



GHWP



GHWP (China) Academy Status Report

Prof. Fei HANG FRMS PhD

Executive Vice President of GHWP (China) Academy
South China University of Technology

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Part I Introduction



SCUT – A Leading University in Innovation



华南理工大学

South China University of Technology

Top
University

"985"
"211"
"Double 1st-
Class"

Since 1918

22nd
Globally in
Engineering



SCUT – A Leading University in Innovation

- A **comprehensive university** Located in Guangzhou.
- Disciplines: Sci & Eng, Medicine, Law, Management, Economics, Literature, Arts



Total area: **4 million** m²



Building area: **3.3 million** m²



Faculty: **4656**



Students: **52k**



36 Colleges (**7** in GZIC)



3 Affiliated hospitals



29 National Key Labs/Eng Research Centers



3 Confucius Institutes

2 Areas **Top 1** globally (US News 2023 of Univ.)

Polymer Science

Food Science & technology

5 Areas ranked **Top 0.1%** globally by ESI

Materials Science

Engineering

Computer Science

Chemistry

Agricultural Science

13 Areas ranked **Top 1%** globally by ESI

Clinical Medicine

Biology & Bio-chemistry

Pharmacology & Toxicology

Social Science

Mathematics

... ..

Renaming to GHWP (China) Academy

From GHWP (Guangzhou) Academy to GHWP (China) Academy

- Nov. 2023, GHWP (Guangzhou) Academy established in SCUT.
- 14th Oct. 2025, application of renaming to **GHWP (China) Academy** submitted in compliance with GHWP's latest "*Measures for the Building of GHWP Academy*".
- 18th Nov, officially renamed to **GHWP (China) Academy** during 4th training in Chongqing and later announced on GHWP's website.



Aim and Missions

- **GHWP-CNA** is the **first GHWP offline training academy** established in SCUT after application approved in Nov. 2023.

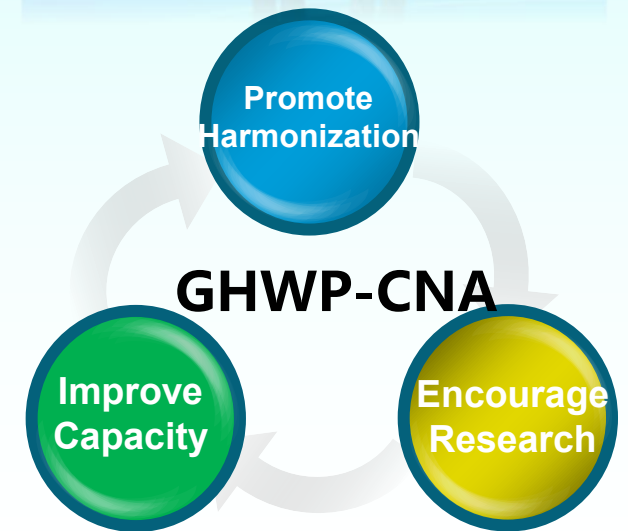
Aim: Education Promotes Global Medical Device Harmonization

Missions

Encourage regulatory science research

Provide training and support CB

Accelerate the convergence, harmonization, and reliance



5 major tasks:

- I. **3 platforms:** Regulation capacity building platform, GHWP data platform, *Exhibition platform;*
- II. **2 trainings** for member countries/regions each year;
- III. Encouraging international exchanges and cooperation in medical device regulation;
- IV. Providing research and consultation on policies, regulations and technical specifications related to the global regulation of medical devices.
- V. Cooperative training for the purpose of training medical device regulator personnel.



Part II Status and Progress

Capacity Building Platform: Excellent Pool of Experts

- **Experts from GHWP leadership, SAB, TC, CB** and globally renowned experts from industry or regulation.
- **SCUT academic team:** Leading professors etc.

Main PI

Academicians	4
Fellow of IUSBSE	3
PI 973/National Key Plan	5
Changjiang DIST. Prof.	15
High-Level Plans Prof.	10
Zhujiang Chair Prof.	10
Key Project PI	18

SCUT Academic Leaders



Prof. Yinjun WANG
Academician, CAE
President of GHWP-CNA



Prof. Liqun ZHANG
Academician, CAE
President of SCUT



Prof. Benzhong TANG
Academician, CAS
Director of HK Branch
of NERC-TRR



Prof. Zhengdi CHENG
NAE member
Dean of School
of Emergent
Soft Matter, SCUT

Capacity Building Platform: Chief Expert

Professor Wang Yingjun, Academician of the Chinese Academy of Engineering
President of GHWP (China) Academy



- **Fellow, International Union of Societies for Biomaterials Science & Engineering (IUSBSE)**
- **Chair, Medical Device Classification Technical Committee, NMPA China**
- **Director of the National Engineering Research Center for Tissue Restoration & Reconstruction**
- **Two-term President of the Chinese Society for Biomaterials**
- **Former President of South China University of Technology**

With over 40 year in biomaterials research, Professor Wang pioneered the theory of bioadaptability and delivered numerous original breakthroughs in bone, dental and blood purification biomaterials, tissue engineering and regenerative medicine, as well as the translational application of AI and 3D technologies, with many of these seminal findings widely adopted in clinical practice. In recent years, she has focused on medical device regulatory science research, and is committed to advancing global harmonization of medical device regulations.

Capacity Building Platform: Guest Professorship

- Provide strategic consulting and support for the academy's development;
- Support training programs and regulatory science research projects.
- Appointment term: 3 years (unremunerated)

GHWP-CNA Guest Professors Appointed in 2025



EunHee Cho



Miang Tanakasemsub



Gao Guobiao

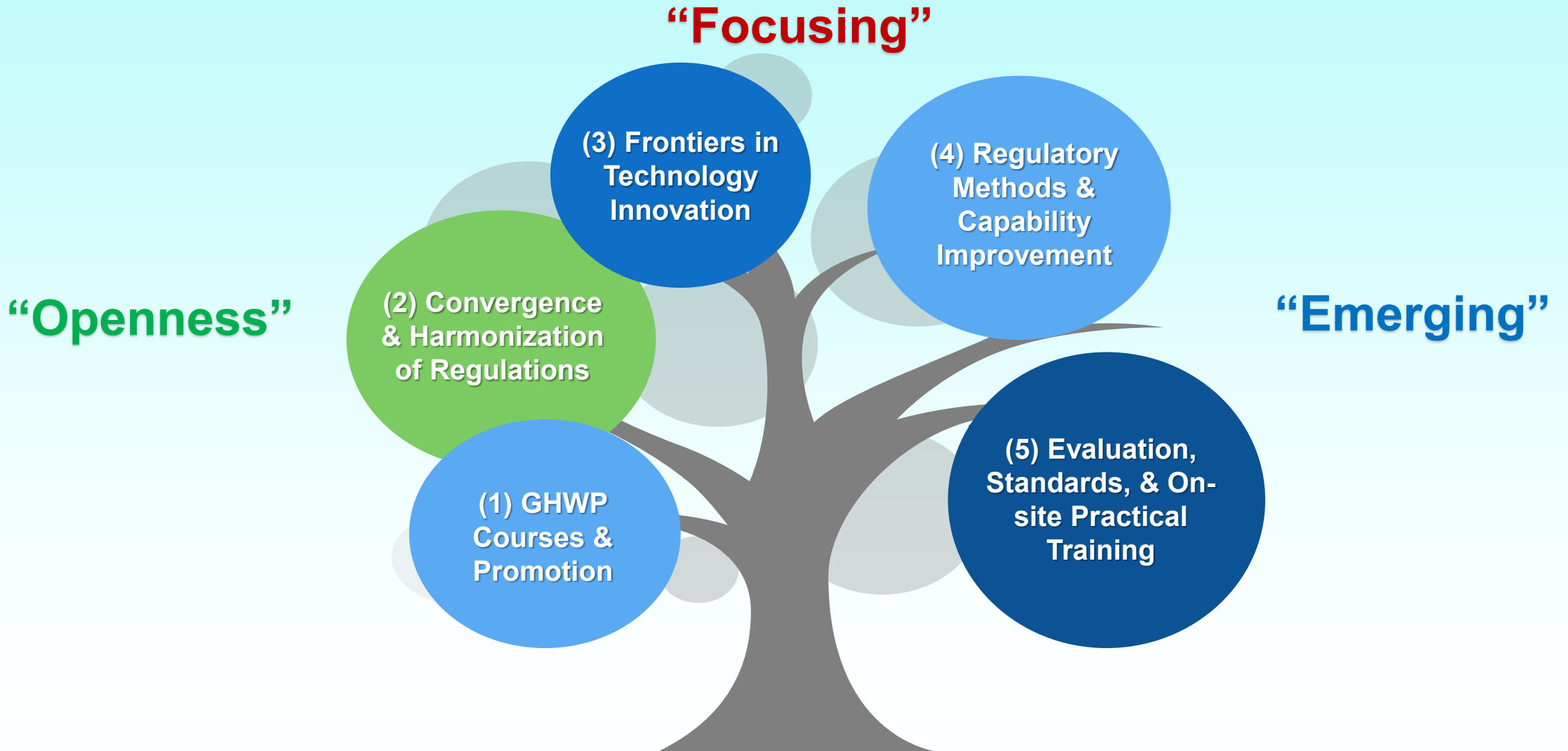


Alfred Kwek

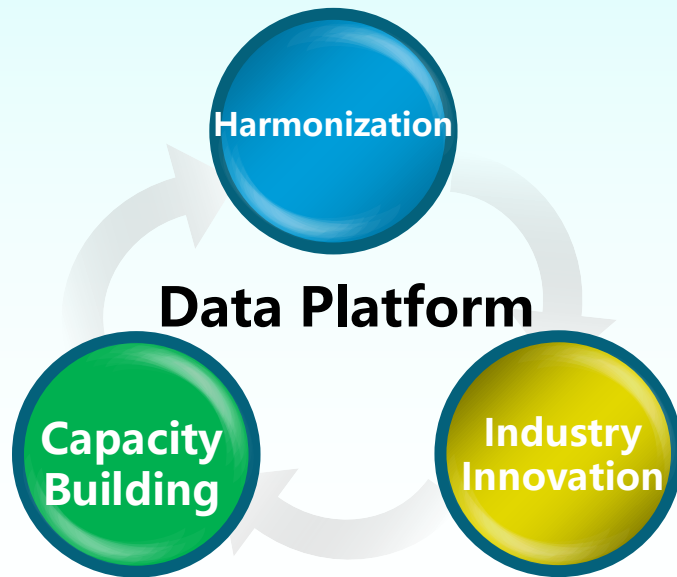


Tran Quan

Capacity Building Platform: Curriculum System



To facilitate the implementation of the GHWP Strategic Framework towards 2026, **GHWP data platform was set up to support capacity building in GHWP-CNA.**



1. Laws and regulations

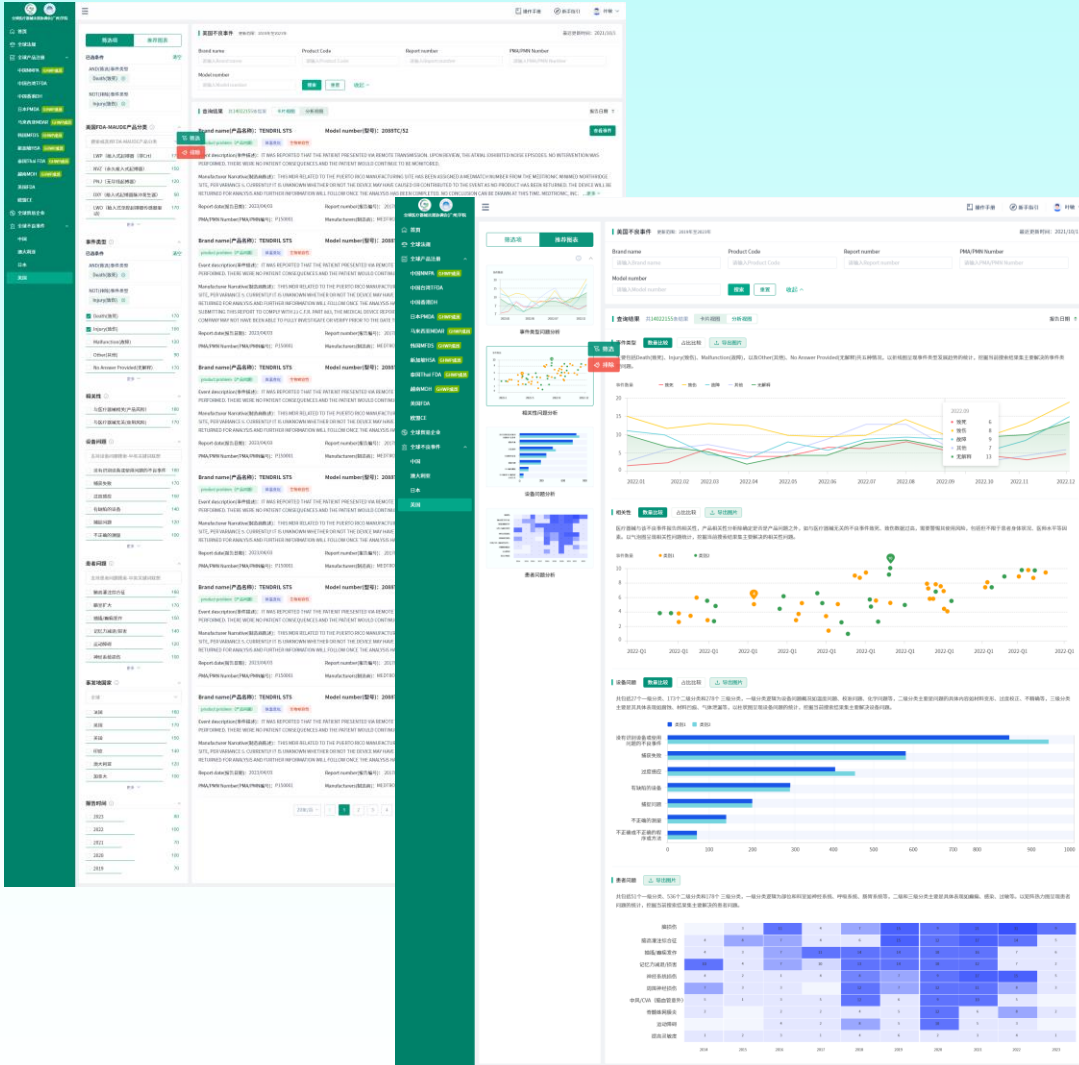
- Interpretation of global medical device regulations and. Real-time content update by AI.

2. Data analysis and research

- Data analysis of the medical device industry. Promote regulatory science research in the medical device industry.

3. Regulation support and strategy development

- Regulation research, registration planning and strategy development



GHWP Data Platform

Global Regulatory Library

Global Product Registration

Global Trade Database

Global Trade Business Pool

Global Adverse Events Database

GHWP Industry White Paper

➤ 1st phase focusing on:

- Artificial intelligence
- Medical imaging equipment
- Medical robots
- Novel biomaterials



➤ Project Team:

- GHWP (China) Academy
- NMPA Institute of Medical Economics
- IBMD
- APACMed
- Industry Partners

➤ Support Strategy Framework 2026:

- The current regulatory framework will not fit for the purpose of regulating emerging technologies due to the drastic differences from traditional medical devices
- Knowledge transfer and capacity building to cater for needs in coping with novel technologies

Aim: Promote knowledge transfer and capacity building in coping with novel technology challenge in medical device regulation and global regulatory harmonization

GHWP-CNA Training: Raising Great Impact

Since Established in Dec. 2023:

- **7** Trainings: 4 GHWP CNA trainings, 3 Topic-Specific trainings
- **2,500** Participators from **31 Countries/Regions**
- **20** GHWP countries/regions covering over 1/2 GHWP members
- **41,000** Online live stream viewers globally



Great Support From GHWP

- Great support from leaderships: **contributed 27 times as speakers/moderators in all 4 trainings.** (5 in 1st, 8 in 2nd, 7 in 3rd, 7 in 4th.)



Great Support From GHWP

- Great support from member countries/regions: **25 speakers from 20 GHWP**
country/region **regulators** (8 in 1st, 5 in 2nd, 6 in 3rd, 6 in 4th)



2025 GHWP-CNA Training at a glance

- **3 trainings: 2 GHWP-CNA training**, 1 Topic-specific training;
- **>1,300** Total offline participations from **19 countries/regions**
- **24,000** Live Stream Viewers globally
- 3rd training in Guangzhou: “Noval Biomaterials Support Global Public Health”, **3 days, 5 topics, 24 lectures, ~330 participates, 13,000 online viewers;**
- 4th training in Chongqing: “High Quality Medical Devices Support Global Public Health ”, **3 days, 8 topics (+3 parallel sessions), 50 lectures, >800 participates, 11,000 online viewers**



2025 GHWP-CNA Training at a glance

- **3 trainings: 2 GHWP-CNA training**, 1 Topic-specific training;
- **>1,300** Total offline participations from **19 countries/regions**
- **24,000** Live Stream Viewers globally;
- **All 4 new member countries/regions participated as speakers/panelist/trainee:**



Botswana



Ghana



Macao, China



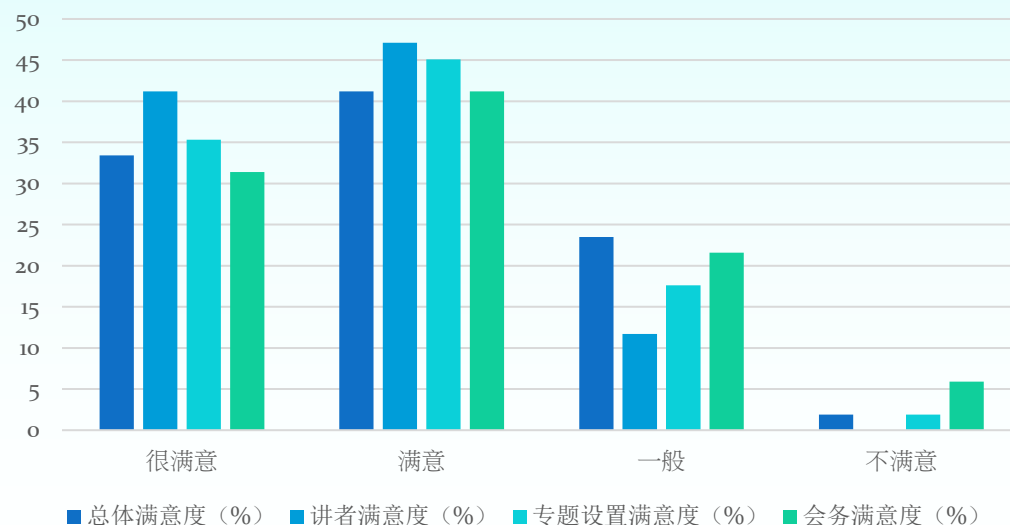
Uzbekistan



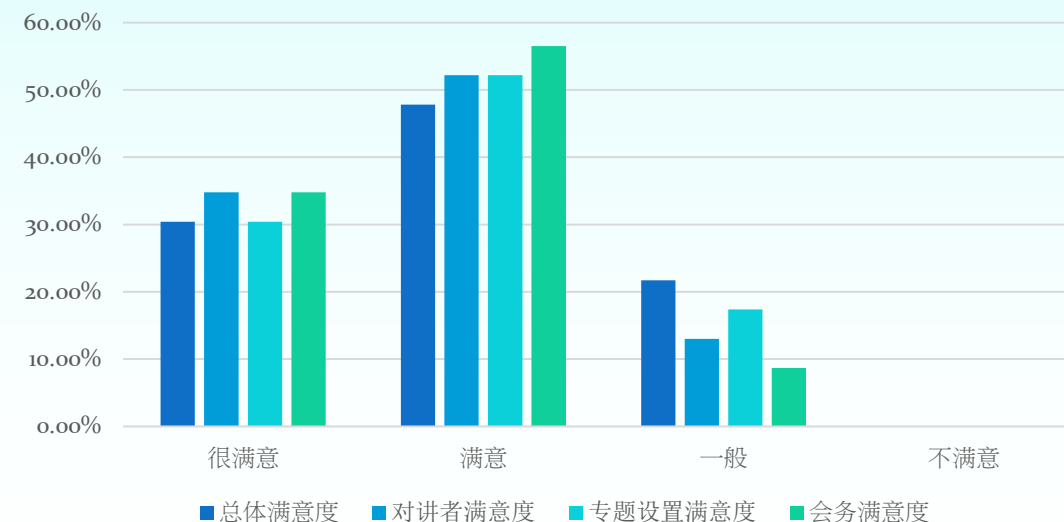
Feedback from 3rd and 4th training participants

- The overall satisfaction from the participants feedback **increased from 85.8 in 3rd training to 87.7 in 4th training.**
- **No dissatisfaction feedback recorded in 4th training.**

Overall satisfaction of 3rd training



Overall satisfaction of 4th training



2025 GHWP-CNA Training at a glance

Topic-Specific training: Medical Device Regulation Convergence and High-Quality Industrial Development on 29th CMEF

On Sept. 26th, on the 29th China International Medical Equipment Fair (CMEF), attracting **200 on-site participants**.

- Promote GHWP's efforts in advancing the convergence, coordination, and trust;
- Introduce GHWP-CNA and promote the 4th training program and 29th annual meeting.



CMEF MEDCONGRESS

扫描二维码 报名参会

医疗器械监管协同与产业高质量发展创新会议

会议时间: 2025年9月26日(星期五)下午14:00-17:00
会议地点: 中国进出口商品交易会展馆(广州) D区广交会展馆二五会议室
主办单位: 全球医疗器械法规协调会(GHWP)学院
承办单位: 新型生物材料与高端医疗器械广东研究院
支持单位: 国家药品监督管理局医疗器械技术审评检查大湾区分中心
广东省药品监督管理局审评认证中心
广东省医疗器械质量监督检验所
广州市黄埔区科学技术局(广州开发区科技创新局)
广州仲裁委员会

时间/Time	主题/Topic	演讲嘉宾/Speaker
14:00-14:30	GHWP发展概况与迈向2030战略框架	高国彪 国家药品监督管理局中心副主任 CMEF组委会委员
14:30-14:45	GHWP学院发展概况与重点工作介绍	杭飞 GHWP学院发展部部长
14:45-15:00	医疗器械监管协同 与成果转化概念验证中心成立介绍	靳静 华南理工大学国家医疗器械重点实验室主任 常务副主任
15:00-15:15	器械大湾区分中心创新发展举措 与重点服务项目介绍	王宏 国家药品监督管理局大湾区分中心副主任
15:15-15:30	广东省药品监督管理局 与支持单位介绍	黄祥卫 广东省药品监督管理局审评认证中心 常务副主任
15:30-15:45	支持产业创新发展举措介绍	段静松 广东省医疗器械质量监督检验所所长
15:45-16:00	广州开发区 黄埔区“生物医药3.0政策”介绍	范露露 广州市黄埔区科学技术局党组书记、副局长
16:00-16:15	推进国际商事仲裁建设, 护航医药产业高质量发展	李俊强 广州仲裁委员会副主任和仲裁员
16:15-16:30	基于AI智能体的医疗器械数智化新模式 暨“智械雷达”产品发布	许建强 国家药品监督管理局审评认证中心主任
16:30-16:45	检验检测技术服务平台 助力医疗器械创新发展	蒙志超 国家药品监督管理局审评认证中心主任
16:45-17:00	从原料创新到监管挑战 —医美医疗器械研发的新路径探索	孟媛 华南理工大学材料科学研究所

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共建全球医疗生态圈



Part III Work Plan 2026

Focusing on the implementation of the **GHWP Strategic Framework towards 2026:**

➤ **GHWP-CNA training:**

- a) Organizing 2 GHWP academy training in May and Nov 2026;
- b) Improve the pool of experts and the guest professorships;
- c) Continuously improve the curriculum.

➤ **Explore "Tailored " topic-specific training for industry or regulators;**

➤ **Update "Industry White Paper " on feedback and public comments;**

➤ **Improving "Data Platform ".**



Thanks! 谢谢!

**Global Harmonization Working Party
China Academy**

Education Promotes Medical Device Harmonization