Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

GHWP White Papers
- Innovative Medical Devices -

GHWP White Paper Initiative

White Paper outlines global trends of technology innovation, challenges, and harmonization recommendation aligned with GHWP Strategic Framework

- **Technological Advancements**
  Digital health, AI, Robot, bio materials, and IVD drive rapid evolution.
- **Regulatory Challenges**
  Traditional regulatory frameworks lag behind fast technical innovation.
- **Global Collaboration**
  Harmonized standards ensure safety and market access.
- **Regulatory Gap & Challenges**
  Balancing innovation and safety; need for agile, harmonized regulation.
- **Regulators' Need for Global Innovation Insights**
  Access to innovation trends, understanding emerging technologies, harmonizing standards, collaborative platforms, and research.
- **Industry's Need for Predictable Regulatory Frameworks**
  Improving predictability, global harmonization, and benefit sharing for patients.
- **GHWP's Core Value of Collaboration of Regulators, Industry, Academia, and Liasion members(eg, APACmed)**
  Bridging innovation and regulation, supporting regulators and industry.

GHWP White Paper Progress Report

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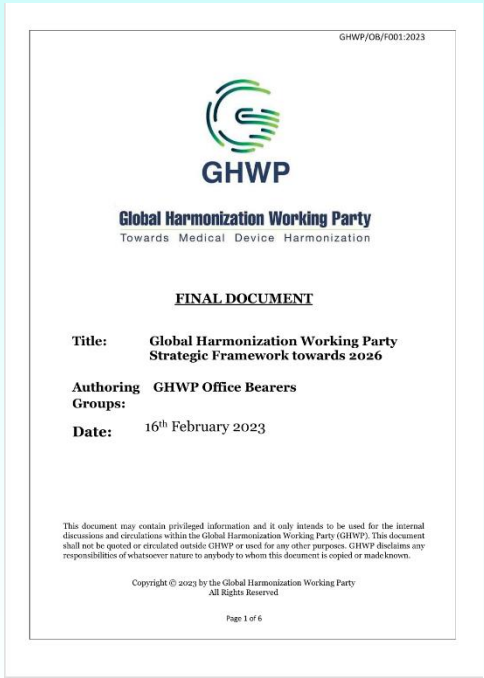
South China University of Technology

Dec. 4th, 2025

Background

Strategic Framework

- 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
- The **"Industry White Paper"** project was therefore initiated and authorized GHWP (China) Academy to implement.



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Global Harmonization Working Party

Towards Medical Device Harmonization

FINAL DOCUMENT

Title: Global Harmonization Working Party Strategic Framework towards 2026

Authoring Groups: GHWP Office Bearers

Date: 16th February 2023

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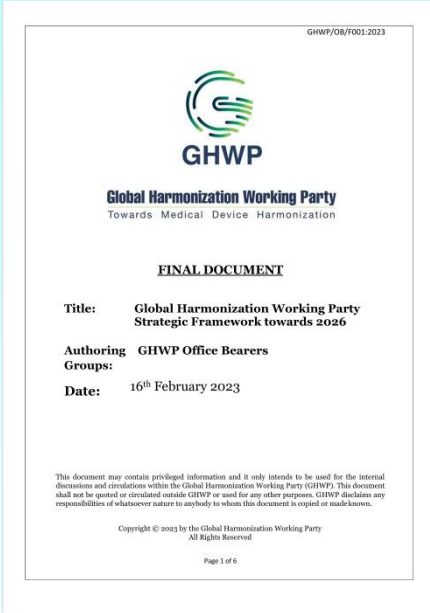
Background

2.4.3 Regulatory Science

We acknowledge the current regulatory framework will not fit for the purpose of regulating emerging technologies (such as digital health solutions) due to the drastic differences from traditional devices. Hence, we are committed to prioritize the knowledge sharing and capacity building to cater for needs in coping with novel technologies **e.g. Software as a Medical Device (SaMD), Artificial Intelligence (AI)/Machine Learning (ML), Next-Generation Sequencing (NGS), 3D printing, Cybersecurity, etc.**



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- The 1st phase white paper includes following emerging technologies:
  - *Artificial Intelligence, Advanced Medical Imaging, Medical Robots, Novel Biomaterials*
- They all develop very fast and clearly demonstrate drastic differences from traditional medical devices:
  - Digital Tech based (AI, Medical imaging, Robots)
  - Working mechanism far from traditional devices (AI, Novel Biomaterials)

White Paper Working Mechanisms

➢ Project Team:

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

- **Industry Partners:**

➢ Mile Stones:

- 1. First notice: May 14, 2025 on 3rd training
- 2. Editors assemble: June 15
- 3. Kick - off meeting: July 30
- 4. First draft and revision meeting: Oct. 1
- 5. Final manuscript submitted : Nov 30
- 6. Final draft released during the 29th Annual meeting

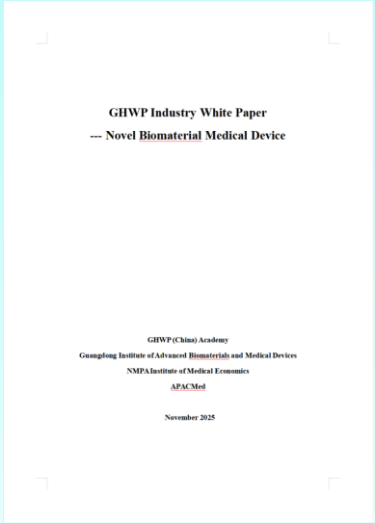
Aim: Promote knowledge transfer and capacity building in coping with novel technology challenge in medical device regulation and global regulatory harmonization

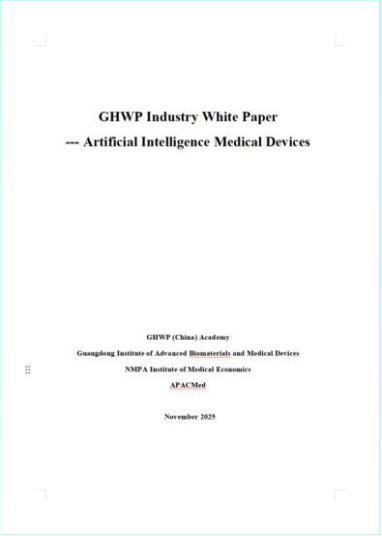
Progress in General

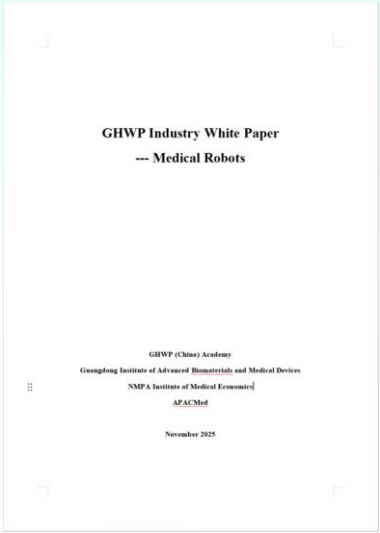
- **The final draft will be released and call for feedback/public comments.**

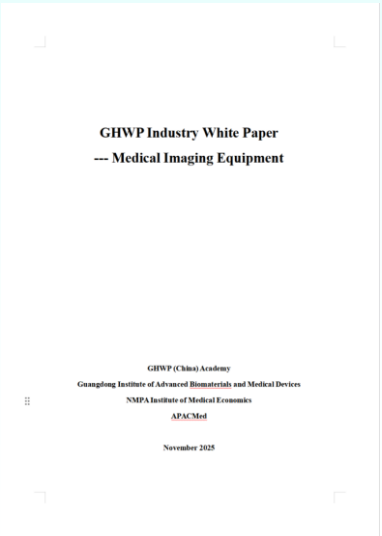
- **Total words: 35,000 words (Online version 22,643 words exclude case study/expert opinions)**
  - Artificial intelligence: 8,373 words (6,231)
  - Medical imaging equipment: 6,577 words (4,312)
  - Medical robots: 10,264 words (6,576)
  - Novel biomaterials: 9,757 words (5,524)

- **Keep update**
  - Revise based on feedback
  - Update on regular basis
  - Update with “Expert Opinions” and “Enterprises Case Study”









Future Work

- **Keep alignment with the latest technology progress and regulation hot topics**

  - **Revise upon the feedback and public comments;**
  - “Enterprise Cases Study” and “Expert Opinions” will be carefully included in the future online version based on the feedback on current draft, and from companies/expert’s opinions. (Data disclosure sensitivity and IP protection)
  - **Update on regular basis** (annually or biennially) with latest progress in tech and development in market, if necessary.

Thanks！谢谢!

Global Harmonization Working Party
China Academy

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