Global Harmonization Working Party
Towards Medical Device Harmonization

Headlines
To Promote & Protect Public Health Through Global Collaboration

Dear GHWP members and GHWP partners,

With your vigorous support and concerted efforts, the 27th GHWP Annual Meeting and TC Meeting was successfully held in Shanghai, China from November 27 to 30, 2023. More than 600 representatives from 25 countries and regions attended the meeting, jointly writing a new chapter of the GHWP endeavor. On behalf of GHWP leadership, I would like to express my heartfelt gratitude to all representatives, experts, and friends. This is the first annual meeting after the election of the new GHWP leadership. Plentiful achievements have been made.

Firstly, we summarized the work achievements of GHWP in the past 9 months. The work achievements mainly included: (1) improving the drafting procedures of GHWP guidance documents for medical devices to advance the quality and efficiency; (2) setting up the Strategic Advisory Board (SAB) to strengthen the research of forward-looking regulatory strategy; (3) establishing the first GHWP Academy to enhance the regulatory capacity building of GHWP member countries and regions; (4) building the first GHWP global industry exchange platform to promote the achievement through exhibition and exchange of innovative medical devices, and (5) intensifying communication with relevant international organizations to foster global medical device regulatory convergence, harmonization, and reliance.

Secondly, we delivered extensive in-depth exchanges and discussions around cutting-edge technologies for medical device innovation. Focused on the opportunities and challenges brought by new technologies, innovative products and new regulatory approaches, multiple topics were discussed at this annual meeting, at which academic discussions were profoundly driven by cutting-edge technologies, regulatory pathways for innovation, regulatory tools fostering innovation, risk management of innovative medical devices, and application practice of unique device identifier (UDI). Owing to novel topics and advanced views, this annual meeting was highly praised by both regulatory authorities and industry representatives.

Thirdly, relevant international organizations, partners, and representatives from some countries and regions reported the latest progress in medical device regulation.

Note: All the Chinese information in the Newsletter is from newspapers and the Internet. All English articles are translated from the Chinese version. In case of any discrepancy, the Chinese version shall prevail.

For a copy of the Newsletter, please visit http://www.uclalac.org

China Center for Food and Drug International Exchange (CCFIDE)

Address: Room 1106, 11th Floor, Office Building B, Maples International Center, No. 32, Wenhua North Street, Haidian District, Beijing 100083, PRC.

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Specifically, the International Medical Device Regulators Forum (IMDRF), World Health Organization (WHO), Africa Medical Device Forum (AMDF), Asia Pacific Medical Technology Alliance (AP health), Medical Device Technology Alliance (MDTA), Global Medical Device Nomenclature (GMDN), Global Diagnostic Imaging, Healthcare IT & Radiation Therapy Association (DUTA) and Inter-American Cooperation for Regulatory Convergence in the Medical Technology Sector (IACR) reported the latest work progress. Representatives from 14 countries and regions reported the latest progress of regulatory work, including China, the European Commission, Indonesia, Japan, Korea, Kuwait, Malaysia, People’s Republic of China, Republic of Korea, Thailand, and Vietnam. Fourthly, a series of important collective decisions were made at this Annual Meeting. Such decisions included (1) approving 8 GGHW guidance documents, (2) approving to set up a special task group to conduct research on common evaluation practice refinement, (3) approving to support Egypt and Cuba as new GGHW members, (4) approving the membership withdrawal request from the U.S. FDA, and (5) approving Medical Device Authority (MDA) Malaysia to host the 28th GGHW Annual Meeting.

Besides busy work, all representatives attended the city tour, visited the beautiful night scene of the Huazeng River, enjoyed the elegance and charm of Shanghai, and experienced the wonderful integration of traditional art and modern music at the Gala Dinner. Looking back on the extraordinary career that GGHW has gone through in the past 27 years, all representatives resonate with common viewpoints and feelings. GGHW has distinct features. With the joint participation of medical device regulatory authorities and industry representatives, GGHW has always directly confronted major issues in the medical device regulatory field, adhered to the coordinated development and growth for both regulators and the industry and actively cope with big challenges in the medical device industry.

GGHW is open and inclusive. At present, GGHW has 34 member countries and regions with SAB, Capacity Building Committee (CBC), and Technical Committee (TC), GGHW can deliver extensive and in-depth discussions on major issues. In this big family, all GGHW member countries and regions consult on an equal footing and pool their wisdom, striving to seek common development and create a bright future together.

GGHW is enterprising and pioneering. Over the years, GGHW has always focused on the major topics of medical device regulation and industry development, endeavoring to actively serve GGHW member countries and regions and contribute to global public health by constantly innovating platforms and carriers. GGHW upholds laws and regulations. Major decisions of GGHW are made according to its Terms of Reference and House Rules (TARHFR).

GGHW member countries and regions, regardless of large or small, communicate on an equal footing, and are strongly encouraged to contribute more wisdom and strength to global medical device regulatory convergence, harmonization, and reliance by making full use of their resources. During the annual meeting, representatives from regulatory authorities and industry repeatedly talked about regulatory convergence, harmonization, and reliance. In addition to mission and vision, every organization has its strengths and weaknesses. An organization can only achieve better development through open communication, GGHW has established its strategic focus and work priorities.

GGHW will be powerful and goal-driven to concentrate on doing our work. Insisting on the principles of equality, openness, robustness, and win-win, GGHW will continue to cordially cooperate with international organizations, relevant countries and regions, and partners that are committed to fostering regulatory convergence, harmonization, and reliance.

Professor Fong lifts new height, sound mindset brings best condition and broad layout brings wonderful outcome. Looking into the future, GGHW will continue to explore the achievement of global medical device regulatory convergence, harmonization, and reliance with more united strength, more open mind, more enterprising attitude, more pragmatic style, striving to make new and greater contributions to the promotion and protection of global public health.

Best regards,

Dr. Xu Jinghe
GGHW Chair
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GHWP Chair

Dr. XU Jinghe

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The 27th Annual Meeting of GHWP Held in Shanghai

The 27th Annual Meeting and the 27th Technical Committee Meeting of the Global Harmonization Working Party (GHWP) were held in Shanghai from Nov. 27 to 30. Li Li, commissioner of China's National Medical Products Administration (NMPA), attended and addressed the event.

Li said that as a major country in the medical device industry, China has seen continuous progress in the research and development and innovation of medical devices and the formulation of relevant laws, regulations and standards, and conducted extensive international exchanges and cooperation in medical device regulation, effectively promoting the high-quality development of the industry.

Noting that the GHWP is an important international organization of global medical devices, he said the NMPA will participate in the work of the GHWP more deeply. The NMPA will strengthen exchanges and mutual learning with regulatory authorities worldwide, jointly accelerate the convergence, harmonization, and reliance in the regulation of global medical devices, and support global medical device technological innovation and cooperation, so as to make more contributions to building a global community of health for all, he said.

During the meeting, Xu Jinghe, deputy commissioner of the NMPA, and Muralitharan Paramasivam, chief executive officer of the Medical Device Authority (MDA) under the Ministry of Health of Malaysia, jointly signed a memorandum of understanding on cooperation on medical devices between China's NMPA and Malaysia's MDA. The two sides reached consensus in further enhancing exchanges and cooperation in the regulation of medical devices.

This is the first GHWP annual meeting held in China since Xu assumed the presidency of the GHWP. Over 600 representatives from more than 25 countries and regions worldwide participated in the event. The 4-day meeting focused on accelerating the convergence, harmonization, and reliance in the regulation of global medical devices.

27th Annual Meeting of GHWP Held in Shanghai

GHWP actively promotes diverse international cooperation

The 27th Annual Meeting and TC Meeting was grandly kicked off on 4-day meeting on November 27, 2023, in Shanghai. During the GHWP Capacity Building open meeting from November 27 to November 28, GHWP has held 4 side meetings for international cooperation, including the bilateral meeting between GHWP and Ministry of Health, Indonesia, the multilateral meeting between GHWP and representatives from international organizations and liaison members such as APACMed, DITTA, and GMTA, the bilateral meeting between China National Medical Products Administration (NMPA) and Ministry of Food and Drug Safety (MFDS) of Republic of Korea as well as both industry representatives, and the multilateral meeting between GHWP and international medical device industry representatives.

GHWP always adheres to the principles of equality, openness, robustness, and win-win, GHWP members and countries and regions have enhanced their friendly collaboration and expressed their intentions to sign bilateral strategic agreements. As an important platform, GHWP has facilitated to develop closer bilateral and multilateral exchange and cooperation between regulatory authorities and industry representatives.

The hosting vitality and extensive influence of GHWP can act as a direct dialogue and joint participation of regulatory authorities and industry representatives, rely on the unity and cooperation to promote best practices among regulators of GHWP member countries and regions, and it is originated from the active exchange and regular sharing between GHWP and relevant international organizations.

GHWP leadership always works hard with the leadership of other international organizations that are embracing the same goal to seek opportunities for cooperation, and plays an active role as an international platform by striving to foster multi-tier and multi-sector exchange and cooperation among GHWP member countries and regions.

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Global harmonization of medical devices is an important trend in the development of the medical device industry, and China has been actively participating in and promoting international cooperation and standards setting. The NMPA, as the central authority of the Chinese regulatory body, has been actively participating in and promoting international cooperation and standards setting.

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GHWP Capacity Building Discussed on Annual Meeting

At 9:00 a.m. (CST) on November 27, 2023, the 27th GHWP Annual Meeting and TC Meeting was grandly kicked off in Shanghai, China. The Global Harmonization Working Party (GHWP) was established in 1997, the predecessor of which was the Asian Harmonization Working Party (AHWP). GHWP is an international organization with long history and wide membership. With the joint participation of regulatory authorities and industry representatives, GHWP has been actively engaged in promoting global medical device regulatory convergence, harmonization and reliance through the concerted efforts of regulatory authorities and industry representatives.

GHWP is committed to enhancing the regulatory capacity building of GHWP member countries and regions, striving to contribute more wisdom and strength to the quality improvement of global medical devices and the protection of global public health. This GHWP Annual Meeting was hosted by the GHWP secretariat. Dr. Xu Jinghe, GHWP Chair and Deputy Commissioner of China Medical Products Administration (NMPA) delivered opening remarks and welcomed nearly 700 attendees from 25 countries and regions around the world who were present at the meeting, including experts in the medical device industry, counterparts from regulatory authorities, and representatives of medical device enterprises.

The meeting from November 27 to 28 focused on GHWP capacity building, with the theme of “Opportunities and Challenges in Regulation of Innovative Medical Devices”. Under this theme, 6 topics were set. Senior experts from regulatory authorities and industry representatives cordially invited to introduce medical device regulations, share best practices, and join panel discussions around such new cutting-edge technologies as artificial intelligence (AI), software as a Medical Device (SaMD), 3D printing, and next generation sequencing (NGS). Innovation is the most highlighted key word of this annual meeting. Jia Jianxiang from China NMPA, Miyaski Tomoyuki from the Pharmaceuticals and Medical Devices Agency (PMDA) of Japan, Soo Park from the Ministry of Food and Drug Safety (MFDS) of Republic of Korea, Lailing Liu from Health Sciences Authority (HSA) of Singapore, and Razan Asady from the Saudi Food and Drug Authority (SFDA) of Kingdom of Saudi Arabia introduced their regulatory policies on encouraging medical device innovation around the topic of regulatory pathways for innovative medical devices.

Cooperation is the most important spirit of this annual meeting. In the panel discussion on the topic of medical device adverse event monitoring and vigilance and change management, Kitty Mao from GE Healthcare as the moderator, organized an in-depth panel discussion on good vigilance practices for innovative medical devices, attended by Guo Pei from Peking University, Saibah Yaakop from the Ministry of Health (MOH) of Malaysia, Kusakabe Tetsuya from PMDA of Japan, and Shang Wei from Allergan Aesthetics. This topic aims at exploring opportunities for cooperation between regulatory authorities and industry representatives in medical device adverse event monitoring.

This annual meeting is timely focused on hot issues, with special topics such as new cutting-edge technologies medical devices and regulatory practices, regulatory pathways for innovative medical devices, regulatory tools to foster innovation, risk management of innovative medical devices, unique device identifier (UDI) application practices, and digital regulation of medical devices, etc. The 27th GHWP Annual Meeting has provided an opportunity for global regulatory authorities and industry representatives to exchange ideas, share experiences, and develop cooperation, thus jointly boosting the innovation and program of the medical device industry.

GHWP Constantly Deepens Bilateral Dialogues

The 27th GHWP Annual Meeting and TC Meeting was grandly kicked off a 4-day meeting on November 27-2023 in Shanghai. During the GHWP TC open meeting on November 26, GHWP held another 3 bilateral meetings to deepen conversations with regulatory authorities including PMDA of Japan, Egyptian Drug Authority of Egypt, and CEMCO of Cuba. Adhering to the principles of equality, openness, robustness, and win-win, GHWP had an in-depth dialogue with the Advanced Medical Technology Association (AdvaMed) and reached agreements.

GHWP is participating in the 2023 China International Import Expo, aiming to promote international cooperation in the medical device industry.

Global Medical Device Regulatory Association holds a meeting in Shanghai, China. Global Medical Device Regulatory Association (GHWP) in the years' technical committee meeting, in 11.30 GHWP Technical Committee (TC) meeting during the meeting, GHWP held an open meeting on November 26, GHWP held another 3 bilateral meetings to deepen conversations with regulatory authorities including PMDA of Japan, Egyptian Drug Authority of Egypt, and CEMCO of Cuba. Adhering to the principles of equality, openness, robustness, and win-win, GHWP had an in-depth dialogue with the Advanced Medical Technology Association (AdvaMed) and reached agreements.

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Global Medical Device Regulatory Conference Held in Shanghai

The 27th GHWP Annual Meeting and TC Meeting was kicked off on November 27, 2023, in Shanghai. This event has provided an opportunity for global regulatory authorities and industry representatives to exchange ideas, share experiences, and develop cooperation, thus jointly boosting the innovation and program of the medical device industry.

GHWP Capacity Building Discussed on Annual Meeting

2023年11月27日北京时间上午9时，第27届全球医疗器械法规协会conference(GHWP)年会在北京举行。会议于11月27日在京召开，来自全球的医疗器械法规专家、学者及企业代表齐聚一堂，共商医疗器械领域的发展与合作。

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Firstly, we summarized the work achievements of GHWP in the past 9 months. The work achievements mainly included: (1) improving the drafting procedures of GHWP guidance documents for medical devices to advance the quality and efficiency; (2) setting up the Strategic Advisory Board (SAB) to strengthen the research of forward-looking regulatory strategy; (3) establishing the first GHWP Academy to enhance the regulatory capacity building of GHWP member countries and regions; (4) building the first GHWP global industry exchange platform to promote the achievement through exhibition and exchange of innovative medical devices, and (5) intensifying communication with relevant international organizations to foster global medical device regulatory convergence, harmonization, and reliance. Secondly, we delivered extensive and in-depth exchanges and discussions around cutting-edge technologies for medical device innovation. Focusing on the opportunities and challenges brought by new technologies, innovative products and new regulatory approaches, multiple topics were designed for this annual meeting, at which academic discussions were profoundly delivered on cutting-edge technologies, regulatory pathways for innovation, regulatory tools fostering innovation, risk management of innovative medical devices, and application practice of unique device identifier (UDI).

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GHWP (Global Harmonization Working Party) is an international organization to support and promote public health through global collaboration.

GHWP Members
GHWP’s membership is comprised of the Technical Staff Committee (TSC) of the ICF and its members, other representatives from international regulatory authorities, and other stakeholders.

GHWP Leadership
The GHWP leadership is elected by the GHWP members. The current Chair is Dr. [Name], and the Co-Chairs are [Names].

GHWP’s Mission
GHWP’s mission is to promote and protect public health through global collaboration. The organization aims to harmonize medical device regulation globally, ensuring that patients receive the safest and most effective medical devices.

GHWP’s Activities
GHWP conducts various activities, including annual meetings, TC meetings, workshops, and online courses. These activities aim to enhance the regulatory capacity of member countries and regions.

GHWP’s Partnerships
GHWP partners with various international organizations, including the ICF, the International Medical Devices Regulatory Forum (IMDRF), and the World Health Organization (WHO). These partnerships help in sharing knowledge and best practices.

GHWP’s Goals
GHWP’s goals include harmonizing medical device regulation globally, ensuring patient safety, and promoting innovation in medical devices. The organization works towards achieving these goals through collaboration and knowledge sharing.

GHWP’s Impact
GHWP has significantly contributed to the harmonization of medical device regulation globally. The organization’s work has led to improved patient safety and access to innovative medical devices.

GHWP’s Challenges
The organization faces challenges such as the need for more resources, the complexity of global regulation, and the need for greater engagement from member countries.

GHWP’s Future
GHWP aims to continue its work towards harmonization, innovation, and patient safety. The organization plans to expand its partnerships, increase its membership, and develop new activities to meet its goals.

GHWP’s Call to Action
GHWP encourages all stakeholders to support its mission and contribute to the harmonization of medical device regulation globally. By joining GHWP or supporting its initiatives, stakeholders can make a significant impact on improving patient health and safety.