The manufacturer's role in ensuring quality, safety & performance

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

Conformity assessment provides confidence in safety & performance

- 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. **Postmarket surveillance system**
3. Technical documentation
4. Declaration of conformity
5. Manufacturers and device registration

https://www.imdrf.org/sites/default/files/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n78-2012-conformity-assessment-medical-devices124102.pdf

A robust QMS: our license to operate

Compliance

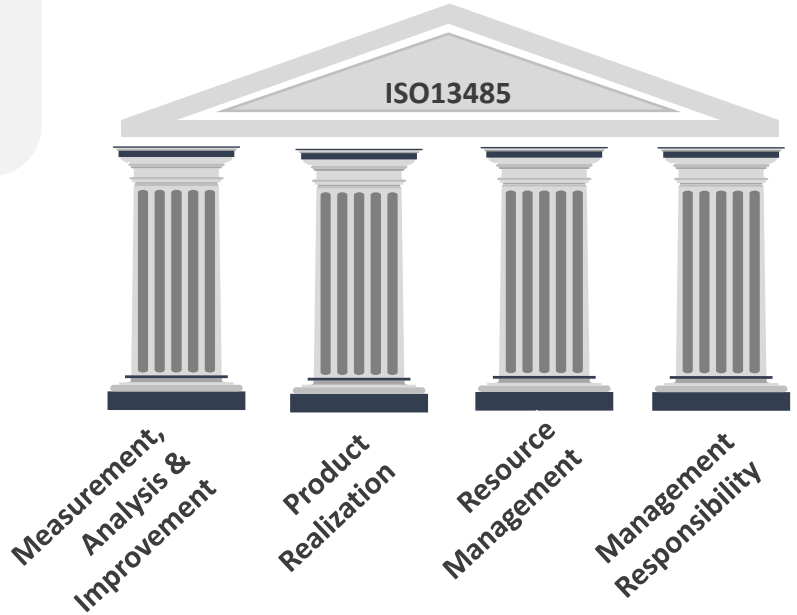
Laws, regulations & relevant essential principles of safety and performance is crucial

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

QMS covers the full product lifecycle

Management
Evaluates top management's responsibility, quality policy, planning, resource management, and organizational structures

Design & Development
Audits full product lifecycle, including planning, inputs, outputs, verification, validation, design transfer, & design changes

Production & Service
Covers environmental controls, infrastructure, equipment calibration, process validations, traceability & nonconforming materials handling

Purchasing Controls
Examines supplier evaluation, selection, performance monitoring, and purchasing controls

Measurement, Analysis & Improvement Process
Reviews mechanisms for customer feedback, internal audits, control of nonconforming product & CAPA

Authorization & Registration
Ensures devices & facility registrations are accurately authorized and documented according to local jurisdictional requirements

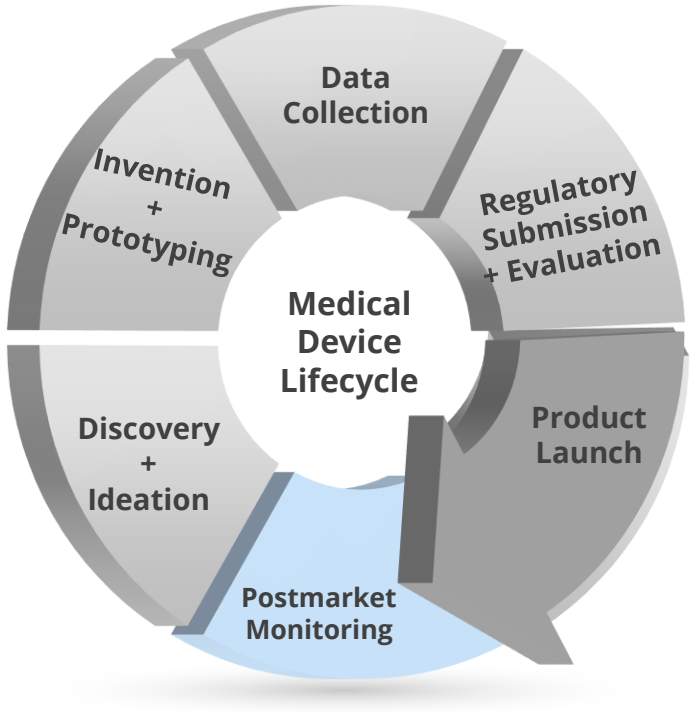
Adverse Event Reporting
Audits procedures & records for reporting AE & issuing field safety corrective actions/advisory notices to authorities

Postmarket surveillance: monitoring MD/IVD performance in real world

Continuous postmarket surveillance is **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



What this means in practice

Staying abreast of all regulatory changes where we market to ensure our QMS meet the requirements & adjust accordingly to implement changes

Conduct internal audits and management reviews

Maintain current technical documentation and declarations of conformity

Implement design, labeling, manufacturing, and PMS changes under change control

Meet regulatory timelines for reporting, registration, renewals, and corrective actions

Regulators provide oversight, but

manufacturers hold the primary responsibility for demonstrating & maintaining conformity


Muchas
Gracias!