IMDRF International Medical Device Regulators Forum

Navigating Divergent Device Classifications Industry Experience Across Jurisdictions

Yasha Huang
Head of Regulatory Policy Asia Pacific
Roche Diagnostics

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The Why

Divergence in risk classification may contribute to unnecessary barriers that delay timely patient access to safe and effective medical devices and IVDs.

The Global Challenge of Regulatory Divergence

Global Progress:

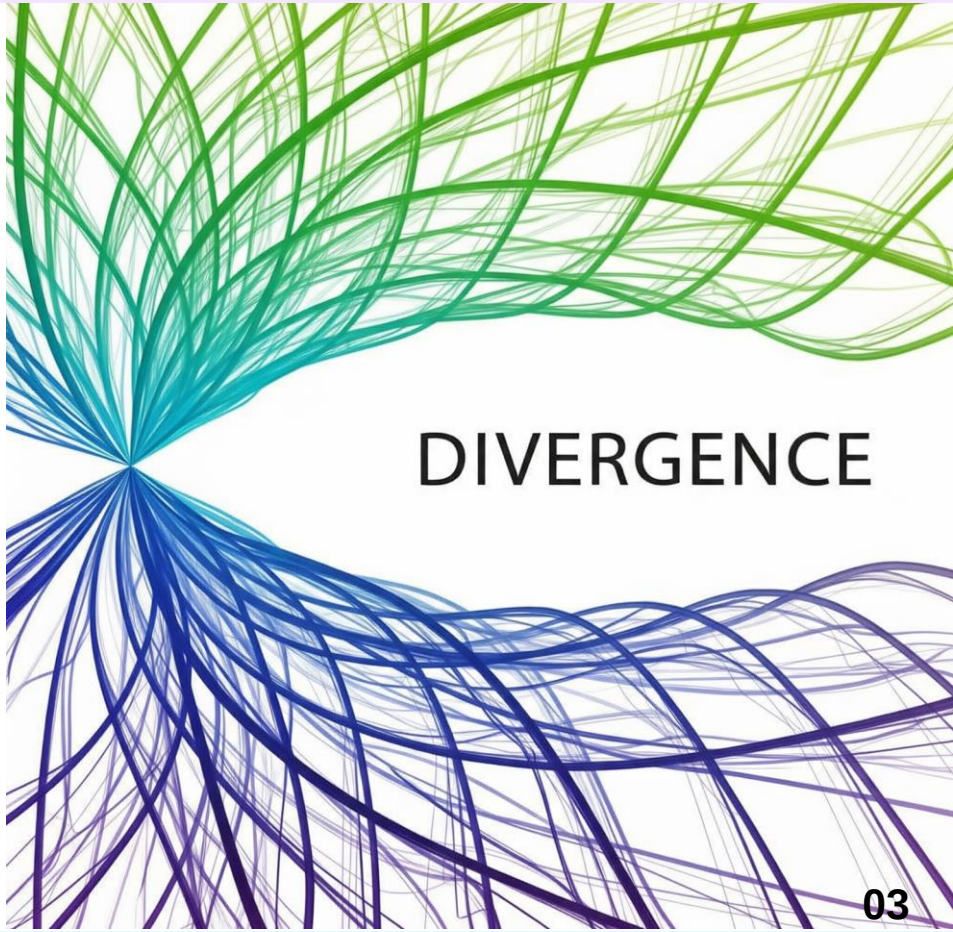
Significant efforts made to align with IMDRF/GHTF risk-based principles over the last decade.

Divergence Persists:

Key differences in risk classification remain across major jurisdictions, more prominent for certain products.

Why Does Divergence Still Exist?

- **Philosophical divides in risk assessment**
  - Inherent risk of the device or mitigated risk such as doctors' involvement and intended use/use environment.
- **Mindset/pace in risk class re-evaluation**
  - More proactive/speedy vs more static/slower
- **Difference in regulatory unit of analysis**
  - Device alone vs component of a system
- **Interpretation about the role in decision making**
  - Simple tool vs key determinant in medical decisions
- **Regulatory precedent and path dependency**
  - Established precedents vs novel technologies



Case Study 1: IVD Instrument - Cobas 6800

Country	Classification	Country	Classification
A	Class 1	F	Class III
B	Class II	G	Class II
C	Class IV	H	Class IIa
D	Class A	I	Class D
E	Class II	J	Class I

Note: Countries were anonymized but this is real data from 10 IMDRF MC members.
Country E & F & J has a total of 3 risk classes while others have a total of 4 risk classes for IVDs.

Case Study 2: Professional-use SARS-CoV-2 test

Country	Classification	Country	Classification
A	Class 3	F	Class III
B	Class III	G	Class III
C	Class IV	H	Class III
D	Class B	I	Class D
E	Class II	J	Class III

Note: Countries were anonymized but this is real data from 10 IMDRF MC members.
Country E & F & J has a total of 3 risk classes while others have a total of 4 risk classes for IVDs.

Case study 3: Antibody Reagent (anti-CD30)

Country	Classification	Country	Classification
A	Class 2	F	Class I
B	Class III	G	Class II
C	Class II	H	Class IIb
D	Class C	I	Class B
E	Class I	J	Class III

Note: Countries were anonymized but this is real data from 10 IMDRF MC members.
Country E & F & J has a total of 3 risk classes while others have a total of 4 risk classes for IVDs.

The Ripple Effect of Divergence

Risk Classification: The Foundation

Primary Determinant:
Classification largely determines the Conformity Assessment and evidence requirements

Informs:
Pathways, Timelines, and testing

Regulatory Hurdles

Creates **significant complexity** without adding benefits to patient safety

Adds **uncertainty** when practicing reliance
Complicates the process of regulatory reliance

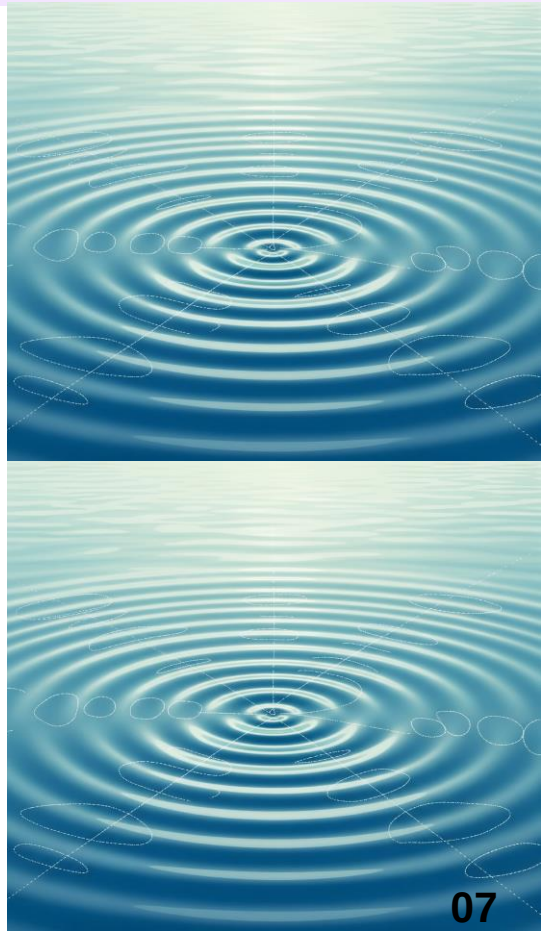
Places a significant strain on manufacturers' resources

Adverse Patient Outcomes

Hinders access to innovation:
Essential Devices may not reach patients in a timely manner or at all

Poor Health Outcomes: Delayed diagnosis or lack of diagnosis can lead to poor patient health outcomes

The combined effect of reduced access and poor health outcomes has a detrimental impact on global health



Bridging the Gaps

- Standardizing Classification
- Implement abridged assessments to make wise use of the trusted reviews already performed
- Leveraging innovative methods to address evidence gaps

Recommendations to Ensure Timely Access

Regulators

Implement Good Regulatory Practices

Adopt International Standards

Continue to harmonize risk classifications

Industry

Proactive Engagement

Comprehensive Justification

Support and Participate

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Thank you/Questions

If any questions, please contact me at yasha.huang@roche.com