GHWP

Global Harmonization Working Party

Towards Medical Device Harmonization

PROPOSED FINAL DOCUMENT

Title: **Global Harmonization Working Party Strategic Framework towards 2026**

Authoring Groups: **GHWP Office Bearers**

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1. Introduction

Established in 1996, GHWP (formerly known as Asian Harmonization Working Party – AHWP) is a non profit organization started by a voluntary group of regulator and industry members worldwide, with a goal of establishing a harmonized regulatory framework for implementation amongst its members.

Effective 1 December 2021, the organization move forward and rebrand to Global Harmonization Working Party with a member strength of 32 countries/regions. To this end, GHWP leadership and its members believe it is optimum timing to re-brand the organization to truly reflect its membership.

In terms of formally participating members, the GHWP is the largest co-operative organization in the world with a focus on harmonization of the regulation of medical devices, in vitro diagnostics and digital health.

In the past 27 years, GHWP has achieved great success including but not limited to:

--**Membership**: The membership has grown from the initial 14 to 32 in 2021, expanding from Asia to the Middle East, America and Africa.

--**Working model and structure**: Established a Secretariat office helmed by the Secretary General on administrative matters, GHWP Administration Services Limited for financial governance and technical working structure overseen by a Technical Committee consisting of Working Groups charged with a focus on the development of the technical aspects of introduction and implementation of the harmonized regulatory framework amongst GHWP members.

-- **Guidance/trainings**: Published more than 40 technical guidance documents and organized more than 40 trainings/workshops, with over 5000 participants globally.

--**Partnership with other like-minded international organizations**, including:

- International Medical Device Regulators Forum (IMDRF)
- The International Organization for Standardization (ISO)
- International Electrotechnical Commission (IEC)
- Joint Advisory Group (JAG) of IEC TC 62 and ISO/TC 210
- Asia Pacific Medical Technology Association (APACMed)
- Global Diagnostic Imaging, Healthcare IT & Radiation Therapy Trade Association (DITTA)
- GS1
- The Global Medical Device Nomenclature (GMDN) Agency
- The Global Medical Technology Alliance (GMTA)
- The Inter-American Coalition for Regulatory Convergence for the Medical Technology Sector (IACRC)
- World Health Organization (WHO)
- Organisation for Economic Co-operation and Development (OECD)
- Asia-Pacific Economic Cooperation (APEC)

However, even with the organization's achievements to date there are remaining and new

challenges as the **medical technology transforms and regulatory science evolves**.

While some members are still in the development phase of the local regulatory framework for medical devices, other more mature markets are busy coping with the **novel technologies e.g. Software as a Medical Device (SaMD), Artificial Intelligence (AI)/Machine Learning (ML), New-Generation Sequencing (NGS), 3D printing, Cybersecurity** and constantly reforming their regulatory frameworks based on latest developments in regulatory sciences.

Since many elements of these newly emerging regulatory frameworks are still in the formative stages, there is opportunity for the prospects of an internationally harmonized framework for the regulation of medical devices, particularly in **GHWP**, but also beyond as membership of the Organisation continues to grow.

As such, regulatory authorities and industry members in **GHWP** of all sizes and maturity levels would benefit from such a regulatory harmonization and knowledge sharing platform in order to constantly optimize the local regulatory practices to ensure safety, quality and performance of medical devices available to their citizens.

This GHWP Strategic Framework document serves as a guide for its members to prioritize regulatory activities in accordance with our **Vision, Mission, Mechanism, and Strategic Objectives** by 2025.

2. Strategic Framework Towards 2025

2.1 Our Vision

To achieve international harmonization of Medical Devices regulatory framework among regulatory authorities, convergence of regulatory requirements, open and trust-based efforts between regulatory authorities and the industry across the globe.

2.2 Our Mission

To strategically accelerate medical device regulatory convergence through promoting an agile and fit-for purpose regulatory model for medical devices based on latest development in regulatory science. To lead and promote systematic capacity building for future-ready regulatory professionals in light of emerging technologies while enabling patient safety and timely access to safe and effective medical devices.

2.3 Mechanism

- GHWP TC will **regularly review the existing guidance documents** and will phase out or update as appropriate, based on scientific and technological advancement, and internationally recognized best practices.

- GHWP TC working group is responsible for proposing new work items based on emerging technologies and advancement in regulatory science.

At the time of this document release, the world is still in the midst of global pandemic that is going to the phase of endemic. However, with the lessons learnt around regulatory agility e.g. Emergency Use Authorization (EUA), legislative framework and tools built, stronger than ever collaboration between regulatory authorities and the ecosystem, we are confident that joining forces at international platforms like GHWP will set us up for better success in coping with new challenges in the future.

2.4 Strategic Objectives

2.4.1 Membership

As we are convinced about the tremendous value of international and cross-regional collaboration and harmonization of medical device regulations, the GHWP will welcome any non-members to join and form alliances to expand the reach globally.

2.4.2 Regulatory Convergence

A. Information sharing

We believe information sharing is critical to facilitate regulatory convergence; hence, GHWP is committed to organizing the annual meeting once a year, TC meetings twice a year, Working Group meetings at least once a quarter and reporting to TC at the annual meeting, to facilitate information and best practice sharing.

Additionally, we recognize the needs of members and will support the set-up of internationally synchronized and encrypted IT platforms to facilitate confidential information sharing.

As it is imperative that only safe and effective medical devices are used by the public, sharing of post-market information will expediate the detection of unforeseen problems related to safety and performance of devices. We will develop a global post-market exchange program and encourage participation in sharing of information among members. To this end, we expect to initiate a post-market database at GHWP or Regional Hub level. This may include

- Usage of available basic UDI databases through aligning identification of local devices to established global UDI systems.
- Adoption of agreed definitions and requirements, e.g. Product notification; Safety alerts; Adverse Event Report (AER) requirements; Field safety corrective actions (FSCA); Recall and Non-recall actions

B. Translating GHWP Guidance into local regulatory framework as appropriate

We will encourage members to constantly adopt and implement the principles in GHWP guidance documents to the local regulatory framework. We will also use this as **a key performance indicator to assess regulatory convergence**.

C. Harmonized regulatory model

We will encourage members to adopt a harmonized **nomenclature** system for medical devices, recognize and leverage **international standards**, accept and recognize ISO certificates and/or MDSAP certificates for **QMS certification**, the **clinical performance evaluation and conformity testing** conducted by other trusted agencies.

We will encourage emerging regulatory authorities to design the approach for their regulatory framework in a phased system and with reference to the AHWP Playbook

We encourage like-minded regulatory authorities or those from the same region to embark on **Memorandum of Understanding (MOU)** to maximize regulatory resource efficiency supported by confidentiality agreement, where appropriate.

2.4.3 Regulatory Science

We acknowledge the current regulatory framework will not fit for the purpose of regulating emerging technologies (such as digital health solutions) due to the drastic differences from traditional devices. Hence, we are committed to prioritize the knowledge sharing and capacity building to cater for needs in coping with novel technologies **e.g. Software as a Medical Device (SaMD), Artificial Intelligence (AI)/Machine Learning (ML), Next-Generation Sequencing (NGS), 3D printing, Cybersecurity, etc.**

We also acknowledge the needs for regulatory authorities and industry to modernize the regulatory process and tools. Hence, we will support the modernization and digital transformation of such process and tools e.g. virtual audit, rolling submission, cloud submission, etc.

2.4.4 Regulatory Reliance

We acknowledge the world-wide regulatory resource constraints, hence are committed to promote the regulatory models as proposed in the WHO Good Reliance Practice guidance i.e. work-sharing, abridged pathway using reliance, regional reliance mechanism, unilateral recognition, and mutual recognition.

We encourage members to make best use of available resources and expertise, avoid duplication, and concentrate regulatory efforts and resources where most needed.

We recommend GHWP members, regardless of the market size, maturity level, or existing resources within that jurisdiction to practice reliance principles throughout different stages of the product life-cycle, i.e. establishment licensing, marketing authorization, quality management system audits, post market surveillance, and post-approval changes.

2.4.5 Capacity Building

Following the release of Competency Frameworks and Training Curriculum white papers for regulators and industry regulatory professionals, GHWP will further build the training curricula to better suit member needs.

We will also develop and implement a certification program of regulatory trainings for both regulatory authorities and industry members. The program will be a combination of face-to-face and virtual training, with the set up of a technical helpdesk being explored to serve them. The ultimate goal of which is contribution of improved patient access to high quality and safe medical devices.

We will establish GHWP Academy for regulatory authorities and industry members:

- Training hubs that deliver face to face training workshops, seminars and certification courses.
- Online training platform that delivers:
    - Real-Time/Live workshops, webinars and Certification courses
    - Self-Directed (Learner-Paced) Learning Courses and Certification Courses
    - Interactive Learning Experience
- Curriculum team to establish training materials and delivery programs both on-line and face-to-face
- Regional Focus groups set up to facilitate:
    - Local sharing of experiences, understanding of both new and emerging technologies
    - Exchange programs for regulators
    - Phased introduction of regulations encouraged for emerging regulatory framework

2.4.6 Global Partnership

We will continuously enhance partnerships with strategic alliances to facilitate regulatory convergence programs e.g. IMDRF, APACMed, DITTA, GS1.

We will work to establish formal relationship with WHO Regional Offices to carry out trainings and facilitate reliance programs.

The document will continuously evolve with innovative mindset and response with agility to meet the ever changing environment.