NATIONAL MEDICAL PRODUCTS NEWSLETTER

中国食品药品国际交流中心

GHWP

Global Harmonization Working Party

Towards Medical Device Harmonization

Headline

To Promote & Protect Public Health Through Global Collaboration

GHWP特别报道

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 and 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 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). 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.

头条

通过全球合作，保护和促进公众健康——GHWP主席感谢信

GHWP特别报道

GHWP成员国家和地区代表、GHWP合作伙伴：

在大家的鼎力支持和共同努力下，第27届全球医疗器械法规协调会(GHWP)年会暨技术委员会会议于11月27日至30日在中国上海成功召开。来自25个国家和地区的600多位代表参加此次盛会，共同续写了GHWP奋进跨越的新篇章。我代表GHWP领导团队，向各位代表、各位专家、各位朋友，表示衷心的感谢。

这次大会是GHWP新领导团队组建以来召开的第一次大会，取得了丰硕的成果：

一是对GHWP9个多月来的工作成果进行了全面总结。通过完善医疗器械技术指南制定程序，保障技术指南制定的质量与效率；通过建立战略咨询委员会，加强监管前瞻性战略研究；通过建立全球第一家GHWP培训学院，推进成员国家和地区监管能力建设；通过搭建全球第一家产业交流平台，推进创新医疗器械成果展示交流；通过加强与相关国际组织沟通，推动全球医疗器械监管趋同、协调和信赖。

二是围绕医疗器械前沿技术和创新产品进行广泛深入的交流研讨。大会设立多个专题，聚焦新技术、新产品和新模式带来的新挑战，就医疗器械前沿技术、创新医疗器械监管路径、支持创新的监管工具、创新医疗器械风险管理、UDI应用实践、数字化监管等进行了学术研讨，主题新颖、观点前卫，深受监管机构和业界的欢迎。

三是GHWP合作伙伴、相关国际组织和部分国家、地区代表通报了医疗器械监管最新进展。世界卫生组织(WHO)，国际医疗器械监管机构论坛(IMDRF)，非洲医疗器械论坛

Specifically, the International Medical Device Regulators Forum (IMDRF), World Health Organization (WHO), Africa Medical Devices Forum (AMDF), Asia Pacific Medical Technology Association (APACMed), Global Medical Technology Alliance (GMTA), Global Medical Device Nomenclature (GMDN), Global Diagnostic Imaging, Healthcare IT & Radiation Therapy Trade Association (DITTA), Globe Standard 1 (GSI), and Inter-American Coalition for Regulatory Convergence in the Medical Technology Sector (IACRC) reported the latest work progress. Representatives from 11 countries and regions reported the latest progress of regulatory work, including Chile, the European Commission, Indonesia, Japan, Kingdom of Saudi Arabia, Laos PDR, 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 GHWP guidance documents, (2) approving to set up a special task group to conduct research on common evaluation reliance practice, (3) approving to accept Egypt and Cuba as new GHWP members, (4) approving the membership withdrawal request from the U.S. FDA, and (5) approving Medical Device Authority (MDA), Malaysia to host the 28th GHWP Annual Meeting.

Besides busy work, all representatives attended the city tour, visited the beautiful night scene of the Huangpu 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 course that GHWP has gone through in the past 27 years, all representatives resonate with common viewpoints and feelings.

GHWP has our distinct features. With the joint participation of medical device regulatory authorities and industry representatives, GHWP 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 medical device industry.

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

GHWP is enterprising and pioneering. Over the years, GHWP has always focused on the major topics of medical device regulation and industry development, endeavoring to actively serve GHWP member countries and regions and contribute to global public health by constantly innovating platforms and carriers.

GHWP upholds laws and regulations. Major decisions of GHWP are made according to its Terms of Reference and House Rules.

(AMDF)，亚太医疗技术协会(APACMed)，全球医疗技术联盟(GMTA)，全球医疗器械术语系统(GMDN)，全球诊断影像、医疗IT和放射治疗行业协会(DITTA)，国际物品编码组织(GS1)，美洲医疗技术监管趋同联盟(IACRC)等组织通报了相关领域最新工作进展。智利、欧盟、印尼、日本、沙特、老挝、马来西亚、中国、韩国、泰国、越南等11个国家和地区报告了最新监管工作情况。

四是大会集体审议共同决策作出了系列重要安排。审议通过8项技术指南文件；审议设立特别工作组开展审评共识实践；审议批准埃及、古巴为GHWP新成员；审议同意美国FDA退出GHWP；审议同意马来西亚医疗器械管理局举办第28届GHWP年会。

在紧张而繁忙的工作之余，我们共同游览了美丽的黄浦江夜景，领略了"东方明珠"上海这座国际化现代化大都市的风采和魅力；我们共同参加了Gala Dinner，在欢快喜庆的氛围中共享了传统艺术与现代音乐的美好交融。

回顾GHWP27年来走过的不平凡历程，与会代表畅叙了共情同感：

GHWP是一个优势鲜明的国际组织。作为全球唯一的由医疗器械监管者代表和产业界代表共同组成的国际组织，GHWP始终直面医疗器械领域的突出问题，坚持监管和行业协同发展、共同成长，积极应对医疗器械领域的重大挑战。

GHWP是一个开放包容的国际组织。目前GHWP有34个成员国家和地区，设有战略咨询委员会、能力建设委员会、TC专家委员会，对重大事项进行广泛而深入的研讨。在这个大家庭中，各成员国家和地区平等协商、集思广益、共谋发展、共创未来。

GHWP是一个开拓进取的国际组织。多年来，GHWP始终面向未来，聚焦医疗器械监管和产业发展的重大课题，不断创新平台和载体，积极为成员国家和地区服务，努力为全球公众健康服务。

GHWP是一个崇法尚规的国际组织。GHWP的重大决策均按照GHWP章程、规则进行。大小国家和地区平等交流。同时，GHWP鼓励各成员国家和地区充分利用自身资源，为全球医疗器械监管趋同、协调和信赖贡献更多的智慧和力量。

GHWP 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. Convergence is the trend of development, harmonization is the consistency of action, and reliance is the goal of endeavor.

We must be aware that achieving global medical device regulatory convergence, harmonization, and reliance is a common expectation, and at the meanwhile, it is a gradual process of growth that takes time. The world is diverse. GHWP member countries and regions are at different stages of development, embrace different resources and with different regulatory capacities. In this context, it is impossible to accomplish regulatory convergence, harmonization, and reliance overnight. Instead, we must go forward step by step.

We must be aware that we should not be only aiming high and looking far, but also be down-to-earth to achieve global medical device regulatory convergence, harmonization, and reliance. In the face of a new round of scientific and technological revolution and industrial transformation, we must focus on the present and plan for the future in the long term. We should proceed from consensus, grasp critical links, go ahead steadily and firmly, and consolidate at every step. Practical results will further foster the in-depth participation of all GHWP member countries and regions and build a stronger sense of accomplishment and fulfillment.

We must be aware that we should not only adhere to our own good traditions but also actively draw on others' successful experiences to achieve global medical device 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. GHWP has established its strategic focus and work priorities. We will be problem-oriented and goal-driven to concentrate on doing our work. Insisting on the principles of equality, openness, robustness, and win-win, GHWP will continue to cordially cooperate with international organizations, relevant countries and regions, and partners that are committed to fostering regulatory convergence, harmonization, and reliance.

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

Best regards,

Dr. XU Jinghe

GHWP Chair

会议期间，各监管部门和业界代表提到最多的是监管的趋同、协调和信赖。趋同是发展大势、协调是一致行动、信赖是奋斗目标。

必须看到，实现全球医疗器械监管趋同、协调和信赖，既是大家的美好期待，也是一个渐进的成长过程。当今的世界是多样的世界，各成员国家和地区发展阶段不同、资源禀赋不同、监管能力不同，推进监管趋同、协调和信赖，不可能一蹴而就，必须循序渐进。

必须看到，实现全球医疗器械监管趋同、协调和信赖，既要登高望远，也要脚踏实地。面对新一轮科技革命和产业变革，我们必须立足当前、谋划长远，从共识出发，抓关键领域，稳扎稳打、步步为营，以实实在在的成效让所有的成员国家和地区深入参与，拥有更多的成就感和获得感。

必须看到，实现全球医疗器械监管趋同、协调和信赖，既要努力坚守自身的优秀文化，也要积极吸纳他人的成功经验。任何组织都有其独特的使命和愿景，也都有其自身的优势和不足，只有开放交流互鉴，才能实现向上发展。GHWP已确立了发展的战略重点和优先事项，我们将坚持问题导向和目标导向，集中力量办好自己的事情。GHWP将继续秉持平等、开放、稳健、共赢的原则，同热心致力于推动医疗器械监管趋同、协调和信赖的国际组织、相关国家和地区以及合作伙伴开展真诚的合作。

眼界决定境界、心态决定状态、格局决定结局。展望未来，GHWP将以更加团结的力量、更加开放的胸怀、更加奋进的姿态、更加务实的作风，加快推进全球医疗器械监管趋同、协调和信赖，为保护和促进全球公众健康作出新的更大的贡献。

全球医疗器械法规协调会主席

徐景和

2023年12月5日

27th Annual Meeting of GHWP Held in Shanghai

GHWP特别报道

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 related 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 Paramasua, 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 on 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.

The 27th GHWP TC Meeting Successfully Held

GHWP特别报道

On November 29, 2023, the 27th Global Harmonization Working Party (GHWP) Technical Committee (TC) Meeting grandly kicked off in Shanghai, China. Dr. Xu Jinghe, GHWP Chair and Deputy Commissioner of the National Medical Products Administration (China NMPA), attended the meeting and delivered a speech.

As pointed out by Dr. Xu Jinghe, GHWP (Global Harmonization Working Party) is a big family that unites all forces and facilitates consensus. GHWP TC is responsible for organizing the formulation of GHWP guidance documents, which is the key to fostering global medical device regulatory convergence, harmonization and reliance. GHWP TC should actively formulate GHWP guidance documents around cutting-edge innovative technologies and best regulatory practices, and constantly optimize the working mechanism for drafting, solicitation of public opinions, revision, and approval of GHWP guidance documents. Moreover, GHWP TC should also further encourage the participation of GHWP members, improve the quality of GHWP guidance

第27届全球医疗器械法规协调会年会在上海召开

GHWP特别报道

11月27日至30日，第27届全球医疗器械法规协调会(GHWP)年会暨技术委员会会议在上海召开。国家药监局党组书记、局长李利出席年会大会并致辞。

李利表示，作为医疗器械产业大国，中国医疗器械研发创新活力不断增强，法规标准建设持续推进，监管国际交流合作广泛开展，有力推动了产业高质量发展。GHWP是全球医疗器械领域重要的国际组织，中国国家药监局将更加深度参与GHWP各项工作，加强与世界各国和地区监管交流互鉴，共同推动全球医疗器械监管的趋同、协调和信赖，支持全球医疗器械技术创新与合作，为构建人类卫生健康共同体作出新的更大贡献。

年会期间，国家药监局副局长徐景和与马来西亚医疗器械管理局局长穆拉里塔兰•帕拉马苏共同签署《中华人民共和国国家药品监督管理局和马来西亚医疗器械管理局医疗器械合作谅解备忘录》，双方就进一步加强两国医疗器械监管交流与合作达成共识。

此次年会是中国国家药监局副局长徐景和出任GHWP主席后在中国召开的第一次年会。来自全球25个国家和地区的600多名代表参会。年会围绕加快推进全球医疗器械监管趋同、协调和信赖进行了为期4天的研讨交流。

第27届全球医疗器械法规协调会技术委员会会议召开

GHWP特别报道

2023年11月29日，全球医疗器械法规协调会(Global Harmonization Working Party, GHWP)技术委员会(Technical Committee, TC)会议在中国上海召开。GHWP主席、国家药监局副局长徐景和出席会议并讲话。

徐景和指出，GHWP是一个团结各方力量、凝聚共识的“大家庭”，TC组织GHWP技术指南文件制定，是推进全球医疗器械监管趋同、协调与信赖的关键。TC应积极围绕前沿创新技术、监管最佳实践制定技术指南，不断优化指南文件的起草、征求意见、修订和批准的工作机制，进一步提高GHWP成员的参与度，

documents, and continuously strengthen cooperation with relevant international organizations.

GHWP TC Meeting is an important part of the GHWP Annual Meeting. At the GHWP TC Meeting, the work progress of all Work Groups (WGs) was reported in the fields of pre-market/post-market medical device regulation, clinical evaluation, quality management system, standards, unique device identifier (UDI), and nomenclature. Besides, an in-depth discussion was also delivered on such topics as the formulation and revision of GHWP guidance documents and new work programs. More than GHWP TC leadership, Chairs, Co-chairs, secretaries, and TC advisers of all WGs and more than 600 attendees from 25 countries and regions were present at the GHWP TC Meeting.

提升技术指南的质量，并持续加强与相关国际组织合作。

TC会议是GHWP年会的重要组成部分，会议对各工作组在医疗器械监管的上市前、上市后、临床评价、质量管理体系、标准、UDI及命名等领域的工作进展进行了汇报。重点围绕GHWP技术指南的制修订、新工作项目等议题进行深入讨论。来自GHWP TC领导层，各工作组主席、副主席、秘书、TC顾问等以及来自25个国家和地区的600余人参加了会议。

GHWP Actively Promotes Diverse International Cooperation

GHWP特别报道

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 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 member 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 or multilateral exchange and cooperation between regulatory authorities and industry representatives.

The lasting vitality and extensive influence of GHWP consist in the 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 is originated from the active exchange and regular sharing between GHWP members 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.

全球医疗器械法规协调会积极开展多元国际交流合作

GHWP特别报道

2023年11月27日，为期四天的第27届全球医疗器械法规协调会(GHWP)年会暨技术委员会在上海召开。11月27至28日GHWP能力建设开放会议期间，同期召开了四场国际合作边会，包括GHWP与印度尼西亚监管机构的双边合作会议、GHWP与国际组织及联络机构代表DITTA、GMTA、APACMed的多边合作会议、中韩两国监管机构和业界代表双边交流会议、GHWP与国际医疗器械业界代表多边交流会议等。

GHWP始终秉持着平等、开放、稳健、共赢的原则，在本届年会期间，许多成员国家和地区通过GHWP这一重要平台，增进了相互的友好合作关系，互相表达了签署双边战略协议的意向，由监管机构和业界开展更加紧密的双边或多边合作交流。

GHWP的持久活力和广泛影响在于监管机构和行业的直接对话和共同参与，也在于GHWP与成员国家和地区监管人员的团结合作和推动实践，还在于GHWP与相关国际组织的积极交流和定期分享。GHWP领导层与其他志同道合的国际组织领导层一直致力于寻求合作的切入点，积极发挥平台作用，促进成员国家和地区多层次、多领域的交流与合作。

GHWP Capacity Building Discussed on Annual Meeting

GHWP特别报道

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 is 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 were 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 Jianxiong from China NMPA, Miyasaka Tomoyuki from the Pharmaceuticals and Medical Devices Agency (PMDA) of Japan, Seil Park from the Ministry of Food and Drug Safety (MFDS) of Republic of Korea, Lailing Liew from Health Sciences Authority (HSA) of Singapore, and Razan Asaly from the Saudi Food and Drug Authority (SFDA) of Kingdom of Saudi Arabia introduced the 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 Gao Pei from Peking University, Salbiah 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 focuses on hot issues, with special topics such as new cutting-edge technologies medical devices and regulatory practices, regulatory pathways for innovative medical devices, regulatory

全球医疗器械法规协调会深入研讨能力建设议题

GHWP特别报道

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调会(GHWP)年会暨技术委员会会议在中国上海隆重开幕。GHWP成立于1997年，前身是亚洲医疗器械法规协调会(AHWP)，是历史悠久、成员广泛的国际组织，由监管机构和行业代表共同参与，致力于通过监管机构和行业的共同努力，推进全球医疗器械监管趋同、协调与信赖，提升成员国家和地区的监管能力，为全球医疗器械产品质量提高、公众健康权益保障，贡献更多的智慧和力量。本届年会由GHWP秘书处主办，GHWP主席徐景和博士出席会议并做开幕致辞，来自世界25个国家和地区近700位医疗器械领域专家、监管机构同仁以及医疗器械企业代表参会。

11月27日–11月28日是会议的能力建设环节，主题为"创新医疗器械发展与监管的机遇和挑战"，分设六大专题，邀请来自监管机构和业界的资深专家，围绕人工智能、独立软件、3D打印、下一代测序技术(NGS)等前沿技术，介绍监管法规、分享最佳实践、进行小组研讨。

创新，是本届年会能力建设环节最闪亮的核心词。中国NMPA的贾健雄、日本PMDA的MIYASAKA Tomoyuki、韩国MFDS的Seil Park、新加坡HSA的Lailing LIEW、沙特SFDA的Razan Asaly共同就"创新医疗器械的监管途径"，介绍了本国鼓励医疗器械创新的监管政策。

合作，是本届年会能力建设环节最重要的信念。在"医疗器械不良事件监测、警戒制度和变革管理"为主题的小组讨论中，来自GE公司的Kitty Mao召集北京大学高培教授、马来西亚卫生部的Salbiah Yaakop、日本PMDA的KUSAKABE Tetsuya和Allergan Aesthetics 公司的尚玮就创新医疗器械的良好警戒规范进行了深入的研讨，探寻监管机构和业界在不良事件监测工作的合作切入点。

会议紧跟前沿、聚焦热点，在日程设计上安排了医疗器械领域的前沿技术和监管实

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 progress of the medical device industry.

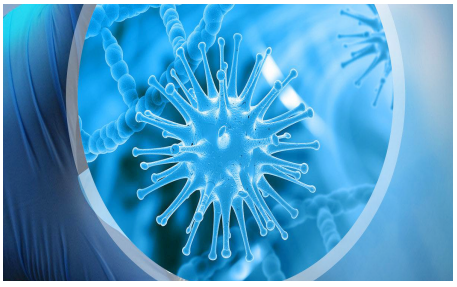
践、创新医疗器械的监管途径、促进创新的监管工具、创新医疗器械的风险管理、医疗器械唯一标识(UDI)应用实践、医疗器械数字化监管等专题。通过本届会议，全球的监管机构和行业代表能够相互交流、分享经验、开展合作，共同推动医疗器械领域的创新和发展。

GHWP Constantly Deepens Bilateral Dialogues

GHWP特别报道

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 29, GHWP held another 3 bilateral meetings to deepen conversation with regulatory authorities including PMDA of Japan, Egyptian Drug Authority of Egypt, and CECMED 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.



全球医疗器械法规协调会持续深入双边对话

GHWP特别报道

2023年 11月27日，为期四天的第27届全球医疗器械法规协调会(GHWP)年会暨技术委员会在上海召开。11月29日GHWP技术委员会(TC)开放会议期间，GHWP同期召开了三场双边会谈，分别与日本、埃及、古巴医疗器械监管机构进行深入对话。

秉持着平等、开放、稳健、共赢的原则，GHWP与先进医疗技术协会(AdvaMed)代表进行了深入的探讨，达成了一致的意见。

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- 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.
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China Center for Food and Drug International Exchange (CCFDIE)
中国食品药品国际交流中心
Address: Room 1106, 11th Floor, Office Building B, Maples International Center, No. 32, Xizhimen North Street, Haidian District, Beijing, 100082, PR.C.
中国北京市海淀区西直门北大街 32 号枫蓝国际中心 B 座写字楼 11 层 1106 室
邮编 :100082
Tel: 010–8221 2866
Email: ccfdie@ccfdie.org
Fax: 010–8221 2857
Website: www.ccfdie.org