Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

Sharing best practices on innovative pathways for changes

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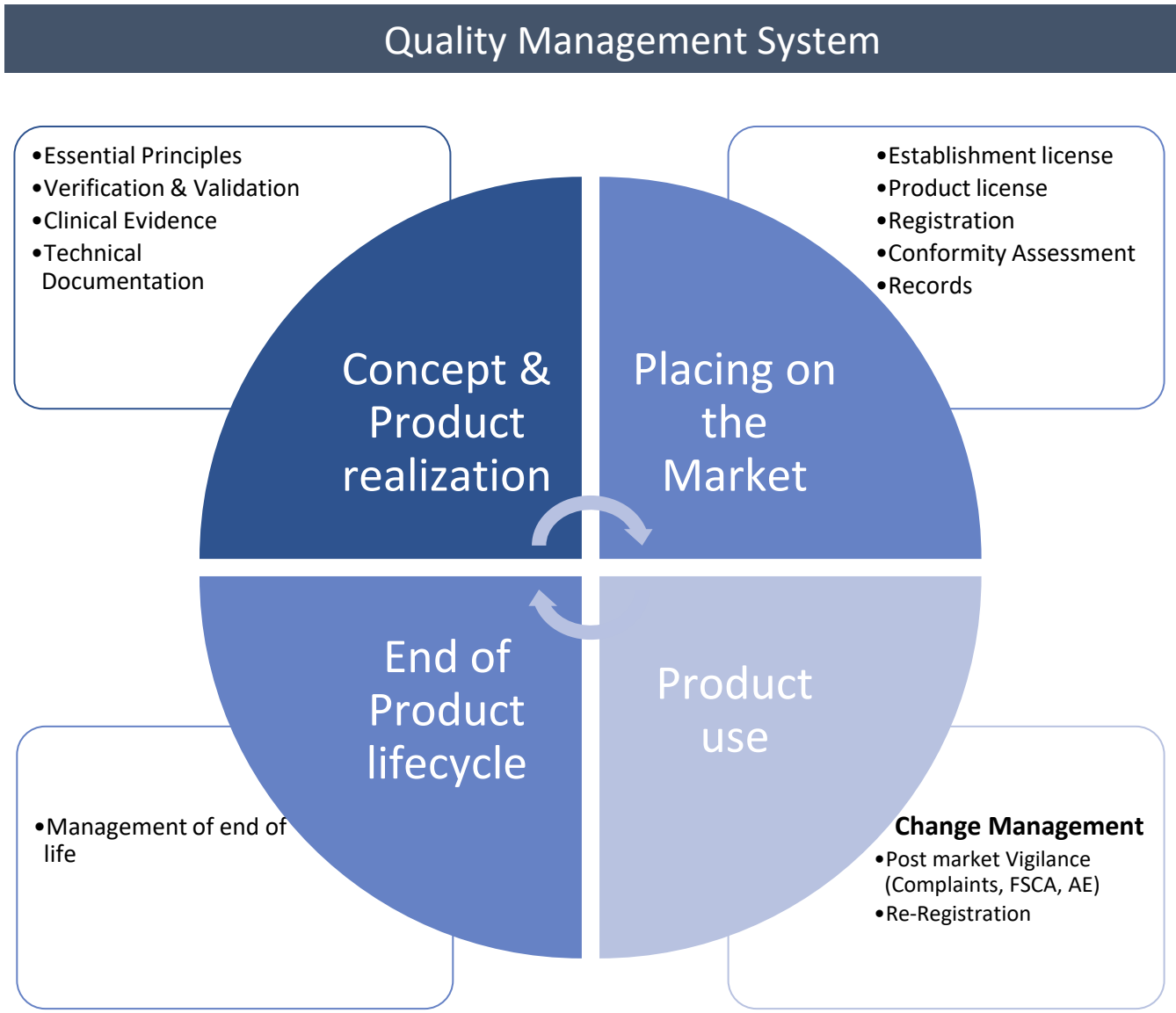
27th GHWP Annual Meeting and 27th GHWP TC Meeting, 27th - 30th Nov 2023
Shanghai International Convention Center

The Medical Device Lifecycle



Need of a fit for purpose Change Management as current regulatory approaches do not cover unique needs of innovative devices such as SaMD, AI, ML

- Change Notification process is worldwide *an important part of the post market surveillance process*
- Currently change management *requirements and procedures* strongly differs across jurisdictions.
- SaMD products are likely to be *updated* on a *regular basis with significant frequency*
- Existing regulatory frameworks have *not* been built to accommodate the *frequent changes* that accompany SaMD products. - “Major” changes require *premarket review* (often taking months of time) prior to implementation.

Benefit of a fit for purpose Change Management

- Enable timely and efficient deployment of product improvements while also ensuring safety and effectiveness
- Streamlined processes - easy to follow
- Avoid lengthy change reviews
- Less workforce and lower costs
- Harmonisation and convergence

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Innovative pathways for changes

A wide range of possibilities. . .

Simplified Change Management

Predetermined Change Control Plans

Software Precertification-Programs

Recognition/Reliance

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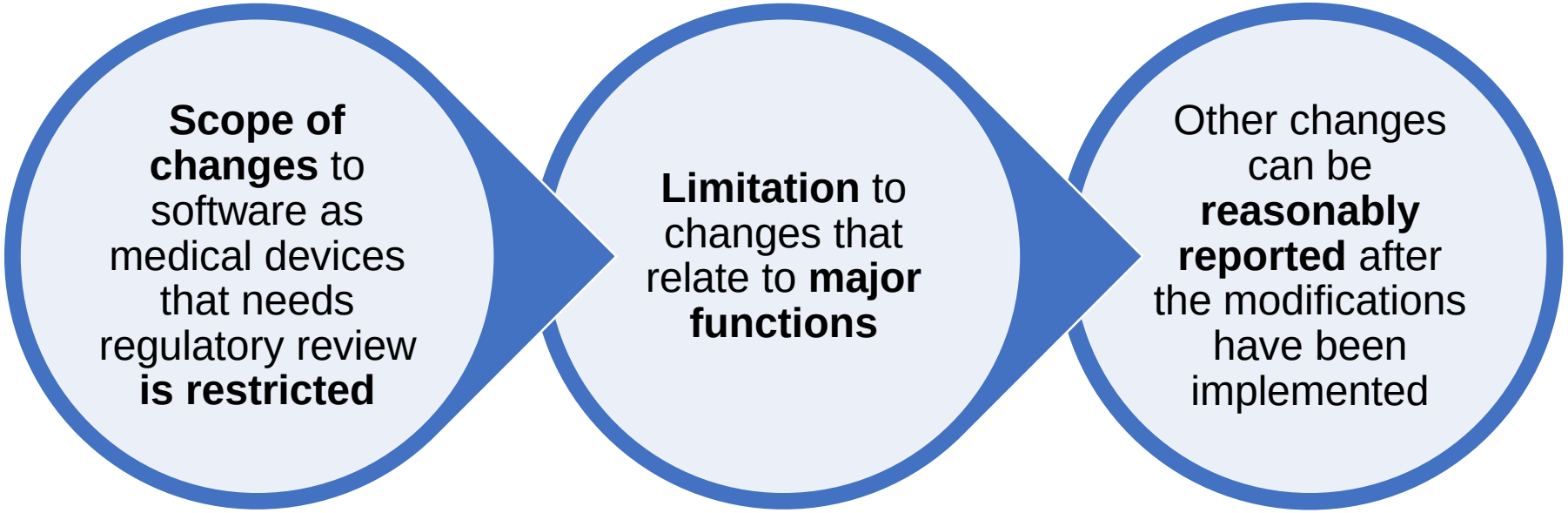
Simplified Change Management of Software as Medical Devices



- analysis algorithms (analysis methods),
- development language,
- operating environment,
- communication functions.

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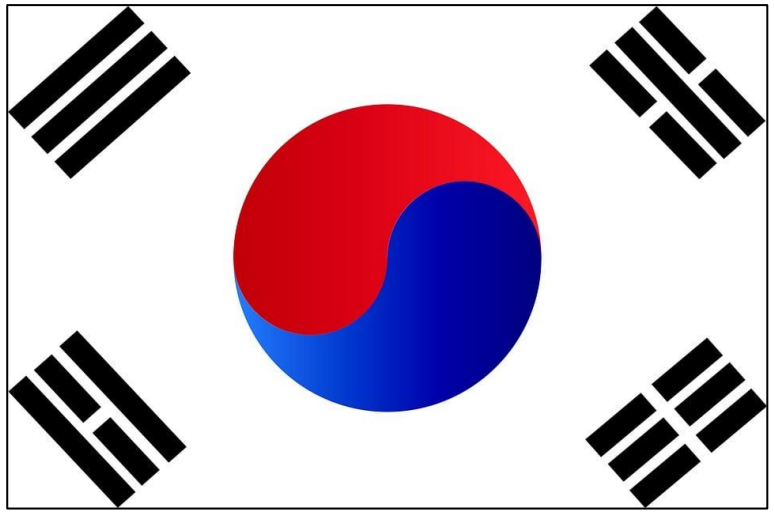
Simplified Change Management of Software as Medical Devices



A change management framework to enable agile modifications while maintaining a high-level of safety.

South Korea - Regulations on Approval, Notification, Review of Medical Devices, June-2023

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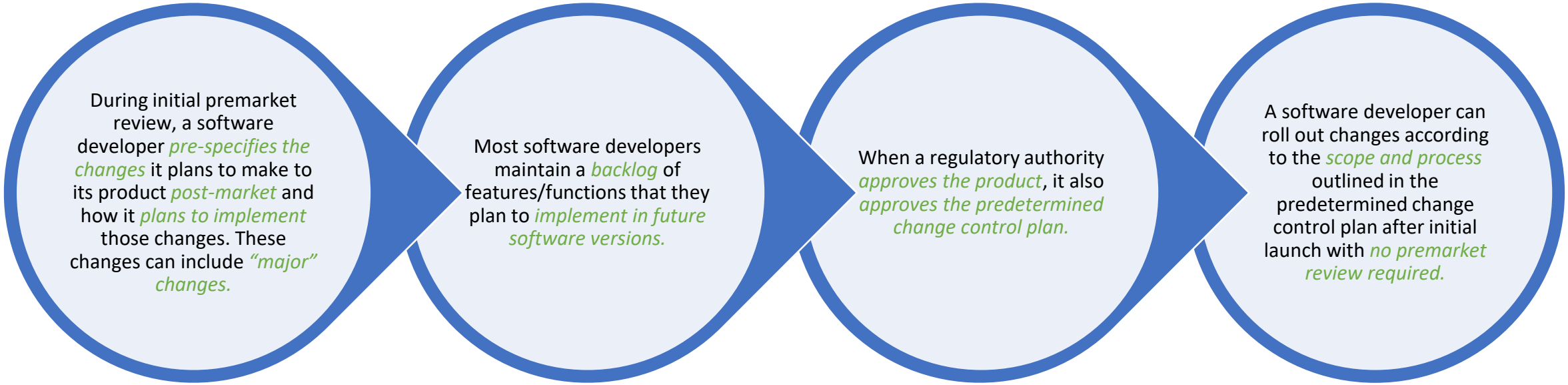
Pre-determined Change Management Protocol (PCMP) of Software as Medical Devices



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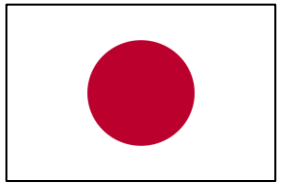
Pre-determined Change Management Protocol (PCMP) of Software as Medical Devices



Japan MHLW/PMDA

IDATEN-*Improvement Design within Approval for Timely Evaluation and Notice*
Post-Approval change Management is introduced to enable continuous improvements

PCCP-US *Draft Guidance* *for Industry and Food and Drug Administration Staff – Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions – April 2023*

Draft Guidance on *Machine Learning-enabled Medical Devices (MLMD)* -
Consultation launched in August **2023** introduces a mechanism for Health Canada to pre-authorize planned changes to address risks through a pre-determined change control plan

(Pre)certification Program

Innovative Medical Devices can be designated by the Regulatory Authority and a manufacturer may be **certified** as an innovative medical device manufacturer by **demonstrating excellence in organization, product development, quality systems**, etc. through an **initial review** of the organization.

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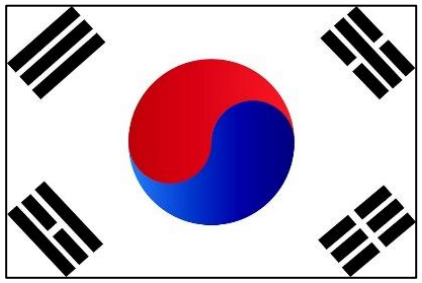
(Pre)certification Program for Innovative Medical Device Manufacturer

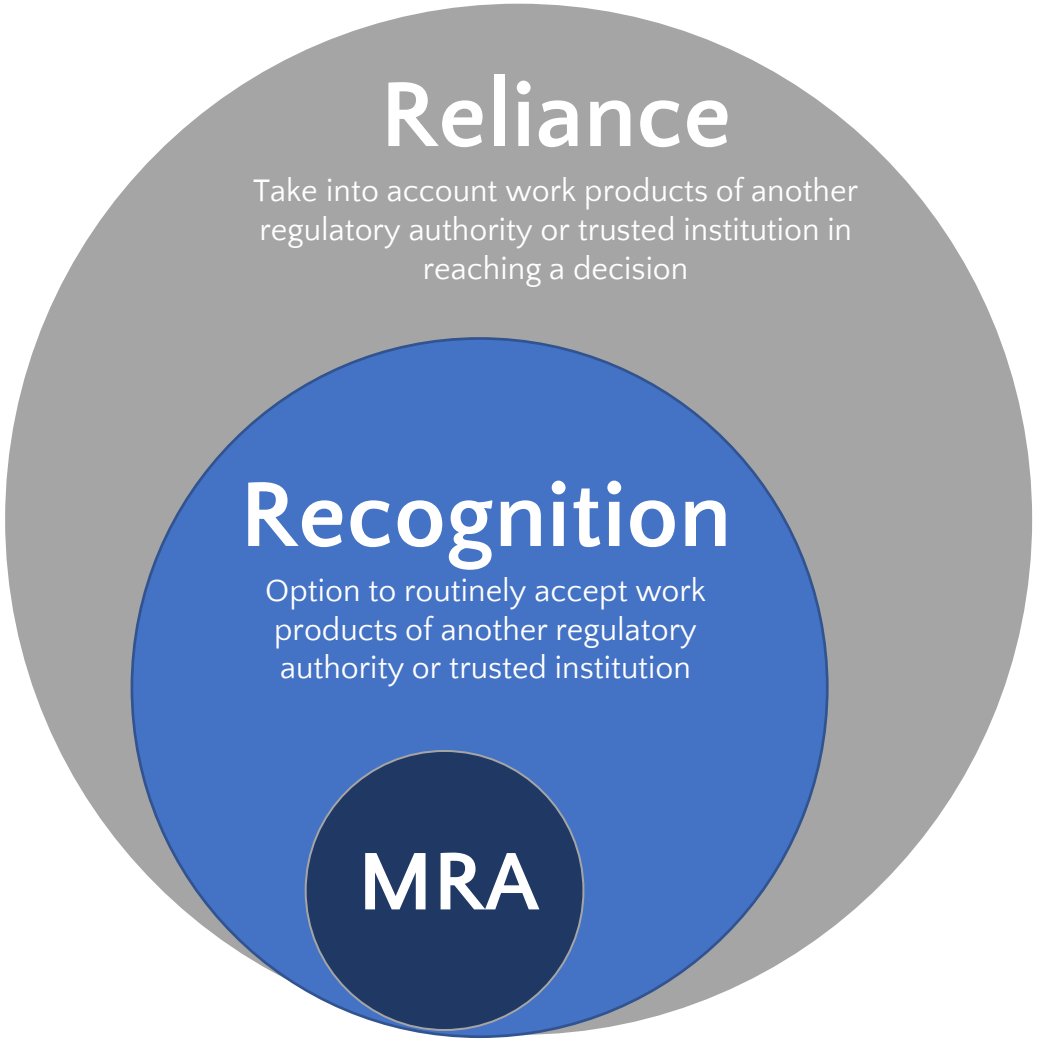


South Korea – Act on Nurturing Medical Devices Industry and Supporting Innovative Medical Devices, February-2022 & Regulations on Special Cases concerning Innovative Software Medical Devices, South Korea, February-2021

US FDA Software Precertification Pilot Program

Reliance/Recognition into the modernized pathway to handle changes

Regulatory authorities recognize change approvals from **a stringent regulator, a comparable regulator, or a reference agency** in order to reduce duplicative efforts, as well as the time and resources needed for review.



Source: https://www.nap.edu/read/25594/chapter/4#26

Reliance/Recognition

TGA recognised overseas market authorisation evidence - new submissions and changes

Regulators / Approvals	Manufacturer Evidence (QMS Certificate)	Evidence of Product Assessment		
		Class 2	Class 3	Class 4 Since Jul 2021
EU IVDD	Annex IV.3	N/A	N/A	Annex IV – Design examination
	Annex VIII	N/A	Annex V – Type Examination	Annex V - Type Examination
EU IVDR	Annex IX (QMS) Chapter I	Annex IX, Sections 4.4 to 4.8 Section 5.1 of Annex IX	Annex IX, Chapter II Section 5.1;	Annex IX (QMS) Chapter II – Design examination
	Annex XI (Production QMS) except Section 5	N/A	Annex X –Type Examination	Annex X -Type Examination
FDA 510(k)	MDSAP Certificate	510(k) Summary	510(k) Summary	Cannot be used
FDA PMA	MDSAP Certificate or PMA	N/A	PMA	
Health Canada	MDSAP Certificate	N/A	Medical device licence Class III	
Singapore HSA		Class B licence	Class C licence Since Sep 2022	
MDSAP	MDSAP Certificate	N/A	N/A	

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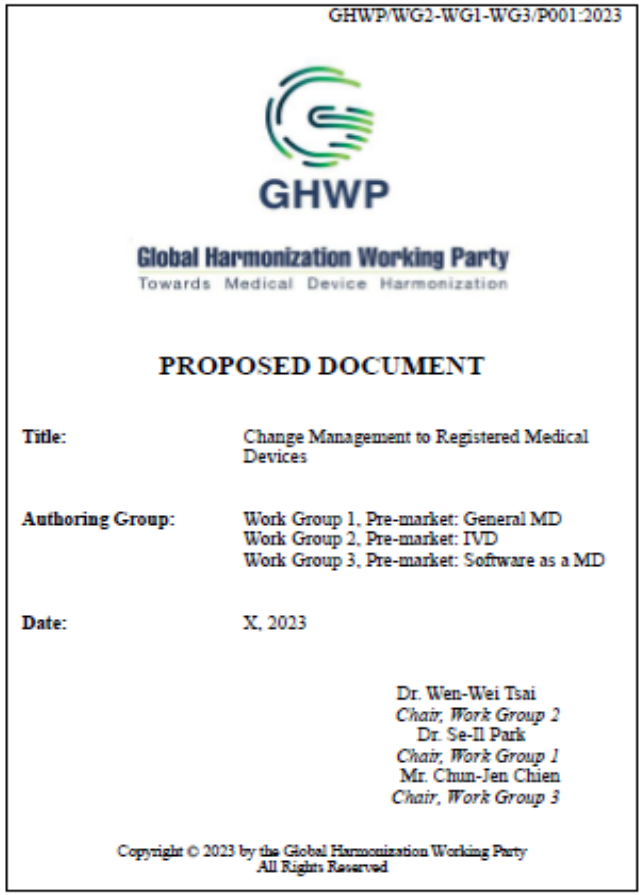

GHWP/WG2-WG1-WG3/P001:2023

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PROPOSED DOCUMENT

Title: Change Management to Registered Medical Devices

Authoring Group: Work Group 1, Pre-market: General MD
Work Group 2, Pre-market: IVD
Work Group 3, Pre-market: Software as a MD

Date: X, 2023

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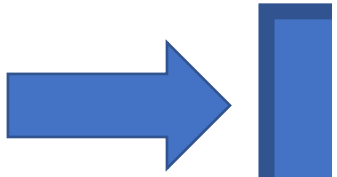

Contents


Thank you!