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MEDICAL DEVICE STANDARDS: HARMONIZATION AND REGULATORY CONVERGENCE IN SUPPORT OF HEALTH CARE SECTOR SERVICES

Why Participate?

ROLE OF THE REGULATOR IN THE DEVELOPMENT OF STANDARDS.

- PARTICIPATION ENCOURAGES HARMONIZATION
- PARTICIPATION PROVIDES INSIGHT TO NEW TECHNOLOGY

OMB Circular A-119

Updated the Federal Agency requirements for:

- Participation
- Whether to use a standard to meet an Agency need
- Role of Agency Standards Executives
- How to report on the development and use of standards
- Factors to assess effectiveness of conformity assessment
- Guidance on rulemaking and guidance documents
- Public notification of Agency Participation in Standards
- Updating of regulations IBR
- Encourage Agencies to use same versions of standards
- When to consult with USTR on international obligations
- Preference to VCS over GUS in regulation

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FDA Policy Participation In Standards

21 CFR 10.95, Participation in outside standard-setting activities

FDA Policy on Standards “Policy regarding the development and use of standards with respect to international harmonization of regulatory requirements and guidelines”, 60 FR 53078 (Oct. 11, 1995).

FDA Staff Manual Guide - SMG

SMG 9100.1 FDA Staff Manual Guides, Volume IV – Agency Program Directives

- Policies of each Center in FDA
- Development and Use of Standards
- Definitions
- Roles/Representation

21st Century Cures Act:
Section 3053 – Recognition of Standards

Updates to Sec 514(c) of the FD&C Act focus on [CDRH Standards Recognition Program]:

- transparency of regulatory decisions related to standards recognition
- improve the number of standards recognized form outside stakeholder requests
- ensure training to all employees involved with premarket review
- Update guidance demonstrating principles for recognizing and withdrawing standards
- Moving outward focus on how Agency action supports harmonization among regulatory authorities in the regulation of devices.

Enhance stakeholder requests for recognition and FDA transparency

(i) **Any person may submit a request for recognition** under subparagraph (A) of all or part of an appropriate standard established by a nationally or internationally recognized standard organization.

(ii) Not later than 60 calendar days after the Secretary receives such a request, the Secretary shall —

(I) make a determination to recognize all, part, or none of the standard that is the subject of the request;

and

(II) issue to the person who submitted such request a response in writing that states the Secretary's rationale for that determination, including the scientific, technical, regulatory, or other basis for such determination.

Public notification on non, partial and full recognition

(iii) **The Secretary shall make a response issued under clause (ii)(II) publicly available**, in such a manner as the Secretary determines appropriate.

(iv) The Secretary shall take such actions as may be necessary to implement all or part of a standard recognized under clause (ii)(I), in accordance with subparagraph (A).

Regulatory transparency on rational for recognition

(D) The Secretary shall make publicly available, in such manner as the Secretary determines appropriate, **the rationale for recognition under subparagraph (A) of all, part, or none of a standard, including the scientific, technical, regulatory, or other basis for the decision regarding such recognition.**

Training on the use of standards -

(4) The Secretary **shall provide to all employees** of the Food and Drug Administration who review premarket submissions for devices periodic **training on the concept and use of recognized standards** for purposes of meeting a premarket submission requirement or other applicable requirement under this Act, including standards relevant to an employee's area of device review.

Guidance and harmonization

Guidance —The [FDA], shall review and update, if necessary, previously published guidance and standard operating procedures identifying the **principles for recognizing standards**, and for withdrawing the recognition of standards, under section 514(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360d(c)), **taking into account the experience with and reliance on a standard by foreign regulatory authorities and the device industry, and whether recognition of a standard will promote harmonization among regulatory authorities in the regulation of devices.**

CDRH Standards Program

17 Specialty Task Groups (STGs)

- Cover 23 different Scientific/Device areas.

Participate in ~ 600* national and international committees

1254 currently recognized standards

2-6 recognition FR notices each year

* Typically see a 5-10% increase in requests for new standards development activities each year.

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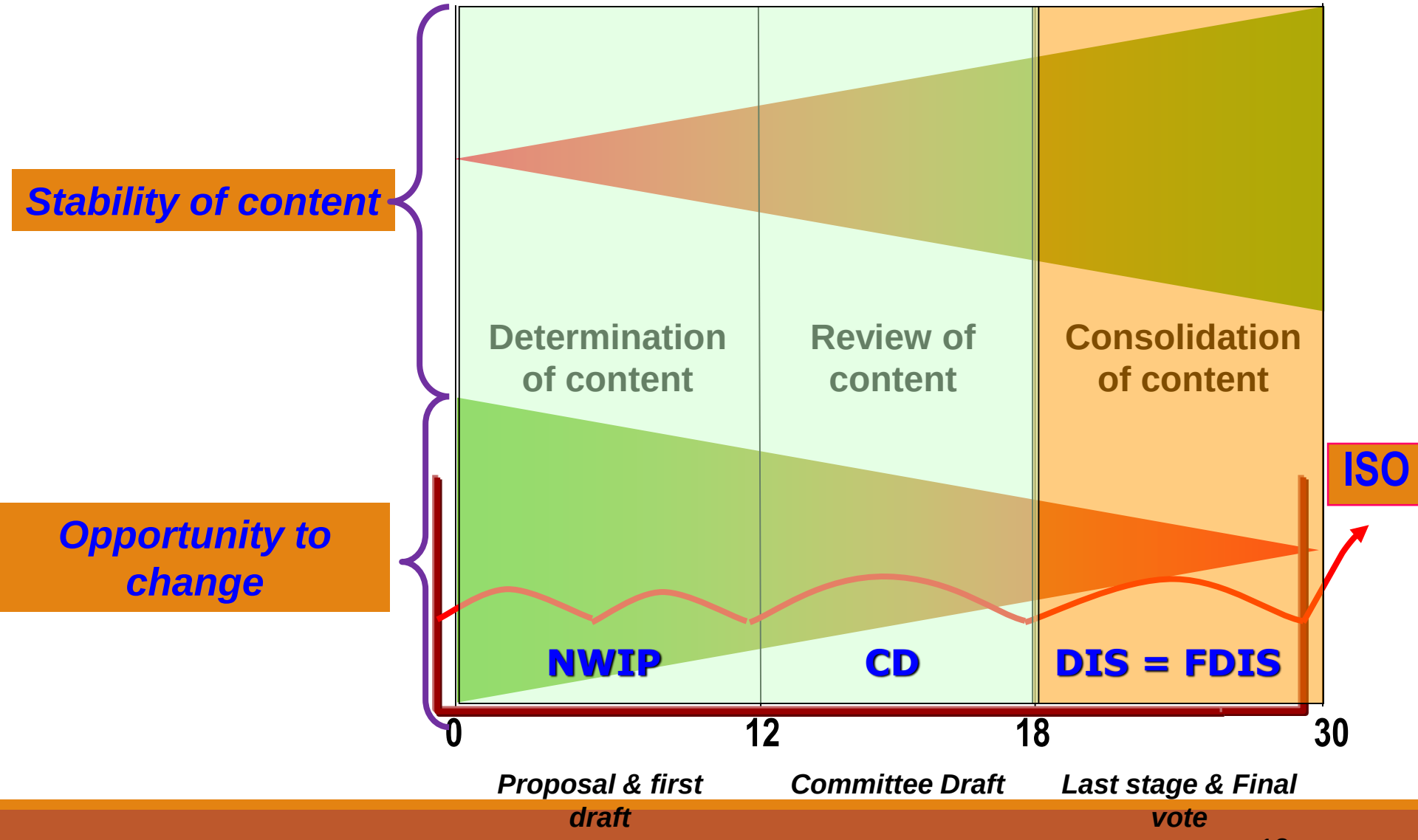
Why we want to be involved in standards early -



The Ideal Relationship Between Regulation and Standards

How to get there? Communication and Hard Work -

- Participation by all Stakeholders in Standards Development including Regulatory Authorities
- Standards Developers would have an Understanding of the Needs of Regulators
- Importance of **Public Private Partnerships** with National and International organizations.

Why Is Regulatory Participation in Standards Development So Important?

- International standards have definite impact on a sector's competitiveness, markets, and regulations around the world
- To initiate work and influence outcomes, involvement is key
- Engage with a wide range of stakeholders
- Active engagement is well worth the investment

U.S. FOOD & DRUG ADMINISTRATION

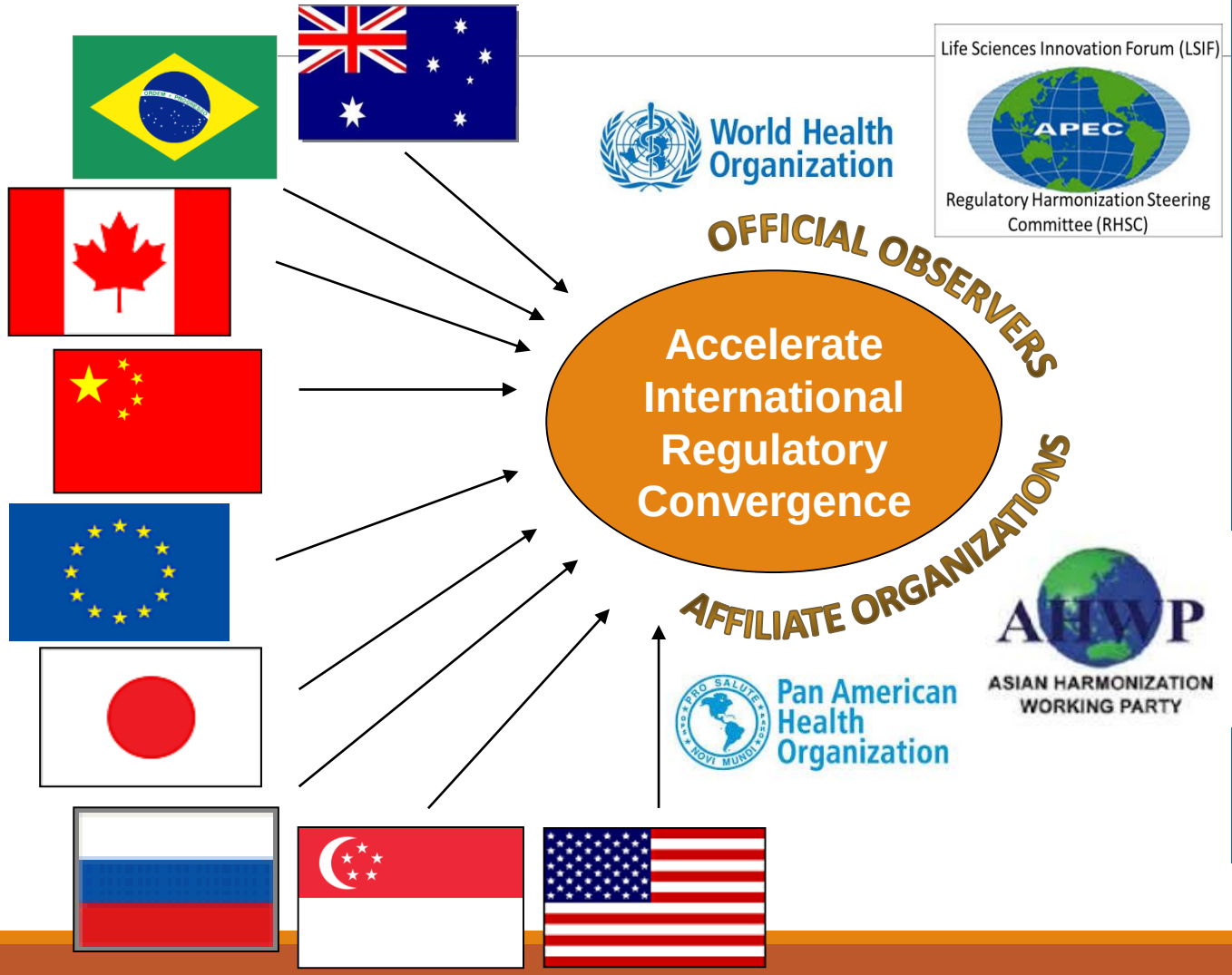
Understanding the Needs of the Regulatory Authorities (RAs) in Standards

International Medical Device Regulators Forum Overview

IMDRF International Medical Device Regulators Forum

http://www.imdrf.org

IMDRF -



- Forum established in 2011 **to accelerate international medical device regulatory harmonization and convergence** building on the work of the Global Harmonization Task Force (GHTF)
- Address **common public health regulatory challenges** to convergence due to the globalization of medical device production and the emergence of new technologies
- **Accelerate innovation by clear and practical regulatory expectations**

IMDRF Working Groups (WGs)

7 Active Working Groups – Comprised of regulators only or regulators and stakeholders depending on the topic.

- **Standards**
- Software as a Medical Device (SaMD)
- Patient Registries
- Good Regulatory Review Practices
- Adverse Event Terminology
- Regulated Product Submission (RPS)
- National Competent Authority Report (NCAR)

2 Closed Working Groups

- Medical Device Single Audit Program (MDSAP)
- Unique Device Identification (UDI)

Standards WG

Goals

Improve the quality of international medical device standards for regulatory use and increase confidence in standards and how they can be better used for regulatory purposes by:

- Increasing Regulators' engagement with IEC/ISO and National Committees
- Developing resources, knowledge and expertise to improve standards

Standards WG - Current Work

Development of a white paper addressing issues such as:

- Current landscape of standardization for medical devices
- Evidence of the value of international standards for regulatory use
- Anticipated benefits of greater reliance upon international standards in medical devices
- Current problems with international standards
- Identify ‘Essential Principles for Standards’ Utility’ (Needs) of RAs
- Engagement with International SDOs

IMDRF Member Concerns

- In general, regulatory authorities (RAs) are not active in the development of international standards
  - Lack of resources or awareness
  - There is increased involvement with horizontal standards but more limited involvement in vertical standards
- Lack of stakeholder balance in P-Member Countries
  - Membership is mostly from Regulated Industry
  - Not clear if RAs are involved in standards development as comments are not identified by stakeholder
  - Unknown if clinical community was involved in development
- **Not clear if standard will be accepted by RA based on P-member vote**

Additional Considerations

To meet RA needs, standard should include, e.g. -

- Rationale for scope and content
- Identification of strengths and weaknesses (limitations)
- Information regarding repeatability and reproducibility; or if side-by-side testing is required
- How to identify “worst-case” device for testing
- How to identify a device for comparison
- Information regarding sample size
- Clear criteria to demonstrate conformity and reporting requirements
- Red-lined changes for revisions
- Plain language
- Translation into different languages

Conclusion

How can you get involved in IMDRF?

- Participation in working groups that are open to stakeholders
- Reviewing and providing feedback on draft documents
- Attending IMDRF stakeholder sessions
- Meetings are held in March and September
- 2018 Meetings to be held in China (2018 Chair)

This is Hard Work!!

Famous Quote:

- “Opportunity is missed by most people because it comes dressed in overalls looking like hard work.”
  – Thomas A. Edison


Merci beaucoup
Thank You
お疲れ様
Danke
Gracias
Grazie
Dank u
谢谢你
Thanks
Obrigado

Thank you!

- CDRH Standards Program

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