
FDA U.S. FOOD & DRUG ADMINISTRATION

# Optimizing Standards for Regulatory Use

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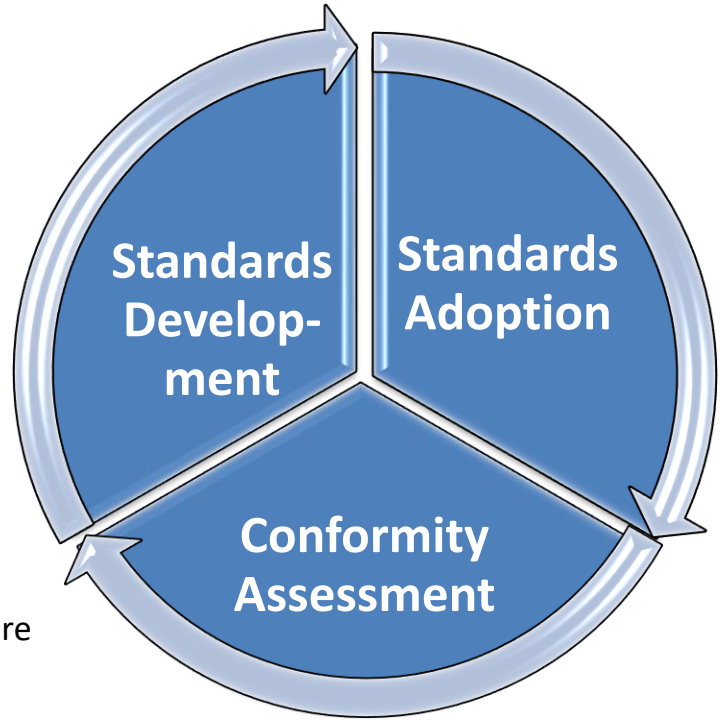
# Total Standards Life Cycle

**Communication on RA needs/differences during development**
Committee make up
Testing V/V during development?




**Recognition**
- How does recognition enhance the use of the standard?
- What information can accompany recognition?
- Educational needs for stakeholders.

**Standards Assessment**
- Effectiveness of standard
- Data to support standards future
- Issues with CA

**Adoption/Implementation**
- Is there a need for Transition for implementation?
- Country/Regional Deviations
- Regulatory challenges

**Conformity Assessment**
- Do standards lend themselves to adequate Conformity Assessment Reports (e.g. TRFs)
- Enhance the use of declarations of conformity in device submissions

# FDA-Recognized Standards

- FDA strongly encourages the use of recognized standards in premarket submissions
- FDA's recognition communicates a common pathway to demonstrate how a product meets a particular requirement
- Declarations of conformity (DOCs) may be used with recognized standards, potentially reducing the amount of supporting data and information submitted to FDA

# Use of Consensus Standards

- Voluntary
  - Only mandatory if cited in regulation ('incorporated by reference')
- Used in any type of submission
  - PMA, 510(k), etc.
- Used with a DOC (recognized standards only) or 'General Use' (any standards, recognized or not)

# Supplemental Documentation

- Information that establishes traceability from the declaration of conformity
- Needed when:
  - Standard does not feature test methods or acceptance criteria
  - Modifications or adaptations have been made to the recognized standard
- The ultimate goal: a standard that clearly outlines expectations for manufacturers and regulators

See the FDA's *Appropriate Use of Voluntary Consensus Standards* guidance for more information.

# FDA - ACCREDITATION SCHEME FOR CONFORMITY ASSESSMENT (ASCA)

# What is ASCA?

- Accreditation Scheme for Conformity Assessment (ASCA)
- Voluntary program leveraging a well-established international conformity assessment infrastructure
- Capitalizes on voluntary consensus standards in device development and review
- “Puts standards to work” in conformity assessment

ISO/IEC 17011:2017
Conformity assessment — Requirements for accreditation bodies accrediting conformity assessment bodies


← Popular standards

ISO/IEC 17025
Testing and calibration laboratories

## *ASCA Goal: Streamline conformity assessment in premarket review*

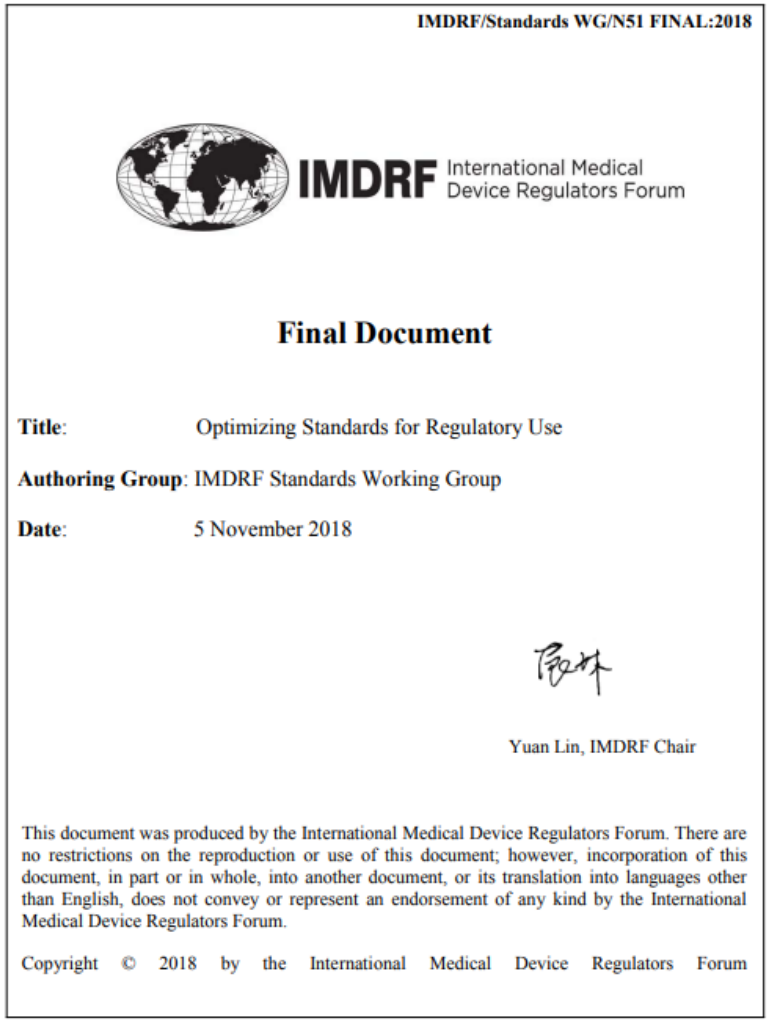
- Communicates expectations on standards use to testing organizations and industry
- Removes the guesswork about supplemental documentation needs
  - Provides templates for declarations of conformity and Summary Test Reports
  - Identifies the minimum documentation needed to accompany a declaration of conformity
- Reduces time needed for the conformity assessment element of device review
  - Less need for Additional Information questions, internal consults and complete test report review

# What does standardization need from regulatory authorities?

IMDRF International Medical Device Regulators Forum

# Guidance Recommendations:

- Standards must be improved for regulatory use
- IMDRF members should participate as early as possible in standards development



IMDRF/Standards WG/N51 FINAL:2018

IMDRF International Medical Device Regulators Forum

**Final Document**

**Title**: Optimizing Standards for Regulatory Use

**Authoring Group**: IMDRF Standards Working Group

**Date**: 5 November 2018

Yuan Lin, IMDRF Chair



FDA

# Challenges to Regulatory-ready Standards

IMDRF Standards Working Group identified:

- *Poor participation by RAs* → can lead to the development of standards that do not include substance and language that are useful for regulatory purposes
- *Unbalanced representation* → can result in some groups' disproportionate voice in and impact on standards development
- *Content of standards can be too flexible/unclear* → can render standards less useful as they may not adequately identify minimum requirements for quality, safety and/or effectiveness/performance.

# Optimizing Standards

- Standards should feature:
  - Clear scope
  - Strong rationale that:
    - Explains the requirements and identifies test methods and/or other means of demonstrating compliance
  - Identification of risk and direction on how to address it
  - Terms and definitions established and accepted in other standards
  - Means to assess clinical performance (if applicable) as part of the normative requirements

# Optimizing Standards

- Standards should feature (continued):
  - Clear and quantitative acceptance criteria
  - If acceptance criteria is not mandatory/present, a justification for why, and how to demonstrate conformance to the standard
  - Well-accepted and verified test methods
  - Transparent and clear (e.g., 'track changes') revisions
  - An annex or table that cross references the standard's clauses to the IMDRF *Essential Principles of Safety and Performance*

# Regulators role in standards

- Clear expectation on how standards use supports regulatory requirement(s)
- Harmonized approach to adoption of standard
  - Complete adoption vs. partial
  - Transition period between versions
  - Voluntary vs. mandatory use
- Understanding on how conformity assessment results are accepted within a specific jurisdiction to supports global harmonization

# Enhancing Participation

- Regulatory Authorities should build a strong standards program that encourages contributions to standards development
- Engagement with SDOs is essential
- Contribute regulatory perspective
- Support harmonized regulatory objectives
- Get involved early
- Consider leadership roles

# Join the Standards Conversation

- Nations (through their ‘national bodies’ or ‘national committees’) are ISO and IEC members; they appoint individuals to represent them
- National bodies are responsible for ISO and IEC work within their countries
- National bodies appoint national or ‘mirror’ committees (called TAGs in the US) whose work mirrors that of the ISO and IEC bodies
  - Develop consensus on issues
  - Review proposals and documents
  - Comment on new standards
- Regulators should participate at both the national (for example, national bodies or mirror committees) and the international levels (ISO and IEC committees)
  - Goal: build regulatory interests into the standards (e.g., test methods, acceptance criteria)
  - Submit effective comments

# International Resources

- **IMDRF *Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices: 2018***
  http://imdrf.org/docs/imdrf/final/technical/imdrf-tech-181031-grrp-essential-principles-n47.pdf
- **IMDRF *Optimizing Standards for Regulatory Use* guidance:**
  http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-181105-optimizing-standards-n51.pdf
- **International Electrotechnical Commission (IEC)**
  http://www.iec.ch/about/activities/standards.htm?ref=home
- **International Organization for Standardization (ISO)**
  https://iso.ch/home.html
- **ISO Conformity Assessment tools to support public policy: the CASCO Toolbox**
  https://www.iso.org/sites/cascoregulators/02_casco_toolbox.html
- **ISO/IEC Directives Parts 1 (Ed. 13, 2017) and 2 (Ed. 7, 2016)**
  https://www.iec.ch/members_experts/refdocs/iec/isoiecdir-1-consolidatedIECsup%7Bed13.0%7Den.pdf
  https://www.iso.org/sites/directives/current/part2/index.xhtml
- **GHWP WG8 - AHWP/WG2-WG8/F002:2014 Role of Standards in the Assessment of Medical Devices**
  http://www.ahwp.info/sites/default/files/2017-07/Final_GHWP_WG2_WG8_F002_2014.pdf

# International Resources, cont'd

- **ISO/IEC Guide 59, ISO and IEC recommended practices for standardization by national bodies 2019**
  https://www.iso.org/standard/71917.html
- **ISO/IEC Guide 63:2012 Guide to the development and inclusion of safety aspects in International Standards for medical devices**
  https://www.iso.org/standard/50729.html
- **ISO/IEC 17007:2009, Conformity assessment – Guidance for drafting normative documents suitable for use for conformity assessment**
  https://www.iso.org/standard/42635.html
- **ISO/IEC 17050-1:2004 Conformity Assessment – Supplier's Declaration of Conformity – Part 1: General Requirements**
  https://www.iso.org/standard/29373.html#:~:text=ISO%2FIEC%2017050%2D1%3A2004%20specifies%20general%20requirements%20for,irrespective%20of%20the%20sector%20involved.
- **ISO/IEC 17050-2:2004 Conformity Assessment – Supplier's Declaration of Conformity – Part 2: Supplemental Information**
  https://www.iso.org/standard/35516.html
- **ISO 14971:2019 Medical devices – Application of risk management to medical devices**
  https://www.iso.org/standard/72704.html
- **Society for Standards Professionals**
  https://www.ses-standards.org/page/A2?
- **World Health Organization WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices 2017**
  https://apps.who.int/iris/handle/10665/255177
- **World Trade Organization Agreement on Technical Barriers to Trade 1994**
  https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm

# FDA Relevant Guidances

- **Recognition and Withdrawal of Voluntary Consensus Standards guidance**
  www.fda.gov/regulatory-information/search-fda-guidance-documents/recognition-and-withdrawal-voluntary-consensus-standards
- **Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices guidance**
  www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices
- **Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions: Guidance for Industry and Food and Drug Administration Staff**
  https://www.fda.gov/media/113230/download

# US Standards Resources

- **Standards & Conformity Assessment Program**
  www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program#intro

- **FDA Recognized Consensus Standards Database**
  www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

**Email**: **CDRHStandardsStaff@fda.hhs.gov**

# FDA ASCA Resources

- **ASCA web page**
  www.fda.gov/medical-devices/standards-and-conformity-assessment-program/accreditation-scheme-conformity-assessment-asca
- **ASCA program guidance**
  https://www.fda.gov/regulatory-information/search-fda-guidance-documents/accreditation-scheme-conformity-assessment-asca-pilot-program
- **ASCA Standards-specific guidances**
  - **Basic Safety and Essential Performance standards-specific guidance:** https://www.fda.gov/regulatory-information/search-fda-guidance-documents/basic-safety-and-essential-performance-medical-electrical-equipment-medical-electrical-systems-and
  - **Biocompatibility standards-specific guidance:** https://www.fda.gov/regulatory-information/search-fda-guidance-documents/biocompatibility-testing-medical-devices-standards-specific-information-accreditation-scheme
- **Ask ASCA! ASCA@FDA.HHS.GOV**

# Industry Education

1. **CDRH Learn: Multi-Media Industry Education**
   - Over 200 modules
   - Videos, audio recordings, power point presentations, software-based “how to” modules
   - Mobile-friendly: access CDRH Learn on your portable devices

   www.fda.gov/CDRHLearn

2. **Device Advice: Text-Based Education**
   - Comprehensive regulatory information on premarket and postmarket topics

   www.fda.gov/DeviceAdvice

3. **Division of Industry and Consumer Education (DICE)**
   - Contact DICE if you have a question
   - Email: DICE@fda.hhs.gov
   - Phone: 1(800) 638-2041 or (301) 796-7100 (Hours: 9 am-12:30 pm; 1 pm-4:30pm EST)
   - Web: www.fda.gov/DICE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