Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

Role of standards and risk management for innovative medical devices

Peter W.J. Linders, independent advisor

27th GHWP Annual Meeting and 27th GHWP TC Meeting, 27th - 30th Nov 2023
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Education: Technical Physics (master), physics & mathematics (PhD)
Professional:

- 39+ years in healthcare industry
- Industry rep. in GHTF/IMDRF, GHWP (via DITTA/COCIR)
- Convener for IEC 61262-series (7 parts)
- Convener for IEC 60601-1-1 (medical electrical systems)
- Co-convener for IEC 82304-1 (health software products)
- Chair of CENELEC/TC 62 (2002-2021)
- Chair of ISO/TC 210 (2015-2022)

Key interests:

- Quality, risk management, post-market, health software
- International standards in medical device regulatory processes

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What are innovative medical devices?

What is innovative in medical terms?

Medical innovation speaks to the process of inventing and adopting new ideas or technical functions in the health care industry, which generally includes two key identifiers; desirability and useability of the innovation. 28 Apr 2022

What is a medical innovations definition?

Medical innovation also means increasing knowledge and transforming existing process and business models to better serve changing needs and expectations. Big data, artificial intelligence, and other technologies are fueling a wave of health innovations around the world.

What are innovative medical devices?

https://www.medicalengineers.co.uk/10-groundbreaking-medical-device-innovations

1. Wearables
2. Medical Robots
3. Telemedicine
4. Immersive Technology (VR, AR, XR, …)
5. 3D Printing
6. Artificial Intelligence
7. Smart bandages
8. Cybersecurity
9. Minimally Invasive Devices
10. IoT and Wearables in Healthcare

What are innovative medical devices?

Let's conclude that:

1. innovative medical device implies unknowns (technology, materials, medical application, …);
2. existing (safety) standards are deficient, by default;
3. so … full-blown risk management is tough if you only use requirements from existing (safety) standards.

What is medical device innovation?

What are the four important stages of the medical device innovation process?

- Phase 1: Device Discovery and Risk Analysis. ...
- Phase 2: Formulation, Concept, and Feasibility. ...
- Phase 3: Design and Development – Verification and Validation. ...
- Phase 4: Final Validation and Product Launch Preparation. ...
- Phase 5: Production, Market Introduction, and Post-Market Follow-Up.

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Expectation from medical device?

We expect medical devices to be:

- EFFECTIVE
- SAFE
- affordable
- available
- …

Focus on Effectiveness & Safety

We expect medical devices to be:

- EFFECTIVE
- SAFE
- affordable
- available
- …

- Thorough understanding of medical application (“intended use”)
- Consulting medical experts
- Robust design
- Lab testing
- Clinical evaluation

- Safety by design
- Safety by risk controls
- Safety by warnings or labeling
- Learn from safety standards
- Continuous surveillance
- …
- **Comprehensive risk management**

What was risk again?

3.18
risk
combination of the probability of occurrence of *harm* (3.3) and the *severity* (3.27) of that *harm* (3.3)

[SOURCE: ISO/IEC Guide 63:2019, 3.10, modified — Note 1 to entry deleted.]

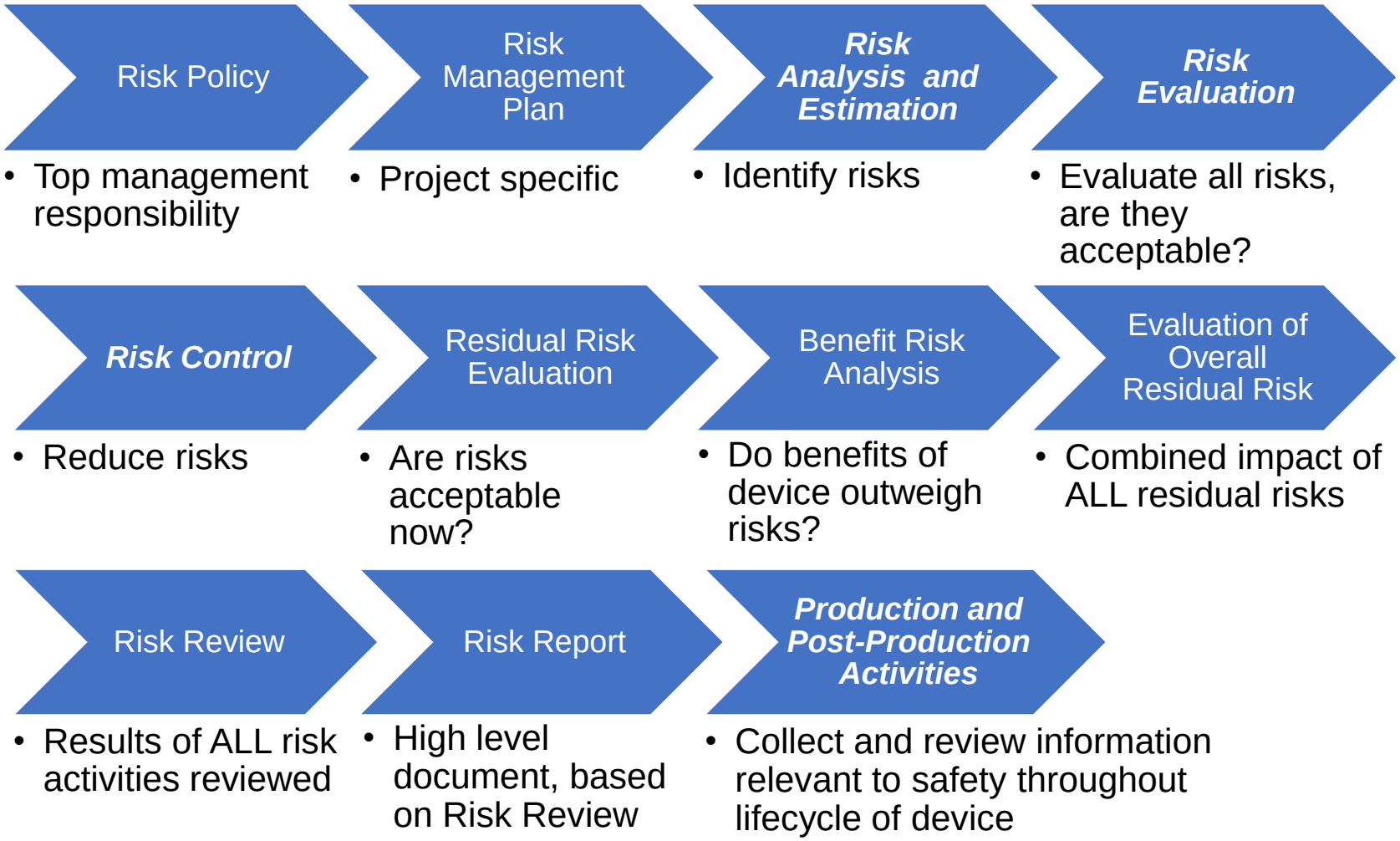
Definition from ISO 14971

Where to consider risk?

*Throughout Total Product Life Cycle**

** Includes decommissioning/disposal*

Overview of risk management



Let's talk "Comprehensive"

Remember?

- Safety by design
- Safety by risk controls
- Safety by warnings or labeling
- Learn from safety standards
- Continuous surveillance
- …
- **Comprehensive risk management**

When speaking about **Comprehensive risk management**, don't forget (as applicable):

- **Documentation** (symbols, IfU, installation manuals, help screens, …)
- **Training** (of users, caregivers, installation engineers, …)
- **Maintenance** (including daily & preventive maintenance, spare parts, repair, …)
- **Disposal/decommissioning** (including data retention and data removal)

and include this in post-market surveillance !!

About the role of standards …

- Standards can play a V.E.R.Y. important role in (regulatory) conformity assessment
- International standards can play a key role in converging regulatory practices
- Luckily, GHWP has a final document on the Role of Standards …

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Fortunately, there is a 2008 GHTF document still available on the IMDRF website:

https://www.imdrf.org/sites/default/files/docs/ghtf/final/sg1/procedural-docs/ghtf-sg1-n044-2008-standards-in-assessment-of-medical-devices-080305.pdf

Role of Standards in the Assessment of Medical Devices
Study Group 1 Final Document GHTF/SG1/N044:2008

About the role of standards …

Rationale (of GHTF/SG1N044:2008)

International consensus standards are a tool for harmonizing regulatory processes to assure the safety, quality and performance of medical devices. This document provides guidance on the use of standards by a manufacturer when demonstrating the device conforms to relevant essential safety and performance principles.

Purpose (abbrev. & slt. reworded)

1. encourage development of intl. consensus standards for use with ‘Essential Principles’;
2. encourage manufacturers to conform with appropriate international standards;
3. persuade Regulatory Authorities to recognize standards that provide manufacturers with **a** method of demonstrating conformity with ‘Essential Principles’;
4. support concept that use of these standards is voluntary.

ISO documents for risk management

ISO published two key documents for medical device risk management:

INTERNATIONAL STANDARD **ISO 14971**

Medical devices — Application of risk management to medical devices

QUIZZ

Do these documents provide that comprehensive, all-encompassing checklist?

application of ISO 14971

Dispositifs médicaux — Recommandations relatives à l'application de l'ISO 14971

Second edition
2020-06

Regulation of innovative devices …

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Agile regulatory rules vital to foster future innovation

Medicines, diagnostics and AI can combine to save lives – here's how to ensure new products reach patients without compromising on safety.

https://www.politico.eu/sponsored-content/agile-regulatory-rules-vital-to-foster-future-innovation/

- How do legislators write rules today that can keep pace with the innovations of tomorrow?
- Artificial intelligence (AI) and big data, wearables and genomics — these are among the most disruptive and unpredictable fields in modern science
- They are among several cutting-edge trends that converge in medical research
- A "regulatory sandbox" optimizes the chances of bringing true innovation to patients in a timely manner, without compromising on quality, safety or efficacy

Regulatory sandbox ??

A regulatory sandbox is a space, crafted and controlled by a regulator, designed to allow the testing of novel products or processes to be conducted under supervision prior to their full entry into the marketplace.

Canada federal regulations

However, be aware of intellectual property rights, patents, etc.
Non-disclosure agreements may be needed.

https://www.canada.ca/en/government/system/laws/developing-improving-federal-regulations/modernizing-regulations/what-is-a-regulatory-sandbox.html

Regulatory sandbox ?

At the recent IMDRF meeting, a session was devoted to Regulatory Sandboxes

Check the 75-page slide deck at:

https://www.imdrf.org/sites/default/files/2023-10/Regulatory%20toolboxes%20to%20foster%20innovation.pdf

How good are standards ??

Standards are good, yet not perfect:

- Present comprehensive information about safety (and performance)
- Represent state of the art (*at the time crafted or revised*);
- May not have been "optimized" for regulatory use *.

So …:

- *use applicable safety requirements from existing standards, AMAP;*
- *critically think about the elements missing in existing standards;*
- *carefully design post-market surveillance;*
- *be fully prepared before meeting your CAB, or entering a sandbox.*

* *we'll talk more about that in the next slide*

How good are standards ??

In 2018, IMDRF published:

- *IMDRF WG lead by EU and US*
- *Regulators and industry*

https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-181105-optimizing-standards-n51.pdf

Final Document

Title: Optimizing Standards for Regulatory Use

Authoring Group: IMDRF Standards Working Group

Date: 5 November 2018

Yuan Lin, IMDRF Chair

Summary conclusions

- Innovative device implies unknowns: for risk management, merely following safety checklists isn't enough
- Use of existing international (safety) standards is an excellent start
- Post-market surveillance and use of "real-world data" are key!
- The same applies to standards: they need to be kept current with user input
- GHWP's voice deserves to be heard more in standards development

Summary recommendations - 1/2

My humble suggestions:

- be(come) active in standards development in ISO and IEC;
- study the IMDRF document "improving standards for regulatory purposes" and convey the key messages to standards development committees;
- coordinate and exchange experience within GHWP to the max: with so many member economies, GHWP can have a clear impact on new or revised standards;
  - *for QMS, GHWP WG7 (incl. WG 6) should be focal point;*
  - *for PMS, GHWP WG4 should be focal point;*
  - *for all other topics: WG8 to set up dedicated subgroups organised per standard to study its content and develop recommendations for users and/or amendment (with at least one regulator or CAB-expert in each).*

Summary recommendations – 2/2

My humble suggestions:

- be(come) active in standards development in ISO and IEC;
- GHWP should aim for developing a list of "identified" standards deemed useful for regulatory purposes among GHWP member economies;
- Examples where GHWP can and should be actively involved:
  - *upcoming revision of IEC 60601-1 to Ed. 4 in IEC TC 62*
  - *survey on thoughts about of ISO 13485 (also on LinkedIn *)*
  - *new work on PMS in ISO/TC 210*
  - *project 5137 on equipment maintenance for HDOs*

* https://www.linkedin.com/feed/update/urn:li:activity:7127674956569579520/


謝謝
Thank You