GHWP

Global Harmonization Working Party

Towards Medical Device Harmonization

FINAL DOCUMENT

Titel:	**GHWP Strategic Framework for Medical Device Regulation – Towards 2030**
	Accelerating Global Harmonization of
	Medical Device Regulations for Public Health
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Executive Summary

The mission of Global Harmonization Working Party (GHWP) is to accelerate the convergence, harmonization and reliance of global medical device regulation, strengthen regulatory capacity building of its member countries/regions, facilitate the international trade of medical devices, therefore protect and promote global public health.

This document outlines the GHWP strategic framework and development roadmap to 2030. Anchored in global health mandates such as the UN's Sustainable Development Goal 3 and key World Health Assembly resolutions, this strategy aims to further advance convergence, harmonization, and reliance for medical device regulation.

The framework includes enhancing organizational leadership, advancing capacity building, accelerating the drafting and adoption of guidance, speeding up approval of advanced technology and increasing reliance agreements. By executing this strategy, GHWP will not only strengthen global public health but also deliver tangible economic value to its members, ensuring the high quality and rapid delivery of medical devices to the public worldwide.

1. Aligning with Global Health Imperatives

UN SDG 3 and WHA Mandates

The GHWP Strategic Framework Towards 2030 is fundamentally anchored in the global commitment to public health, as articulated by the United Nations' Sustainable Development Goal 3 (SDG 3): "Ensure healthy lives and promote well-being for all at all ages." Achieving this goal is impossible without ensuring universal access to safe, effective, and quality-assured medical devices.

UN Sustainable Development Goal 3 (SDG 3) and World Health Assembly (WHA) mandates underscore the global commitment to ensure healthy lives and promote well-being for all. A pivotal aspect of these imperatives is the efficient regulation of medical devices and technologies, which requires harmonized frameworks and international collaboration.

Responding to WHA Mandates

Resolution	Year	Focus Area
WHA60.29	2007	Health Technologies
WHA67.20	2014	Regulatory System Strengthening for Medical Products
WHA76.5	2023	Strengthening Diagnostics Capacity

These resolutions collectively urge WHO's Member States to:

- Develop and strengthen regulatory systems for medical devices
- Enhance international cooperation and harmonization
- Facilitate equitable access to essential health technologies

GHWP drives regulatory convergence, harmonization and reliance, serving as a key enabler for Member Countries/Regions to fulfill these obligations. Its approach ensures regulatory efficiency while maintaining rigorous patient safety standards, accelerating access to life-saving innovations.

2. GHWP Foundational Framework

Development Roadmap of GHWP

GHWP originated as the Asian Harmonization Working Party (AHWP), founded in 1996. As a non-profit international organization, GHWP is one of the major collaborative platform in the field of medical device regulation, jointly participated by regulators and industry representatives.

After nearly 30 years of development, GHWP has established a global membership, encompassing 38 member countries and regions from Asia, Africa, South America and North America, covering nearly 60% of the global population.

Principles and Achievements

- Openness, cooperation, professionalism, and mutual benefit
- Leadership (2023–2025) focused on harmonization, convergence, and reliance within the Strategic Framework towards 2026

- Published 66 technical guidelines focused on major issues of medical device supervision and industrial development

Membership and International Liaison

Recent new members include: Egypt, Cuba, Botswana, Ghana, Macao (SAR, China), and Uzbekistan. GHWP's international liaison continues to expand, with the Middle East Medical Device Imaging and Diagnosis Industry Association (MECOMED) as the latest GHWP liaison member, making a total of 7.

Organizational Structure and Key Initiatives

- Ten key tasks identified annually to drive progress
- Establishment of an independent Strategic Advisory Board and a Capacity-Building Committee
- Launch of the Special Task Group for Common Evaluation Reliance Practice (CERP STG) with a focus on regulatory reliance
- Founding of the GHWP Medical Device Regulatory Training Academy (GHWP Academy) in collaboration with South China University of Technology, Guangdong, China—providing two on-site training sessions each year
- Annual hosting of GHWP International Medical Device Exhibition and the Symposium for Innovative Medical Devices with relevant stakeholder

3. Future Challenges and Opportunities

3.1 Growth and Economic Potential

As innovation and development continue at a robust pace, the medical device market is projected to reach a valuation of $862 billion by the year 2030, growing at a compound annual rate of 5.5%. This sustained growth highlights the substantial economic potential within the sector.

GHWP membership currently encompasses nearly 60% of the global population—a figure that continues to rise. In response to this significant representation and economic influence, GHWP must prioritize the needs of its members from a global viewpoint and seek more effective methods for regulatory convergence, harmonization, and reliance.

3.2 Advancements in Regulation

Regulation within the medical device industry is transitioning into the information age. Artificial intelligence is becoming increasingly integral to regulatory processes, with agencies utilizing AI algorithms to rapidly identify risks and facilitate timely decision-making. Meanwhile, modern medical devices are equipped to gather,

transmit, and analyze vast amounts of data, necessitating innovative approaches to supervision.

3.3 Emerging Focus Areas

With the rise of smart wearable devices and telehealth systems, new regulatory priorities have emerged, including data security, privacy protection, and system compatibility. These concerns reflect both current trends and future challenges, requiring GHWP to collaborate closely with its members to achieve supervision that is agile, scientific, and minimally burdensome.

4. Strategic Objectives for 2030

4.1: Enhancing institutional reform

To constantly expand its membership to enhance its cohesion and creativity.

To task and empower the Strategy Advisory Board (SAB) in conducting research on development strategy and major items, and to boost Capacity Building Committee (CBC) with the GHWP Academy.

To modernize GHWP governance to ensure sustainable, transparent and steady growth.

To strengthen cooperation and collaboration with all stakeholders.

4.2: Accelerating the drafting and adoption of guidance

To meet the needs of the rapid development of the medical device industry and support regulatory harmonization and reliance, accelerate the formulation and revision of important guidance documents. At the same time, encourage member countries and regions to propose mature guidance documents, and afterwards recognize within GHWP after a comprehensive evaluation.

Encourage GHWP members industry representatives to draft white papers on the development of the global medical device industry in key areas, highlighting development achievements and prospects, outlining opportunities and challenges, and proposing innovative development recommendations.

4.3: Strengthening capacity building

Building on the 10 years legacy and continue to develop the Curriculum 2.0, disseminate technology innovation, and translate GHWP's guidance for local implementation.

To establish new academies across different continents to advance GHWP's mission, vision and goals, while enhancing the governance capacity of its member countries/regions.

To enhance the online training platform and in-country training with professional faculty team from relevant international institutions.

4.4: Speeding up approval of advanced medical products

Encourage member countries/regions to develop medical robots, advanced medical imaging equipment, artificial intelligence, new biomaterials and other advanced medical devices as pivotal areas for innovation, actively engaging in the formulation of international standards, and facilitate timely marketing.

4.5: Reliance agreement / collaboration amongst regulators

To coordinate pre-market technical reviews of medical devices, it is recommended to leverage CERP as a platform, while encouraging members to foster collaborative review of medical devices that are used in rare diseases and widespread disease treatments.

To motivate members to actively pursue reliance agreements or explore collaboration as an alternative.

Achieving the goals of SDG 3 requires not just harmonization, but the practical, accelerated application of regulatory reliance among GHWP members. This strategic objective is the mechanism for rapidly delivering safe, high-quality devices to the global public. This requires a dedicated focus on transforming capacity-building programs into practical implementation support, especially for emerging regulators.

GHWP should prioritize the development of clear, actionable frameworks for reliance that reduce regulatory duplication, optimize global review timelines, and ensure that a comprehensive assessment by one mature regulator is leveraged effectively by others to expedite patient access.

4.6: Global medical device regulatory model act

By referencing WHO's Global Model Regulatory Framework for Medical Devices including IVDs and applying learnings from GHWP members with established harmonized regulatory systems, GHWP will draft a global model regulatory act to harmonize pre-market registration, post-market surveillance, and vigilance among GHWP members.

Regulatory Posture When Implementing Strategic Objectives for 2030

These 6 Strategic Objectives for 2030, as outlined above, aim to ensure that GHWP maintains regulatory agility towards regulating medical devices incorporating advanced and digital technologies.

The medical device landscape is increasingly defined by disruptive technologies such as Artificial Intelligence (AI) / Machine Learning (ML), software as a medical device (SaMD), 3D-printing, and personalized implants.

GHWP must collaborate with leading industry leaders and establish itself as the global leader in developing a risk-calibrated, 'innovation-first' regulatory pathway for these products. These 6 Strategic Objectives for 2030 require moving beyond traditional static approval models to foster regulatory frameworks that can safely accommodate continuous learning algorithms and accelerated product development cycles. The focus must be on pre-market pathways that enable timely market access for high-end, transformative innovations.

5. Strategic Engagement

The Economic Value Proposition: A Three-Pillar Approach

Pillar 1: Attract Medical Investment and Foster Innovation.

Position regulatory harmonization as a tool to enhance medical investment and establish the country and region as a regional hub for the medical device industry

Pillar 2: Accelerate Export Growth for Local Industries

Enable local medical device companies to access international markets more efficiently through harmonized regulatory pathways

Pillar 3: Enhance Public Health Outcomes

Provide faster access to innovative medical technologies for patients while maintaining safety standards

6. Global Partnership & Corporate Governance

GHWP collaborates with WHO, ISO, IEC, and other organizations to enhance regulatory professionals' skills, particularly in regions with newly enacted laws and regulations.

Leadership Mechanism

Annual identification of key tasks with target timelines and roadmaps. Joint leadership meetings for key decision making and oversight of annual work plans.

Executive Mechanism

Increase secretariat staff led by the Executive Secretary to support key initiatives, maintain website, manage finances, and organize conferences.

Incentive Mechanism

Implement GHWP outstanding contribution awards and recognition programs, provide international exchange opportunities, and offer visiting professor positions at the GHWP Academy.

Conclusion

GHWP's Strategic Framework Towards 2030 charts a path of openness, cooperation, professionalism, and mutual benefit, providing global guidance for medical device regulation. By fostering regulatory convergence and reliance, GHWP assists Member Countries/Regions in meeting their global commitments, expediting access to innovative, life-saving medical technologies worldwide.

By leveraging its diverse membership and expanding international collaborations, GHWP continues to set the standard for regulatory excellence, innovation, and public health impact. The organization's commitment to capacity-building, regulatory convergence, and public health innovation positions it at the forefront of global efforts to enhance access to safe, effective, and high-quality medical devices.