NATIONAL MEDICAL PRODUCTS NEWSLETTER

中国食品药品国际交流中心

Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

Focusing on Development of Global Industry Facilitating Harmonization and Reliance of Medical Device Regulatory

The 1st GHWP Innovation Medical Device Symposium Held Grandly

GHWP特别报道

On April 12, the First GHWP Innovation Medical Device symposium was held in conjunction with the 89th China International Medical Equipment Fair, attracting more than 200 experts from regulatory authorities and industries of GHWP member countries and regions.

Mr. Gao Guobiao, Party Secretary of the Center for Medical Device Evaluation of NMPA and member of the GHWP Strategic Advisory Board, attended and delivered a speech. The symposium was moderated by Mr. Bryan So. Executive Secretary of GHWP, Ms. Eun Hee Cho, Vice Chair of GHWP, Mr. Li Chao, Managing Director of Reed Sinopharm, Mr. Alfred Kwek, Member of the Strategic Advisory Board of GHWP, and Ms. Miang Tankasemsub, Co-Chair of the GHWP Technical Committee, attended the meeting.

Ms. Eun Hee Cho mentioned in her opening speech, "In order to further enhance harmonization in the regulation of innovative medical devices and further promote innovation in medical devices industries, GHWP and Reed Sinopharm Exhibitions are co-organizing this innovative medical device symposium." Ms. Eun Hee Cho gave a detailed introduction of the background and intention of the symposium.

Mr. Li Chao said, "CMEF is covering the whole industry value chain, which has nearly 5,000 exhibitors, and many of the exhibitors release innovative technology on-site. The joint purpose of the collaboration is to practice the principle of GHWP, promoting regulatory harmonization, convergence and reliance, which will empower the industry and the governance to seek more synergies of the internationalization and localization."

Mr. Gao Guobao pointed out that the medical device industry is an internationally recognized growing industry. In the era of globalization and information technology, the medical device industry is in a key stage of transformation from high-speed growth to high-quality development. In recent years, under the new technology development in artificial intelligence, additive manufacturing, bio-materials, and medical independent software, it requires the collaboration of all regulators and the industry to promote the harmonazation, convergence, and reliance of global medical device regulations.

In Mr. Alfred Kwek's presentation on Global Medical Device Innovation, he mentioned that medical device innovation is a collective effort of the global technological development in the medical field. The rapid transformation and application of advanced technology is a major challenge for regulators in various countries.

Following the opening speech, representatives of regulatory authorities, GHWP representatives and industry representatives from China, Malaysia, Japan and Korea shared and discussed in depth on innovative medical device regulatory policy, and regulatory reliance and industry globalization and industry achievements.

The closing speaker of the symposium, Ms.Miang Tankasemsub, expressed the hope that this symposium will to further drive

聚焦全球产业发展 助力医疗器械监管协调信赖 首届GHWP医疗器械产业创新研讨会隆重召开

GHWP特别报道

4月12日，在第89届中国国际医疗器械博览会（CMEF）期间，首届GHWP医疗器械产业创新研讨会召开，全球医疗器械监管协调会（GHWP）成员国家和地区的监管机构代表和业界代表共200余位专业人士参会。

国家药监局器审中心党委书记、GHWP战略咨询委员会委员高国彪先生出席并致辞。研讨会由GHWP执行秘书长Bryan So先生主持，GHWP副主席Eun Hee Cho女士、国药励展董事总经理李超先生、GHWP战略咨询委员会委员Alfred Kwek先生、GHWP技术委员会副主席Miang Tankasemsub女士等参加了会议。

“为了进一步促进创新医疗器械监管的协同，以及进一步推动医疗器械产业创新，GHWP与国药励展共同举办本次医疗器械产业创新研讨会。”在开场致辞中，Eun Hee Cho女士详细的介绍了本次研讨会创办的背景和初衷。

李超先生表示：“CMEF作为全产业链展示平台，参展企业近5,000家，诸多创新科技现场发布，本次合作希望能够践行GHWP的一些做法，促成监管协同，让行业有更多国际化、本土化的交流合作。”

高国彪先生指出，医疗器械产业是国际公认的朝阳产业，在全球化、信息化的时代，医疗器械产业正处在从高速增长向高质量转型的关键阶段。近年来，在面对人工智能、增材制造、生物材料、医用独立软件等新技术时如何推动全球医疗器械法规的协调、趋同、信赖，需要监管机构和业界共同面对和携手合作。

Alfred Kwek先生在“医疗器械创新概述与发展趋势”主旨演讲中提到，医疗器械创新是全球医疗领域技术开发集体努力的结果，先进科技的快速转化和应用对各国监管机构而言是重大挑战。

开场致辞结束后，来自中国、马来西亚、日本、韩国的监管机构代表、GHWP代表及行业代表围绕全球创新医疗器械监管政策、监管信赖与医疗器械产业全球化与行业成果两个核

synergies to the industry, share challenges in the process, innovate together, continue to carry forward the spirit of cooperation, achieve greater cooperation, and make more contributions to global healthcare in the future.

This symposium attracted several members of the Mozambican health system participated, including Sambo Ernesto, Head of the Procurement Department of the central medical store of the Ministry of Health of Mozambique, Joao Cassiano Carlos, Head of the Central Health Product Evaluation Department of the Division of Evaluation of Medicines, Biological and Health Products. The symposium gave them a more comprehensive understanding of GHWP and would further enhance their understanding in medical device industry of China.

In addition to the symposium, a GHWP thematic exhibition area was set up at the 89th CMEF, focusing on displaying the innovative medical device regulatory policies of Tanzania, Saudi Arabia, Singapore, Malaysia, Vietnam, Thailand, Korea and China. The exhibition empowered industrial innovation and globalization, promoted regulatory harmonization, attracting a large number of medical device upstream and downstream related experts to visit.

The GHWP Innovation Medical Device Symposium is the first strategic collaboration between GHWP and CMEF. It has built an exchange platform for innovation practice of both global leading enterprises and local excellent innovation representatives. It has also effectively promoted the harmonization and reliance of global medical device regulation.

(2024-04-17)

心话题展开深度分享和探讨。

大会闭幕致辞嘉宾Miang Tankasemsub女士表示，希望未来通过研讨会带动行业实现更多协同，一起分享洞察遇到的困难，共同创新，持续发扬合作精神，实现更大程度协同，为全球的医疗卫生做出更多贡献。

值得一提的是，包括莫桑比克卫生部医保局采购司司长Sambo Ernesto，莫桑比克药监局药品、保健品和生物制品审评司司长Joao Cassiano Carlos在内的多名来自莫桑比克卫生系统的人员也参加了会议，对GHWP有了更全面的了解，也进一步增进了对中国医疗器械产业的信任。

此外，大会还在第89届CMEF设置了GHWP主题展区，集中展出了坦桑尼亚、沙特阿拉伯、新加坡、马来西亚、越南、泰国、韩国和中国的创新医疗器械监管政策，为产业创新、监管趋同及全球化发展赋能，吸引了大批医疗器械上下游相关专家参观学习。

此次GHWP医疗器械产业创新研讨会是GHWP与CMEF的首次战略合作，为全球领军企业和本土优秀创新代表搭建了创新实践的交流平台，将有力推动全球医疗器械法规协调信赖。

（2024-04-17）

GHWP Chair and AMDF Chair held online meeting

GHWP特别报道

GHWP Chair Dr. Xu Jinghe and African Medical Device Forum (AMDF) Chairperson Paulyne Wairimu held an online meeting on April 15th. The two sides exchanged views on further strengthening cooperation, reinforcing regulatory capacity building and enhancing medical device regulatory reliance. Both sides agreed on making their joint efforts to actively promote global regulatory convergence, harmonization and reliance.

GHWP leadership and Strategic Advisory Board members also attended this online meeting.

The AMDF was founded in 2012. Its mission is to study and recommend ways to harmonize medical devices and diagnostics regulation in Africa, aiming to improve access to safe and affordable medical devices and diagnostics in Africa though harmonized regulation.

(2024-04-17)

GHWP主席与AMDF主席召开在线视频会议

GHWP特别报道

4月15日，GHWP主席徐景和与非洲医疗器械论坛（AMDF）主席Paulyne Wairimu在线召开视频会议，双方围绕进一步加强合作、推进监管能力建设以及医疗器械监管信赖等进行了交流。双方表示共同努力，积极推进全球监管趋同、协调和信赖。

GHWP领导层和战略咨询委员会委员一同在线参加了会议。

AMDF成立于2012年，其使命是促进非洲医疗器械和体外诊断试剂法规协调，主要任务是通过研究和提供建议，确保在安全有效的前提下提高医疗器械、体外诊断试剂产品的可及性。

（2024-04-17）

GHWP Chair and WHO representatives held online meeting

GHWP特别报道

GHWP Chair Dr.Xu Jinghe and Mr. Hiiti B. Sillo, the Unit Head, Regulation and Safety within the WHO Department of Regulation and Prequalification as well as other WHO representatives held an online meeting on May 7th. The two sides exchanged views on further deepening cooperation and reinforcing

GHWP主席与WHO代表召开在线视频会议

GHWP特别报道

5月7日，GHWP主席徐景和与WHO监管和预认证部、监管和安全部门负责人Hiiti B. Sillo先生及WHO其他代表在线召开视频会议，

regulatory capacity building. Both sides agreed on making their joint efforts to actively promote global regulatory convergence, harmonization and reliance.

GHWP leadership and Strategic Advisory Board members also attended this online meeting.

(2024-05-09)

双方围绕进一步深化合作、推进监管能力建设等进行了交流。双方表示共同努力，积极推进全球监管趋同、协调和信赖。

GHWP领导层和战略咨询委员会委员一同在线参加了会议。

（2024-05-09）

Speech at the First GHWP (Guangzhou) Academy Training

GHWP Chair: Dr. Xu Jinghe

GHWP特别报道

Distinguished Guests, Ladies and gentlemen,

Good morning!

In this bright and vibrant season, we are gathering here in Guangzhou, the beautiful City of Flowers, to participate in the first Global Harmonization Working Party (Guangzhou) Academy Training, themed "Collaborative Empowerment—Innovative Medical Devices Embrace the World". On behalf of GHWP, I would like to express my warm congratulations on the successful opening of the training. I would also like to express our sincere welcome and our deepest gratitude to you for your consistent support and commitment to promoting global medical device regulatory convergence, harmonization, and reliance.

Established in 1997, GHWP is one of the longest-standing and most inclusive international organizations in the global medical device sector. It is the only international platform that is collaboratively advanced by representatives both from regulatory authorities and the industry for the exchange of medical device regulations. Formerly known as the Asian Harmonization Working Party (AHWP), GHWP underwent a historic transformation in 2021 when it rebranded its name, signifying its evolution from a regional to a global organization. Currently, the members of GHWP have expanded from Asia to South America and Africa, covering 34 countries and regions, and accounting for nearly 60% of the world's population. To date, GHWP has issued 56 technical guidance documents and conducted over 40 online and offline trainings, all aimed at enhancing the regulatory capabilities of its member countries and regions.

In the context of deepening globalization and rapid technological development, GHWP, as an international organization with increasingly prominent global influence, always adheres to the principles of openness, cooperation, robustness, and win-win. Great efforts have been made to strengthen communication and cooperation between medical device regulatory authorities and the industry, to facilitate regulatory harmonization and coordination among member countries and regions, and to promote global convergence, harmonization and reliance of medical device regulations. We are firmly confident that our lofty belief and persevering endeavors will constantly open new chapters for the medical device industry in the new era and give an impetus to protecting and promoting global public health.

Since its establishment, the new GHWP leadership has shown exceptional efficiency and a pragmatic approach to our work. Each year, we identify ten key tasks to ensure steady progress towards the goals outlined in our Global Harmonization Working Party Strategic Framework towards 2026. In 2024, we have prioritized the training on technical guidance documents. Through meticulous planning, our working groups are set to roll out a series of online technical guidance documents trainings for our member countries and regions.

At this moment, a latest round of scientific and

首期GHWP（广州）学院培训致辞 GHWP主席：徐景和博士

GHWP特别报道

尊敬的各位来宾，女士们，先生们，

大家早上好！

在这个明媚而充满活力的季节，我们相聚在美丽的花城广州，参加以"协同赋能——创新医疗器械走向世界"为主题的全球医疗器械法规协调会（广州）学院培训。我谨代表GHWP对培训的成功举办表示热烈祝贺，并对大家的到来表示诚挚的欢迎和最深切的感谢，感谢大家始终如一地支持和致力于推进全球医疗器械监管趋同、协调和信赖。

GHWP成立于1997年，是全球医疗器械行业历史最悠久、最具包容性的国际组织之一，也是唯一由监管机构和行业代表共同推进的国际平台，旨在促进医疗器械法规交流。GHWP前身是亚洲医疗器械法规协调会（AHWP），2021年GHWP经历了历史性转变，正式更名为GHWP，标志着GHWP从一个地区性组织发展成为一个全球性组织。目前，GHWP的成员范围已从亚洲扩展到南美洲和非洲，覆盖34个国家和地区，涉及全球人口的近60%。截至目前，GHWP已发布56份技术指南文件，并举办了40余场线上线下培训，努力提升成员国家和地区的监管能力。

在全球化不断深入、科技发展日新月异的背景下，作为全球影响力日益凸显的国际组织，GHWP始终秉持开放、合作、稳健、共赢的原则，大力加强医疗器械监管机构与行业之间的沟通与合作，促进成员国和地区之间的监管协调与合作，并推动全球医疗器械法规趋同、协调和信赖。我们坚信，我们的崇高信念和不懈努力必将不断开创新时代医疗器械行业的新篇章，为保护和促进全球公众健康注入新动力。

自GHWP成立以来，新领导层在工作中表现出卓越的办事效率和务实的工作态度。我们每年都会设立十项关键任务，以确保稳步推进全球医疗器械法规协调会战略框架概述的2026年目标。2024年，我们将技术指南文件培训列为优先事项。经过精心策划，我们的工作组将为成员国和地区推出一系列在线技术指南文件培训。

technological revolution and industrial transformation is gaining momentum, rapidly reshaping the global economy and driving the medical device industry towards explosive growth. Analyses released by relevant organizations indicate that the global medical device market reached USD 616 billion in 2023 and is projected to surge to USD 699.9 billion by 2025. As living standards continue to improve, the general public's demand for personalized, high-end, and intelligent medical devices has become increasingly diverse. More attentions are attached on the safety, effectiveness, accessibility, and applicability of medical devices. With global trade expansion, the medical device industry is eagerly seeking regulatory convergence, harmonization, and reliance. There is also a pressing desire to see innovative medical devices reach the global market in a more affordable, convenient, and streamlined manner, bringing more hope and well-being to global public health.

At present, as the global regulatory and legal systems for medical devices are continuously evolving, themes regarding the comprehensive prevention and control of risks, the full implementation of responsibilities, the overall advancement of systems, and the holistic enhancement of capabilities will never step down . The global medical device industry faces numerous risks and challenges, among which the perspectives of regulatory authorities and policymakers in addressing issues, their attitudes towards problems, the frameworks they use to analyze issues, and their ability to solve problems may also pose risks that demand particular attention. In the face of emerging technologies, processes, materials, products, and new business formats as well as new models, inadequate governance capacity is one of the most significant risks confronted by regulators and policymakers across many countries and regions. An effective measure to prevent and control the risk is to fully improve regulatory and governance capabilities. Global medical device professionals should enthusiastically embrace the new era, eagerly acquire new knowledge, and diligently cultivate new skills. Thus, with broader vision and greater excellence, they will approach the world, the future, and success with greater confidence.

To respond to regulatory needs and expectations from the industry, GHWP decided in 2023 to establish an offline training academy. Its mission is to offer face-to-face training and communication opportunities for regulatory authorities and industry professionals in member countries and regions, to accelerate the improvement of medical device regulatory and governance capabilities, and to lay a more solid foundation for global medical device regulatory convergence, harmonization and reliance. Through a stringent selection process, South China University of Technology was designated as the host institution for the world's first GHWP Academy. With strong support from communities, GHWP (Guangzhou) Academy is operating very well and its first training is opening today. The academy has been making great efforts to make it happen. Let's express our heartfelt gratitude to everyone who has been making great contribution.

Over the next five days, we will delve into understanding GHWP's vision, mission, and goals, as well as its organizational structure, strategic development, operational mechanisms, and technical guidance documents. We will jointly explore review and approval regulations and policies of international medical devices, exchange insights on the innovative achievements in this field, engage in discussions on innovating the legal system for medical device governance, and collectively envision the bright future of innovative development in the global medical device industry.

Ladies and gentlemen,

Chinese President Xi Jinping noted that "People's health is the foundation of social

当前，新一轮科技革命和产业变革蓄势待发，迅速重塑全球经济格局，推动医疗器械行业实现爆发式增长指日可待。相关机构发布的分析报告显示，2023年全球医疗器械市场规模达到6,160亿美元，预计到2025年将激增至6,999亿美元。随着生活水平的不断提高，大众对个性化、高端化、智能化医疗器械的需求呈现多样化特征，并对医疗器械的安全性、有效性、可及性和适用性给予了更多关注。在全球贸易日益扩大的趋势下，医疗器械产业对监管趋同、协调和信赖的期待更加迫切，渴望看到创新医疗器械能够以更经济、更便捷、更顺畅的方式走向世界，为全球公众健康赋予更多的希望，带来更多的福祉。

当前，随着全球医疗器械监管和法律体系的不断发展健全，将始终围绕全面防控风险、全面落实责任、全面推进制度、全面提升能力的主题展开并落实工作。全球医疗器械行业面临诸多风险和挑战，其中监管机构和政策制定者处理问题的视角、对问题的态度、分析问题的框架以及解决问题的能力也可能带来潜在风险，因此需予以特别关注。面对新兴技术、工艺、材料、产品、新业态和新模式，治理能力不足是许多国家和地区的监管机构和政策制定者面临的最大风险之一，因此风险防控的有效措施是全面提升监管和治理能力。全球医疗器械专业人士应怀揣极大热情、拥抱新时代、热切学习新知识、勤奋培养新技能。通过不懈努力，他/她们将以更广阔的视野、更卓越的表现和更大的信心去面对世界、未来，并逐步迈向成功。

为满足监管需求和行业期望，GHWP于2023年决定成立一家线下培训学院，其使命是为成员国和地区的监管机构以及行业专业人士提供面对面的培训和交流机会，加快提高医疗器械监管和治理能力，为全球医疗器械监管趋同、协调和信赖奠定更坚实的基础。经过仔细和严格筛选，华南理工大学被任命为全球首个GHWP学院的主办院校。在各方社区的大力支持下，GHWP（广州）学院运作顺利，并于今天迎来了首期培训开幕。学院为此付出了巨大的努力，让我们向所有为此作出重大贡献的人们表达诚挚的感谢。

在接下来五天里，我们将深入了解GHWP的愿景、使命和目标，以及其组织结构、战略发展、运作机制和技术指南文件，并将共同探讨国际医疗器械审评审批法规和政策，交流该领域的创新成果，探讨医疗器械治理法律体系创新，共同展望全球医疗器械产业创新发展的美好未来。

女士们，先生们，

中国国家主席习近平指出："人民健康是社会文明进步的基础，是民族昌盛和国家富强

civilization and progress and an important symbol of national prosperity." "In this world, countries have been more interconnected and interdependent than ever before. Human beings live in the same global village, as well as the same time and space where history and reality meet, are becoming a community with a shared future." "We should expand our global vision and develop keen insight into the trends of human development and progress, respond to the general concerns of people of all countries, and play our part in resolving the common issues facing humankind."

Ancient Greek philosopher Plato said, "The human goods are said to be health, beauty, strength, and wealth in that order". French thinker Montaigne also raised, "Health is the most precious gift that nature can prepare for us the most fair." Humanity has never ceased to pursue health and happiness. For practitioners dedicated to safeguarding people's health, we need to constantly develop professionalism and abilities so as to better fulfill our lofty mission of protecting public health.

To meet high expectations, GHWP will stay true to its founding mission and make every effort to further improve the technical guidance documents system, enhance regulatory capacity building and improve the level of health protection. In the middle of June, the 28th GHWP Technical Committee (TC) Leadership Meeting will be held in Indonesia, aiming to further advance the formulation and application of technical guidance documents. We will meticulously organize two offline trainings and several online trainings through the GHWP Academy, ensuring that regulatory authorities and the industry are better equipped to navigate this era of rapid change. We will organize the annual exchanges on innovative medical device industry between GHWP and China International Medical Equipment Fair (CMEF) to fully demonstrate the vitality of the industry. Moreover, we will accelerate the development of Common Evaluation Reliance Practice (CERP) to make the first key step towards regulatory reliance. We will convene the Strategic Advisory Board (SAB) meeting to delve into the future strategic development of GHWP. Furthermore, we will organize the annual meeting in Malaysia at the end of this year to discuss and plan key tasks for the next year. We will actively expand GHWP membership and make regulatory harmonization and reliance benefit more countries and regions. In addition, we will strengthen exchanges and cooperation with other international organizations to promote global medical device regulatory convergence, harmonization and reliance.

Knowledge shapes one's future and education may change one's life. With its profound academic attainments, strong academic atmosphere and excellent transformation capacity, South China University of Technology has built a high-end training platform for us. I sincerely hope all participants can value this precious opportunity and receive fruitful gains. First, I strongly encourage you to listen attentively to the experts and scholars to ensure a fruitful learning experience. We are privileged to have renowned international experts and authoritative speakers from regulatory authorities at this training, who have carefully crafted a comprehensive and multidimensional curriculum that promises to be enlightening. Second, please actively engage with your peers to learn industry experience, reflecting deeply on what you learn. The academy has organized several exchange sessions where everyone has the opportunity to both share and learn. I encourage you to proactively contribute your insights and wisdom, for a thinking mind is a sharp mind. I hope that each of you will leave the training with more questions than when you arrived, as these questions are the signs of true learning and insight. Third, try to understand more about the call of the times and the general public, and put what you have learned into

的重要标志。""这个世界，各国相互联系、相互依存的程度空前加深，人类生活在同一个地球村里，生活在历史和现实交汇的同一个时空里，越来越成为你中有我、我中有你的命运共同体。""我们要拓展世界眼光，深刻洞察人类发展进步潮流，积极回应各国人民普遍关切，为解决人类面临的共同问题作出贡献。"

古希腊哲学家柏拉图曾言："第一财富是健康，第二财富是美丽，第三财富是财产。"法国思想家蒙田也曾提出："健康是自然所能给我们准备的最公平最珍贵的礼物。"人类从未停止对健康和幸福的追求。作为致力于保障人民健康的从业人员，我们需要不断提高专业水平和能力，以便更好履行保护公众健康的崇高使命。

为不负厚望，GHWP将不忘初心、砥砺前行，进一步完善技术指南文件体系，加强监管能力建设，提高健康保障水平。6月中旬，第28届GHWP技术委员会（TC）领导人会议将在印度尼西亚举行，旨在进一步推动技术指南文件的制定和应用。我们将通过GHWP学院精心组织两次线下培训和多次在线培训，确保监管机构和行业能够更好应对并适应这个快速变化的时代。我们将每年在GHWP和中国国际医疗器械博览会（CMEF）之间组织一次创新医疗器械行业交流，以充分展示行业活力。此外，我们还将加快制定"医疗器械审评互信实践"（CERP），为实现监管信赖迈出关键的第一步。我们将召开战略咨询委员会（SAB）会议，深入探讨GHWP的未来战略发展。此外，我们将于今年年底在马来西亚举行年会，就明年的主要任务进行讨论和规划，并将积极扩展GHWP成员，使监管协调和信赖惠及更多国家和地区。我们还将加强与其他国际组织的交流与合作，促进全球医疗器械监管趋同、协调和信赖。

知识决定一个人的未来，教育则可能改变一个人的一生。华南理工大学以其深厚的学术造诣、浓厚的学术氛围和卓越的转化能力，为我们搭建了一个高端培训平台。我衷心希望所有与会者都能珍惜这次宝贵的机会，从中取得丰硕的成果。首先，我极力推荐大家认真聆听专家学者的发言，以确保获得丰富的学习体验。我们有幸邀请到国际知名专家和来自监管机构的权威发言人参加此次培训，他/她们精心准备的全面、多维度课程必将给我们带来启发。其次，请大家积极与同行交流，学习行业经验，深刻反思所学。学院组织了多次交流会，让与会者都有机会进行分享和学习，我鼓励大家积极主动分享自己的见解和智慧，因为"不深思则不能造其学"，也由衷希望大家在离开

practice so as not to squander your youth. As the global public increasingly seeks a higher quality of life, it is imperative that we keep abreast of global developments, broaden our international perspectives, and apply our knowledge into practice. Let us work together to bring medical device products to the global stage, to be tested and embraced by customers worldwide.

Last but not the least, I wish the training a complete success and a brighter future for GHWP Academy. Let's join hands to pursue our dreams and make greater contributions to protecting and promoting global public health. Thank you!

(2024-05-27)

培训时都能带着比刚来时更多的问题，因为这些问题才是真正学习和洞察的标志。第三，努力多了解时代和大众的呼声，学以致用，不虚度青春。随着全球公众日益追求更高的生活质量，我们必须紧随全球发展的步伐，拓宽国际视野，并将知识应用于实践。让我们共同努力，将医疗器械产品推向全球舞台，接受全世界客户的考验和欢迎。

最后，预祝此次培训圆满成功，GHWP学院的未来繁花似锦。让我们携手并进、追求梦想，为保护和促进全球公众健康不遗余力、尽己所能。

感谢聆听！

（2024-05-27）

Innovative Medical Devices Embrace the World: The 1st Training of GHWP (Guangzhou) Academy Successfully kicked-off

GHWP特别报道

In the morning of May 27th, the GHWP (Global Harmonization Working Party) (Guangzhou) Academy held its inaugural training session at South China University of Technology in Guangzhou. The event was attended by over 300 participants, including representatives from 12 regulatory authorities of GHWP member countries and regions, representatives from 5 international organizations, and delegates from global medical device industry. The training is jointly organized by GHWP (Guangzhou) Academy and Guangdong Institute of Advanced Biomaterials and Medical Devices. EunHee Cho, GHWP vice chair of industry, presided the opening ceremony. Dr. Xu Jinghe, the GHWP Chair and Deputy Commissioner of the National Medical Products Administration of China (NMPA), attended the ceremony and delivered an opening remark.

In his speech, Dr. Xu congratulated the GHWP (Guangzhou) Academy on its first training session and highlighted the theme, Collaborative Empowerment—Innovative Medical Devices Embrace the World. He emphasized the significance of this training in strengthening global regulatory exchanges and mutual learning, as well as in promoting innovation and development of the global medical device industry. Xu noted that in the context of expanding global trade, there is an increasing demand for regulatory convergence, harmonization, and reliance. It is expected to see more innovative medical device products being better accessible to the global market, in terms of effectiveness, smoothness and convenience, bringing greater hopes and benefits to the public health globally.

Xu Yong, Chair of the GHWP (Guangzhou) Academy and Vice President of South China University of Technology, delivered a speech at the opening ceremony. He expressed that the GHWP Academy will actively promote regulatory capacity building in GHWP member countries and regions. He hoped this training will provide a broad platform for learning and exchange for the participants, and he wished the training a great success. Yingjun Wang, President of the GHWP (Guangzhou) Academy, Dean of Guangdong Institute of Advanced Biomaterials and Medical Devices and an Academician of the CAE, attended the session and extended a warm welcome to the trainees.

After the opening ceremony, Mr Gao Guobiao, GHWP SAB Member, Party Secretary of Center for Medical Device Evaluation, NMPA, kicked-off the first topic of the training session with his speech "Promoting Global Medical Device Regulatory Convergence,

创新医疗器械走向世界：首期GHWP（广州）学院培训顺利开幕

GHWP特别报道

5月27日上午，全球医疗器械法规协调会（GHWP）学院首期培训开幕式在广州华南理工大学举行。来自GHWP 12个成员国家和地区、5个国际组织的医疗器械监管人员及国内外医疗器械生产企业代表等300余人出席。本次培训由GHWP（广州）学院与新型生物材料与高端医疗器械广东研究院联合主办。GHWP业界副主席EunHee Cho主持开幕式。GHWP主席、中国国家药品监督管理局副局长徐景和博士出席并致辞。

徐景和博士在致辞时表示，祝贺首期GHWP（广州）学院培训顺利开班，首期培训聚焦“协同赋能——创新医疗器械走向世界”主题，对加强全球监管交流互鉴、推动全球医疗器械创新发展具有重要意义。徐博士指出，在全球贸易日益扩大的趋势下，医疗器械产业对监管趋同、协调和信赖的期待更加迫切，渴望看到创新医疗器械产品能够以更经济、更便捷、更顺畅的方式走向世界，为全球公众健康赋予更多的希望，带来更多的福祉。

GHWP（广州）学院理事长、华南理工大学副校长许勇随后致辞，表示GHWP（广州）学院将积极推动GHWP成员国家和地区监管能力建设，期望本次培训能为学员们提供广阔的学习交流平台，并祝愿培训取得圆满成功。GHWP（广州）学院院长、新型生物材料与高端医疗器械广东研究院院长、中国工程院（CAE）院士王迎军出席培训，并对参训学员表示热烈欢迎。

第一专题的培训课程在开幕式后顺利开课，GHWP SAB成员、中国国家药品监督管理局医

Harmonization, And Reliance - Overview of GHWP". Ms. Tran Quan, GHWP SAB Member and Quality Assurance and Regulatory Affairs of Baxter, gave keynote speeches on "GHWP Moving towards the 2026 Strategic Framework".

GHWP, originally known as the Asian Harmonization Working Party (AHWP), was officially rebranded in December 2021 to reflect its growing global membership. It is currently the only international platform dedicated to the coordination of medical device regulations, involving representatives from both regulatory authorities and the industry. Today, GHWP has members from 34 countries and regions, extending its reach from Asia to South America and Africa, and covering nearly 60% of the global population. GHWP has issued 56 technical guidelines and delivered more than 40 online and offline training sessions, all aimed at enhancing the regulatory capacity of its member countries and regions.

In response to the new challenges of global medical device regulation, GHWP established the world's first Academy last year—GHWP (Guangzhou) Academy. Wang Yingjun, academician of the CAE and professor of South China University of Technology (SCUT) served as the dean of the academy. Utilizing academic resources of the SCUT, GHWP (Guangzhou) Academy will develop a systematic curriculum on regulatory harmonization and cutting edge medical device technologies. Aiming at building a platform for regulatory capacity enhancement, The Academy will invite regulators and experts of medical device sector from GHWP member countries and regions to delivery lectures and conduct discussions, promoting training and application of regulations, enhancing regulatory capacity in member countries and regions, and realizing global convergence, harmonization, and reliance. The Academy is committed to facilitate the development of the medical device industry and to ensure the safety and efficacy of medical devices for the benefits of the public health and patients globally.

Over this 5-day training, five key topics will be covered, namely “GHWP Promotes Global Medical Device Regulatory Convergence, Harmonization, and Reliance”, “Global Medical Device Industry Innovation Development and Outlook”, “Global Premarket Regulatory Framework of Medical Devices”, “Practices of Chinese Innovative Medical Device Enterprises,” and “Innovative Medical Device Enterprises Going Global, Sharing and Exchanges”. The training aims to further enhance the regulatory capacity of the Global Harmonization Working Party (GHWP) member countries and regions, and to further promote the innovative medical devices to ultimately benefits all patients worldwide.

(2024-05-28)

疗器械技术审评中心党委书记高国彪先生就“促进全球医疗器械监管趋同、协调、信赖——GHWP概况”作主题报告。GHWP SAB成员、百特国际有限公司质量与法规事务副总裁Tran Quan女士发表了题为“GHWP迈向2026战略框架”的主题演讲。

GHWP原为亚洲医疗器械法规协调会（AHWP），随着全球成员数量的增加，2021年12月正式更名为GHWP，是目前全球唯一的由监管机构代表和行业代表共同参与的医疗器械监管法规国际协调平台。如今，GHWP成员已达34个国家和地区，从亚洲扩展至南美洲、非洲，覆盖全球人口的近60%，并相继发布了56项技术指南文件，举办了40余场线上线下培训，努力提升成员国家和地区的监管能力。

为了应对新形势下全球医疗器械监管的新挑战，GHWP在去年成立了全球首个学院——GHWP（广州）学院，由CAE院士、华南理工大学（SCUT）教授王迎军担任学院院长。GHWP（广州）学院将依托SCUT医疗器械相关优势学科建设，系统开发医疗器械监管协同及技术前沿培训课程体系，建设监管能力提升平台，定期邀请GHWP成员国和地区医疗器械监管者及行业专家进行培训并开展研讨，强化各国监管法规的培训与应用，加快提升成员国和地区的监管能力，实现全球医疗器械监管趋同、协调与信赖，促进医疗器械产业发展，确保患者获得更有效和更安全的医疗器械使用。

本次首期GHWP（广州）学院培训为期五天，共设有“GHWP促进全球医疗器械监管趋同、协调、信赖”、“全球医疗器械产业创新发展及展望”、“全球医疗器械注册上市法律制度系列培训”、“中国创新医疗器械企业实训”、“创新医疗器械企业走向世界案例分享与交流”五个专题，旨在进一步提升GHWP成员国家和地区的监管能力，助力创新医疗器械产品惠及全球公众。

（2024-05-28）

Dr. Xu Jinghe Attended the 2nd GHWP (Guangzhou) Academy Training

GHWP特别报道

On November 24, the 2nd Global Harmonization Working Party (GHWP) (Guangzhou) Academy training was held in Shenzhen. With the theme of “Innovative Medical Device Promotes Global Public Health”, the training is aimed at promoting the regulatory capacity building of member countries and regions, and assisting the high-quality development of industrial innovation. Dr. Xu Jinghe, the GHWP Chair and Deputy Commissioner of NMPA, attended the opening ceremony of the training and delivered a speech.

Dr. Xu pointed out that health is the eternal pursuit of humanity, innovation is the core

徐景和出席全球医疗器械法规协调会广州学院第二期培训

GHWP特别报道

11月24日，全球医疗器械法规协调会（GHWP）广州学院第二期培训在深圳举行。这次培训以“高端医疗装备创新助力全球公众健康”为主题，旨在推动成员国家和地区监管能力建设，助力产业创新高质量发展。GHWP主席、国家药监局副局长徐景和出席开班式并讲话。

element to promote social progress, opening up is the only road to prosperity and development of the world, and reliance is an important force to deepen international exchanges and cooperation. GHWP has always been committed to helping its members accelerate the building of regulatory systems and capacity through systematic innovation, and facilitating the early launch of innovative medical devices for the benefit of global public health.

More than 330 experts and scholars from countries and regions including South Korea, Singapore, Indonesia, Malaysia, Thailand, Saudi Arabia, Vietnam, the United States, Hong Kong, China, as well as representatives from Chinese and foreign regulatory authorities and enterprises, attended the training.

(2024-11-24)

徐景和指出，健康是人类的永恒追求，创新是推动社会进步的核心要素，开放是全球走向繁荣发展的必由之路，信赖是深化国际交流合作的重要力量。GHWP始终致力于通过系统创新，助力成员加快监管体系和能力建设，助推创新产品早日上市，造福全球公众健康。

来自韩国、新加坡、印度尼西亚、马来西亚、泰国、沙特阿拉伯、越南、美国、中国香港等国家和地区的专家学者，国内外监管机构和企业代表330余人参加培训。

(2024-11-24)

Notes:
- 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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