Global Frameworks for Medical Devices and In Vitro Diagnostics: Foundational Principles & Regulatory Convergence

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Convergence Accelerates Access

“Don’t be afraid of going slow, just be afraid of standing still.”

Time to Diagnosis Matters

*"A **longer** time from symptom onset to confirmed diagnosis **yielded a worse COVID-19 prognosis**."*[1]

*"**Delay in diagnosis** and limited hospital resources **lead to** a **rapid spread** of COVID-19."*[2]

1. Earlier diagnosis improves COVID-19 prognosis: a nationwide retrospective cohort analysis, June 9, 2021.
2. Effect of delay in diagnosis on transmission of COVID-19, February 25, 2020.

Convergence can expedite access to safe and effective products and improve health outcomes.

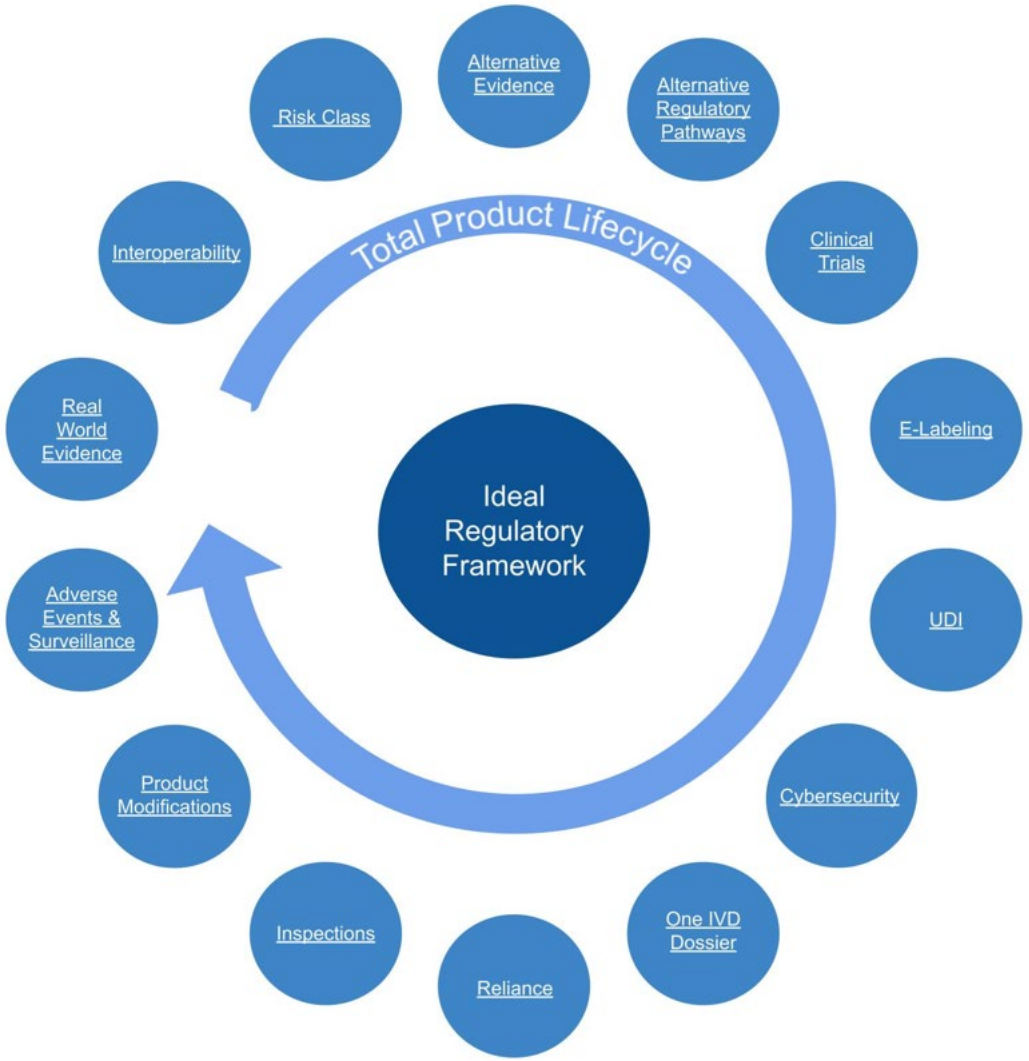
Divergent Regulation

Convergent Regulation

International Medical Device Regulators Forum (IMDRF)

Total Product Life Cycle Convergence

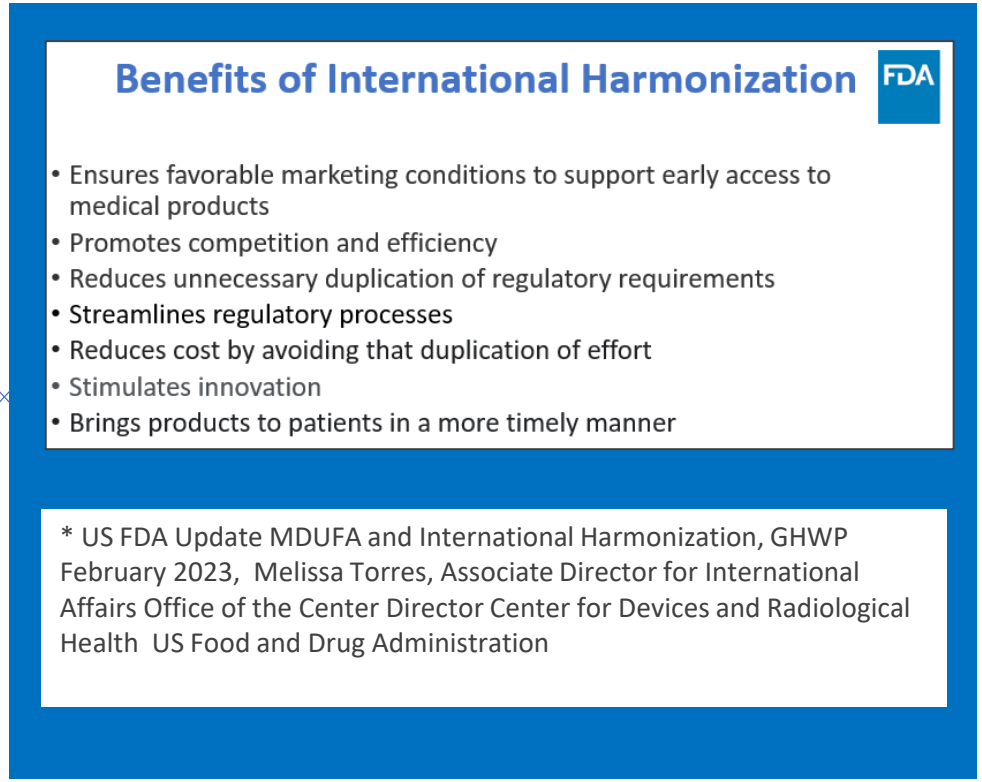
One High Standard No Matter the Jurisdiction



- MD/IVD **classifications** drive downstream requirements
  - IMDRF MD Classification
  - IMDRF IVD Classification
  - SaMD Classification
- Implement **expedited pathways** for innovative products and **emergency use** authorization
- Align to IMDRF **Essential Principles** Guidance to drive evidence requirements
- Leverage **global clinical data** to avoid unnecessary country specific clinical trials
- Adopt **e-labeling** to facilitate quicker availability of product information
- Implement IMDRF **UDI and cybersecurity** guidance's
- Embrace and implement **Reliance throughout the TPLC**
  - Market authorization
  - Pre and post inspections
  - Product Changes
- Adopt a risk-based approach for **product modifications**
- Allow the use of **RWE** to advance and perfect product claims
- Drive **digitization** of the regulatory and healthcare process to help achieve **interoperability**

Benefits of International Harmonization

- Earlier Patient Access
- Reduces unnecessary duplication of regulatory requirements
- Streamlines regulatory processes
- Reduces cost by avoiding duplication of effort
- Stimulates innovation



US FDA/CDRH Approach

US FDA 5-Year Strategic Plan

- **Collaboration** with global regulatory partners
- Use of **international** consensus standards
- Use of internationally **harmonized** documents such as those created by the International Medical Device Regulators Forum (IMDRF)
- Use of **minimal** country specific deviations, if any
- Build **confidence and trust** with other regulators through multilateral and bilateral efforts
- Use of **Least Burdensome** Principles

EXAMPLE: US FDA 5 Year Strategic Plan: Five broad commitments related to international harmonization efforts

1. Expand engagement in international harmonization and convergence efforts through **participation with international regulators** and other key stakeholders in forums, working groups, projects, and committees
2. Further support regulatory convergence by creating a **mechanism for FDA to work with regulatory partners**.
3. **Assess the extent of CDRH implementation of IMDRF technical documents** and make this information publicly available.
4. Support the creation of **a forum to engage with relevant stakeholders** to identify opportunities for regulators to leverage one another's approach to decision making.
5. Participate in outreach activities to other regulatory authorities that **encourage harmonization**

Build Capacity and Understanding of International Best Practice

- The IMDRF Management Committee announced a new membership category - **IMDRF Affiliate Member**

- As an IMDRF Affiliate Member, the regulatory authority may **attend IMDRF Management Committee Open Meetings** and may **participate in open Working Groups**.

- Seek out Affiliate membership, **get involved**, learn and share

WHO Global Model Regulatory Framework and GBT+

Getting to ONE high standard no matter the organization

- The second version made significant progress toward the adoption of international best practice (IMDRF)
- Additional feedback was provided to:
  - Continue **convergence to IMDRF** (e.g., alignment of post market requirements, AE definition, reporting requirements, and timing; eliminate requirements that delay access without adding to patient safety such as in country lot testing)
  - **Align** the **GBT+** to the advances made in the second version of the **GMRF**
  - Create a baseline based in appropriate MD/IVD requirements and implementation of foundational principles like **GRP and Regulatory Reliance**

Having Multiple Jurisdiction Specific Regulations can Delay Access

- Clinical trial and evidence requirements.
- In country testing and reference range studies.
- Country specific dossier formats.
- Country specific labeling.
- Country specific inspections.
- Country specific post market reporting.

Time to diagnosis and treatment matter

Our Future

- Convergence.
- Smart Regulation.
- Capacity Building.

Thank you!!

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