GHWP Strategic Framework for Medical Device Regulation 2030

Accelerating Global Harmonization for Economic Growth and Public Health

September 2025

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Executive Summary

This document outlines the Global Harmonization Working Party's (GHWP) medical device regulatory 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 solidify GHWP's role as the leading platform for global medical device regulatory harmonization.

The framework details a three-phased Strategic Action Plan (2025-2030) to operationalize GHWP's core objectives. This includes establishing a global network of regional offices, enhancing organizational leadership, advancing capacity building, and promoting reliance agreements. Each action is tied to specific Key Performance Indicators (KPIs) to ensure measurable progress.

Recognizing the tremendous strategic importance of the Global Medical Device Regulatory Model Act, the core of the strategy presented in this document is reframing regulatory harmonization as a powerful engine for economic development.

By executing this strategy, GHWP will not only advance global public health but also deliver tangible economic value to its member states, ensuring the safe and rapid delivery of medical innovation to patients 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
WHA76.5	2023	Strengthening Diagnostics Capacity

These resolutions collectively urge Member States to:

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

GHWP (Global Harmonization Working Party) drives regulatory convergence and reliance, serving as a key enabler for countries 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

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

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

Principles and Achievements

- Openness, cooperation, professionalism, and mutual benefit
- Published 66 technical guidelines focused on major issues of medical device supervision and industrial development
- Leadership (2023–2025) focused on harmonization, convergence, and reliance within the Strategic Framework towards 2026

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.

GHWP signed a strategic cooperation agreement with Reed SinoPharm Exhibition to jointly hold the GHWP International Medical Device Exhibition and Symposium for Innovative medical devices annually.

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 evaluation and building mutual trust (CERP STG) focused on regulatory reliance
- GHWP Medical Device Regulatory Training Academy (GHWP Academy) founded in Guangdong, China—delivering two on-site training sessions annually

3. Future Challenges and Opportunities

The Global Medical Device Industry

The global medical device industry is undergoing a transition from rapid growth to quality development and public health is a significant global concern. With the global medical device industry actively innovating and developing, it is predicted that the global medical device market size will reach $719 billion by 2029, with a compound annual growth rate of 5.5%.

GHWP member regions currently represent nearly 60% of the global population with a rapidly expanding membership base. Given this substantial economic potential, GHWP has to address members' needs from a global perspective and consider how to enhance regulatory convergence, coordination, and trust more effectively.

Global Medical Device Supervision

Global medical device supervision is transitioning from the industrial to information age, with AI playing a crucial role. Regulatory agencies are increasingly relying on AI algorithms to quickly identify risks and make timely decisions while modern medical devices collect, transmit, and analyze data, requiring innovative supervision strategies.

For wearable smart devices and telehealth systems, new focuses include data security, privacy protection, and system compatibility. Facing these current and potential transition points, GHWP must coordinate with members for agile, scientific, and minimally burdensome supervision.

4. Strategic Objectives for 2030

4.1: Set up GHWP Medical Regional Offices

By 2030, establish 5 GHWP regional offices to promote GHWP's vision, mission, and objectives locally, and provide feedback on local guidelines. Regional offices will support capacity building, regulator-industry collaboration and innovation.

4.2: GHWP Organization Enhancement

Increase the number of Vice-chairs in GHWP Leadership, Co-chairs in TC Leadership and Co-chairs in TC Working Groups and Special Task Groups to accelerate the realization of GHWP Strategic Initiatives towards 2030.

4.3: Capacity Building

GHWP's Capacity Building Strategy focuses on enhancing regulatory competencies and providing accessible professional development for global regulatory professionals through Curriculum 2.0 and expanded training platforms.

4.4: Promote Speed of Market Entry for Critical Medical Technology

GHWP identifies medical robots, advanced medical imaging equipment, artificial intelligence, and advanced biomaterials as pivotal areas for innovation, actively engaging in the formulation of international standards.

4.5: Signing of Reliance Agreements Amongst Member Regulators

Using CERP as a platform, GHWP will coordinate pre-market technical reviews of medical devices for rare diseases, innovative devices, and widespread disease treatments, fostering global regulatory trust.

4.6: Global Medical Device Regulatory Model Act

Establish a workgroup with world-renowned legal experts, senior level regulators, and technical experts to develop the Global Medical Device Regulatory Model Act.

5. Strategic Action Plan (2025-2030)

To operationalize the 2030 strategic objectives, the following phased action plan with detailed KPIs will be implemented:

Phase 1: Foundation & Planning (2025-2026)

- Conduct feasibility studies for regional offices in 3 priority regions
- Develop standardized operational blueprint for regional offices
- Draft and ratify amendments to GHWP Terms of Reference
- Finalize Curriculum 2.0 framework and launch online learning platform
- Constitute workgroup for Global Regulatory Model Act

Phase 2: Implementation & Expansion (2027-2028)

- Launch first two regional offices with full operations
- Publish first two white papers on AI and Robotics
- Execute first multi-jurisdictional joint review under CERP platform
- Sign first formal reliance agreements between member regulators
- Roll out GHWP professional certification program

Phase 3: Consolidation & Leadership (2029-2030)

- Launch remaining three regional offices (5 total operational)
- Publish and disseminate Global Medical Device Regulatory Model Act
- Expand reliance agreement network to majority of GHWP members
- Complete all five foundational white papers with annual updates
- Position GHWP as leading global voice in emerging medical technologies

6. Strategic Engagement

The Global Medical Device Regulatory Model Act is intended to promote the holistic progress of convergence, coordination and trust in Global Medical Device Regulation from a legal perspective. To achieve this goal, it is proposed to set up a Global Medical Device Regulatory Model Act Research Center. The following plan is designed to proactively incentivize the implementation of the Act by focusing on a compelling economic value proposition.

The Economic Value Proposition: A Three-Pillar Approach

Pillar 1: Attract Foreign Investment and Foster Innovation

Position regulatory harmonization as a tool to de-risk investment and make the country 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

Faster access to innovative medical technologies for patients while maintaining safety standards

7. Global Partnership & Corporate Governance

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

regulations. GHWP aims to formalize its relationship with WHO and sign a memorandum of cooperation (MOC) with IMDRF for training and trust-building projects.

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.

Financing Mechanism

Comprehensive funding system through sponsorship and certificate training courses, with strict fund management ensuring transparent use of funds.

Executive Body

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

Incentive Mechanism

GHWP Lifetime Achievement awards and recognition programs, international exchange opportunities, and visiting professor positions at GHWP Academy.

Conclusion

GHWP's Strategic Framework Towards 2030 charts a path of openness, mutual benefit, and professionalism, providing global guidance for medical device regulation. By fostering regulatory convergence and reliance, GHWP assists countries 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.

By executing this strategy, GHWP will not only advance global public health but also deliver tangible economic value to its member states, ensuring the safe and rapid delivery of medical innovation to patients worldwide.