IMDRF International Medical Device Regulators Forum

Conformity Assessment in Practice: Industry Challenges and Opportunities

Proposals for Discussion

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How can we enhance patient access and deliver new medical technologies to the market through improving conformity assessment process?

Conformity Assessment Element		Discussion Points/Proposals
Conformity Assessment for QMS	**QMS**	● **Broader acceptance of MDSAP audit results among regulatory authorities.**
	Post-market surveillance	● **In Session 3, PMS will be discussed.** ● **In Session 4, RWE will be discussed.**
Conformity Assessment for Device Safety & Performance	**Technical Documentation**	● **In Session 2, Classification will be discussed.** ● **In Session 4, RWE will be discussed.** ● **Developing Guidance explaining the regulatory model and its relationship with the IMDRF Foundational Guidance Documents.** ● **Developing Mapping Consensus International Standards into Essential Principle** ● **Improving Implementation for International Standards into National Standards and Recognition consensus standards in Regulations** ● **Developing Reviewing Criteria, and then Starting pilot study for Class B or C in some jurisdictions.** ● **Align Change Management**

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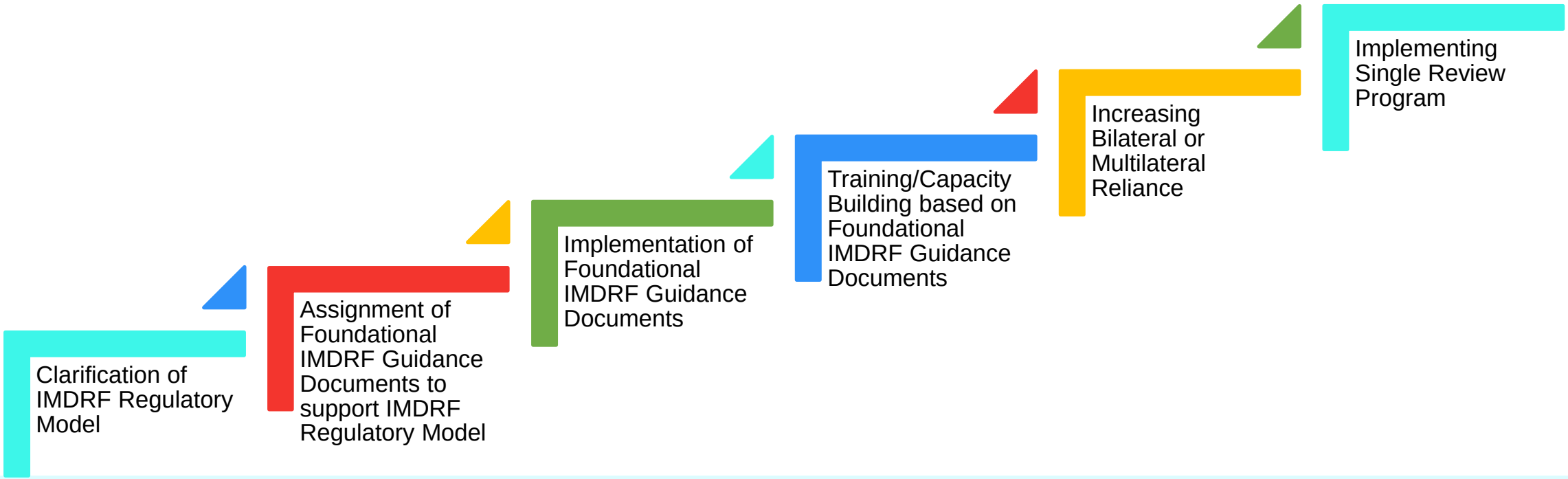
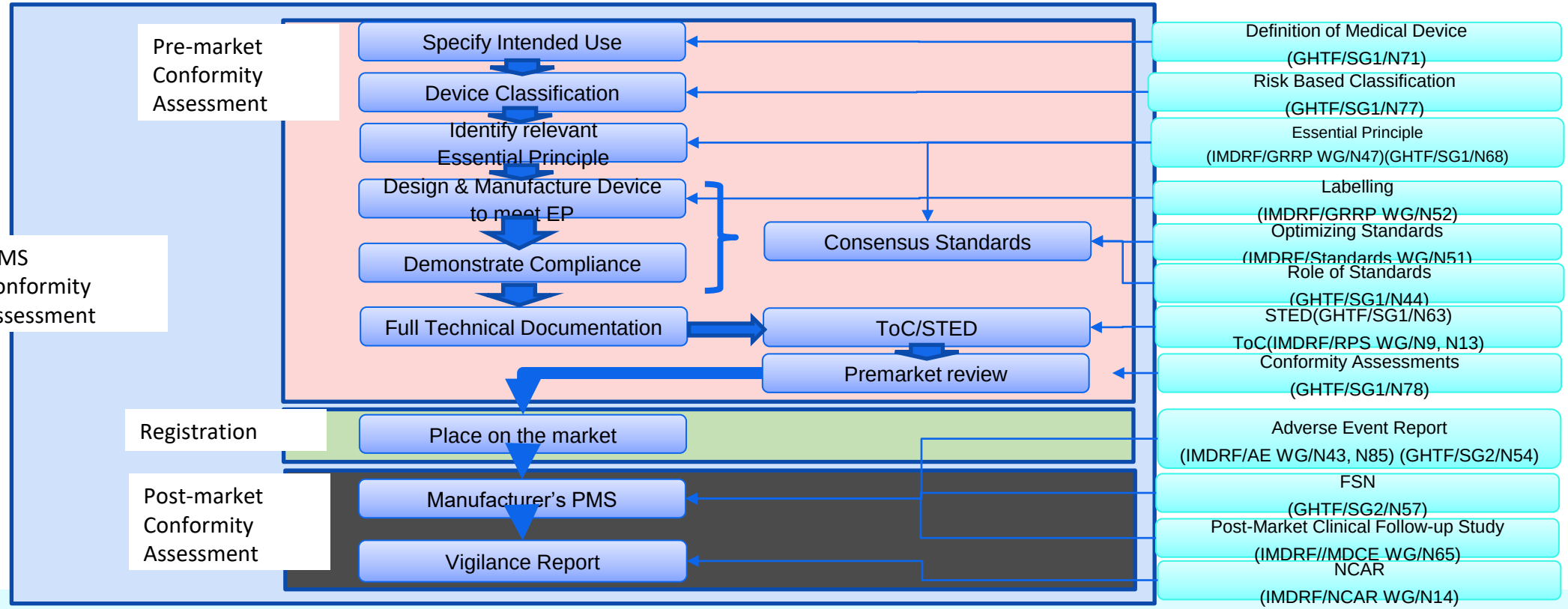
How can we improve conformity assessment process to enhance patient access and accelerate the delivery of new medical technologies to the market ?

Developing Roadmap toward a single review program or the other regulatory convergence.



How can we align Conformity Assessment Process with Harmonized Regulatory Model and IMDRF/GHTF Foundational Doc?

Developing Guidance to explain the regulatory model and its relationship to the IMDRF Foundational Guidance Documents.



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How can we harmonize the reviewing criteria for premarket conformity assessment?

Developing Consensus on International Standards to Essential Principle

5.General principles		Applicable /Not Applicable	Medical Devices/IVD standard or other procedure applied
5.1	*General*		
5.1	5.1.1. Medical devices and IVD medical devices should achieve the performance intended by their manufacturer and should be designed and manufactured in such a way that, during intended conditions of use, they are suitable for their intended purpose. They should be safe and perform as intended, should have risks that are acceptable when weighed against the benefits to the patient, and should not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons.	Applicable	ISO13485 ISO14971
	5.1.2. Manufacturers should establish, implement, document and maintain a risk management system to ensure the ongoing quality, safety and performance of the medical device and IVD medical device. Risk management should be understood as a continuous iterative process throughout the entire lifecycle of a medical device and IVD medical device, requiring regular systematic updating. In carrying out risk management manufacturers should: a. establish and document a risk management plan covering each medical device and IVD medical device; b. identify and analyze the known and foreseeable hazards associated with each medical device and IVD medical device;	Applicable	ISO14155

We need
Mapping or
How to apply
consensus Standards

As review criteria

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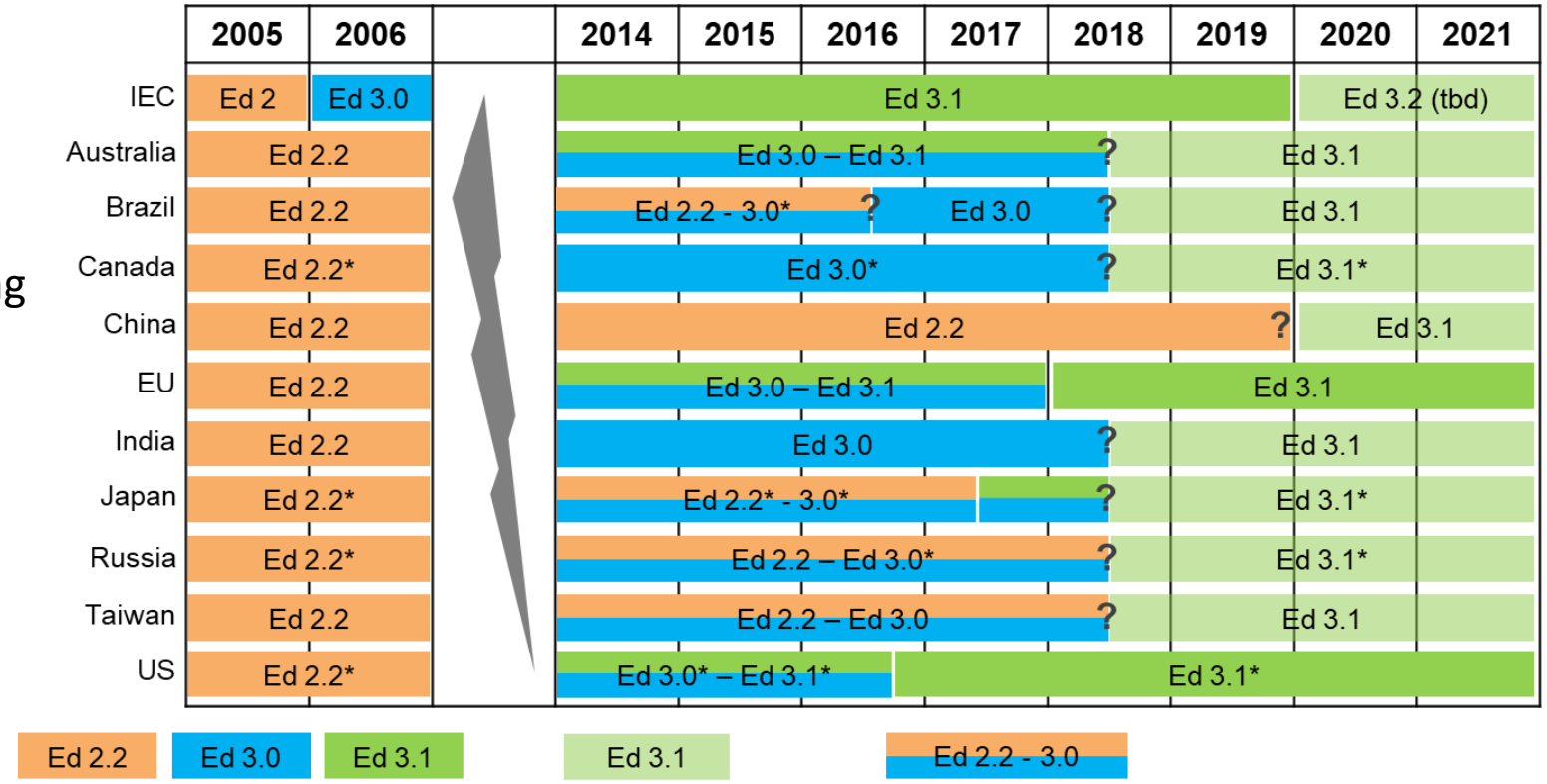
How can we harmonize the implementation timing and transition periods for international standards across jurisdictions?

Improving the Implementation for International Standards into National Standards and Strengthening the regulatory recognision of consensus standards.

E.g.; <Case Study Transition Problem>
Medical device manufacturers encountered significant challenges during the transition from the 2nd to the 3rd edition of IEC 60601-1 in 2015.



Ref; Maurizio Andreano's presentation in DITTA Workshop with IMDRF 2015

* National deviations may apply Information without guarantee

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How can we harmonize the implementation timing and transition periods for international standards across jurisdictions?

We will face significant challenges during the transition from IEC 60601-1 Edition 3 to Edition 4 again.

Manufacturers burden increases as follows.

1. Regulatory Alignment Across Markets

- Manufacturers must **navigate multiple compliance paths for different markets**.
- Some devices require **dual certification** (complying with both editions for different regions).
- Risk of market access **delays if devices are not compliant with the new e**dition in certain regions.

2. Re-Certification Costs & Extended Compliance Burdens

- **Higher financial burden** for companies selling in multiple jurisdictions.
- **Regulatory delays** due to waiting for approvals from various countries.
- Increased **resource allocation** to manage different sets of compliance.

3. Documentation & Submission Complexity

- Increased need for **regulatory affairs personnel** to manage different submission processes.

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How can we align the deviation of classification rule such as SaMD or AI/ML Medical Device across jurisdictions?

Please discuss this issue in Session #2

Background:

1. While most countries classify conventional basic products according to GHTF Risk-based classification principles(GHTF/SG1/N77:2012), the application of these rules varies for new technologies.
2. For product groups in Rule 13, SaMD, and AI/ML devices, some jurisdictions differ in their interpretation of applying Rule 10 (for active devices), especially regarding exclusion criteria.
3. These differences negatively impact efforts to expand reliance and improve early patient access.

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How can we align the deviation of use of Real World Evidence in conformity assessment across jurisdictions?

Please discuss this issue in Session #4

Background:

1. What common barriers to RWE acceptance remain, and how can regulators, industry, and other stakeholders work together to overcome them?
2. What is needed to advance the regulatory use of RWD/RWE?
3. “Fit for purpose” in RWE – relationship between study question, data quality, and analytical methods.

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How can we start the single review program based on CAB systems by IMDRF GRRP guidance documents?

Developing Reviewing Criteria, and then Starting pilot study for Class B or C in some jurisdictions.

For Assessor in RA.
Competency and Training
for RA Assessor (IMDRF N63)

Regulatory Authority

For Recognition of CAB
- Assessment and Decision Process for the Recognition of a CAB (IMDRF N66)
- Assessment Methods for Recognition of CABs (IMDRF N61)
- Organization Recognition Requirements and Processes" (IMDRF N59)

Recognition

Conformity Assessment Bodies

For Reviewer
Competency and Training (IMDRF N40)

CAB Report by IMDRF N71

Data exchange on the database

For the Acceptance of CAB Report by jurisdictions

For Reviewing of MD
Reviewing Criteria, Standards??
Essential Principle (IMDRF N47)
Labeling (IMDRF N52)
Consensus standard (IMDRF N51)
RPS ToC ?
The others?

Pre-market Reviewing

Medical Device

Required Next Step For GRRP

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How can we align change management in conformity assessment for premarket.

Explore product change requirements, discuss international best practices.

Background:

1. Conformity Assessment Guidance (GHTF/SG1/N78:2012) is not covered change management.
   Just now, IMDRF SaMD WG is developing Predetermined Change Control Plan.
2. Definitions of product changes (significant vs non-significant or other language) and regulator review triggers prior to introduction to the market vary greatly across jurisdictions.
3. This results in significant complexity when managing requirements in multiple jurisdictions & may not be risk-based.
4. Diverse regulatory approaches can confuse relying agencies and make it difficult to practice post-market reliance.

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How can we align Efficient Post-market conformity assessment .

Improving post-market surveillance. Please discuss this issue in Session #3

Background:

1. IMDRF/GHTF Guidance for NCAR, AET were applied post-market surveillance activities.
2. Adverse event reporting – gaps and missing data?
3. Implementation for Data analytic tools.
4. Enhance patient safety by improving post-market surveillance activities.

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Thank you/Questions