GHWP

Global Harmonization Working Party

Towards Medical Device Harmonization

DRAFT DOCUMENT

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Global Harmonization Working Party Strategic Framework towards 2026 – DRAFTv3

1. Introduction

Established in 1996, the Asia Harmonization Working Party (AHWP) is a non profit organization started by a voluntary group of regulator and industry members from Asia and beyond, with a goal of establishing a harmonized regulatory framework for implementation amongst its member economies.

In 2021, AHWP has 31 members. In terms of formally participating members, the AHWP is the largest co-operative organization in the world with a focus on the regulation of medical devices, in-vitro diagnostics and digital health. One more member has since been added to form a 32-member body globally.

To this end, the GHWP leadership and its 32 members believe it is optimum timing to re-brand the organization to truly reflect its membership. Effective 1 December 2021, the organization moved forward and rebranded as the Global Harmonization Working Party.

In the past 25 years, the AHWP has achieved great success including but not limited to:

--**Membership**: The membership of AHWP has grown from the initial 14 members to currently 32 members, expanding from Asia to the Middle East, North and South America and Africa.

--**Working model and structure**: AHWP has established a Secretariat office lead by the Secretary General on administrative matters, AHWP Services Limited (ASL) for financial governance and technical working structure overseen by a Technical Committee consisting of nine Working Groups charged with a focus on the development of the technical aspects of introduction and implementation of the harmonized regulatory framework amongst AHWP member economies.

-- **Guidance/trainings**: AHWP has published more than 40 technical guidance documents and organized more than 40 training/workshop programs, with, collectively, over 5000 participants globally.

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

- The International Medical Device Regulators Forum (IMDRF);
- The International Standards Organisation (ISO);
- The International Electrotechnical Commission (IEC);
- Joint Advisory Group (JAG)
- The Asia Pacific Medical Technology Association (APACMed);
- The Global Trade Association representing Medical Imaging, Radiation Therapy and Healthcare IT Industry (DITTA);
- GS1;
- Global Medical Device Nomenclature Agency (GMDN);
- The International Anti-Corruption Resource Center (IACRC)

- The World Health Organisation (WHO);
- The organisation for Economic Co-operation and Development (OECD);
- The Asia-Pacific Economic Co-operation Forum (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 many member economies are still in the development phase of a local regulatory framework for medical devices, other more mature markets are busy coping with the **novel technologies e.g. Software as Medical Device, 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 development of an internationally harmonized framework for the regulation of medical devices, particularly in **GHWP** member economies, but also beyond as membership of the Organisation continues to grow.

As such, regulatory authorities and industry members in **GHWP** economies of all sizes and maturity levels would benefit from such a regulatory harmonization and knowledge sharing platform in order to constantly optimize 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 2026.

2. Strategic Framework Towards 2026

2.1 Our Vision

To achieve international harmonization and convergence of medical device regulations through regulatory reliance among regulatory authorities as well as 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 the latest developments in regulatory science. To lead and promote systematic capacity building for future-ready regulatory professionals in light of emerging technologies.

2.3 Mechanism

- The GHWP TC will **regularly review the existing guidance documents** and will phase out or update as appropriate, based on scientific and technological advancements or member's regulatory landscape developments.

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

At the time of this document release, the world is still in the midst of global pandemic that is evolving to being endemic in the global population. 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 value and benefits of international and cross-regional collaboration through harmonization of medical device regulations, the GHWP welcomes new 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 a conference once a year, TC leaders/meetings once a year, Working Group meetings as needed, all with the aim of facilitating 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 only safe and effective medical devices are approved for use, sharing of post-market information will expediate the detection of unforeseen problems related to safety and performance of devices. We will explore a global post-market exchange program and encourage participation in and sharing of information among members. To this end, 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 member economies 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 certificate for **QMS certification**, and the **clinical performance evaluation and conformity testing** conducted by other trusted agency.

We will encourage emerging regulatory authorities to design the regulatory framework in a phased approach with reference to the **AHWP Playbook**.

We will encourage like-minded regulatory authorities or those from the same region to embark on **Mutual Recognition Agreement** to maximize regulatory resource efficiency.

2.4.3 Regulatory Science

We acknowledge the current regulatory framework may not be fit for the purpose of regulating emerging technologies (such as digital health solutions) because of significant differences from traditional devices. We are committed to prioritizing the knowledge sharing and capacity building to cater for needs in coping with novel and emerging technologies **e.g. SaMD, AI/ML, NGS, 3D printing, Cybersecurity, etc.**

We also acknowledge the needs for regulatory authorities and industry to modernize its 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, and are committed to promoting 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 member economies 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. licensing establishment, marketing authorization, quality management system audits, post market surveillance, and post-approval changes.

2.4.5 Capability Building

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

We will 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 trainings. We will explore the establishment of Technical helpdesk to serve the regulatory authorities and industry members.

We will establish

- the GHWP Academy for regulatory authorities and industry members:
- Training hubs that deliver face to face training workshops, seminars and certification courses.
- An 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
- A curriculum team to establish training materials and delivery programs both on-line and face-to-face
- Set up of Regional Focus groups to facilitate:
    - Local sharing of experiences, understanding of technologies both new and emerging
    - Exchange programs for regulators
    - Encouraging phased introduction of regulation for emerging economies

2.4.6 Global Partnership

We will continuously enhance partnerships with strategic alliances to facilitate regulatory convergence and reliance programs e.g. IMDRF, APACMed, DITTA, GS1. (Invite IMDRF to become a GHWP collaborative member).

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

This document will continuously evolve and respond to meet the ever changing environment.