

# Sharing best practices on innovative pathways for changes

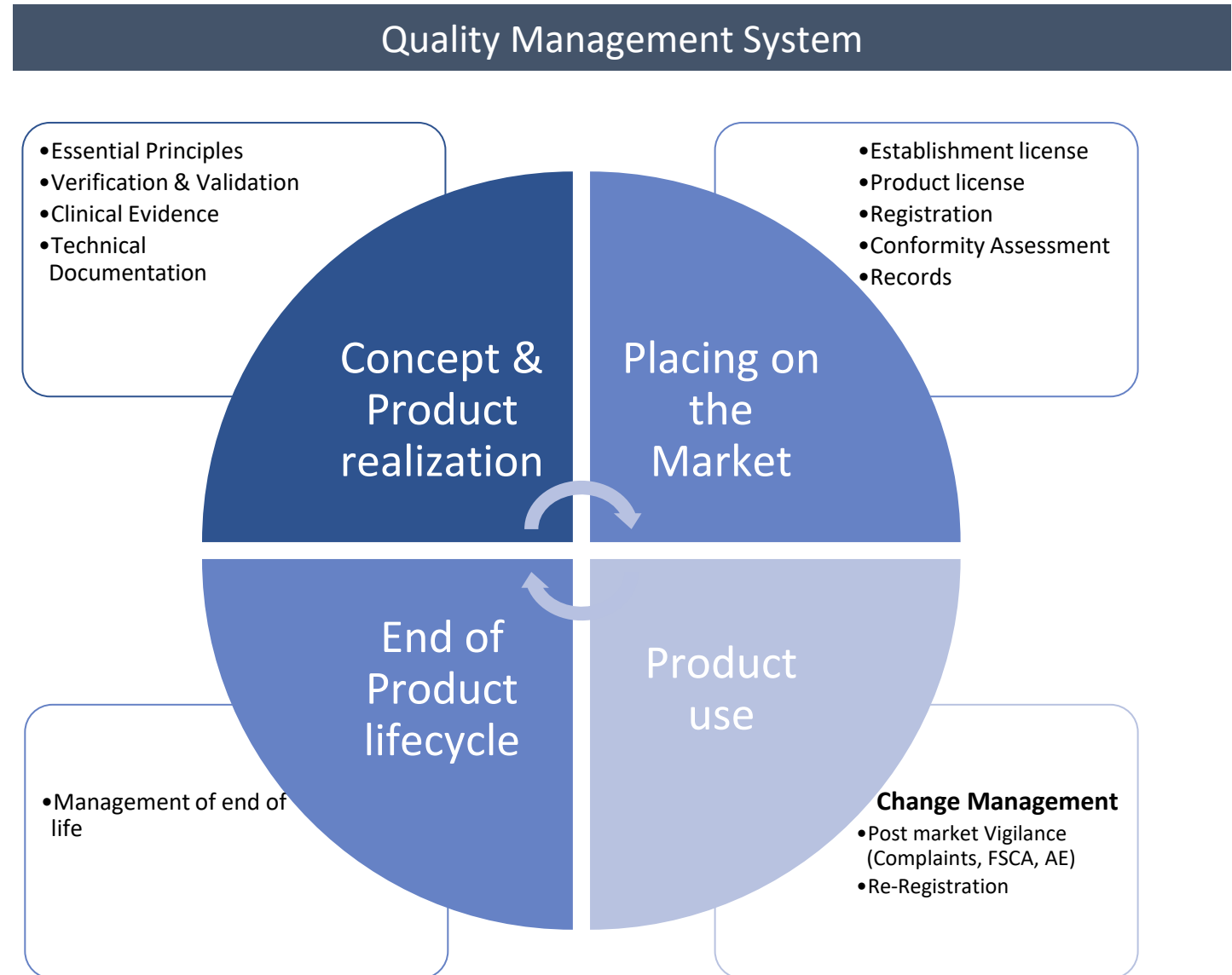
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## The Medical Device Lifecycle





## **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



# Innovative pathways for changes

*A wide range of possibilities. . .*

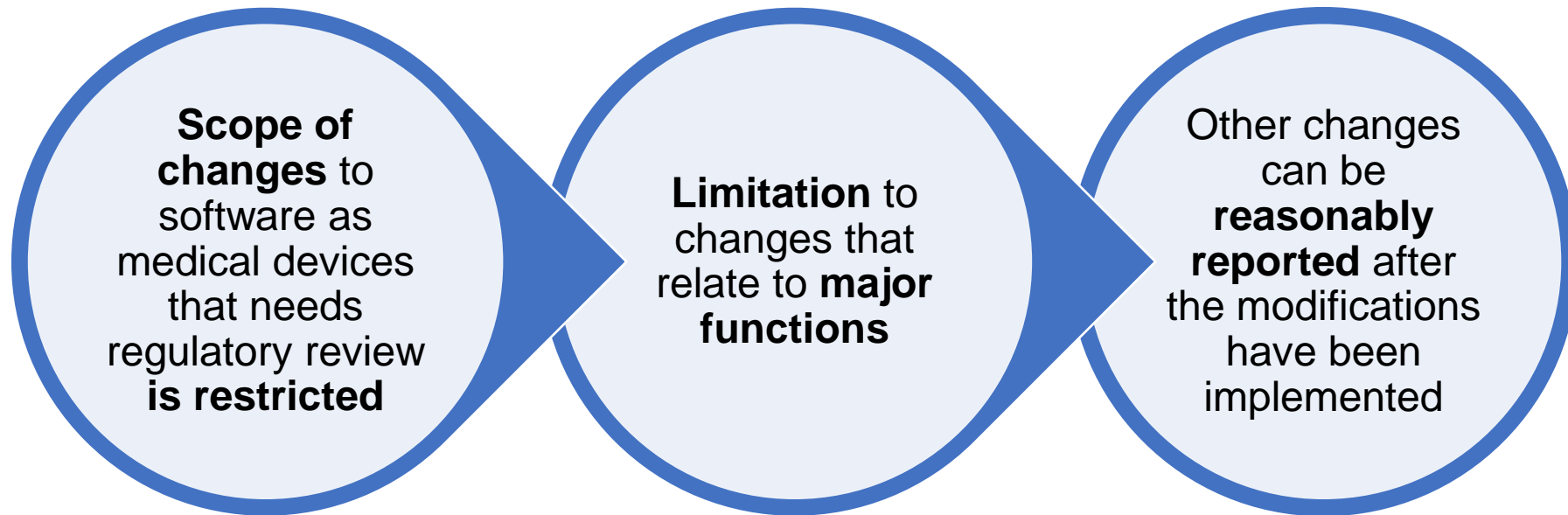
Simplified Change  
Management

Predetermined  
Change Control  
Plans

Software  
Precertification-  
Programs

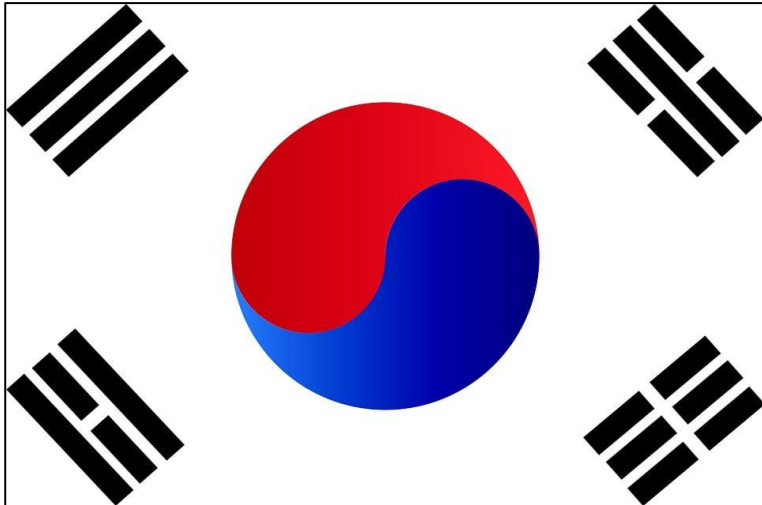
Recognition/Reliance

# Simplified Change Management of Software as Medical Devices



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

# 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*



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

During initial premarket review, a software developer *pre-specifies the changes* it plans to make to its product *post-market* and how it *plans to implement* those changes. These changes can include “*major changes*”.

Most software developers maintain a *backlog* of features/functions that they plan to *implement in future software versions*.

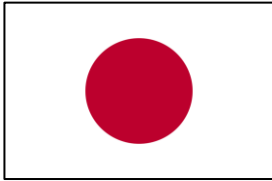
When a regulatory authority *approves the product*, it also *approves the predetermined change control plan*.

A software developer can roll out changes according to the *scope and process* outlined in the predetermined change control plan after initial launch with *no premarket review required*.



# 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**



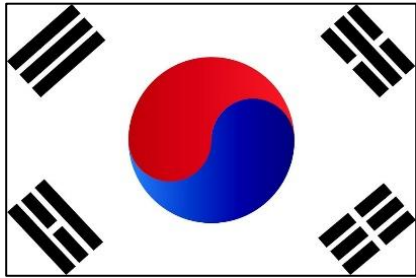
**Draft Guidance on Machine Learning-enabled Medical Devices (MLMD) -**  
Consultation launched in August **2023** introduces a mechanism for Health Canada to pre-authorize planned changes to address risks through a pre-determined change control plan

# (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.

# (Pre)certification Program for Innovative Medical Device Manufacturer



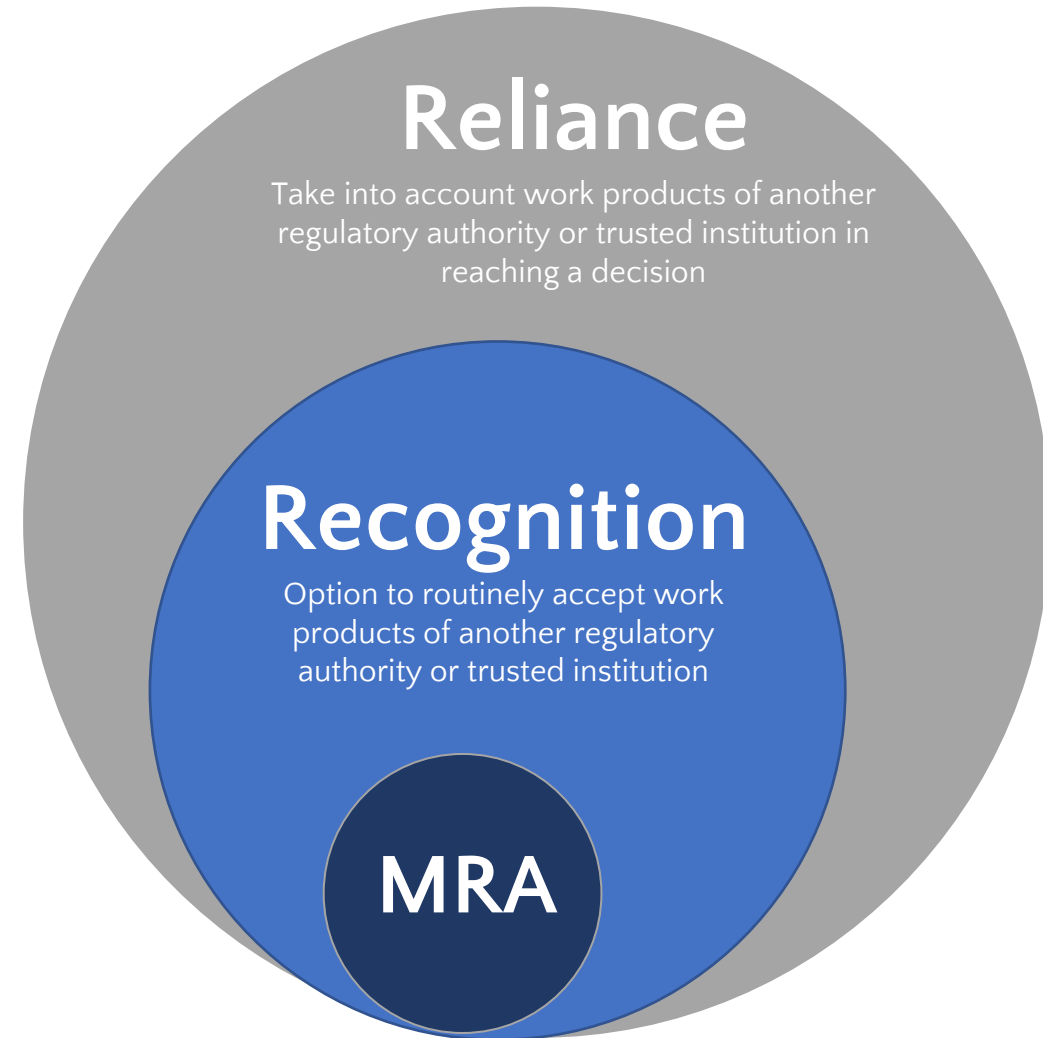
South Korea – Act on Nurturing Medical Devices Industry and Supporting Innovative Medical Devices, February-2022 & Regulations on Special Cases concerning Innovative Software Medical Devices, South Korea, February-2021



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.





## 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 <small>Since Jul 2021</small>
<b>EU IVDD</b>	Annex IV.3	N/A	N/A	Annex IV – Design examination
	Annex VIII	N/A	Annex V – Type Examination	Annex V - Type Examination
<b>EU IVDR</b>	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
<b>FDA 510(k)</b>	MDSAP Certificate	510(k) Summary	510(k) Summary	Cannot be used
<b>FDA PMA</b>	MDSAP Certificate or PMA	N/A	PMA	
<b>Health Canada</b>	MDSAP Certificate	N/A	Medical device licence Class III	
<b>Singapore HSA</b>		Class B licence	Class C licence <small>Since Sep 2022</small>	
<b>MDSAP</b>	MDSAP Certificate	N/A	N/A	



# Global Harmonization Working Party

Towards Medical Device Harmonization

GHWP/WG2-WG1-WG3/P001:2023



Global Harmonization Working Party  
Towards Medical Device Harmonization

## PROPOSED DOCUMENT

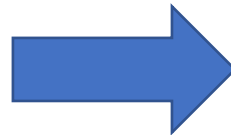
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Change management to registered Medical Devices  
GHWP/WG2-WG1-WG3/P001:2023

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