10th Meeting (Hybrid)

14.03. 24

Role of manufacturers in ensuring quality, safety & performance

Fatemeh Razjouyan, Director of regulatory policy, international and harmonization; Medtronic

Tammy Steuerwald, Global Head of Regulatory Policy, Foundational Principles & Supranational Organizations; Roche Diagnostics

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Regulators and manufacturers are committed to timely patient access to safe, effective, and quality MD/IVDs

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Conformity assessment is essential for the healthcare ecosystem

- MD/IVDs are:
  - ✓ Safe
  - ✓ Perform as intended
  - ✓ Conform to the Essential Principles of Safety and Performance for MD/IVDs

Conformity assessment is fundamental to MD/IVD integrity and reliability

1. Quality management system (QMS)
2. System for postmarket surveillance
3. Technical documentation
4. Declaration of conformity
5. Registration of manufacturers and their MD/IVD by regulatory authority

https://www.imdrf.org/sites/default/files/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n78-2012-conformity-assessment-medical-devices-121102.pdf

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A robust QMS: our license to operate

Compliance

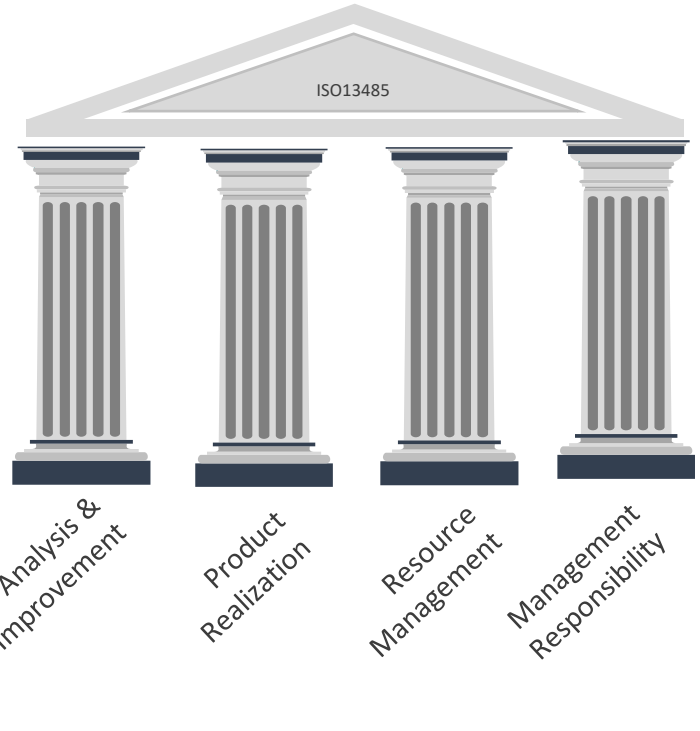
Laws, regulations & relevant essential principles of safety and performance is crucial

Closed-loop QMS:

Ensuring continuous control & improvement (e.g., supplier release controls)

International standards:

MDSAP & ISO 13485 serve as benchmarks for QMS in regulatory alignment



Controlled development:

QMS confirms our MD/IVDs are developed in controlled & safe environment

Business operations

Supports robust business operations, integrating post-market surveillance for lifecycle management

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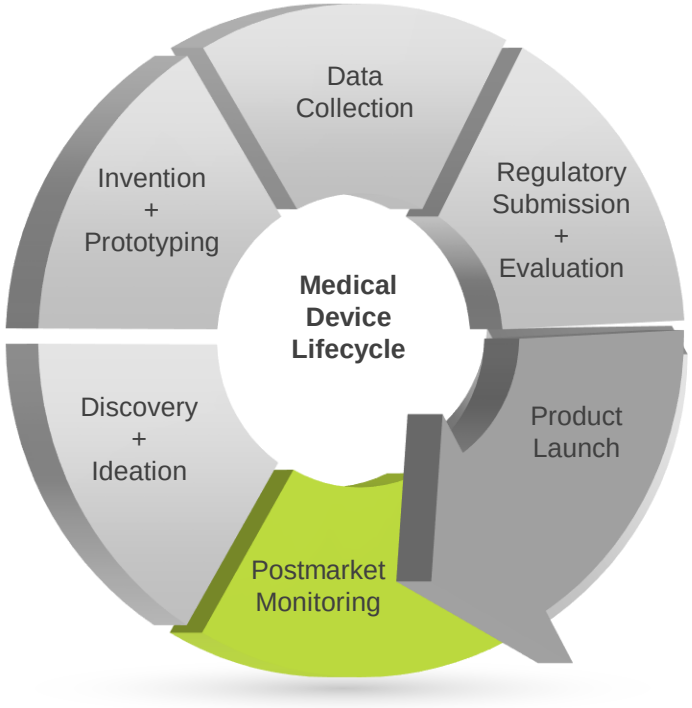
Postmarket surveillance: monitoring MD/IVD performance in real world

Continuous postmarket surveillance is required and vital for safety and generates learning to improve current and future products

Manufacturers are required to document complaints and determine if an investigation is needed and determine reportability in each jurisdiction

Our TPLC approach ensures vigilant tracking of product performance from launch through postmarket activities



Technical documentation validates our MD/IVD safety and compliance

Crucial for demonstrating compliance with Essential Principles of Safety and Performance

Includes development, design, and manufacturing processes

Shows how MD/IVD meets safety and performance standards & postmarket monitoring plan

NRA/CABs review to assess whether documented evidence supports claims of conformity for its intended use & environment

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We maintain other key technical documents to ensure thorough documentation and compliance

Design history file

Shows MD/IVD design & changes & includes records necessary to demonstrate design was developed in accordance with approved design plan & requirements of QMS

Design master record

Contains information needed to build and test MD/IVD (e.g., packaging and labeling specifications, servicing procedures, design specifications, etc.)

Design history record

Contains records that track actual production of each device, from manufacturing dates to quality control measures

Declaration of conformity and registration are also part of conformity assessment

Declaration of conformity (DOC)

- Is manufacturer's formal attestation that MD/IVDs meet applicable standards and regulatory requirements
- Includes information on device identification, classification, compliance with safety and performance principles, and labeling instructions

Registration by NRA

- Is the regulatory control for medical devices
- Manufacturers must provide necessary information for registration and listing before placing MD/IVD on the market

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Resource drain of conformity work?

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Without sufficient regulator bandwidth, patient access to lifesaving medical devices will be highly impacted

~75%

One study revealed that, “[a]bout 75% of regulatory authorities are unable to perform all core functions consistently well and depend often on better resourced authorities.”[1]

Lack of regulatory capacity, “[h]ampers efforts to ensure the quality, efficacy and safety of health products.”[2]

These constraints become even more visible during a public health emergency and may have a direct adverse effect on patient access to potentially lifesaving medical treatments and diagnostics

1. Global regulatory agility during covid-19 and other health emergencies; Enhanced collaboration among authorities is key to ensuring timely access to high quality health products worldwide. Accessed April 3, 2021.
2. Roadmap for access to medicines, vaccines, and other medical products. 2019-2023. Accessed May 9, 2021.

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Sufficient legal foundation and international alignment improves access

Good Regulatory Practices (GRP):

- Mandates a whole-of-government policy for developing technical regulations across all sectors, ensuring regulations are consistent, high-quality, and economically viable
- Serves as a quality control mechanism for developing regulations, aligning national regulations with international standards, and minimizing economic restrictions
- Facilitates economic growth as it ensure products are safe and effective to the same high standards and can easily be exported

World Trade Organization – Technical Barriers to Trade (WTO/TBT):

- Aims to prevent technical regulations from becoming discriminatory trade barriers while allowing measures for legitimate objectives like health and environmental protection
- Encourages basing measures on international standards to streamline global trade and maintain a predictable trading environment through transparency

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“The future of medical products regulation is in convergence/ harmonization, collaboration, and networking based on Reliance and trust.”[1]

Reliance is not a less stringent form of regulatory oversight or outsourcing of regulatory mandates, nor does it compromise independence [2]

A decision to “regulate through reliance” is the hallmark of a modern and efficient regulatory authority [2]

Reliance applies to the total product lifecycle (e.g., product approvals and inspections)

1. Azatyan, S., MD, PhD. WHO Good Reliance Practices guidelines to support regulatory decision making [Conference Presentation], https://www.interamericancoalition-medtech.org/regulatory-convergence/wp-content/uploads/sites/4/2021/08/OMS.pdf, slide 17.
2. Good Reliance Practices in the Regulation of Medical Products, Annex 10, https://www.wto.org/english/tratop_e/trips_e/techsymp_290621/gaspar_pres3.pdf.

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Examples of existing Reliance frameworks for MDs/IVDs

Medical Device Single Audit Program (MDSAP)

- A single regulatory audit satisfies the requirements of multiple regulatory jurisdictions

Australia TGA's Reliance

- TGA has relied on certifications from NB and Health Canada Medical Device Active License Listing ("MDALL") since 2010
- In 2018, reliance was expanded to other regulators such as Japan and the U.S.

Singapore's Abridged Pathway

- Applies to all classifications requiring regulator review & significantly reduces time to market
- Shortens the review time from 310 days to 220 days for class D higher-risk products
- Reduces the required information for review
- Reference regulators include Australia, Canada, Europe, Japan, and the US

Singapore – Thailand Reliance Program

- Initially piloted with only class D/class 4 products; is now open to all classes of medical devices
- Reduces the review time to 60 days (the TFDA review times for class 2, 3, and 4 devices for standard applications can be up to a year)

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How Reliance can be applied to conformity assessment to accelerate patient access to innovative and life-saving MDs/IVDs

1

Apply Reliance to total product lifecycle

- Leverages key regulatory decisions, such as inspection, premarket approval, and postmarket change approval performed by regulatory authorities, Notified Bodies, and recognized institutions
- E.g., recognizing and fully relying on MDSAP and ISO 13485

2

Implement & rely on internationally recognized consensus standards

- Facilitates acceptance of testing to a collection of harmonized standards thus streamlining the conformity assessment process

3

Implement IMDRF recommendations

- Facilitates Reliance by driving convergence (e.g., adopting IMDRF best practices, IMDRF essential principles of safety performance of medical devices and IVD)

4

Accept harmonized and electronic formats & signatures

- One dossier format (e.g., IMDRF Table of Contents)

5

Minimize the need for juristiction-specific clinical data

- Directly accept clinical data that's sufficiently diverse to eliminate duplication

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A globally harmonized approach benefits all stakeholders

1 Patients

- Timely access to life saving MDs/IVDs
- Confidence in safety and quality of MDs/IVDs
- Innovative products – development and time to market

2 Health Authorities

- Patient safety
- Pandemic preparedness
- Fostering innovation
- Leverage resources
- Collaboration
- Efficiencies
- Postmarket monitoring
- Facilitates reliance

3 Industry

- Promotes a transparent, efficient, and predictable regulatory environment
- Supports innovation driven by patient needs
- Reduces regulatory redundancy that pulls resources away from research & development

THANK YOU

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