Health Products Regulatory Conference

Regulating Tomorrow: Approaches for Emerging Trends

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Overview

- Healthcare Landscape and Digital Health Solutions
- Key Regulatory Challenges
- Regulatory Framework and Approaches
- Future Considerations

Healthcare Landscape and Digital Health Solutions

- Singapore's Healthcare Landscape – Singapore as a digital Health Hub
  - Shift from traditional non-connected medical devices towards software-driven integrated healthcare solutions
  - Growing adoption of digital health technologies
  - Increasing connectivity in healthcare delivery

Healthcare Landscape and Digital Health Solutions

Problem

Solution

Benefit

Regulatory Approval

SELENA+ (Singapore Eye LEsioN Analyzer Plus) system

- Traditionally, diabetic patients have retinal photographs taken once a year to detect signs of diabetic eye disease. Retinal images are manually screened which takes 2 to 4 weeks, causing a time lag
- Using AI capabilities, SELENA+ analyses retinal photographs using a deep-learning system to automatically detect three major eye conditions including diabetic eye disease
- Given faster results, this allows clinicians to reach out to patients earlier and make better decisions supported by AI
- First approved by HSA in October 2019 under the Priority Review Scheme

Source: https://www.synapxe.sg/healthtech/health-ai/selena

Key Regulatory Challenges

- Adoption of digital health technologies and shift towards software-driven healthcare solutions brings about new challenges:

Rapid development, update cycles and iterations	Cybersecurity	Validation of AI/Machine Learning Capabilities
Maintaining regulatory oversight while enabling innovation	**Managing evolving security threats and vulnerabilities**	**Demonstrating performance in real-world use**
• Software update cycles shortened to weeks or months vs traditional devices which may take years • Addition of bug fixes and new features that may affect device performance or safety	• Interconnected medical devices being a more attractive target for cyber attacks • Need to protect patient safety, ensure continued device performance • Ongoing security patches in an evolving cybersecurity landscape	• Consistent performance across different patient populations in Singapore's context • Monitoring for performance drift or bias over time as devices learn from new data

HSA's Regulatory Framework and Approaches

Regulatory Controls

- Covers whole medical device life cycle
- Dealer Controls
- Product Controls
- Post-market obligations

Risk Based Approach

- Rule-based classification system
- Products classified at higher risk are subject to greater regulatory control and oversight

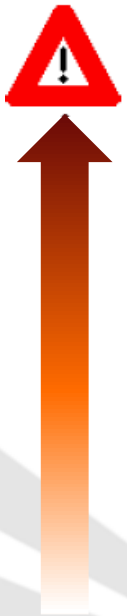
Approaches

- Pathways tailored to complement HSA's regulatory controls
- Total Product Life Cycle (TPLC)
- Change Management Program for Software as a Medical Device (SaMD)

Comprehensive framework aligned with International Medical Device Regulators Forum (IMDRF)

Risk Based Approach

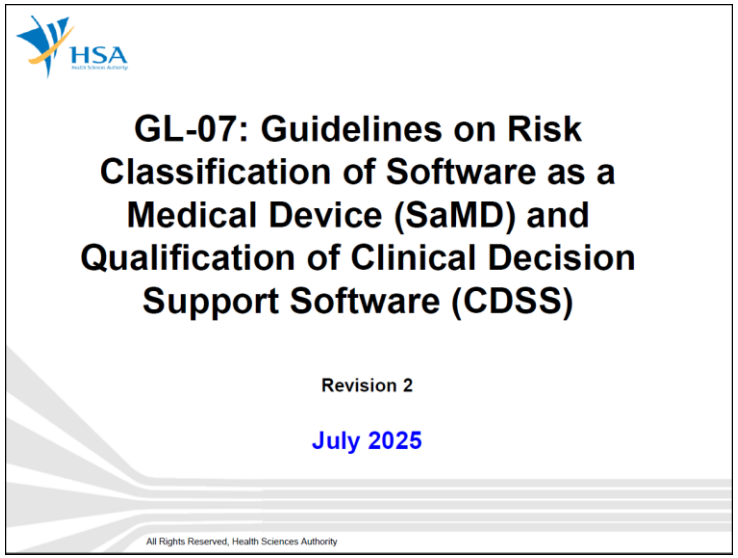
- Using a rule-based classification system that is internationally aligned, medical devices are classified into 4 risk classes, Class A (lowest risk) to Class D (highest risk).
- **Products classified at higher risk are subject to greater degree of regulatory control**



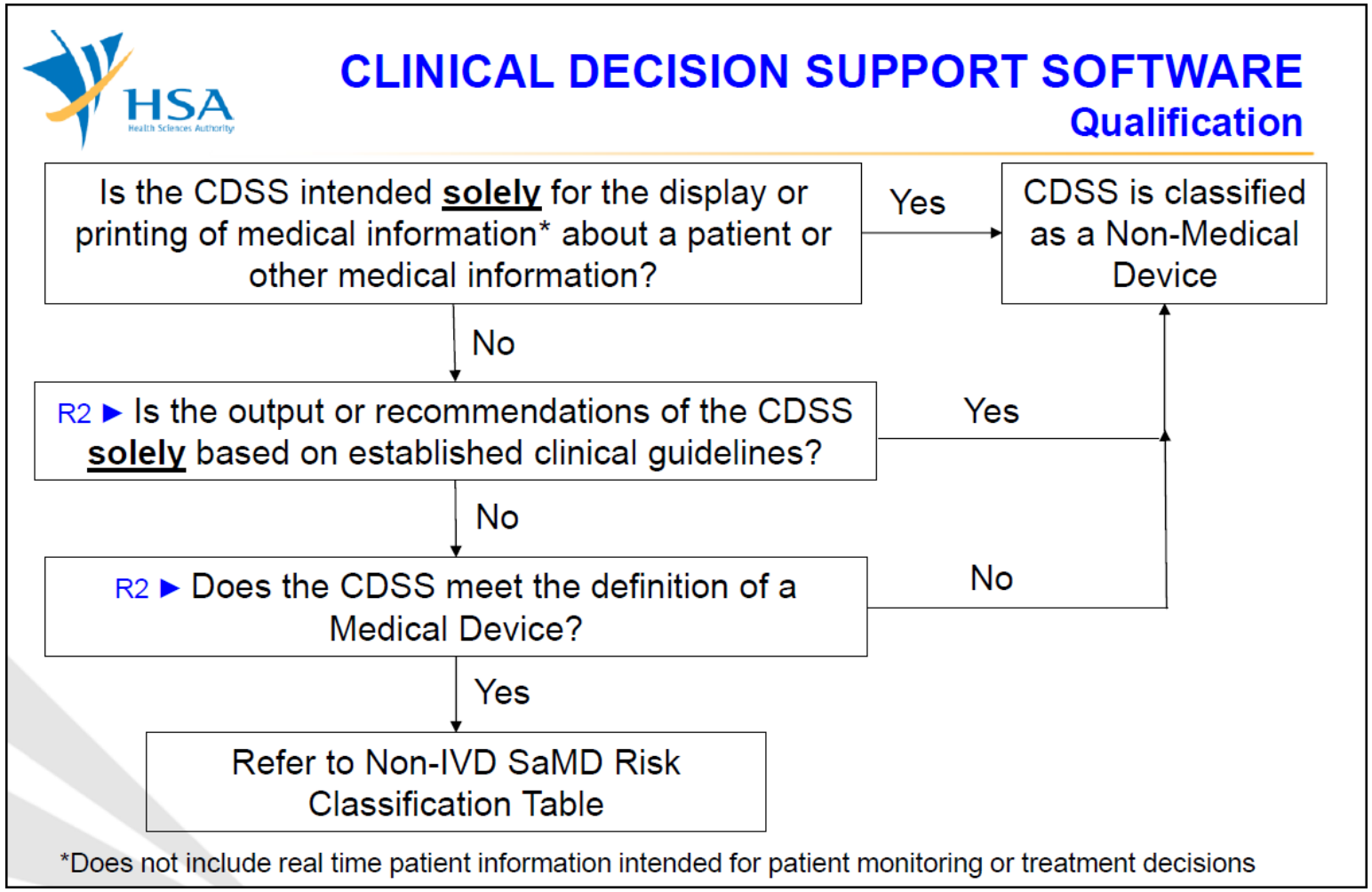
Risk Class	Dealer's Licences	Product Registration	Post-market Obligations
D	Requirement: Conformance to ISO 13485 or SS 620*	Required: Evaluation and registration with HSA	Applicable to all risk classes
C			
B			
A	Requirement: Declaration of conformity to a Quality Management System (QMS)	Not Required: Declared under Class A Medical Device Register	

** Singapore Standard SS 620 : 2016 – Good Distribution Practice for Medical Devices - Requirements*
*** QMS - Quality Management System: ISO 13485 / SS 620 GDPMDS*
**** ASEAN Common Submission Dossier Template*

Guidelines on Risk Classification of SaMD and Qualification of CDSS



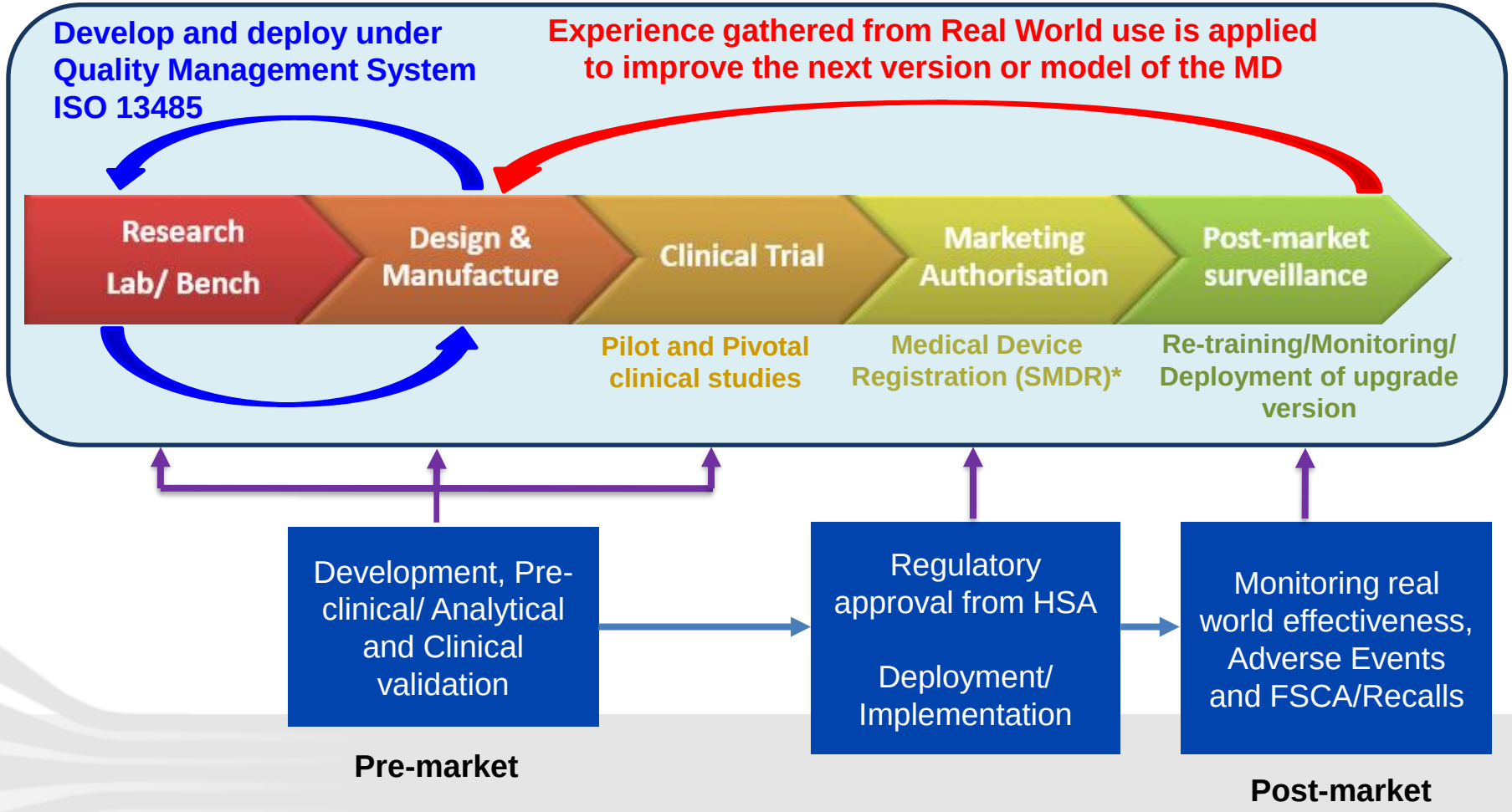
- Revision 2 released in July 2025
- Includes additional criterion (i.e. Output/recommendations of CDSS is solely based on established clinical guidelines) to determine whether a CDSS is considered a non-MD



Ongoing refinement of regulatory framework for digital health

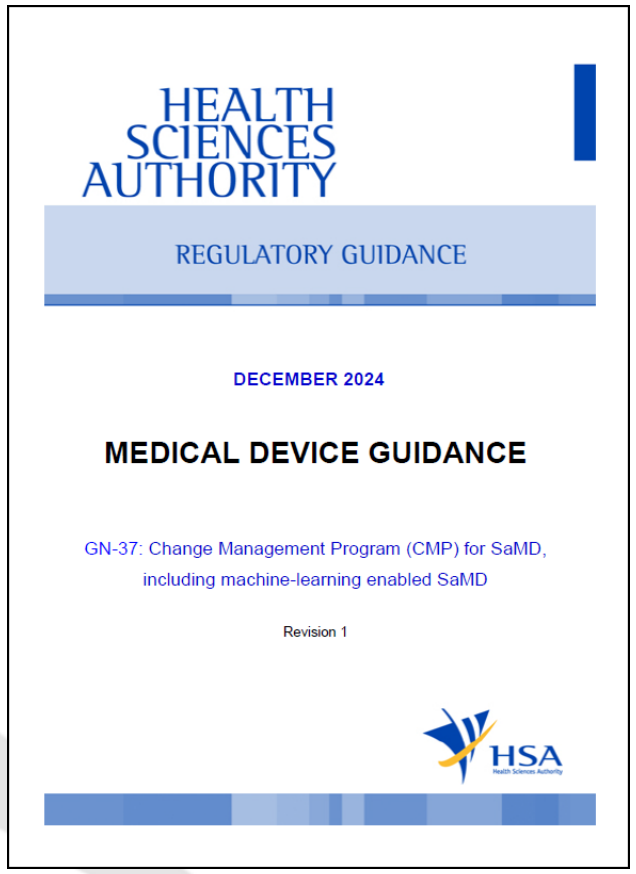
Product Lifecycle Approach

- HSA adopts a **product lifecycle approach** which is especially critical for SaMDs due to their fast iteration processes throughout their useful life.



Singapore Medical Device Register (SMDR) – A register that lists all medical devices registered with HSA

Change Management Program (CMP)


HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

DECEMBER 2024

MEDICAL DEVICE GUIDANCE

GN-37: Change Management Program (CMP) for SaMD, including machine-learning enabled SaMD

Revision 1

HSA

- **Optional** HSA pathway launched December 2024 for faster SaMD updates implementation
- Facilitates changes to all SaMDs including Machine Learning (ML) enabled SaMDs
- Agile regulatory approach designed for the rapid iterative nature of SaMDs
- Pre-specified changes, once approved, can be implemented without separate submissions to HSA
- Assurance of effectiveness and safety through conformity to standards such as ISO 13485 and IEC 62304

New regulatory pathway designed to enable innovation while balancing safety and performance

Change Management Program (CMP)

Faster Time to Market

Implement approved pre-specified updates immediately

Reduced Regulatory Burden

Elimination of multiple Change Notification submissions and associated fees

Clinical Benefit

Bug fixes, feature enhancements and performance improvements can be rolled out rapidly

Enables Innovation

Algorithm improvements and performance optimisation

Operational Benefits

Predictable update cycles and reduced regulatory workload

Future Considerations

Emerging Trends Requiring Regulatory Attention

Advanced AI/ML Applications

- Autonomous diagnostic systems
- Predictive analytics for patient outcomes

Real-World Evidence and Performance Monitoring

- Continuous performance assessment
- Post-market surveillance

Generative AI and Agentic AI

- AI systems generating recommendations
- Autonomous AI agents contributing to clinical decision making

HSA's Approach Moving Forward

Fundamental Principles and Missions remain unchanged

- Patient safety and product effectiveness as core priorities
- Risk-based regulatory approach
- Evidence-based decision making

Key Focus Areas

- Strengthening international collaboration and harmonization
- Developing adaptive regulatory frameworks for emerging technologies
- Supporting innovation through regulatory science

Key Takeaways

Digital Health is Transforming Healthcare

- Rapid adoption of digital health solutions
- New regulatory challenges require adaptive approaches

HSA's Regulatory Agility and Adaptive Framework

- Risk-based approach that evolves with technology
- Adaptive pathways, such as Change Management Program
- Agile regulatory responses to emerging digital health trends

Enabling Innovation While Ensuring Safety

- Faster time-to-market through new pathways
- Reduced regulatory burden without compromising oversight
- Support for industry through collaborative approach

Thank You

Contact information

Click here