



GHWP



GHWP(Guangzhou) Academy Status Report

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Dec. 12th, 2024



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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 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

...

Introduction - Aims and Missions of GHWP-GZA

“Education promotes global medical device harmonization”

- **GHWP-GZA is the first GHWP offline training academy** established in SCUT after application approved in **Nov. 2023**.
- On 27th annual meeting, Dr. Xu presented the bronze plate to GHWP-GZA
- The first president is **Prof. Wang Yinjun (Academician of CAE)**.



Missions

Encourage Regulatory Science Research

Provide Training and Exchange

Accelerate the convergence, harmonization, and reliance



Education Philosophy – “OMF”

“Education promotes global medical device harmonization”

“Open”

➤ Open education

- Open to all GHWP countries/regions
- Encourage non-members to participate to enhance GHWP influence

➤ Open pool of experts

- Experts from different fields are welcome

➤ Open contents

- Combining current GHWP online training and offline training



“Merging”

➤ Interdisciplinary merging

- Merging of regulation and cutting edge innovation

➤ People merging

- People from regulation, industry, research...
- People from different cultures

➤ Regulation merging

- Promoting the convergence, coordination and reliance of medical device regulations

“Focus”

➤ Focus on frontiers:

- Frontiers in industry innovation
- Frontiers in regulatory science research

➤ Focus on global/regional concern in medical device regulations

➤ Focus on offline training

5 major tasks:

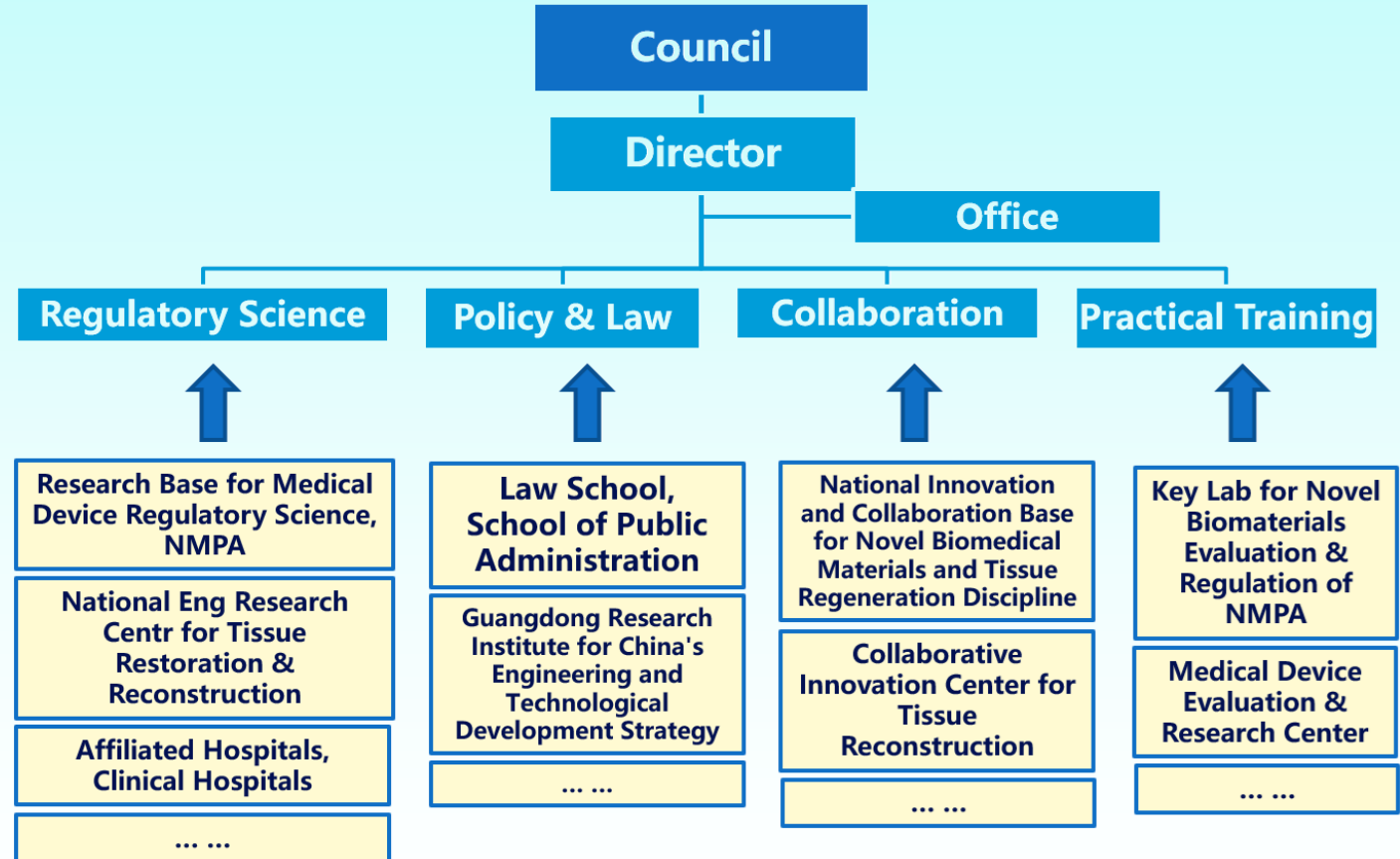
- I. **2 trainings** for member countries/regions annually, **total of 300-400 persons**;
- II. **3 platforms**: Global regulation capacity building platform, GHWP data platform, Exhibition platform;
- III. Encouraging international exchanges and cooperation in medical device regulation;
- IV. Providing research and consultation on policies, regulations and technical specifications related to the global regulation of medical devices.
- V. Carry out cooperative training for the purpose of training medical device regulatory personnel.



Part II Current Progress

Organizational Structure

- GHWP-GZA operates under the **leading of the council**. The President is responsible of the operation and management. “College” under SCUT administration.
- **A dedicate admin office has been set up.**
- **Independent financial system.** The budgets is supervised by the Council



Website (EN & CN) : <http://ghwpgza.ibmd.org.cn/>



The image shows a screenshot of the GHWP-GZA website and a search result for 'ghwp' on Baidu. The website header includes the GHWP logo, the text 'Global Harmonization Working Party(Guangzhou) Academy', and the Chinese text '全球医疗器械法规协调会(广州)学院'. The main content area features a banner for '创新医疗器械走向世界' (Innovative Medical Devices Go Global) and 'GHWP Guangzhou ACADEMY TRAINING'. Below the banner, there are sections for '学院新闻' (Academy News) and '培训报' (Training Report). The search result for 'ghwp' on Baidu shows the website URL 'ibmd.org.cn' and a snippet of text: '全球医疗器械法规协调会(广州)学院' (Global Harmonization Working Party (Guangzhou) Academy). The snippet mentions that the academy was established as a non-profit organization and is responsible for organizing the formulation of GHWP guidance documents.

6 Functions, 3 Entries

1 About us: Introduction

2 GZA News

3 Cloud Training: online course

4 Data Center: Capacity Building

5 Council Center

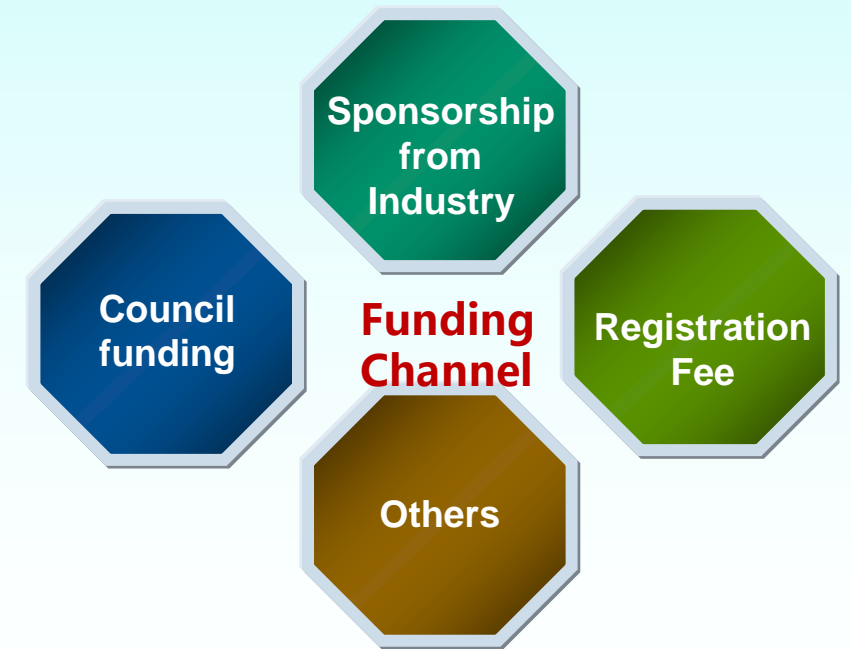
6 Member Club: Q&A

Stable Fund-raising Channel: Non-profitable

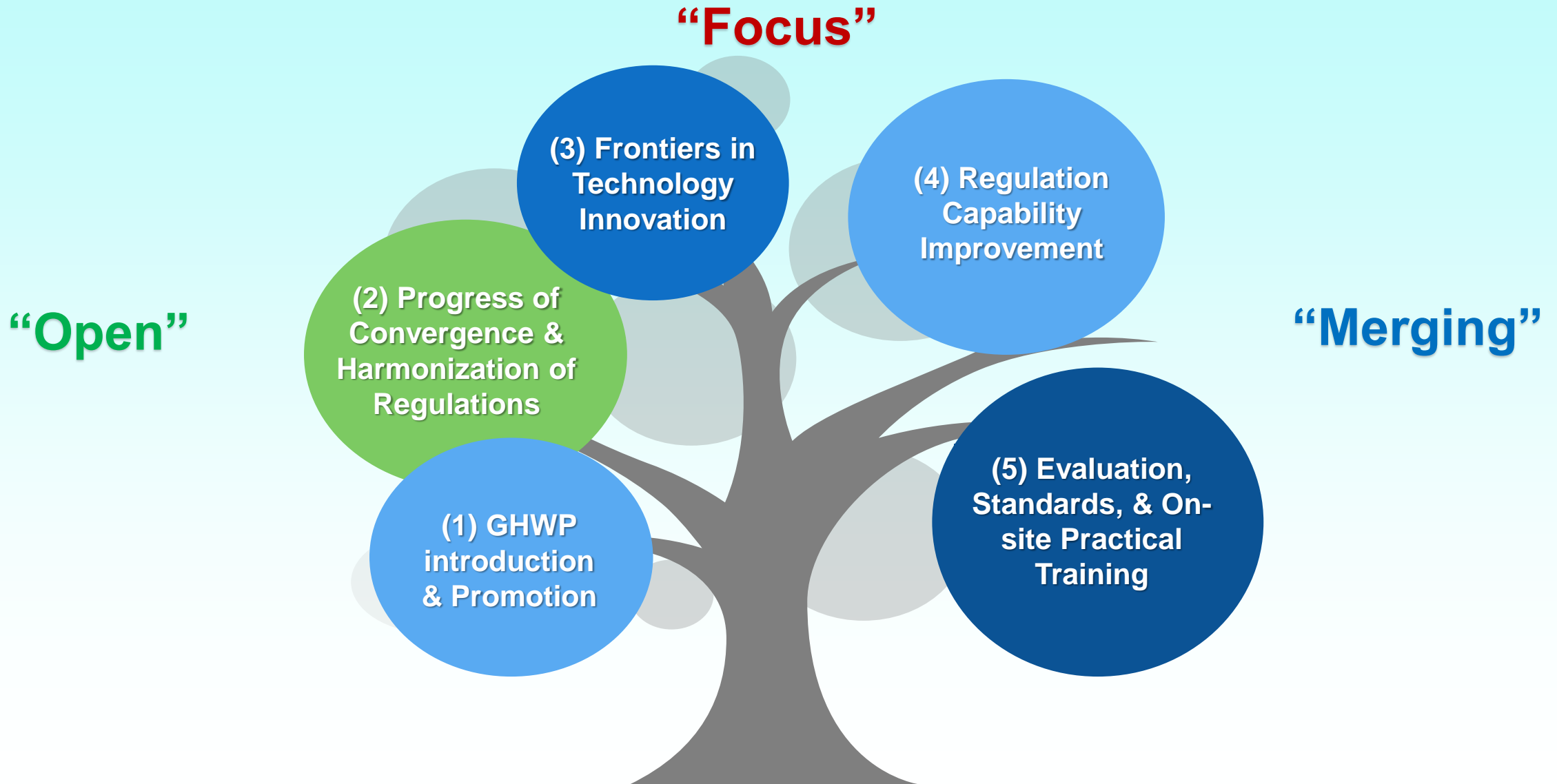
A stable channel has set up:

- Operation: **Funding from 24 council members**
- Training: **Registration fee** and **sponsorships** from industry partners

24 council members of GHWP-GZA



Capacity Building Platform: Curriculum System



Capacity Building Platform: Excellent Pool of Experts

- **Experts from GHWP leadership, SAB, TC, CBC; Member countries/regions and globally renowned experts in medical devices.**
- **SCUT Training team: Academicians, Changjiang Chair Professors etc (>300).**

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 Reviewer	18

Interdisciplinary

Academic Leaders



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



Prof. Liqun ZHANG
Academician, CAE
President of SCUT



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



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



Support capacity building and industry innovation

GHWP Data Platform

**Global Regulation
Library**

**Global Product
Registration**

**Global Trade
Database**

**Global Trade
Business Pool**

**Global Adverse Events
Database**

1. Laws and regulations

- Interpretation of global medical device regulations and laws. Content real-time updating 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

美国不良事件 更新时间: 2023年9月20日 最新更新时间: 2023/10/1

Brand name: Product Code: Report number: PMA/PMA Number:

Model number:

查询结果 共14022235条信息

Brand name(产品名称): TENDRIL STS Model number(型号): 2088TC/52

Event description(事件描述): IT WAS REPORTED THAT THE PATIENT PRESENTED VIA REMOTE TRANSMISSION. UPON REVIEW, THE ATRIAL EXHIBITED NOISE EPISODES, NO INTERVENTION WAS PERFORMED. THERE WERE NO PATIENT CONSEQUENCES AND THE PATIENT WOULD CONTINUE TO BE MONITORED.

Manufacturer Narrative(制造商叙述): THIS MDR RELATED TO THE PUEBLO RICO MANUFACTURING SITE HAS BEEN ASSIGNED A MISMATCH NUMBER FROM THE MEDTRONIC MINNED NORTHGRIDGE SITE. PER VARIANCE 5, CURRENTLY IT IS UNKNOWN WHETHER OR NOT THE DEVICE MAY HAVE CAUSED OR CONTRIBUTED TO THE EVENT AS NO PRODUCT HAS BEEN RETURNED. THE DEVICE WILL BE RETURNED FOR ANALYSIS AND FURTHER INFORMATION WILL FOLLOW ONCE THE ANALYSIS HAS BEEN COMPLETED. NO CONCLUSION CAN BE DRAWN AT THIS TIME. MEDTRONIC, INC. ...更多 >

Report date(报告日期): 2023/04/03 Report number(报告编号): 201785-2023-13005 Product Code(产品编号): NIN
PMA/PMA Number(PMA/PMA编号): P150001 Manufacturers(制造商): MEDTRONIC PUEBLO RICO OPERATIONS CO. Is this an Adverse Event Report(是否产品问题报告): NO

Brand name(产品名称): TENDRIL STS Model number(型号): 2088TC/52

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查询结果 共14022235条信息

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事件类型问题分析

事件类型问题分析

相关性问题分析

设备问题分析

患者问题分析

Brand name(产品名称): TENDRIL STS Model number(型号): 2088TC/52

事件类型:

医疗问题与设备不良事件的相关性, 产品相关性分析能确定不良事件问题之外, 医疗问题与设备不良事件的关系, 例如数据过高, 需要警惕其使用风险, 但结果不意味着身体状态、医疗水平等因素。以气密性不良和柔性导线统计, 数据量主要来自设备不良事件的问题。

其包括27个一级分类, 17个二级分类和78个三级分类, 一级分类为设备问题/问题/故障/故障, 二级分类主要是问题的具体内容/材料/故障, 过程/过程, 三级分类主要是设备/材料/故障, 气体/故障, 以问题/设备/材料/故障/过程/过程, 数据量主要来自设备不良事件的问题。

没有识别到设备或医疗设备不良事件

设备问题

其包括27个一级分类, 17个二级分类和78个三级分类, 一级分类为设备问题/问题/故障/故障, 二级分类主要是问题的具体内容/材料/故障, 过程/过程, 三级分类主要是设备/材料/故障, 气体/故障, 以问题/设备/材料/故障/过程/过程, 数据量主要来自设备不良事件的问题。

医疗问题	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27
感染	+																										
阻塞/堵塞/梗阻	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
记忆力减退/遗忘	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
神经系统损害	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
四肢/四肢	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
中风/卒中 (缺血性/出血性)	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
骨髓水肿/骨髓炎	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
运动障碍	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
疲劳/疲劳	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+

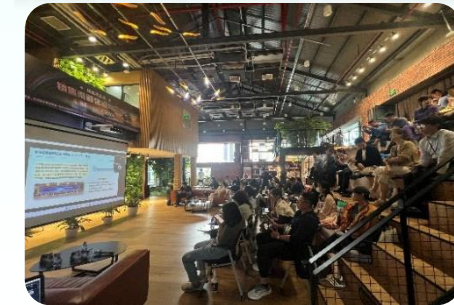
2024 GHWP-GZA Training at a Glance

- **2 GHWP-GZA training(330 + 350 people)**, 2 theme training (120 + 40 people);
- **1st GHWP-GZA training "Collaborative Empowerment—Innovative Medical Devices Embrace the World", 27th-31st May, Guangzhou, 5 days, 5 topics, 24 lectures, total 40 hrs;**
- **2nd GHWP-GZA training "Innovative Medical Device Promotes Global Public Health ", in Shenzhen, 24th-26th Nov., 3 days, 5 topics, 24 lectures, total 24 hrs**
- **>17000 Live stream viewers globally: >5000+ >12000 viewing (each training has a half day GHWP session free online);**



2024 GHWP-GZA Training at a Glance

- **2 free training slots** for every GHWP member countries/regions regulators in every training
- Attract nearly **700 participators** from **16 GHWP countries/regions**, covering nearly **1/2 GHWP members** raising great impact;



Great Support From GHWP

- **Great support from GHWP leaderships (SAB/TC/CBC) : 5 speakers/moderators in the 1st training, 6 speakers/moderators in the 2nd training;**



Great Support From GHWP

➤ **20 GHWP country/region regulator speakers: from 5 countries/regions in 1st and 7 in 2nd**



Great Support From GHWP

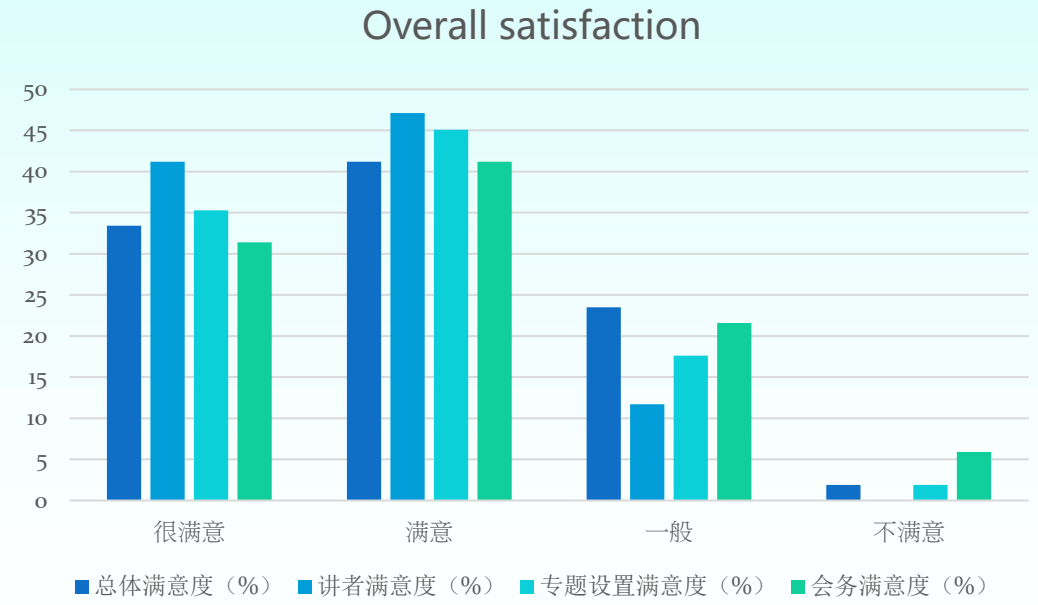
➤ **20 GHWP country/region regulator speakers: from 5 countries/regions in 1st and 7 in 2nd**



Feedback From 1st Training Participants

The overall satisfaction is 81.7. The distribution of scores is generally normal, highly credible, and skewed toward higher scores reflecting higher levels of satisfaction. The rating of the speakers and the topic setting reflect higher satisfaction.

	Overall	Speakers	Course Design	Service
Very Satisfied	33.4% (17)	41.2% (21)	35.3% (18)	31.4% (16)
Satisfied	41.2% (21)	47.1% (24)	45.1% (23)	41.2% (21)
Average	23.5% (12)	11.7% (6)	17.6% (9)	21.6% (11)
Not satisfied	1.9% (1)	0% (0)	1.9% (1)	5.9% (3)



GHWP-GZA To-do Checklist

Commitments from GHWP-GZA application:

Check	Major Tasks	Completion status
<input checked="" type="checkbox"/>	2 training/annual, 300-400 people	Organized 2 GHWP-GZA trainings, ~700 people; 2 theme trainings, ~200 people
<input checked="" type="checkbox"/>	Establish academy within 6 month	Organization structure completed with article and charter; deliver the 1st training in May successfully
<input checked="" type="checkbox"/>	Dedicate management team	Management office set up and employ dedicate team; 12 management documents
<input checked="" type="checkbox"/>	Set up stable fund-raising channel	Found council with 24 members; 2 council meetings; ensure virous financial channels
	3 Platforms: CB, Data, Exhibition	CB Platform: Continually improving curriculum and expert pool; Data Platform: Done Exhibition Platform: Under construction



Part III Development Plan

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

➤ **Improving GHWP-GZA training:**

- a) Organizing 2 GHWP training in 2025 in May and Nov (TBC);
- b) Continuously improve the curriculum and the pool of experts/speakers;

➤ **Explore regular training:**

- a) **Provide on-demand, customized training for industry** on regulation harmonization, technology frontiers, regulations and standards;
- b) **Provide training for regulatory authorities** on medical device regulatory personnel;
- c) **Organize Training abroad.**

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

- Set up **open research projects on** regulatory science research;
- Organize “White Paper”
- Improving **GHWP-GZA administration:**
 - a) Complete the registration of the non-profitable organization;
 - b) Set up the working mechanism with Capacity Building Committee;
 - c) Improve the website and database;
 - d) Build up the academy's own training conference system
 - e) Further improve the organizational structure, more office staff;



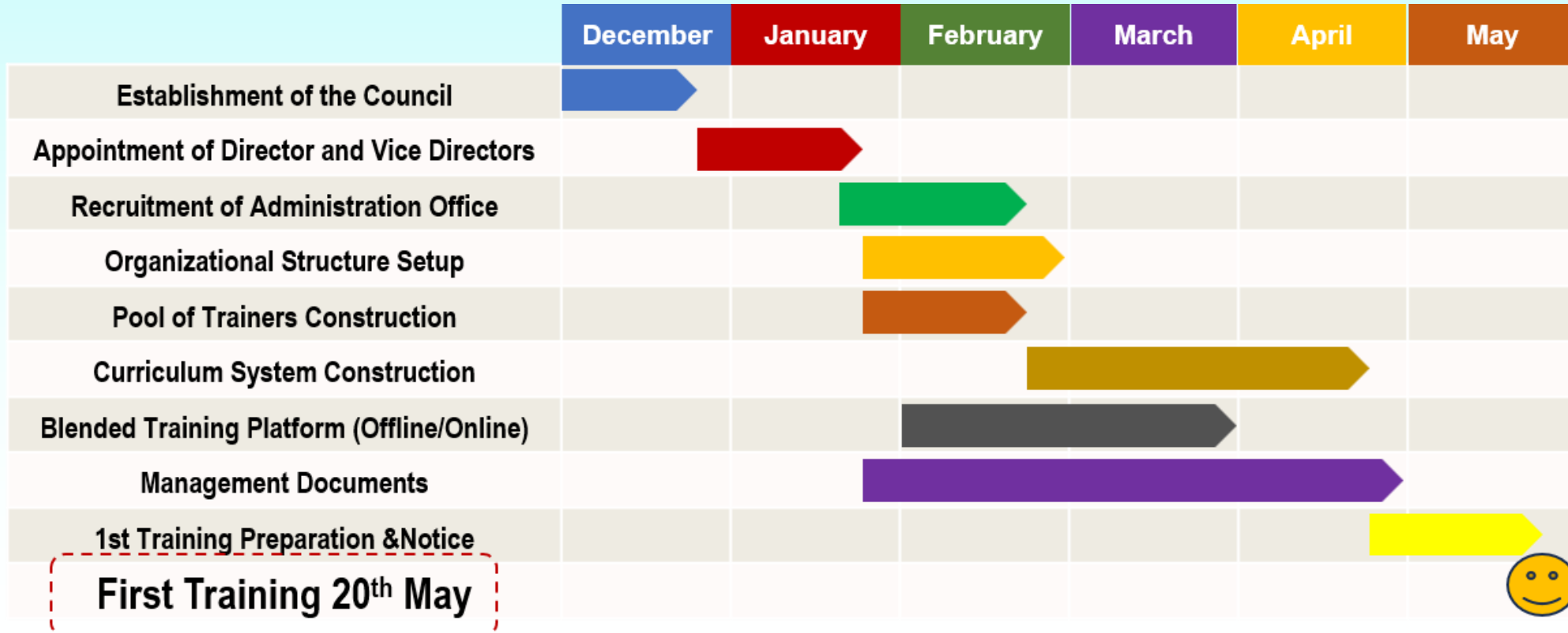
Thanks! Terima kasih! 谢谢!

**Global Harmonization Working Party
--Guangzhou Academy**

Twoards Medical Device Harmonization

Development Plan

- **The GHWP-GZA aims to complete the establishment within 6 months**
- **1st offline training by End of May 2024**



Curriculum System

(1) GHWP Promotion

- GHWP's mission, organizational structure, development strategy, and operational mechanisms.
- GHWP's technical guidelines and guiding principles.

(2) Convergence and Harmonization of Regulations

- Innovations in global medical device regulations in terms of concepts, legal systems, mechanisms, approaches, strategies, and cultures.
- Convergence, coordination, and Harmonization of medical device regulations.

(3) Frontiers in Technology Innovation

- Current status, focuses and strategies in the global medical device industry innovation.
- Advancements in cutting-edge technologies.

(4) Regulatory Methods and Capability Improvement

- GHWP-developed courses (including: GHWP Medical Technology Regulatory Agency Training Course and Medical Technology Regulatory Capability Framework White Paper).
- Development of medical device regulatory science.
- Opportunities and challenges in the medical device industry and regulation.

(5) Evaluation, Standards, and On-site Practical Training

- Comparative courses on technical evaluation standards and methods from GHWP member countries/regions.
- On-site practical training in cutting-edge technologies and evaluation methods in both industry and regulation.

Stable Fund-raising Channel: Non-profitable

A stable channel has set up:

- Operation: **Funding from 24 council members**
- Training: **Registration fee and sponsorships** from industry partners

Training cost = \$140k ~ 280k/training x 2

Operation expenses = \$200k/annual

Total budget = ~ \$620k / annual

24 council members of GHWP-GZA

