chapter 7. Regulatory pathways **NEW**
- Chapter 8. Additional topics
- Chapter 9. Implementation **NEW**



# Risk based approach

- Classification system vs Regulatory controls
- Four risk classes: A, B, C, D
- Risk-based classification rules
- Different conformity assessment per risk class

**Fig. 4.1**  
Impact of device classification on regulatory scrutiny



Note: as the regulatory requirements increase, so does the scrutiny by the NRA.  
Source: reproduced from *Principles of medical devices classification* (32).

Classification system



Regulatory controls

# Two phase approach



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		

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		

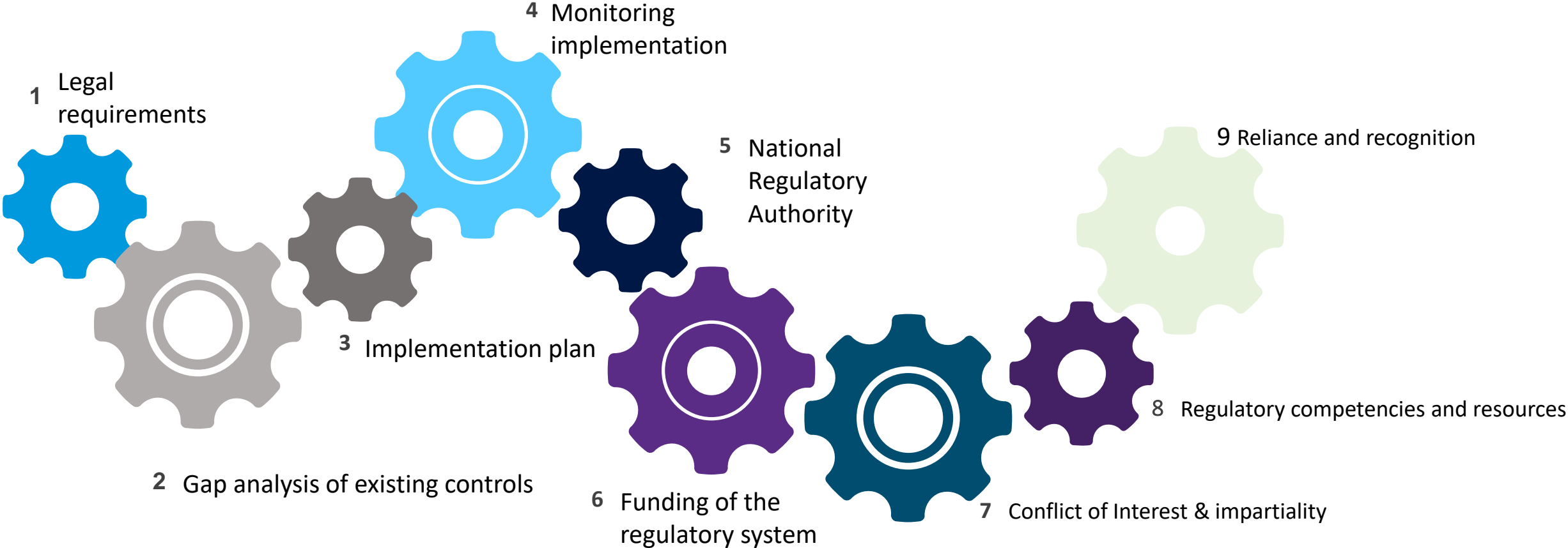
# WHO Global model regulatory framework: Conformity assessment by risk class of medical device

## *(risk based approach)*

### Conformity assessment processes as determined by device class

Conformity assessment element	Class A	Class B	Class C	Class D
<b>Quality management system (QMS)</b>	Regulatory audit normally not required, except where assurance of sterility or accuracy of the measuring function is required.	The NRA should have confidence that a current and appropriate QMS is in place or otherwise conduct a QMS audit prior to market authorization.	The NRA should have confidence that a current and appropriate QMS is in place or otherwise conduct a QMS audit prior to market authorization.	The NRA should have confidence that a current and appropriate QMS is in place or otherwise conduct a QMS audit prior to market authorization.
<b>Technical documentation<sup>16</sup></b>	Pre-market submission normally not requested.	Not normally reviewed pre-market. The NRA may request and conduct a pre-market or post-market review sufficient to determine conformity with essential principles.	The NRA will undertake a review sufficient to determine conformity with essential principles prior to the device being placed on the market.	The NRA will undertake an in-depth review to determine conformity with essential principles, prior to the device being placed on the market.
<b>Declaration of conformity</b>	Submission normally not requested.	Review and verify compliance with requirements by the NRA.	Review and verify compliance with requirements by the NRA.	Review and verify compliance with requirements by the NRA.

# Enabling conditions for effective regulation of medical devices including IVDs



# Shaping the future of medical devices regulation

**New Table of contents**

Chapter 1-3. Introduction, purpose, scope and terminology

Chapter 4. Definition, classification, essential principles, and conformity assessment of medical devices

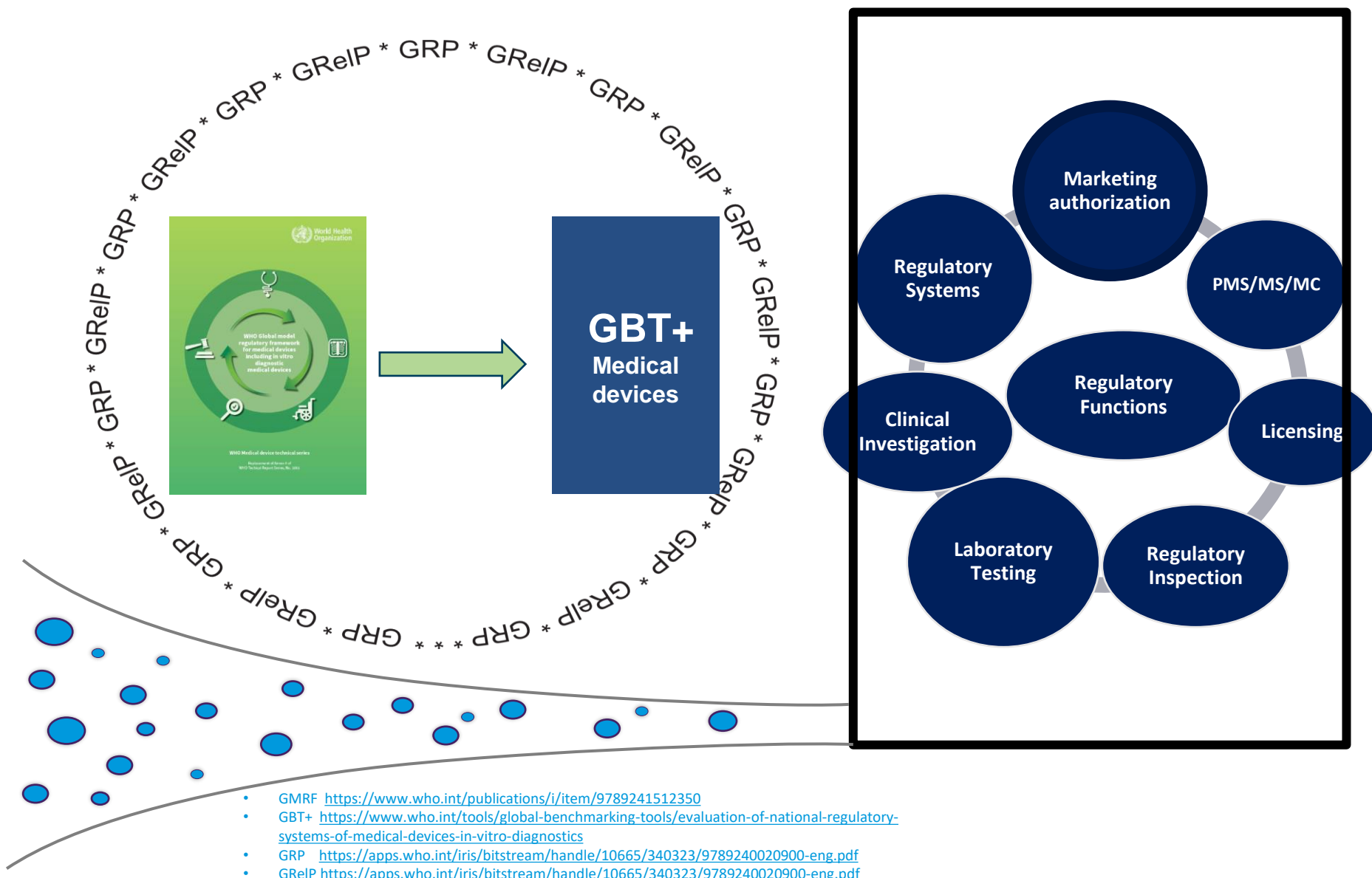
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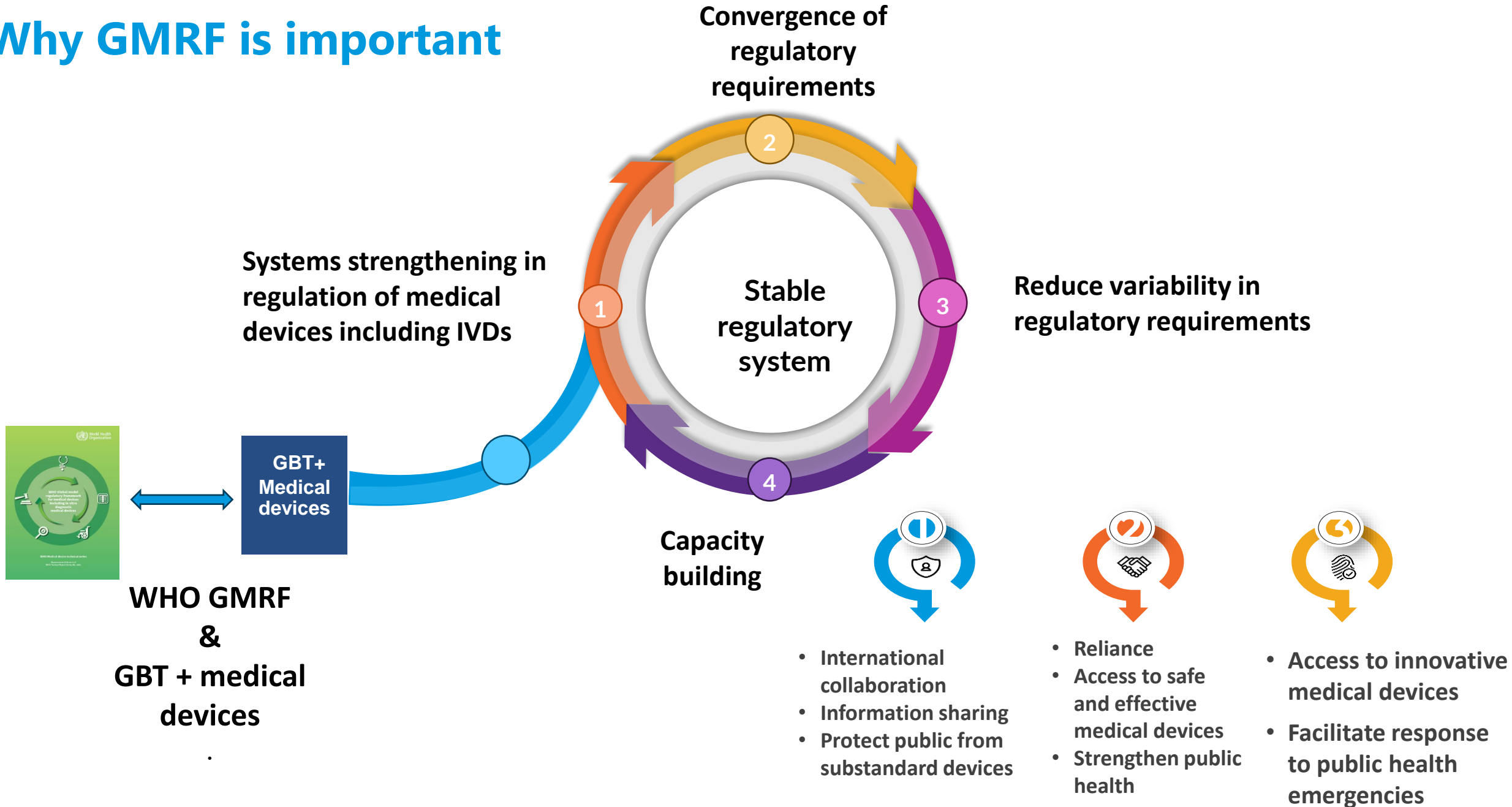
Chapter 8. Additional topics

Chapter 9. Implementation



- GMRF <https://www.who.int/publications/i/item/9789241512350>
- GBT+ <https://www.who.int/tools/global-benchmarking-tools/evaluation-of-national-regulatory-systems-of-medical-devices-in-vitro-diagnostics>
- GRP <https://apps.who.int/iris/bitstream/handle/10665/340323/9789240020900-eng.pdf>
- GReIP <https://apps.who.int/iris/bitstream/handle/10665/340323/9789240020900-eng.pdf>

# Why GMRF is important



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## In concluding my remarks

- GMRF (revised in 2023) is a game-changer in regulation of medical devices
- Instrumental in rollout of GBT+MD, specifically on implementation of the IDPs
- Facilitate a harmonized approach for developing regulatory frameworks for medical devices, globally
- Implementation of reliance for efficient regulatory framework.



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# Thank you

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