

AHWP Capacity Building: Fundamentals, Challenges, Way Forward

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Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

World Connectedness

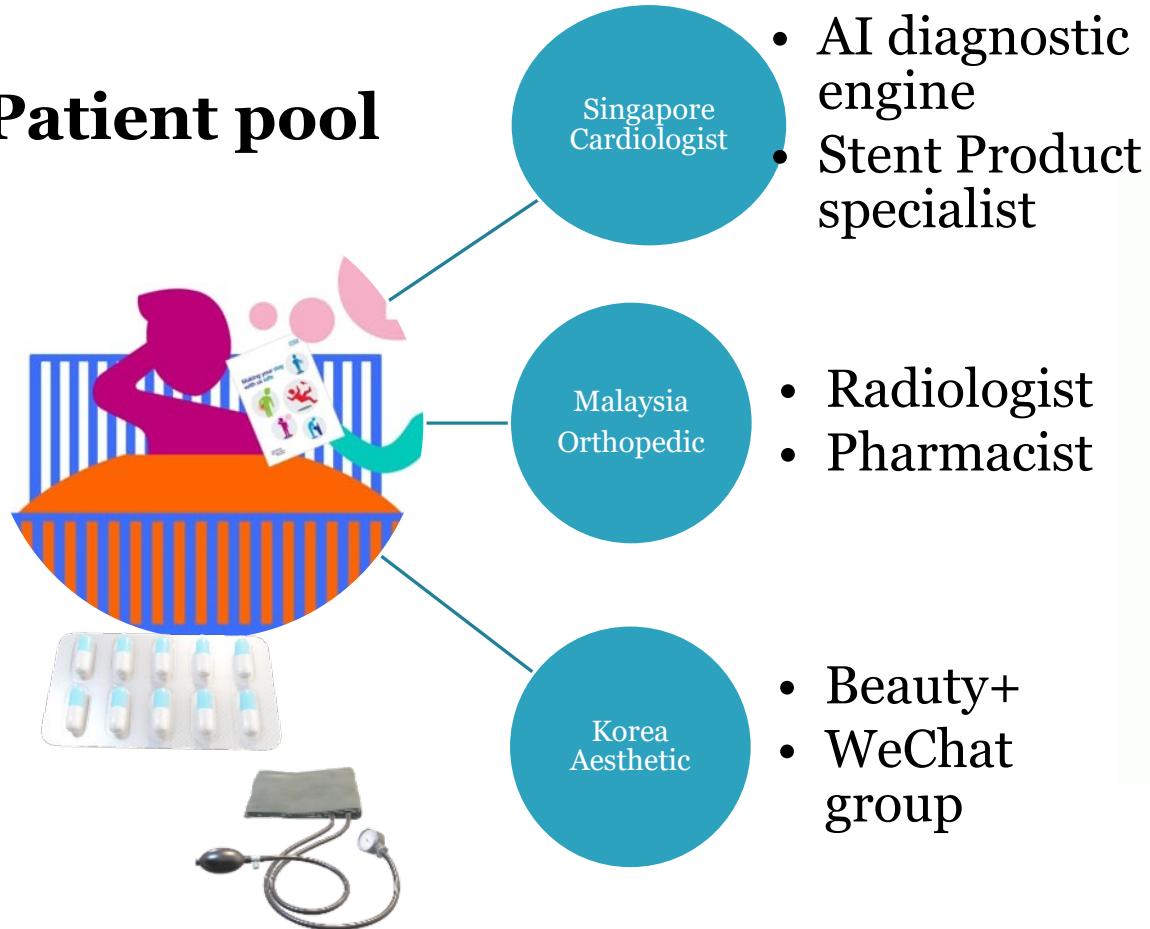
A world map with a dark blue background. The map is overlaid with a network of glowing white and light blue lines and nodes. The nodes are represented by small circles, some of which are larger and have a concentric ring effect, suggesting hubs or major centers. The lines connect these nodes across the globe, illustrating a global network or connectivity.

- Every doctor & **healthcare** services are just a finger touch away.
- Some of the most remote areas on the planet earth can now consult **the expert** in renowned medical hub globally
- Disruptive technologies enable patients to have instant access to quality data , information, diagnosis and treatment options.

Telemedicine

**Cross border, Cross discipline
Business model disruption**

Patient pool



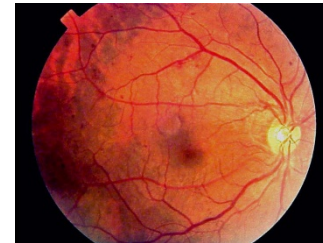
Is AI screening accuracy better than human?

The Doctor that never sleep! 24/7 availability (web base)

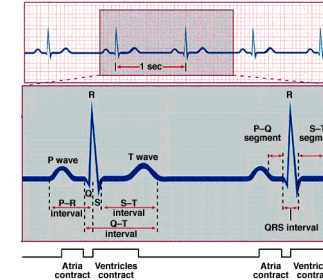
- User + GP + Point of Care assisted by Virtual Specialists

Eye : Retinopathy for Diabetes

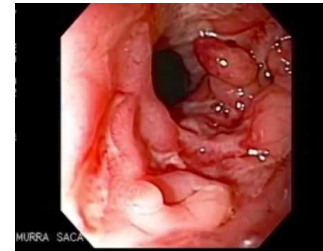
Accuracy >90% *



Heart : Prediction of heart attack



Endoscope Colon : detection of growth

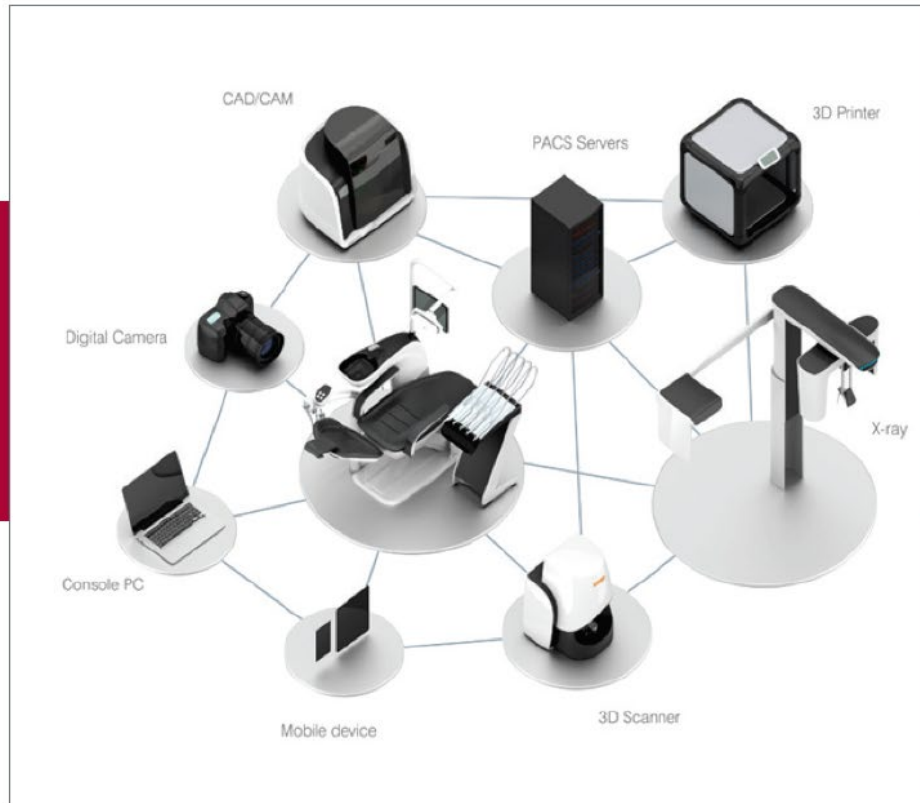


* Source: JAMA Ophthalmology

Current Impact of Digital Dentistry in Orthodontics

Change towards the digital era is an irreversible global trend.

This multilevel quality improvement afforded through digital technology is recognized in workflow and efficiency, record keeping, data fidelity and therapeutics.



1. A new set of skills among dental professionals
2. New materials for creating new digital dentistry solutions
3. Who does what in the dental workflow is shifting
4. Software developments and new apps for dental professionals
5. New regulations for digital dentistry

The Spirit of Regulation

1. Primary goal: to protect public health and safety
2. Ensure that useful new technologies are made available while preventing unsafe and ineffective devices from reaching the market
3. Regulations clearly articulated to stakeholders
4. Adequate post-market and pre-market controls
5. Being cognizant of ongoing international convergence efforts to avoid regulatory controls that conflict with the goal and spirit of international convergence.

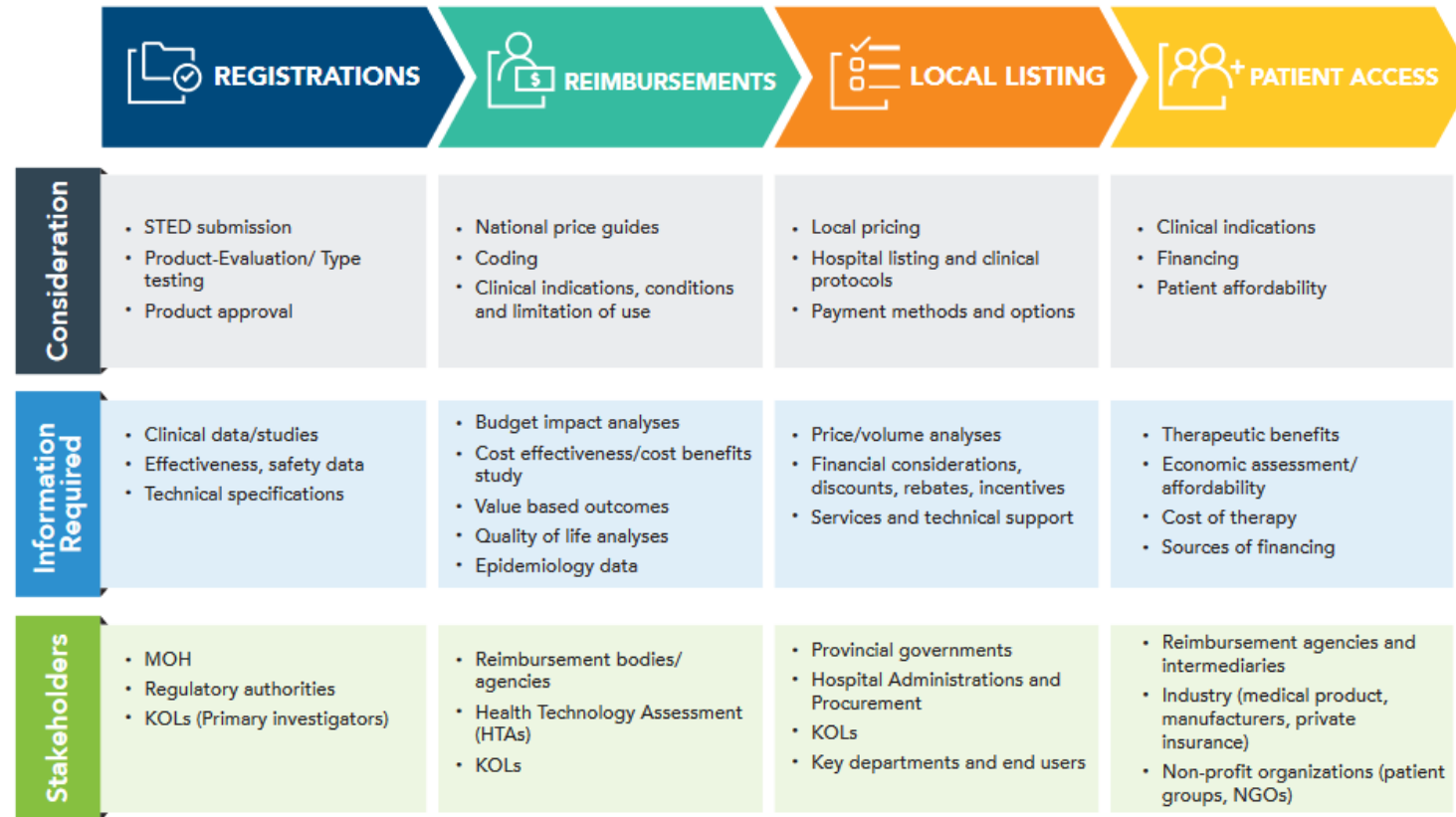


Bridging Theory & Practice: What are the Challenges?



Complex Market Access

- Market access was previously more focused on pricing and reimbursement. However, a changing healthcare macro-environment demands interplay of other considerations such as regulatory, supply chain & channels, training & education



Multiple Regulatory Systems

- Interconnectedness and flow of information is increasingly critical in medical device markets, especially in the digital economy.
- Multiple regulatory systems cause inefficiencies and complexities in pre- and post-market activities
- Creates barriers for local companies to access overseas markets and for foreign companies to access local market.
- Important to agree and implement harmonised global standards



Regulation Disconnect from Developing Technologies

- Regulations need to be flexible enough to understand & accommodate fast evolving technology trends.
- **A disconnect can lead to irrelevant controls & hinder innovation.**
- Regulators to be in touch and up to date with emerging medical technologies.

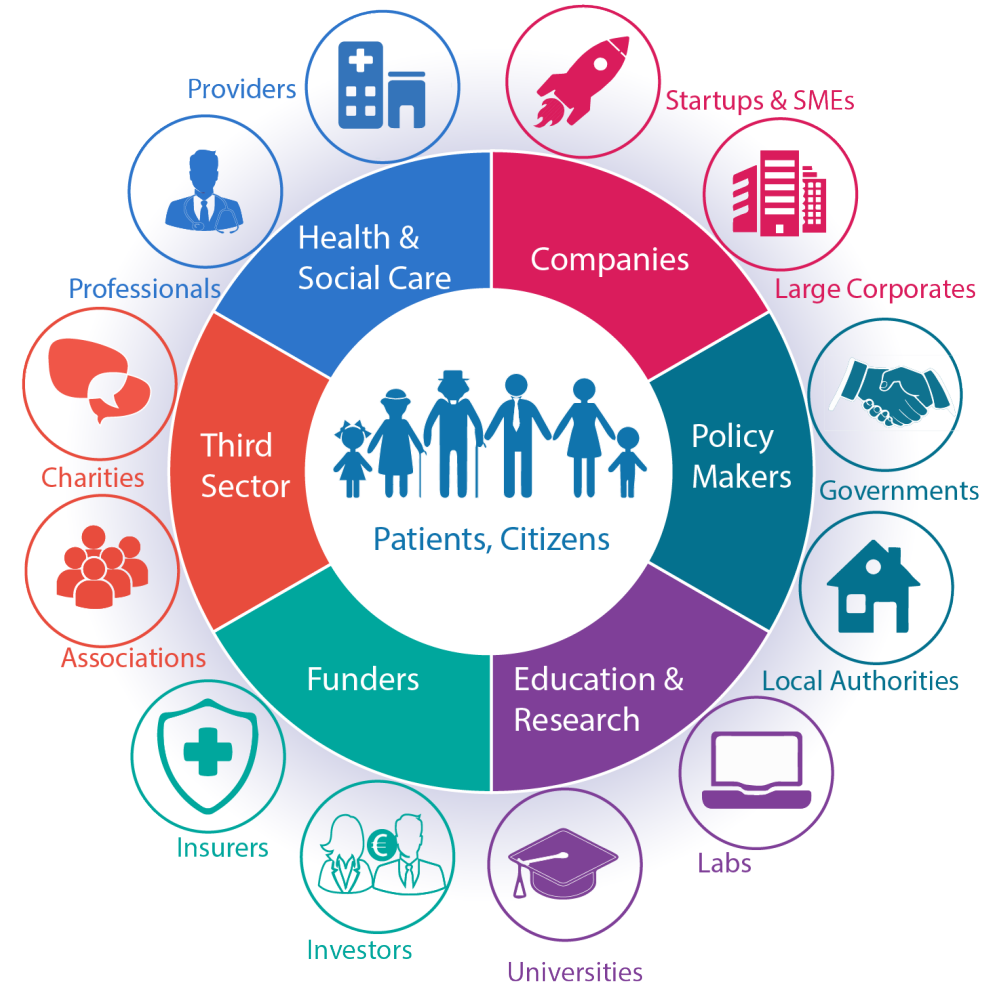


Identifying Correct Stakeholders

Various stakeholders play important roles across the medical device's lifecycle.

Not identifying the correct stakeholders and their activities may cause gaps in regulatory oversight or impractical regulations.

Especially when developing new regulations, stakeholder involvement early in the process is crucial.



Shortage of Regulatory Professionals

- Lack of capacity across and within countries
- Pharma-oriented mindset Vs Medical Device approach
- Regulatory profession is a multi-disciplinary field requiring knowledge of law, policy, technology to ensure smooth processes!



Image courtesy: University of St Thomas

Addressing Challenges

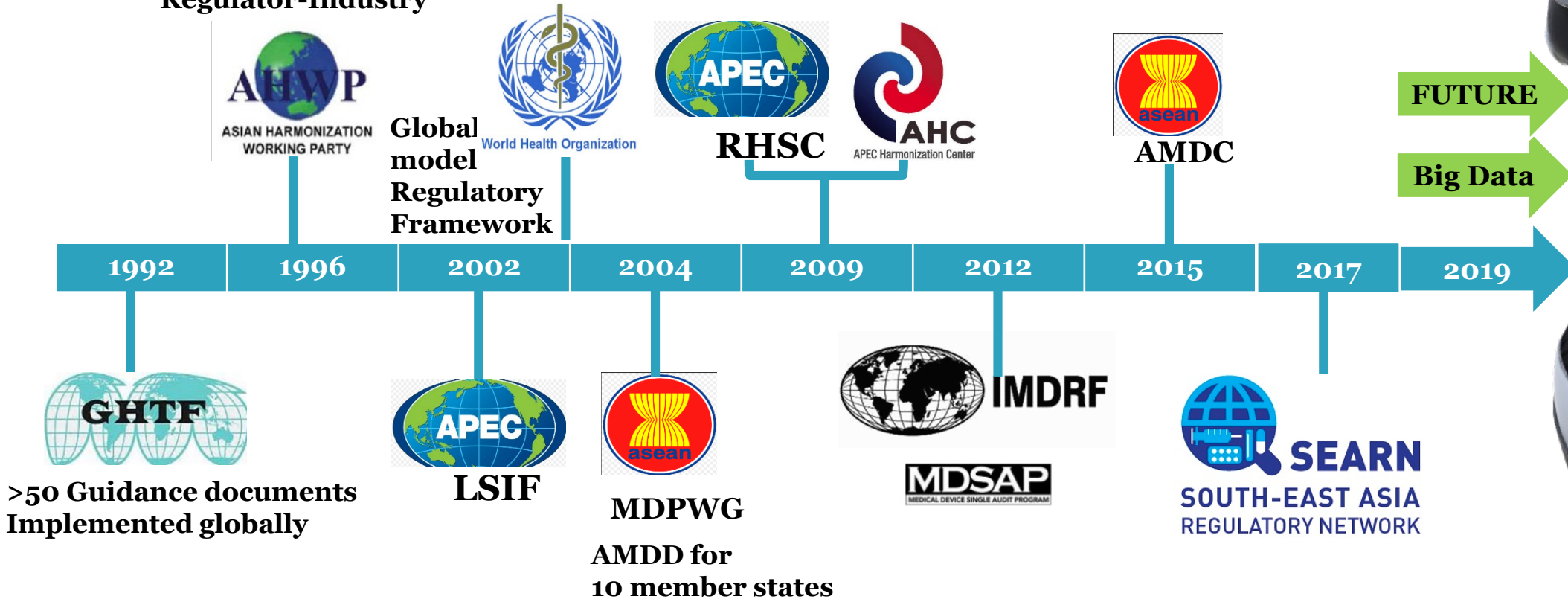
- Efforts in Global Harmonization, Convergence, Reliance
- Reduce regulatory burden and technical barriers
- Cross border leveraging of expert resources and best practice sharing
- Capacity building efforts - Clear need to improve competence and regulatory literacy.

However! More work needs to be done...

- Standardized curriculum
- Regular and frequent trainings
- Harmonized concepts and contents
- Continuing learning and mentoring opportunities in - country to support advancing knowledge and skills
- Addressing all stakeholders

Journey to Regulatory Harmonization

30 member economies
Regulator-Industry



FUTURE
Big Data



AHWP GOAL

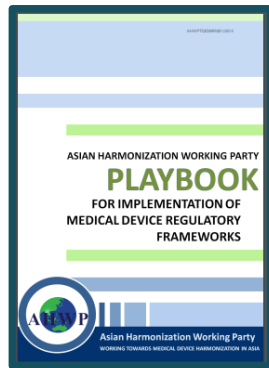
To study and recommend ways to harmonize medical device regulations in the Asian & other regions & to work in coordination with other international organizations of similar objectives



Our Capacity Building Journey

2014 - 2017

2018 - 2019



Competency Framework for Medical Technology Regulators



Thailand in-country regulator training - 35 participants

White Paper

- 1 Approach to Develop the Competency Framework
- 2 Survey Findings
- 3 Introducing Framework
- 4 Guidelines on Use of Framework

Webinar

Deloitte.



**Competency Framework for
Medical Technology Regulators**

Published: Competency Framework for Medical Device Regulators

A joint initiative of AHWP, APACMed and Deloitte

Intention of Competency Framework

- Designed as a tool for developing prioritized training curricula for MedTech regulators.
- Intended to be used by MedTech regulators and their training partners e.g. international organizations, donors, academia, associations, subject matter experts.
- Both the framework and curriculum framework initiatives should involve multiple stakeholders, who can play a pivotal role across the process: gap assessment, curriculum framework, training delivery & evaluation.

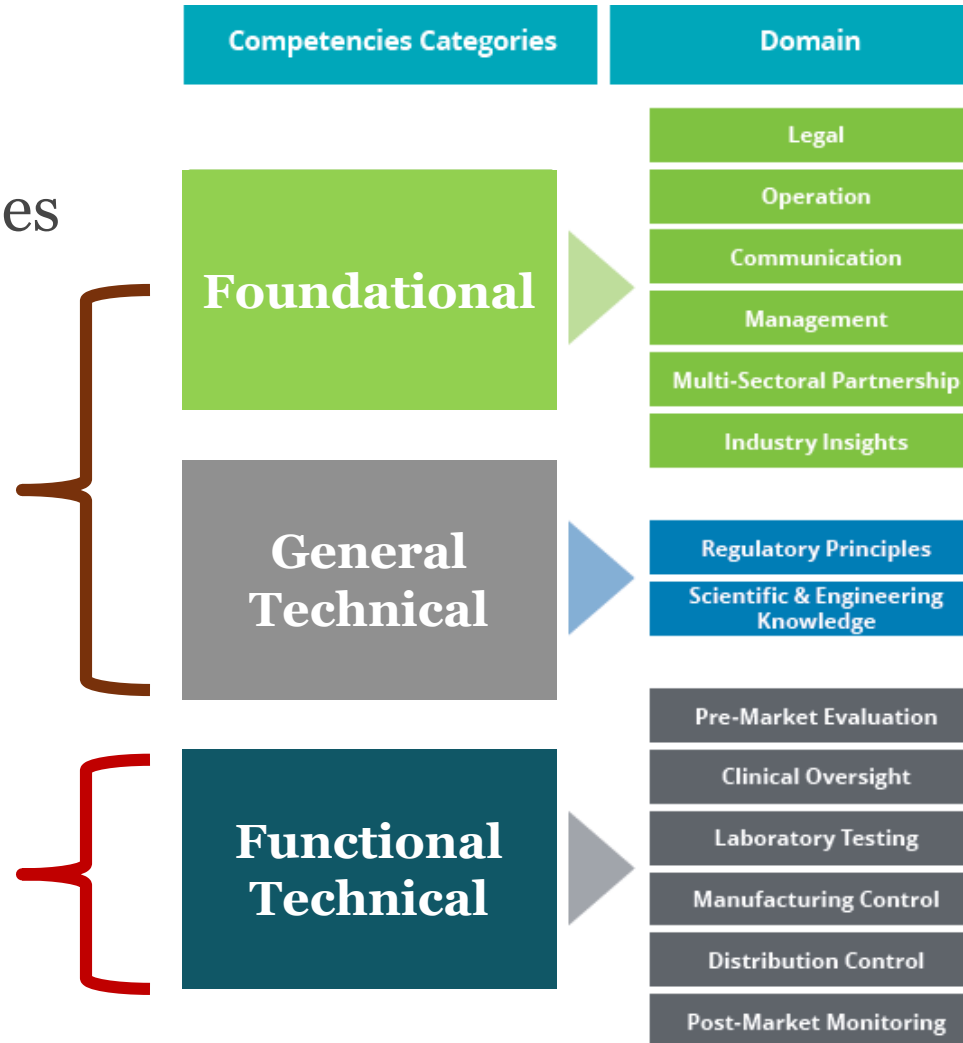


Brief Overview of Competency Framework White Paper

Establishes a high-level framework by structuring and prioritizing competencies across three dimensions:

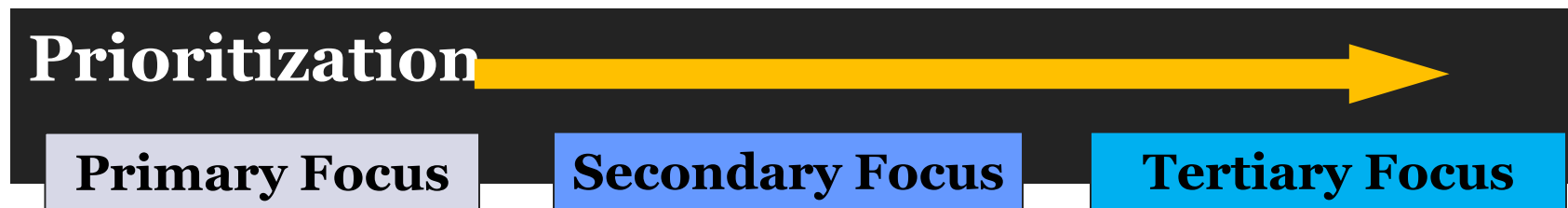
Basic essential competencies regarded as universal for regulators in different economies

Additional core competencies split into six (6) modules, in accordance with different needs & development stages of regulatory authorities in different economies



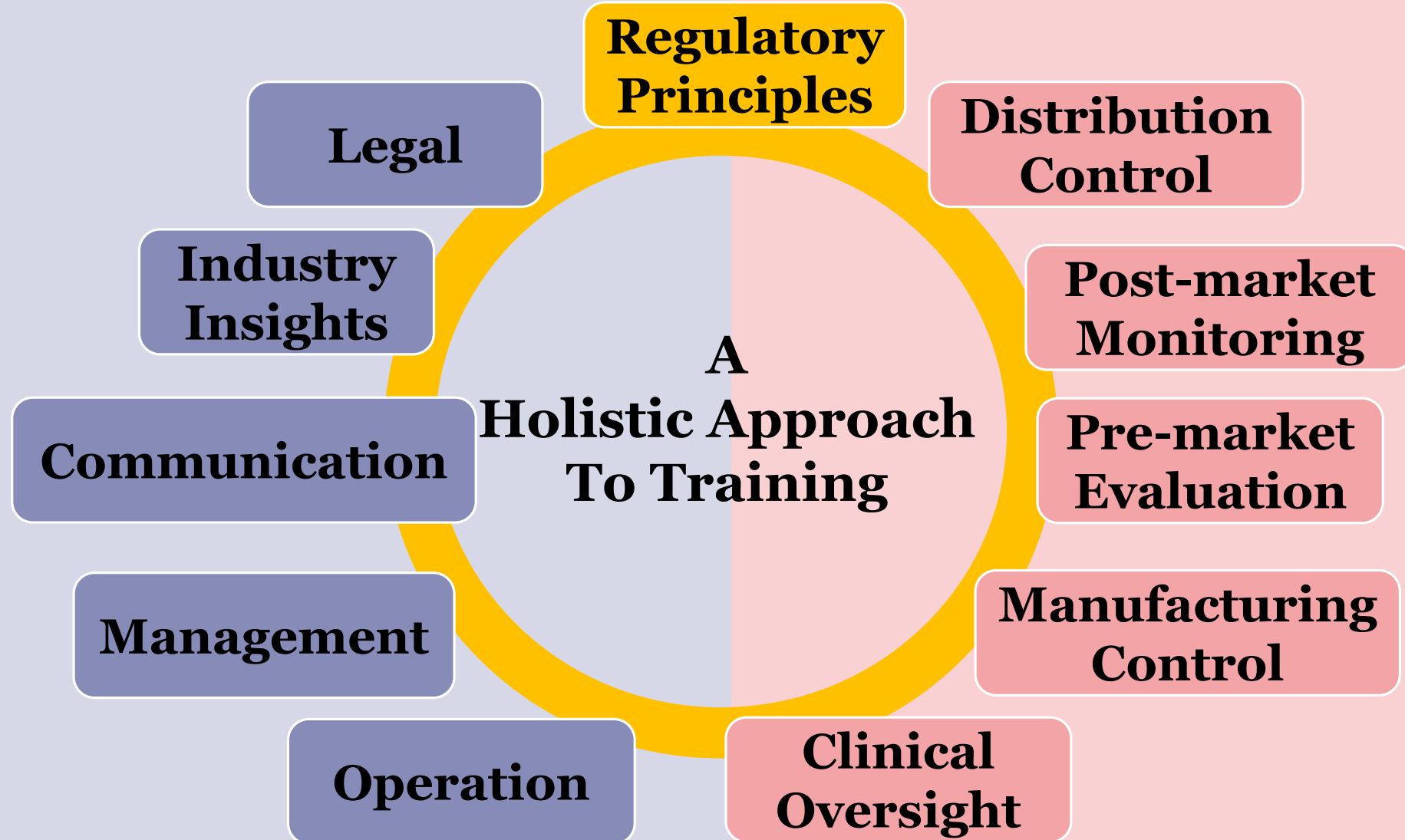
Prioritizing Training

- Competencies have been further divided into **Primary Focus**, **Secondary Focus**, and **Tertiary Focus**, based on the level of importance as rated in the regulator's self-assessment.
- For economies to prioritize their training resources - especially for economies with limited resources.
- Training initiatives should be designed and implemented in a phased approach.



**Equal importance to:
Soft Skills**

Hard Skills



Potential Ideas Moving Forward



Roll Out Competency Framework

- A holistic training framework is necessary to build competency, with both soft & hard skills.
- Training with focus on technical aspects.
- Complement with “soft skills” training initiatives.



Image courtesy: thelocal.dk

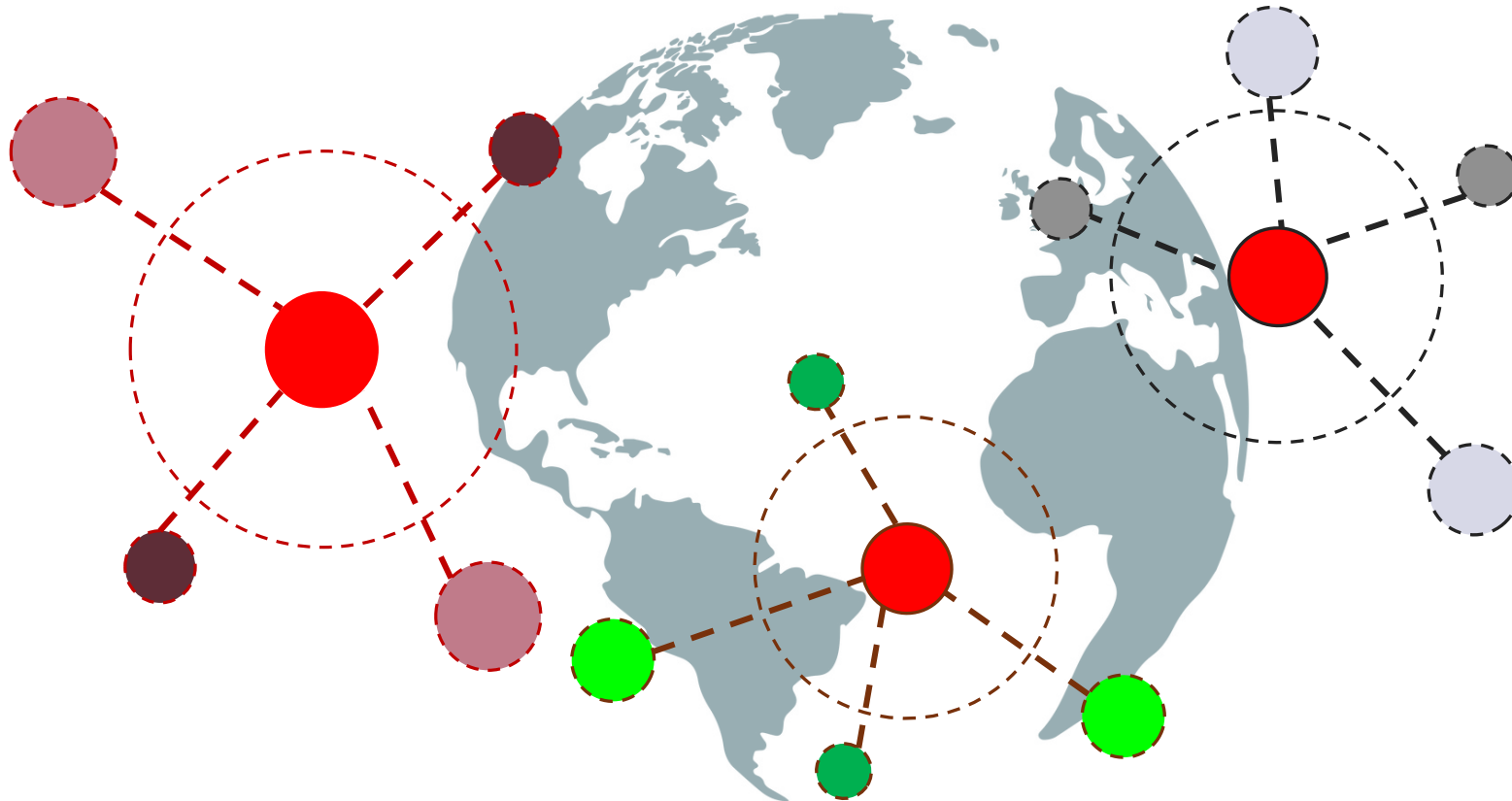
Develop Regulatory Curriculum

- Use the framework as a starting point to develop the regulatory curriculum
- Need subject matter experts to contribute to regulatory curriculum



Centers of Excellence

- Serve as training focal points to each region



Thank You!
Shukran!