



GHWP

Global Harmonization Working Party

Towards Medical Device Harmonization

Regulators and Industries at GHWP

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Tech Innovation vs GHWP/IMDRF

Technology Innovation



Medical Robot



USB Bluetooth SmartPhone Android WindowXP



RobotSuit ChatGPT



3D-bioprinter BionicNeuronw

Harmonization of leadership of Korea.

1996	1999	2000	2007	2010	2014	2016	2022	2023	2025+
<ul style="list-style-type: none"> 1996-97 GHWP formed in APAC. 		<ul style="list-style-type: none"> 2000 - Formally elect GHWP Chair, Annual meeting in Singapore. 	<ul style="list-style-type: none"> 2006 – GHWP annual meeting in Seoul 	<ul style="list-style-type: none"> 2014 – Korean Chair and TC co-chair of GHWP and annual meeting in Seoul 		<ul style="list-style-type: none"> 2017 – Korea, official member of IMDRF 	<ul style="list-style-type: none"> 2021 – Korea, Chair of IMDRF 	<ul style="list-style-type: none"> 2023 - Annual meeting in Shanghai, China 	
			<ul style="list-style-type: none"> 2009 ~ 2015; Korean Co-Chair of WG4 			<ul style="list-style-type: none"> 2020 ~ Korean TC Co-Chair, WG Chair and WG Co-Chair 		<ul style="list-style-type: none"> 2023~ Korean Strategic Advisory Board and Korean Vice Chair of GHWP 	

[WW Medical Device Market]

unit : mil





Foundation Principle of GHWP

- GHWP(ex-AHWP, rebranded in 2021) is established as a non-profit organization that brings regulatory **authorities and industry together to harmonize scientific and technical aspects of regulations.**
- The Working Party is a group of experts from **regulatory authorities and the medical device industry.**
- Vision to achieve international harmonization of Medical Device regulatory framework among regulatory authorities, convergence of regulatory requirements, open and **trust-based efforts between regulatory authorities and the industry** across the globe.
- Goals
 - To develop and recommend approaches for the global convergence and harmonization of medical device regulations
 - To facilitate the exchange of knowledge and expertise amongst regulators and the industry for the establishment of harmonized requirements
 - To promote capacity building in members and to foster strategic membership expansion.
 - To work in collaboration with related international organization such as IMDRF, ISO, IEC, etc.



How to contribute to GHWP

◆ Leadership participation

- Commit to promote the goals of GHWP and knowledge sharing of the industry
- Refinement in GHWP strategy, event planning and execution.

◆ TC leadership and Working Group

- Strong supporters of the GHWP goals based on experience and expertise.
- Execute the policies and decisions of GHWP and provide professional support to achieve goals of GHWP.
- Sharing latest technology and various industry cases with regulators.
- Input based on interaction with various stakeholders such as healthcare providers, etc.
- Develop policy technical documents and white papers for endorsement with co-work of industry and regulators.

◆ TC advisors

- Bring their knowledge and experience to support GHWP activities
- Provide objective advice, gauging future trends for new strategic positioning, advocating GHWP work with the increase in its visibility globally.
- Provide input through comments and recommendation on the scope of the work.

◆ Financial support

GHWP Strategic Framework

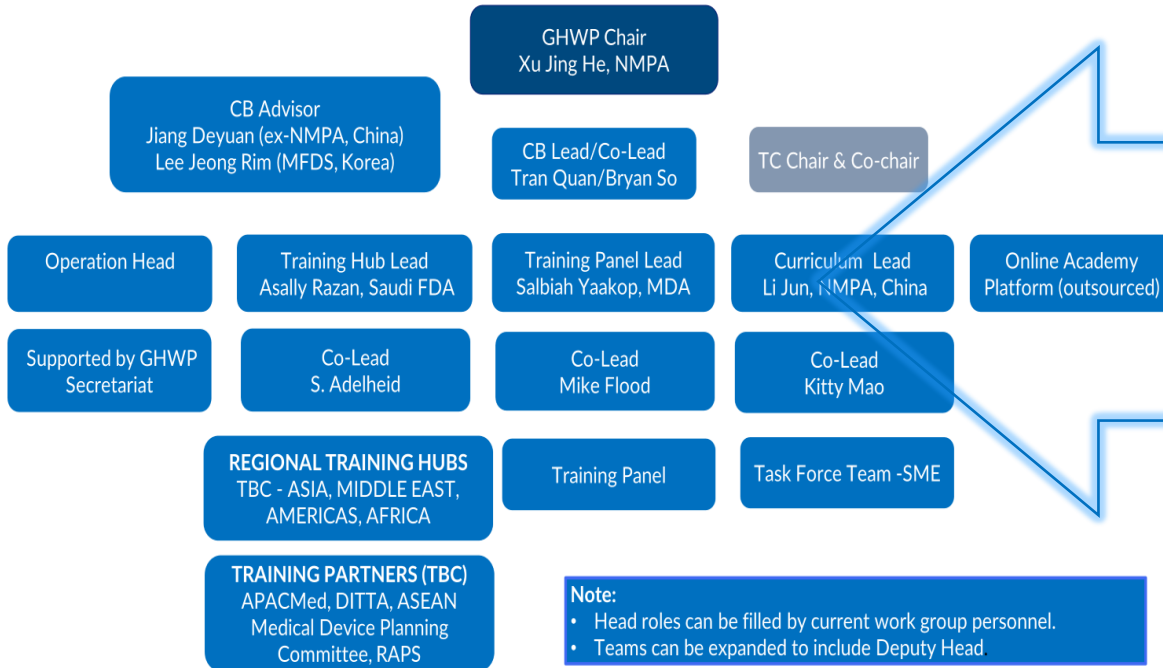
1. Membership expansion(32members as of 2023)
2. Regulatory Convergence ; information sharing, guidance adoption, harmonized regulatory model.
3. Regulatory Science ; SaMD, AI, ML, NGS 3D, Cybersecurity, etc.
4. Regulatory Reliance
5. Capacity Building ; GHWP Academy for regulators and industry
6. Global Partnership ; IMDRF, APACMed, GS1, DITTA, etc.

Expectation from Regulators and Industry

- ✓ Advocate group to promote GHWP to non-members through global network.
- ✓ Information sharing of various knowledge and experience on innovative technology and trend.
- ✓ Training curriculum development and strategy development for capacity building.
- ✓ Support expert trainers, speakers, etc.
- ✓ Network enabler based on established global partnership

Capacity Building

GHWP Capacity Building Structure



Regulators and Industry

- ✓ Develop Capacity Building strategy and roadmap in alignment with GHWP strategy, vision and mission
- ✓ Plan and oversee Capacity Building program development and implementation
- ✓ Support sustainable funding.
- ✓ Plan and develop up-to-date capacity building curriculum for GHWP
- ✓ Plan and develop training curriculum for regulatory authorities / Industry across the globe
- ✓ Others

Value of International Cooperation

Medical Device Reg. Environment

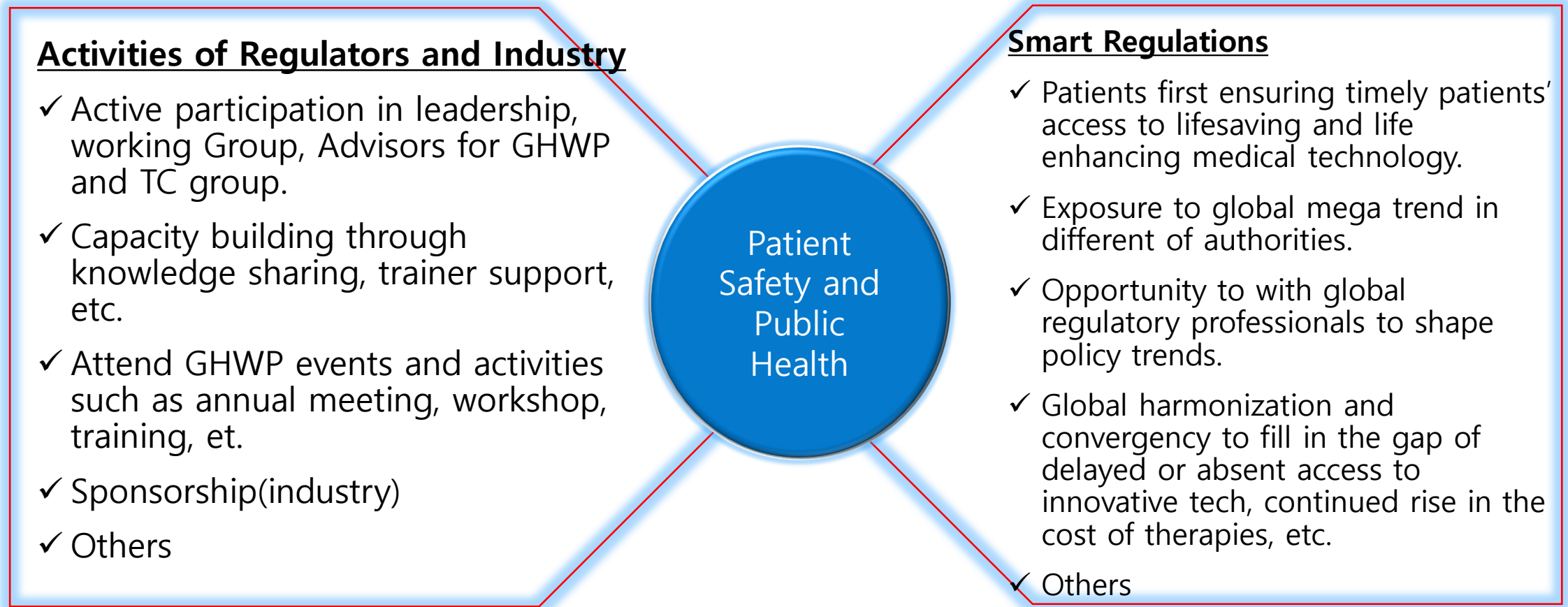
- Regulated industry regardless of business sizes and scope, small to big, low tech to innovations.
- National culture, politics, economy, historical issues, etc. affects the business environment.
- Increasing recognition of medical device as a major future of healthcare sector.
- Regulatory compliance is critical for sustainability.
- Scarcity of resources both human and financial at both Regulators and industry.

Value to Regulators and Industry

- ✓ Int'l org. helps Global mega trend understand different authorities are dealing with an issue.
- ✓ Participating can allow regulatory professionals to work collectively to shape policy trends.
- ✓ Supports a strong reg. system that ensures the safety and effectiveness of devices and promotes patient timely access to lifesaving and life enhancing medical technologies.
- ✓ Harmonization can fill in the gap of delayed or absent access to innovative tech, continued rise in the cost of therapies, etc.

Patient
Safety and
Public
Health

How to contribute global harmonization



감사합니다