IMDRF International Medical Device Regulators Forum

African Union | AUDA-NEPAD AFRICAN UNION DEVELOPMENT AGENCY | World Health Organization

AFRICA MEDICAL DEVICES FORUM

PAULYNE WAIRIMU

Chair: AMDF

26th September 2023
IMDRF Management Committee
Open Session

African Medical Devices Forum

AMDF Leadership

Chair: Paulyne Wairimu (Kenya)

Vice- Chair: Dimakatso Mathibe (South Africa)

Rapporteur: Frank Laban (Zambia)

AMDF Membership

- ✓ Kenya
- ✓ South Africa
- ✓ United Republic of Tanzania
- ✓ Zanzibar
- ✓ Zambia
- ✓ Botswana
- ✓ Uganda
- ✓ Rwanda
- ✓ Burundi
- ✓ Ethiopia
- ✓ Nigeria
- ✓ Ghana
- ✓ Senegal
- ✓ Congo
- ✓ Namibia
- ✓ Zimbabwe
- ✓ Morocco
- ✓ Egypt

African Medical Devices Forum

AMDF ACTIVITIES

Harmonization

January-23
GHWP Riyadh meeting, Increase membership for AMDF to GHWP for harmonization

AMRH-SC

April and June -23
Submission of developed resources to maternal/newborn and child health

Supporting Local Manufacturing of Diagnostics

August-23
The establishment of the African initiative for Diagnostics access

Building

Utilization of the Virtual platform for capacity building initiatives.
Physical workshop planning ongoing

WHA

June-23 Adoption of the resolution supporting diagnostics access to African member states

IMDRF International Medical Device Regulators Forum

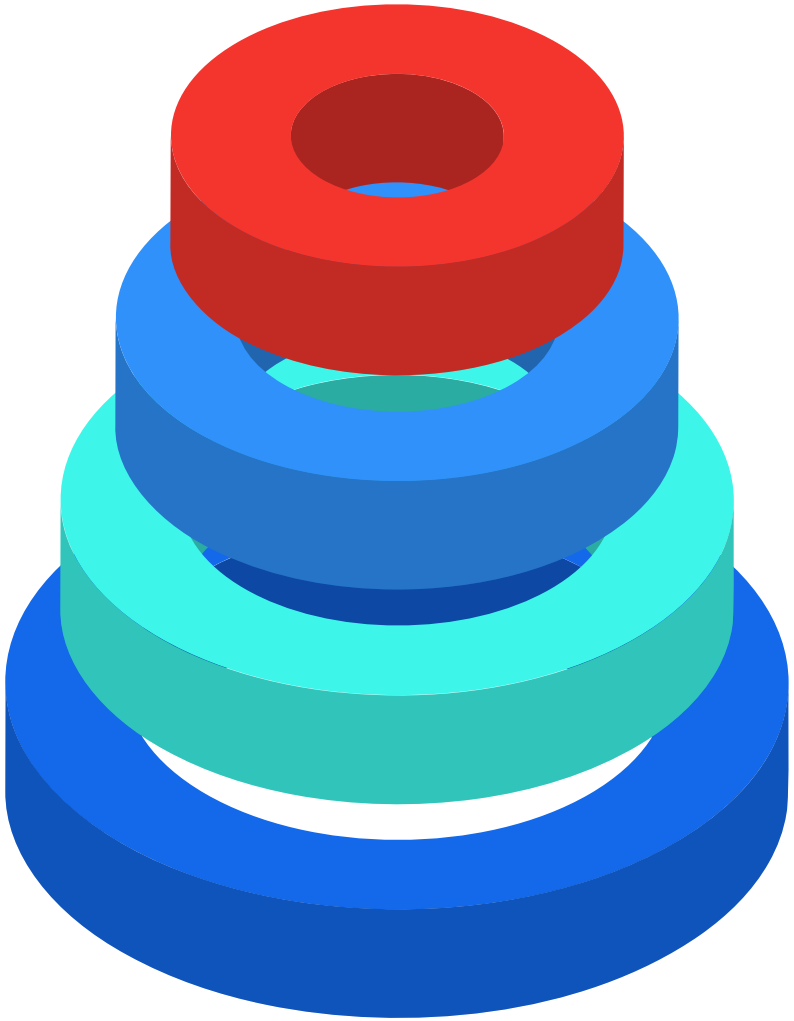
Areas of Focus-

Operationalization of Africa Medicines Agency

-AMDF- Resource to the Operationalization of the African Medicines Agency
-AMDF Attended the biannual meeting in June with a view of aligning the workplan with the continental initiative

Capacity Building

Domestication and uptake of the developed resources, which include guidance document on Market authorization, Control of Import &Exports, Quality audits and registration of establishment of medical devices.



Maternal, Newborn and Child health Guidance Document Development

With the support of Partner,
-AMDF Developed a resource to support in regulating maternal, newborn and child health sub population medical devices
-The use of IMDRF Guidance document as a resource.

Enabling Access to Resource for Medical Devices to Regulators

Developed resources are made available to national regulatory authorities with a view of accelerating access.

IMDRF International Medical Device Regulators Forum

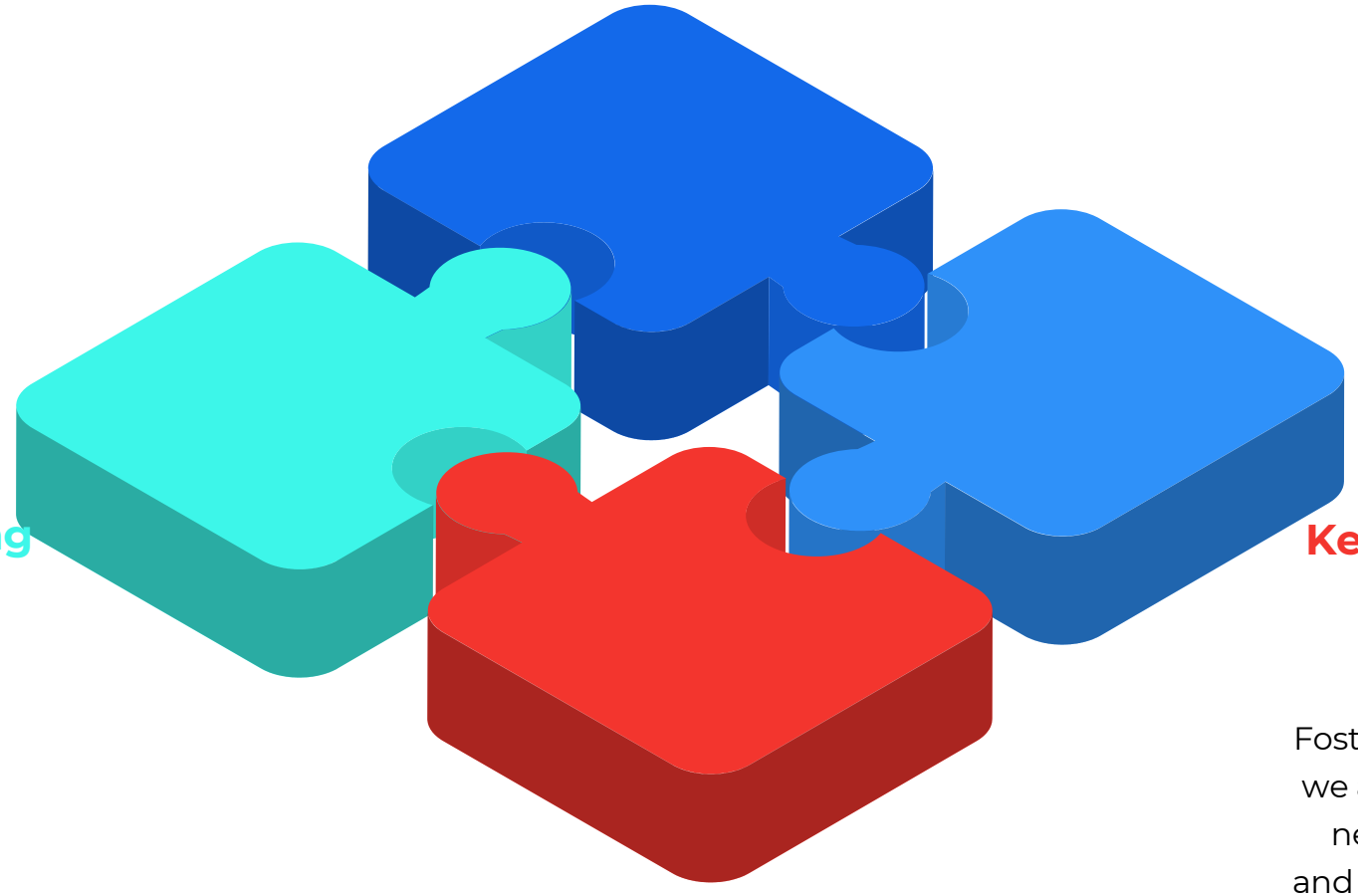
AMDF-RHI-IMDRF

Regional Harmonization

-Elevate the standards of Documents that NRA's use for conformity, enabling Access and Removing Barriers

Capacity Building and Technical Knowhow Exchange

-Africa has its set of challenges that when shared make regulatory harmonization efforts realized potential



Information Sharing

-Platform for information sharing on Opportunities, Challenges and Areas of collaboration

-Fostering an environment for responsive regulatory practices

Keeping abreast with Current Practices

Fostering an environment where we are able to keep abreast with new information, technologies and practices in the regulation of Medical devices and Diagnostics.

IMDRF International Medical Device Regulators Forum

African Medical Devices Forum

Thank you/Asante Sana

Paulyne Wairimu
Email: Pwairimu@pharmacyboardkenya.org

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International Medical Device Regulators Forum

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EUROPEAN UNION Chair

Update on Medical Device PWA of APEC RHSC

Cheng-Ning Emily Wu | TFDA, Chinese Taipei

26 September 2023

European Commission

Funded by the European Union

OVERVIEW

IMDRF
International Medical Device Regulators Forum

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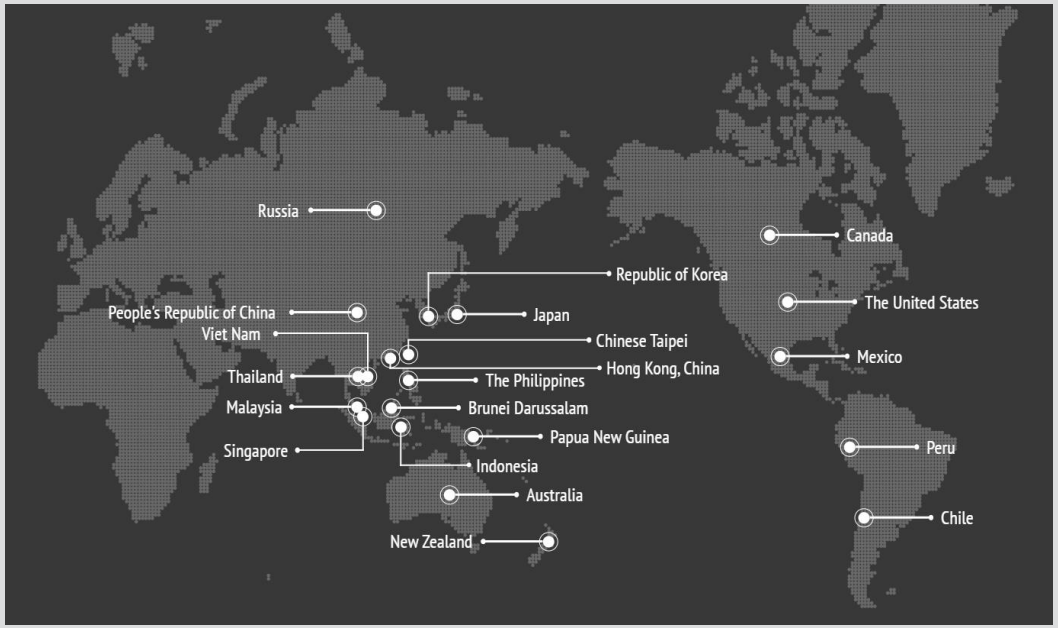
Asia-Pacific Economic Cooperation (APEC)

APEC

21 member economies: Australia; Brunei Darussalam; Canada; Chile; People's Republic of China; Hong Kong, China; Indonesia; Japan; Republic of Korea; Malaysia; Mexico; New Zealand; Papua New Guinea; Peru; The Republic of the Philippines; The Russian Federation; Singapore; Chinese Taipei; Thailand; United States of America; and Viet Nam.



https://www.apec.org/about-us/about-apec/member-economies

Asia-Pacific Economic Cooperation

APEC RHSC

- **Mission**: facilitate regulatory cooperation among medical product regulatory authorities, build human capacity in regulatory science among medical product regulatory staff, and promote political will for convergence and reliance among regulatory policymakers in APEC
- **Establishment**: 2009
- **Scope**: Pharmaceutical Products & Medical Devices
- **Members**:
  - Regulators from APEC Economies
  - Industry coalitions:
    - Research-based Pharmaceuticals
    - Medical Devices
    - Generic Pharmaceuticals
    - Biotechnological Products
    - Advanced Therapies
  - CoE Coalition of Training Partners

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RHSC Priority Work Areas

Priority Work Areas (PWAs)

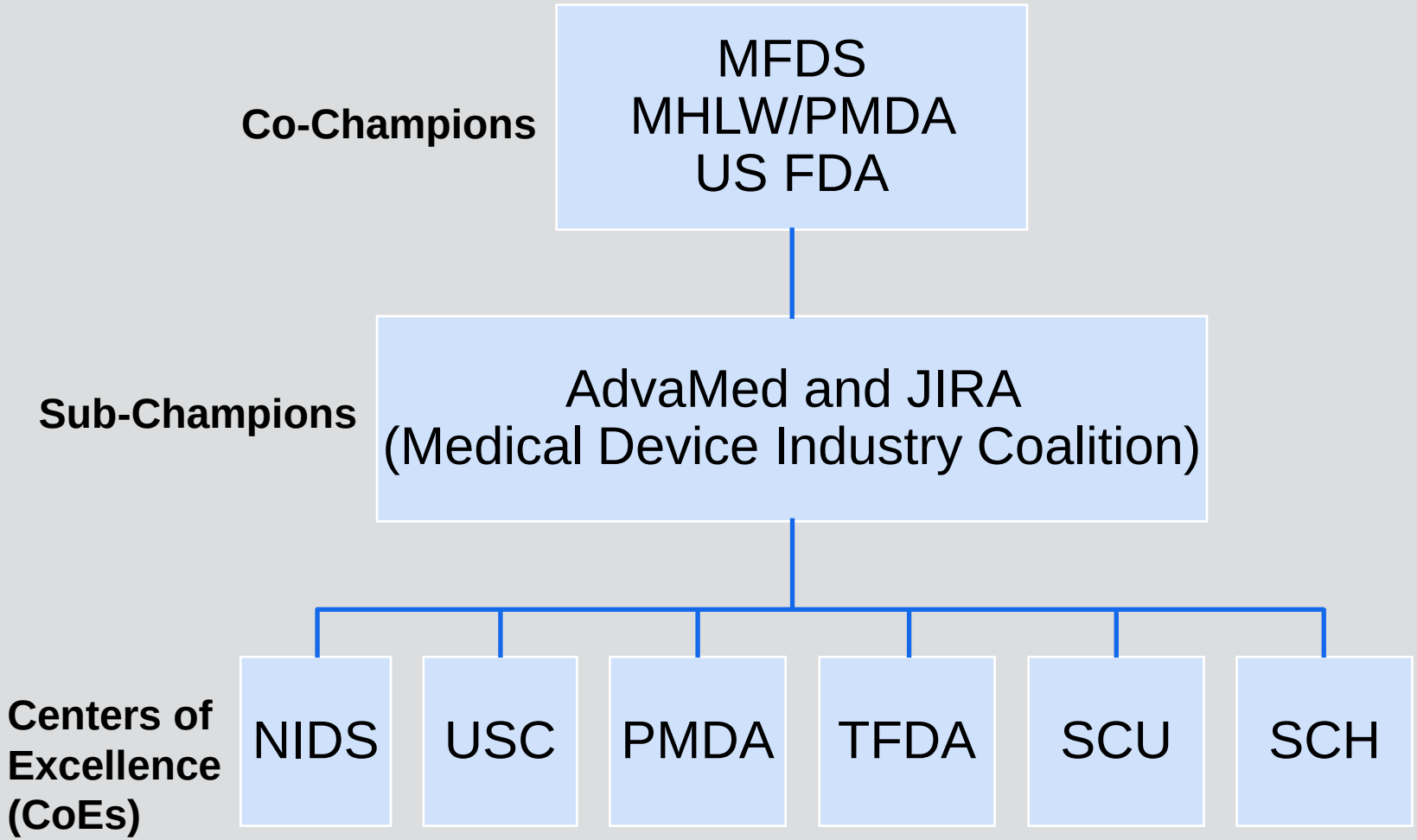
- Multi-Regional Clinical Trials and Good Clinical Practice Inspection (Japan, Thailand)
- Pharmacovigilance (Korea)
- Biotherapeutic Products (Current PWA Management: US, BIO)
- Advanced Therapy Products (Singapore, US)
- Good Registration Management (Chinese Taipei, Japan)
- Global Supply Chain Integrity (US)
- **Medical Devices** (Japan, Korea, US)

Medical Device PWA

Goals of PWA

- Promote international harmonization initiatives (i.e., GHTF/IMDRF guidance documents)
- Build regulatory capacity and knowledge
- Support harmonized implementation efforts among APEC economies

Medical Device PWA Structure



Medical Device PWA Roadmap

- Promotes regulatory convergence for medical device regulatory systems
- Focuses on training and education efforts related to topics across the Total Product Life Cycle (TPLC) of medical devices:
  - Premarket
  - Postmarket
  - Quality Management System (QMS)

PWA Core Curriculum

- Annex to the PWA roadmap
- “Reference library” of harmonized guidance documents on TPLC topics
- Medical Device PWA includes specified GHTF/IMDRF documents
- Both medical devices and in vitro diagnostic (IVD) medical devices are inclusive
- Co-Champions continuously update Core Curriculum with intersessional approval

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Center of Excellence Programs

CoE Programs Held since IMDRF-23

CoE	Economy	Program	Format	Date
Taiwan Food and Drug Administration (**TFDA**)	Chinese Taipei	2023 APEC Medical Devices Regulatory Science CoE Workshop	In-Person & Virtual	29-31 Aug

CoE Programs Planned for 2023

CoE	Economy	Planned Program	Format	Date
University of Southern California (**USC**)	United States	Medical Devices 2023: Harmonizing Medical Device Regulation	In-Person & Virtual	12-13 Oct
Pharmaceutical and Medical Devices Agency (**PMDA**)	Japan	Medical Devices Review (APEC Center of Excellence Workshop: PMDA-ATC Medical Devices Workshop 2023)	Virtual	14-16 Nov
Soonchunhyang University (**SCH**)	Korea	2023 SCH APEC Medical Device CoE Training	In-Person & Virtual	7-8 Nov (In-Person) & 1-24 Nov (Virtual)
Sichuan University (**SCU**)	China	(CoE workshop)	TBC	TBC
Northeastern University (**NEU**)	United States	(Pilot CoE workshop)	TBC	TBC

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Next Steps

Next Steps

- APEC Senior Officials and Ministers continue to find a new home organization for RHSC under the APEC umbrella.
- To further regulatory convergence and cooperation efforts, RHSC held a face-to-face meeting on 12 April 2023 in Oakland (USA) and is considering the next meeting for December 2023.
- Work is to be continued in accordance with RHSC Vision 2030 and Strategic Framework.

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International Medical Device Regulators Forum

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THANK YOU / QUESTIONS

Email emilywu@fda.gov.tw

European Commission

Funded by the European Union

Global Harmonization Working Party

GHWP

Towards Medical Device Harmonization

GHWP Updates

Ir Bryan SO

GHWP Executive Secretary General

Managing Director, Business Development

Multi-Scale Medical Robotics Center, The Chinese University of Hong Kong

Hong Kong SAR, China

Global Harmonization Working Party

GHWP Towards Medical Device Harmonization

The Global Harmonization Working Party was **formed in 1996-97** by a group of committed regulatory affairs professionals working towards greater harmonization of medical device regulations

The Party, formerly known as Asian Harmonization Working Party, was **rebranded to Global Harmonization Working Party (GHWP) in 2021**

At present there are 33 member countries/regions in GHWP, where **regulatory authority and industry representatives have equal voting rights** in GHWP annual meetings

GHWP Members from 33 Countries/Regions & 6 Liaison Partners

GHWP Members		
Brunei Darussalam	Kingdom of Saudi Arabia	Singapore
Cambodia	Kyrgyz Republic	South Africa
Chile	Laos PDR	State of Kuwait
Chinese Taipei	Malaysia	Sultanate of Oman
Hong Kong SAR, China	Mongolia	Tanzania
India	Myanmar	Thailand
Indonesia	Pakistan	United Arab Emirates
Japan	People's Republic of China	United States of America
Jordan	Philippines	Vietnam
Kazakhstan	Republic of Kenya	Yemen
Kingdom of Bahrain	Republic of Korea	Zimbabwe

GHWP Liaison Members (Liaison Partners)
Asia Pacific Medical Technology Association (**APACMed**)
Global Diagnostic Imaging, Healthcare IT, and Radiation Therapy Trade Association (**DITTA**)
Global Medical Device Nomenclature Agency (**GMDN Agency**)
Global Medical Technology Alliance (**GMTA**)
GS1
Inter-American Coalition for Regulatory Convergence for the Medical Technology Sector (**IACRC**)

GHWP Chair and Leadership 2023-2025

Dr. Xu Jinghe
GHWP Chair
Deputy Commissioner
NMPA, China

Ms. EunHee Cho
GHWP Vice-chair (Industry)
RA Director, Abbott Medical, Korea

Dr. Abdullatif S. Al Watban
GHWP TC Chair
Executive Director, Medical Devices Evaluation
Medical Devices Sector, SFDA, Saudi Arabia

Ms. Jun Li
GHWP TC Co-chair (Regulatory Authority)
Deputy Director General
Department of Medical Device Regulation
NMPA, China

Ms. Miang Tanakasemsub
GHWP TC Co-chair (Industry)
Head of Regulatory Affairs, Asia Pacific
Johnson & Johnson Vision, Thailand

GHWP Organization Structure

New

GHWP
Chair (Regulatory Authority)
Vice-Chair (Regulatory Authority)
Vice-Chair (Industry)

Strategic Advisory Board (SAB)

Capacity Building

Secretariat Office
(in Hong Kong SAR, China)

GHWP Academy
(to be established)

New

GHWP Technical Committee (TC)
TC Chair (Regulatory Authority)
TC Co-Chair (Regulatory Authority)
TC Co-Chair (Industry)

GHWP Administration Services Ltd (ASL)
(in Hong Kong SAR, China)

Advisory Panel to TC

Working Groups (WGs)
WG1 - Pre-market: General MD
WG2 - Pre-market: IVDD
WG3 - Pre-market: Software as a Medical Device
WG4 - Post-market
WG5 - Clinical Evidence for Performance & Safety
WG7 - Quality Management System*
WG8 - Standards
WG9 - UDI & Nomenclature

** WG 6 combined into WG 7*

GHWP Strategic Advisory Board (SAB)

- To bring knowledge and experience to support in **high-level planning and steering on the development of GHWP**, and the promotion of GHWP's mission, vision, and goals
- To **provide advice, recommendation, insights and intelligence for the strategic positioning and development of GHWP**
- The role of SAB should be **differentiated from GHWPTC Advisory Panel**, which offers technical/professional advice towards meeting the goals of GHWP
- **Experts from regulatory authorities of GHWP member countries or regions** with robust medical device regulatory systems, or other **international or regional organizations** as SAB Members, including the participation of **experts from industry** on need basis
- **Number of members in the SAB shall not exceed ten (10),** preferably from different continents

Full text available under GHWP House Rules 20

GHWP Strategic Advisory Board (SAB) – Cont.

- **"GHWP Procedure for Strategic Advisory Board Establishment and Operation"** with more details on the operations of the SAB was released in July 2023, and available on GHWP website

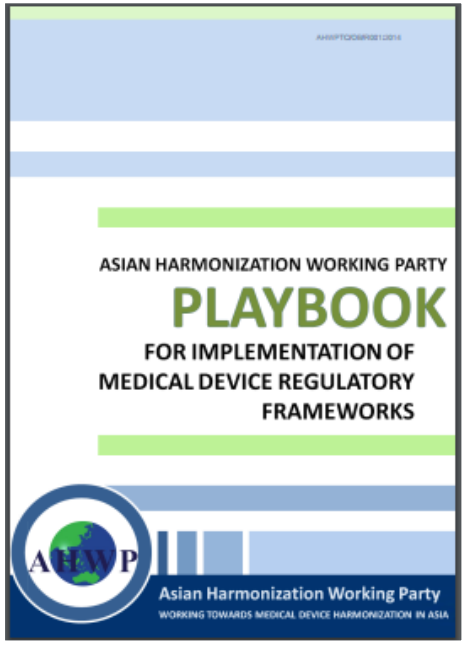
- **Roundtable Meeting shall generally be held by video conference**, or as a side event at the GHWP TC meeting

- SAB Member(s) will be awarded with a letter of appointment by GHWP Chair at the first GHWP Annual Meeting following their appointment

- Appointment to the SAB is **on a voluntary basis**

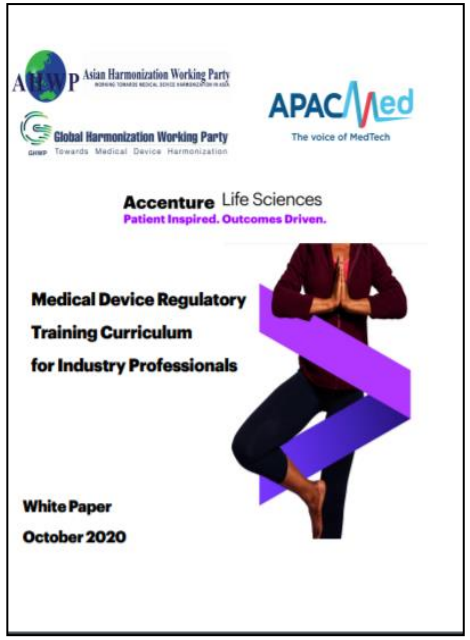
Full text available at GHWP website: http://www.ghwp.info/index.php/node/884

GHWP from Playbook to Academy

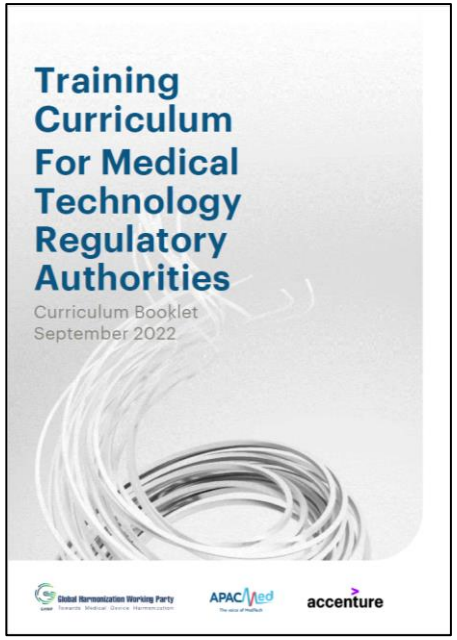


Playbook for implementation of medical device regulatory frameworks

Competency framework for medical technology regulators



Medical Device Regulatory training Curriculum for Industry Professionals



Training Curriculum for Medical Technology Regulatory Authorities

GHWP Academy

GHWP Capacity Building Online Training System

2014 - 2017	2018 - 2019	2020-2021	2022-2023	2023-2026

GHWP Academy

Purpose

- To facilitate the implementation of the *Global Harmonization Working Party Strategic Framework towards 2026*, and fulfill GHWP's mission, vision and goals, GHWP Leadership decides **to establish the GHWP Academy in its member countries and regions** for
  - **carrying out training, research and knowledge exchange** in the field of medical devices
  - **enhancing medical device regulatory capability** of its member countries and regions
  - promoting global medical device regulations toward **convergence, harmonization and reliance**

Full text available at GHWP website - http://www.ghwp.info/node/888

GHWP Academy

Mode of Training

- GHWP Academy **mainly focuses on on-site trainings**, while online trainings are also encouraged to benefit a wider range of participants

Call for Comments

- "Measures for the Building of GHWP Academy" on GHWP website on 13th Sep 2023
- Deadline for submission of comment **by 28th Sep 2023**

Application for GHWP Academy

- Deadline for submission of application form & full proposal will be on **23rd Oct 2023**

Full text available at GHWP website - http://www.ghwp.info/node/888

GHWP 27th Annual Meeting & Technical Committee Meeting

27th to 30th November 2023

Shanghai International Convention Center, Shanghai, China

Welcome to Join Us !!

Global Harmonization Working Party

GHWP Towards Medical Device Harmonization

GHWP

Global Harmonization Working Party

Towards Medical Device Harmonization

THANK YOU / QUESTIONS

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DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

IMDRF International Medical Device Regulators Forum

DITTA Report

IMDRF Open Stakeholder Forum

September 26, 2023

Patrick Hope, DITTA Chair

Executive Director, Medical Imaging and Technology Alliance

COCIR Advancing Healthcare · JIRA · Medtech Canada · MITA Medical Imaging & Technology Alliance · THAIMED · IMEDA · 中国医疗器械行业协 China Association for Medical Devices Ind · ABIMED Associação Brasileira da Indústria de Tecnologia para Saúde · Kmdica Korea Medical Devices Industrial Coop. Association · KMDIA Korea Medical Devices Industry Association · TECHNATION CA

DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

DITTA Global Presence

2018: DITTA recognized as a non state actor in official relations with WHO
2016: Signed MoU with the World Bank
2015: Granted NGO status with WHO
2014: Established official liaison with now-GHWP

DITTA: 11 WORKING GROUPS

DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

1. Regulated Product Submission (RPS) Working Group — MITA
2. Cybersecurity Working Group — MITA
3. Medical Device Single Audit Program (MDSAP) Working Group — MITA
4. Unique Device Identification (UDI) Working Group — MITA
5. MSW & AI Working Group — COCIR
6. Clinical Evaluation Working Group — COCIR
7. Standardisation (STA) Working Group — COCIR
8. Good Regulatory Review Practices (GRRP) Working Group — JIRA
9. Global Health (GH) Working Group — COCIR
10. Environmental Policy (ENVI) Working Group — COCIR
11. Good Refurbishment Practice (GRP) Working Group — JIRA

IMDRF; GHWP; IEC; ISO

World Health Organization; WORLD BANK GROUP; IAEA International Atomic Energy Agency

BASEL CONVENTION; UNEP; IEC; ISO

COCIR Advancing Healthcare; JIRA; Medtech Canada; MITA Medical Imaging & Technology Alliance; THAIMED; IMEDA; 中国医疗器械行业协 China Association for Medical Devices Industry; ABIMED Associação Brasileira da Indústria de Tecnologia para Saúde; Kmdica Korea Medical Devices Industrial Coop. Association; KMDIA Korea Medical Devices Industry Association; TECHNATION CA

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DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

GMTA-DITTA WORKSHOP OVERVIEW

COCIR Advancing Healthcare · JIRA · Medtech Canada · MITA Medical Imaging & Technology Alliance · THAIMED · IMEDA · 中国医疗器械行业协 China Association for Medical Devices Ind · ABIMED Associação Brasileira da Indústria de Tecnologia para Saúde · Kmdica Korea Medical Devices Industrial Coop. Association · KMDIA Korea Medical Devices Industry Association · TECHNATION CA

2. DITTA PRIORITIES

DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

- Global harmonization of medical device regulations
- Convergence of regulatory frameworks
- Regulatory reliance
- Support training and capacity building

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DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

3. Feedback on IMDRF Work items and other relevant topics

- Good Regulatory Review Practices (GRRP)
- Medical Device Cybersecurity Guide (CYBER)
- Artificial Intelligence /Machine/Learning-enabled Devices (AI/ML)
- Software as a Medical Device (SaMD)
- Standards
- Unique Device Identification Application Guide (UDI)
- Medical device single audit program (MDSAP)
- RPS/eSTAR
- Health Equity

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DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

3. Feedback on IMDRF Work items

1. Good Regulatory Review Practices (GRRP)

- DITTA welcomed the publication of the IMDRF N71 "Medical Device Review Report: Guidance regarding information to be included"
- DITTA supports further development of key elements for the CAB review system

DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

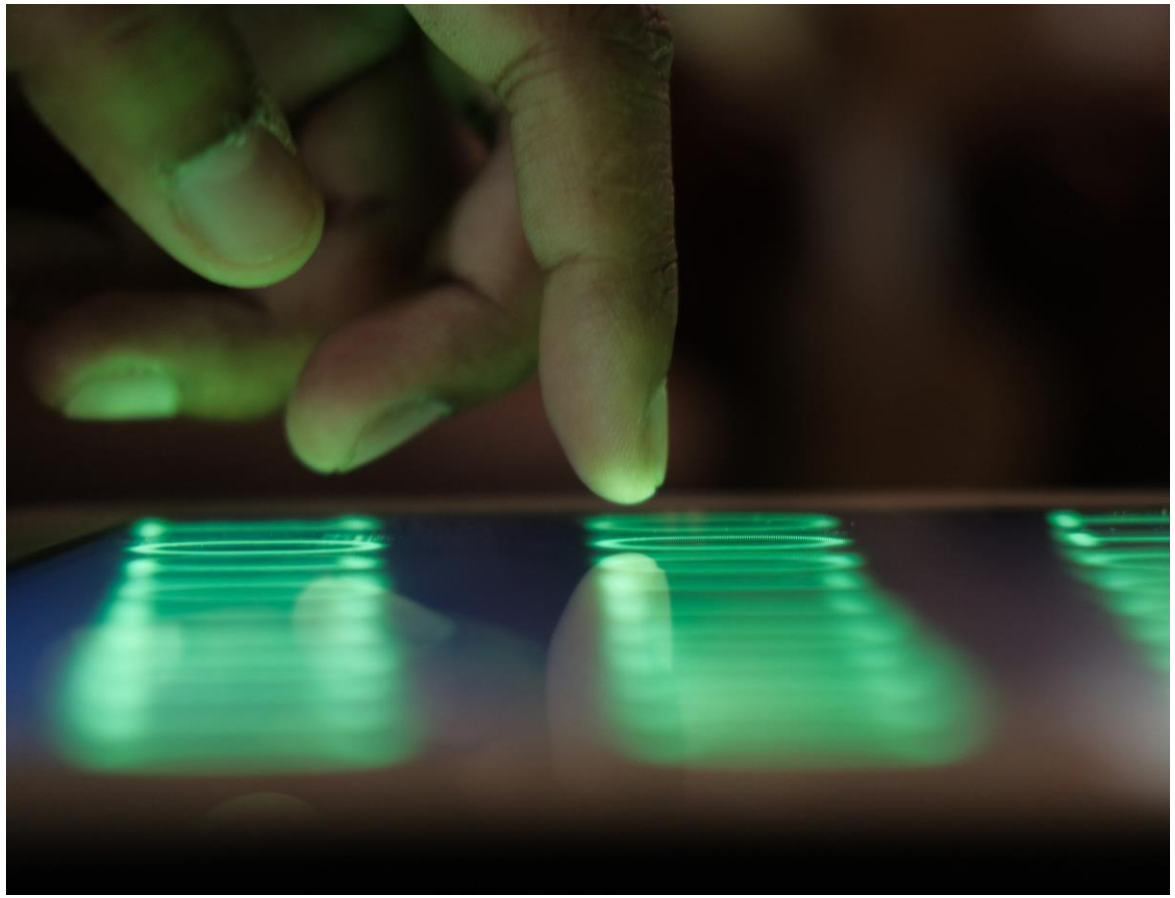
3. Feedback on IMDRF Work items

2. Medical Device Cybersecurity Guide (CYBER)

- DITTA is committed to working with the IMDRF to ensure that medical devices are deployed securely on networks and operate in a safe, effective way.

3. Artificial Intelligence/Machine Learning-enabled (AI/ML)

- DITTA supports the development of IMDRF guidance on Good Machine Learning Practice and Pre-Determined Change Control Plans.



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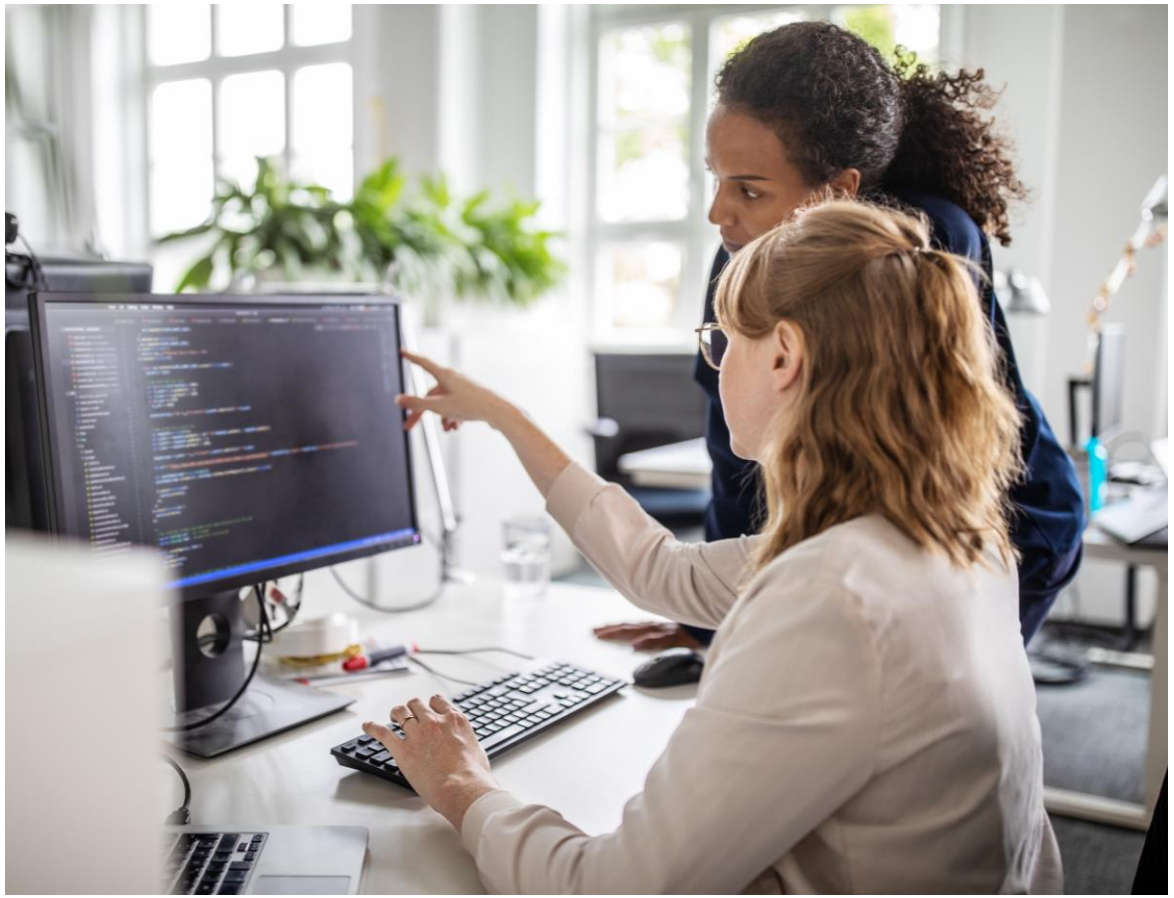
3. Feedback on IMDRF Work items



4. Software as a Medical Devices (SaMD)

- Support current activity to revise the existing SaMD documents.
- "SaMD Key Definitions (N10)" and on "Possible Framework for Risk Categorization and Corresponding Considerations (N12)"

5. Standards -Improving the quality of international medical device standards for regulatory use

- International standards are vital for global convergence
- Support "Standards Liaison Program Framework" (IMDRF/Standards WG/N72)
- IMDRF should actively use its liaison status at ISO and IEC to ensure regulators' input into development of standards for regulatory use is implemented.

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3. Feedback on IMDRF Work items

6. Unique Device Identification Application Guide (UDI)

- See DITTA Whitepaper on UDI: *Challenges with Implementing Global Unique Device Identification Requirements and Solutions*
- Support global harmonization of UDI requirements via implementation of the existing IMDRF documents
- Recommend updating documents:

"IMDRF/UDI WG/N53 "Use of UDI Data Elements across different IMDRF Jurisdictions"

"IMDRF/UDI WG/N48 "Application Guide"

7. Medical device single audit program (MDSAP)

- DITTA recommends that additional jurisdictions accept MDSAP reports in place of their need for audits
- DITTA encourages jurisdictions to become Members or Affiliates of the MDSAP Consortium

3. Feedback on Other Regulatory Initiatives

8. RPS/eSTAR

- DITTA members are participating in the eSTAR joint pilot with US FDA and Health Canada
- We welcome additional jurisdictions participating in future eSTAR expansion

9. **Health Equity**

- DITTA shared comments in support of the *Guiding Principles to Support Medical Device Health Equity*
- Support including additional factors such as socioeconomic and age

DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

THANK YOU!

www.globalditta.org

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Digital Label

Leveraging technology to streamline access to information and reduce costs

Diana Kanecka, GMTA

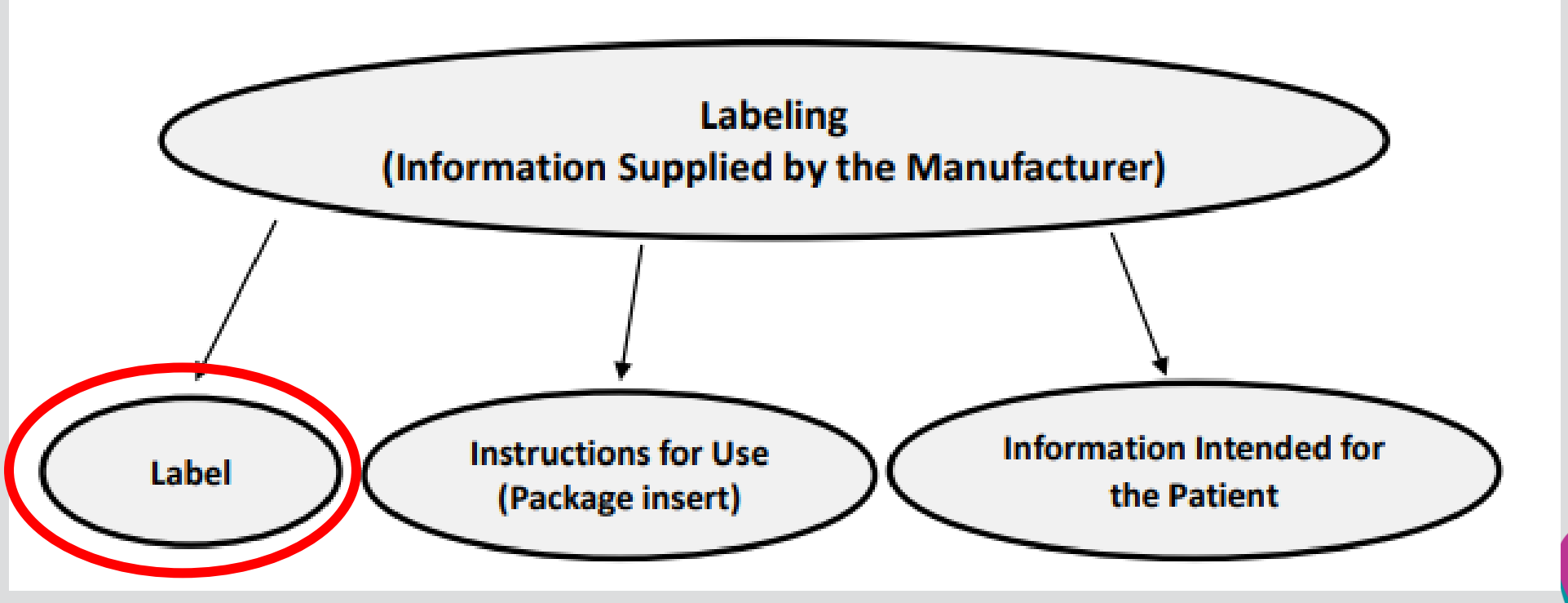
GMTA Global Medical Technology Alliance
Innovating for a Healthier World

26 September 2023

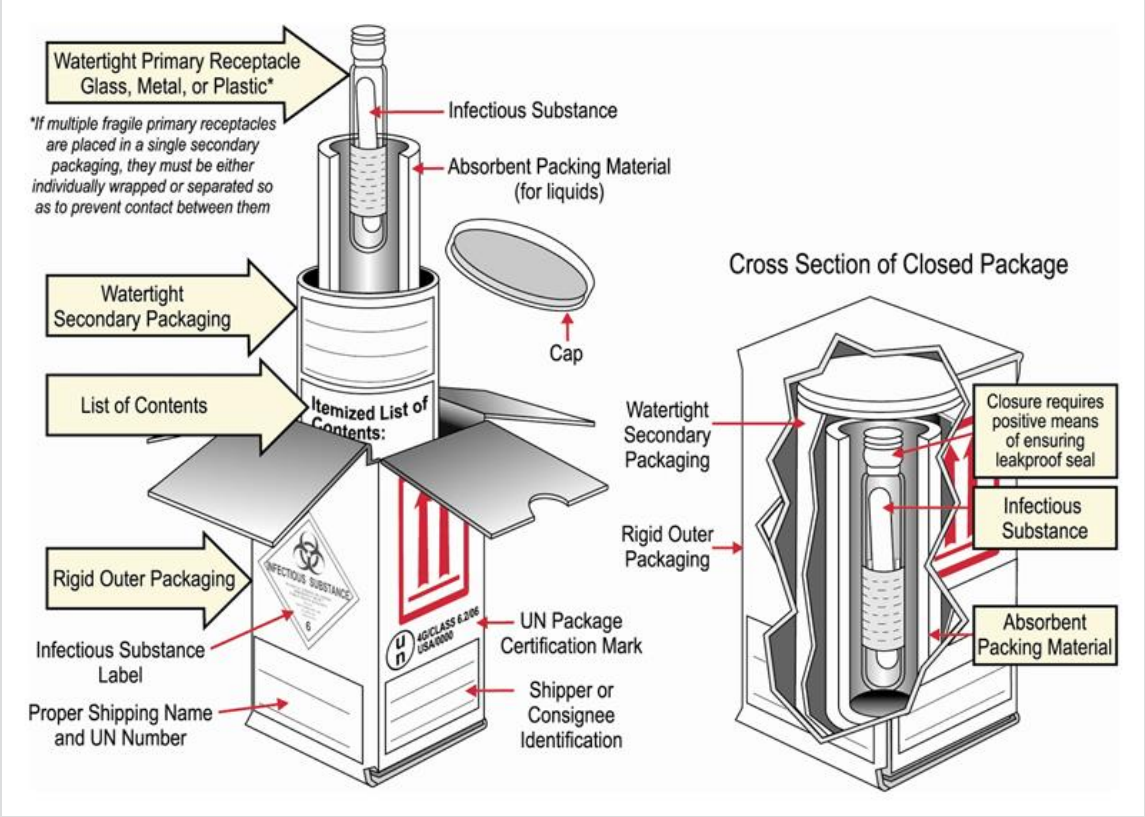
European Commission

Funded by the European Union

Focusing on:


Labeling
(Information Supplied by the Manufacturer)
Label
Instructions for Use
(Package insert)
Information Intended for
the Patient

What is in a label? – Key information:



Identify

Handle

Safety

Global Medical Technology Alliance
Innovating for a Healthier World

And yet - more regulations – more label requirements:

- Conformity Marks
- Economic operators
- Local registration information…

Challenges of current labels:

Raising cost to serve

Proliferation of country specific label requirements

Lack of a harmonized approach on what is essential to be on the label

Difficulty to read specific information – small print and overcrowding of the label

Labelling changes can cause inefficiencies within the system and may impact product availability

What is a digital label?

Digital **label**

Printed digital display on the product where additional prescribing, product information, country specific requirements for medical device can be displayed

Comes in the form of **barcodes, 2D data matrix, RFID, NFC, QR codes, blockchain, website link**

Examples of coded elements

UPC-A & E	I 2 of 5 (ITF)	Pharmacode	QR Code
EAN-8 & 13	Cod-a-bar	Data Matrix	Micro QR Code
EAN 128	Code 39	PDF-417	Human Readable
Code 128	GS1-RSS	Micro PDF-417	

6

Opportunities digital label offers:

Provides information to regulators and users in a format that is much clearer and avoids cluttered labels and packaging and information overload, as information can be better depicted electronically – **enhancing safety information**

Ensures rapid access to up-to-date information for health care professionals, hospitals, users, health authorities and other stakeholders

Can link the user to the latest electronic instructions for use (e-IFU) or an electronic implant card, if applicable

Can be used for **informing the authorities and users** on the registration status and on the economic operators **in their specific region** without the need for labelling the device packaging itself and confusion when multiple EOs are involved

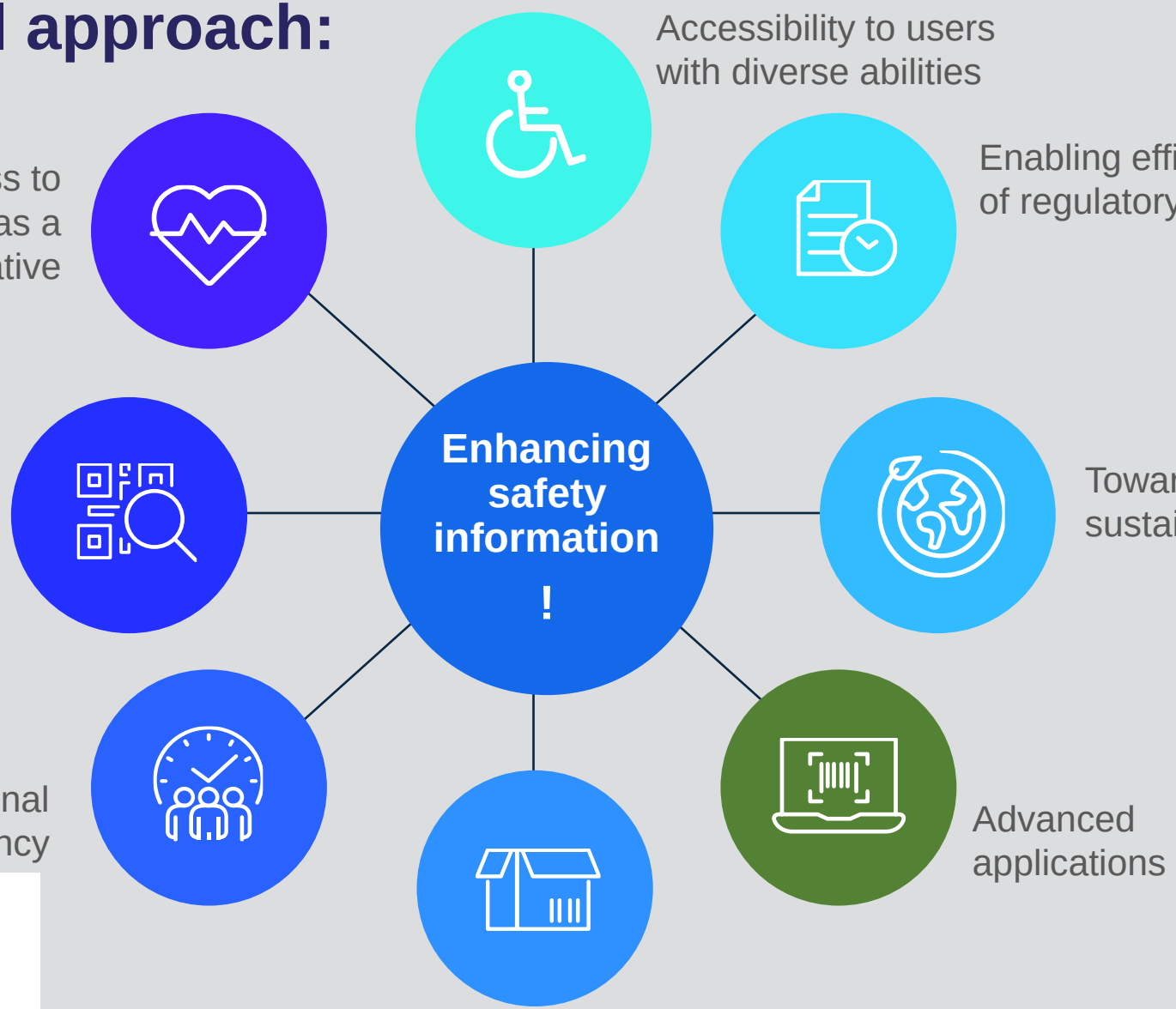
Can accommodate a wider range of information to the user and inform the user on environmental sustainability for re-use, recycle and repurpose of e.g., packaging materials

Can improve supply management.

Digital labels reduce complexity of packaging line management and its associated activities which helps to reduce stock shortages, wastage, and improved access for patients

Can enhance sustainability goals. By eliminating paper labels, digital labelling improves environmental sustainability, reduces wastages and deforestation

Benefits of a digital approach:



Recommendations:

- Digitization of the regulatory system and acceptance of digital labels
- Agree and align on what is the KEY information that needs to be on the label (device identification and safety perspective)
  - Limit label requirements to those elements that are essential for identification of the device and safety and allow for additional information to be accessed via a digital label
- Include stakeholders in the process to enable additional information to be made available to users via a digital label

THANK YOU / QUESTIONS

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