Importance of International Standards and Reliance

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Chair, ISO TC210 – Quality Management and corresponding general aspects for products with a health purpose including medical devices

What is a “Standard”?

- “a level of quality, especially one that people think is acceptable” (Oxford English Dictionary)
- Consensus *document* used to create uniformity and harmonization over a specific topic

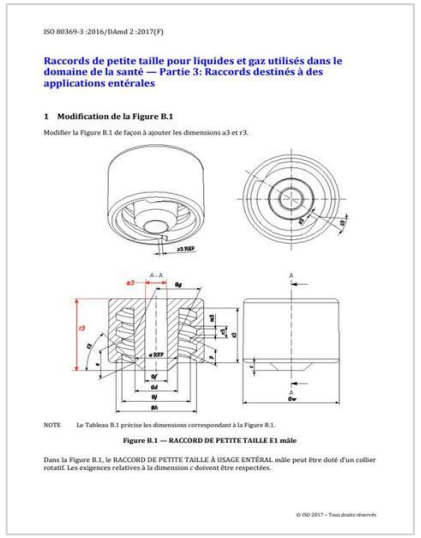
Instructions of Shuruppak
2600 BCE
Mesopotamia
(Source: Wikimedia Commons)

Reforms of Urukagina
2500 – 2340 BCE
Sumeria
(Source: Wikimedia Commons)

Code of Hammurabi
1755–1750 BCE
Egypt
(Source: SpiroSk Photo.)

Types of Medical Device Standards

- Specification/Design Standards
- Performance standards
- Guidelines/Technical Reports
- Systems standards
- Product Standards


ISO 80369-3 :2016/DAmd 2 :2017(F)

Raccords de petite taille pour liquides et gaz utilisés dans le domaine de la santé — Partie 3: Raccords destinés à des applications entérales

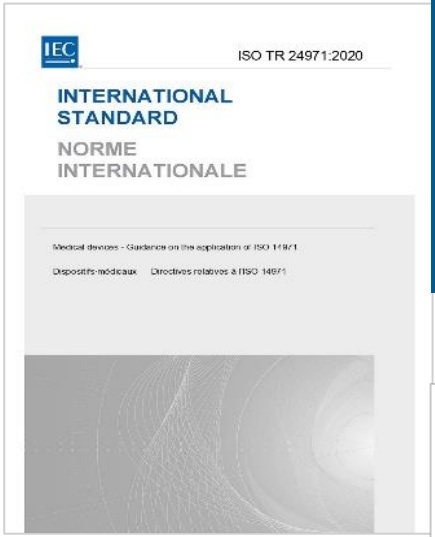
1 Modification de la Figure B.1

Modifier la Figure B.1 de façon à ajouter les dimensions a3 et r3.

NOTE Le Tableau B.1 précise les dimensions correspondant à la Figure B.1.

Figure B.1 — RACCORD DE PETITE TAILLE E1 mâle

Dans la Figure B.1, le RACCORD DE PETITE TAILLE À USAGE ENTÉRAL mâle peut être doté d'un collier rotatif. Les exigences relatives à la dimension c doivent être respectées.


IEC

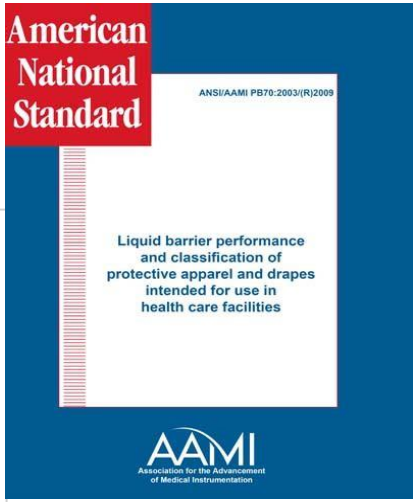
ISO TR 24971:2020

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical devices - Guidance on the application of ISO 14971

Dispositifs médicaux Directives relatives à l'ISO 14971


American National Standard

ANSI/AAMI PB70:2003/(R)2009

Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities

AAMI

Association for the Advancement of Medical Instrumentation


EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 13485

July 2003

ICS 03.120.10; 11.040.01

Supersedes EN ISO 13485:2000 and EN ISO 13488:2000

English version

Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)

Dispositifs médicaux - Systèmes de management de la qualité - Exigences à des fins réglementaires (ISO 13485:2003)

Qualitätsmanagementsysteme - Medizinprodukte - Systemanforderungen zur Erfüllung gesetzlicher Anforderungen (ISO 13485:2003)

This European Standard was approved by CEN on 16 June 2003.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Management Centre has the same status as the official versions.

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cen

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

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Ref. No. EN ISO 13485:2003 E


SNI

Standar Nasional Indonesia

SNI IEC 60601-2-19:2014

Peralatan elektromedik – Bagian 2-19: Persyaratan khusus untuk keselamatan dasar dan kinerja esensial inkubator *infant*

(IEC 60601-2-19:2009, IDT)

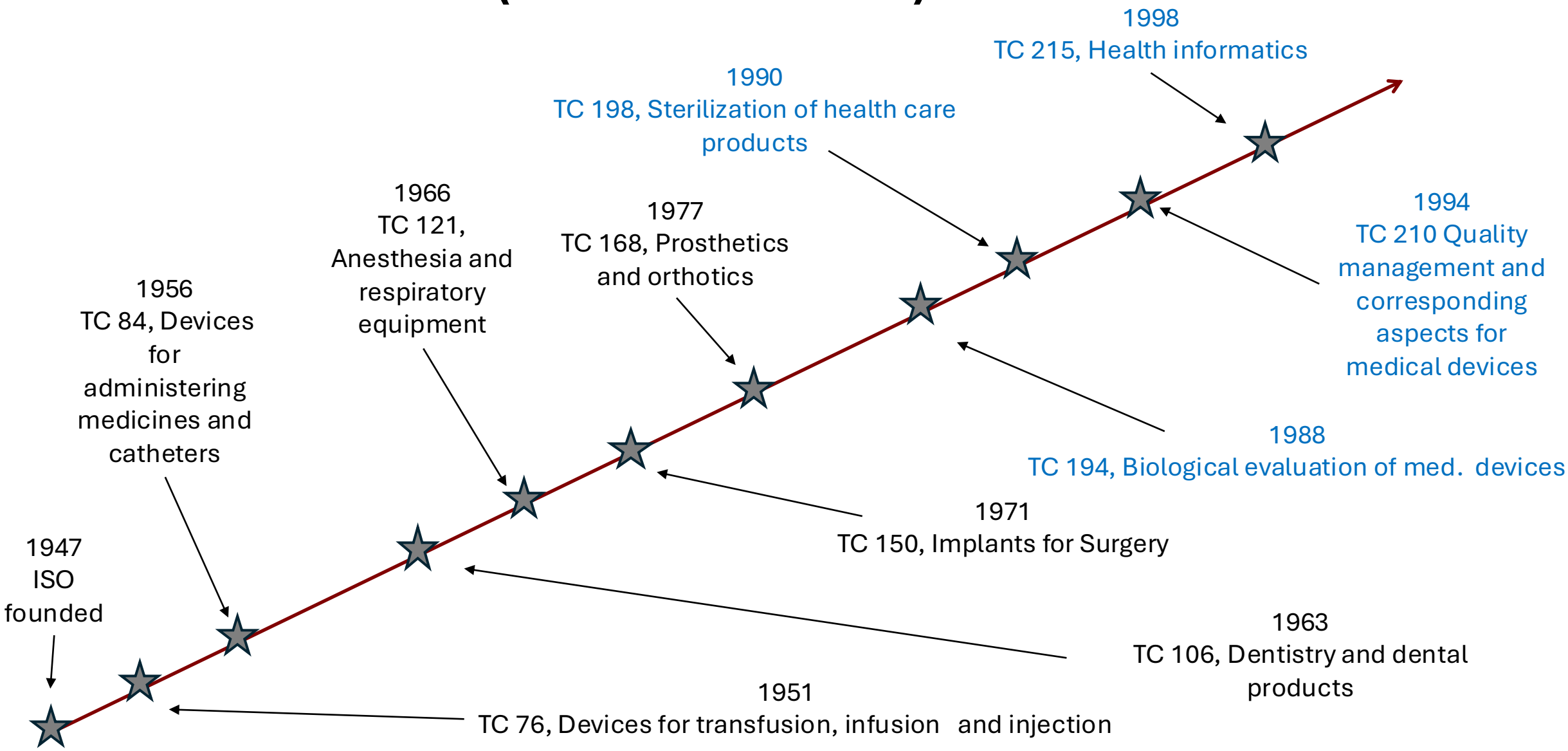
ICS 11.040.10

Badan Standardisasi Nasional BSN

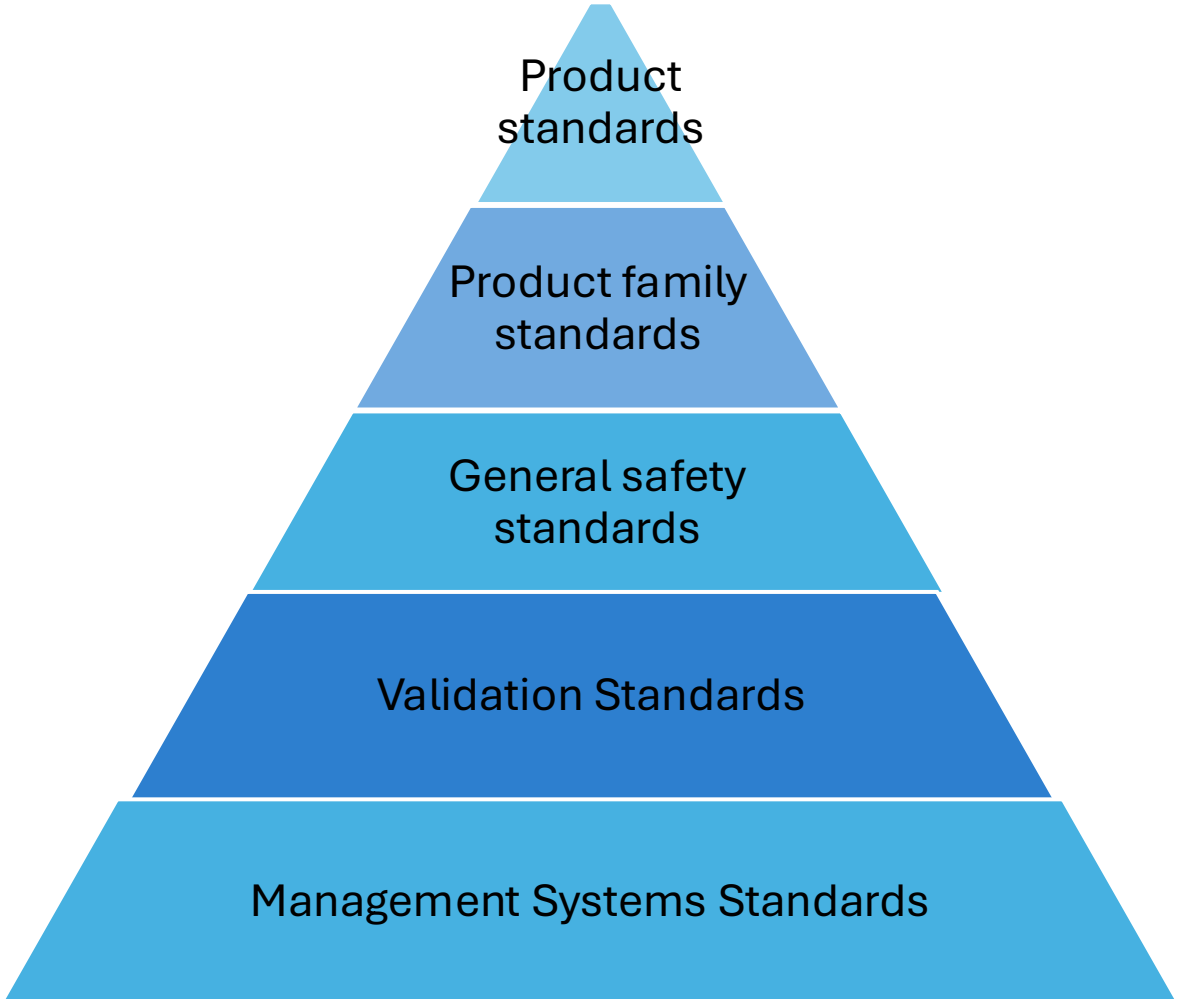
Another Distinction: Horizontal versus Vertical Standards

- Horizontal (cross-cutting)
  - ISO 13485: Quality systems
  - ISO 10993: Biocompatibility
  - IEC 60601-1 : General and Electrical Safety
- Vertical (device-specific)
  - ISO 81060-2: Non-invasive sphygmomanometers
  - ISO 11318: Cardiac defibrillators
  - IEC 60601-2-33: MRI

MOVE FROM A PRODUCT TO A SYSTEMS FOCUS (ISO CASE STUDY)

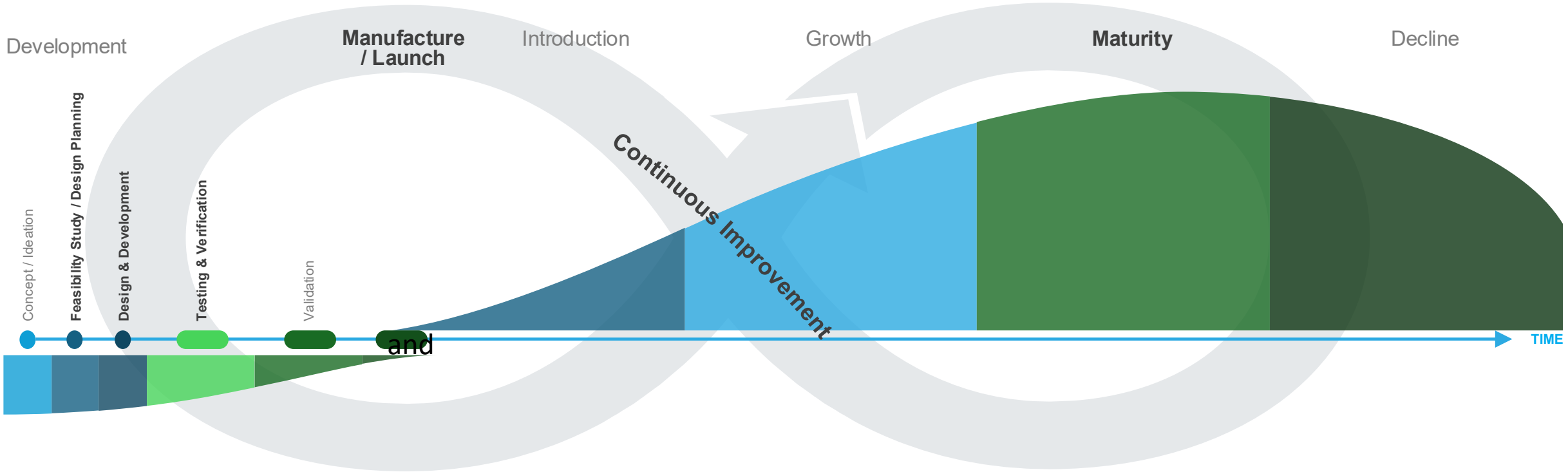


The Systems Approach



- Specific product standards are frequently necessary but are not sufficient.
- Safety and effectiveness are characteristics of a device but are the output of a system designed to deliver those characteristics.
- Today's body of medical device standards promote safety and effectiveness thought the production system and across the life of a device.

TOTAL PRODUCT LIFECYCLE



Quality, safety and effectiveness require the use of standards and controls across the Total Product Lifecyle—from the design phase to decommissioning and disposal

ISO/TC 210: Quality management and corresponding general aspects for products with a health purpose including medical devices

Scope

Standardization of requirements and guidance in the field of quality management and corresponding general aspects, for products with a health purpose, including connectors for liquid and gases.

Excluded:

- *generic quality management standards dealt with by ISO / TC 176;*
- *quality management standards for pharmaceutical products and healthcare services;*

Note: Products with a health purpose include products for use in relation to health, including medical devices, adjacent products [or could also say accessories] and those with a risk profile similar to medical devices.

Participation – the key to a quality standard!

45 participating and 28 observing member countries

Several Global Liaison organizations

Scope includes:

- ISO 13485 (Quality management systems)
- ISO/TS 23485 (Guideline for the application of ISO 13485)
- ISO/IEC 14971 (Risk management)
- ISO/TR 24971 Guidance on the application of ISO 14971
- IEC 62366 (usability).
- ISO 20416 (post-market surveillance)
- ISO 20417 (labelling)
- ISO 15223 (symbols)
- IEC 62304 (medical device software)
- ISO/IEC 80369 and ISO 18250 series (small bore connectors)
- Any many more!!!!

STRUCTURE OF ISO/TC 210

Working groups (WGs) – example:

WG1: Quality management systems (ISO 13485)
WG2: Risk management (ISO 14971)
WG3: Usability (IEC/ISO 62366)
WG6: Post-market surveillance guidance

ISO/TC210 is attended by:

Regulators, Industry leaders,

Technical experts, Notified bodies

Organized in relevant working groups – covering most of the elements

* number includes updates

Structure | Liaisons

Reference ↑	Title
ISO/TC 210/AHG	Ad-hoc group for ISO 22740
ISO/TC 210/AHG 4	Assessment of ISO 13485
ISO/TC 210/AHG 5	Collaboration with IMDRF on guidance documents
ISO/TC 210/ATTF	Arabic translation task force
ISO/TC 210/CAG	Chair Advisory Group
ISO/TC 210/JWG 1	Joint ISO/TC 210-IEC/SC 62A WG : Application of risk management to medical devices
ISO/TC 210/JWG 2	Joint ISO/TC 210-IEC/SC 62A WG : Medical device software
ISO/TC 210/JWG 3	Joint ISO/TC 210-IEC/SC 62A WG : Medical device usability
ISO/TC 210/JWG 4	Joint ISO/TC 210 - IEC/SC 62D WG: Small bore connectors
ISO/TC 210/STTF	Spanish translation task force
ISO/TC 210/WG 1	Application of quality systems to medical devices
ISO/TC 210/WG 2	General aspects stemming from the application of quality principles to medical devices
ISO/TC 210/WG 3	Symbols and nomenclature for medical devices
ISO/TC 210/WG 5	Connectors for reservoir delivery systems
ISO/TC 210/WG 6	Application of post market surveillance systems to medical devices
ISO/TC 210/WG 7	Good engineering maintenance management

Ongoing Work in ISO/TC 210

Current Revisions and Projects – Highlights:
ISO 13485 stable until 2031 / ISO/TS 23485 under development

Filter [7] : ☐ Published ☑ Under development ☐ Withdrawn ☐ Deleted Search in the list

Standard and/or project under the direct responsibility of ISO/TC 210 Secretariat ↑	Stage	ICS
ISO/CD 15223-2 [Under development] Medical devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 2: Symbol development, selection and validation	30.00	
ISO/AWI TR 20416 [Under development] Medical devices — Post-market surveillance for manufacturers	20.00	
ISO/WD TS 23485.2 [Under development] Medical Devices — Quality management systems — Guideline for the application of ISO 13485:2016	20.60	
ISO/TS 24971-2 [Under development] Medical devices — Guidance on the application of ISO 14971 — Part 2: Machine learning in artificial intelligence	60.00	11.040.01 35.240.01 35.240.80
ISO/WD TS 24971-3 [Under development] Medical devices - Guidance on the application of ISO 14971 — Part 3: Combination products	20.60	
IEC/CD TS 62366-2 [Under development] Medical devices — Part 2: Guidance on the application of usability engineering to medical devices	30.60	
IEC/AWI 80369-5 [Under development] Small-bore connectors for liquids and gases in healthcare applications — Part 5: Connectors for limb cuff inflation applications	10.99	

Ongoing Work in ISO/TC 210

Trends Driving the Work

- Regulatory tightening (MDR/IVDR, FDA updates)
- Increased focus on patient safety
- Digitalisation & software-heavy devices
- Global consistency / harmonisation
- Better clarity for audits
- Reducing unnecessary complexity in standards

Benefits of Contributing

Why Participate in ISO/TC 210?

- Influence the development of the standards you must comply with
- Gain early insight into changes
- Understand the intent behind requirements
- Enhance internal interpretation and implementation
- Build strong expert networks

Benefits of Contributing

Benefits for Companies

- Reduced compliance risk
- Improved audit outcomes
- Faster adaptation to new standards
- Better understanding of expectations from regulators
- Opportunities for internal competence building
- Competitive advantage

Benefits of Contributing

Practical Impact:

- **Clarifying unclear requirements in drafts**

- **Influencing on International Standards**

  Participation gives your organization the ability to:

  - Suggest changes
  - Comment on drafts
  - Vote on key decisions

  This influence ensures that standards remain practical, implementable, and aligned with real-world industry needs.

- **Bringing industry experience into the standard**
- **Helping avoid over-regulation or unrealistic demands**

The Medical Device Standards Value Proposition

Medical sector standards promote health, safety, security, privacy, access, and harmonization and serves to deliver **better patient outcomes.**

$$S + E + A = BPO_{max}$$

Optimizing standards for regulatory purposes

IMDRF International Medical Device Regulators Forum

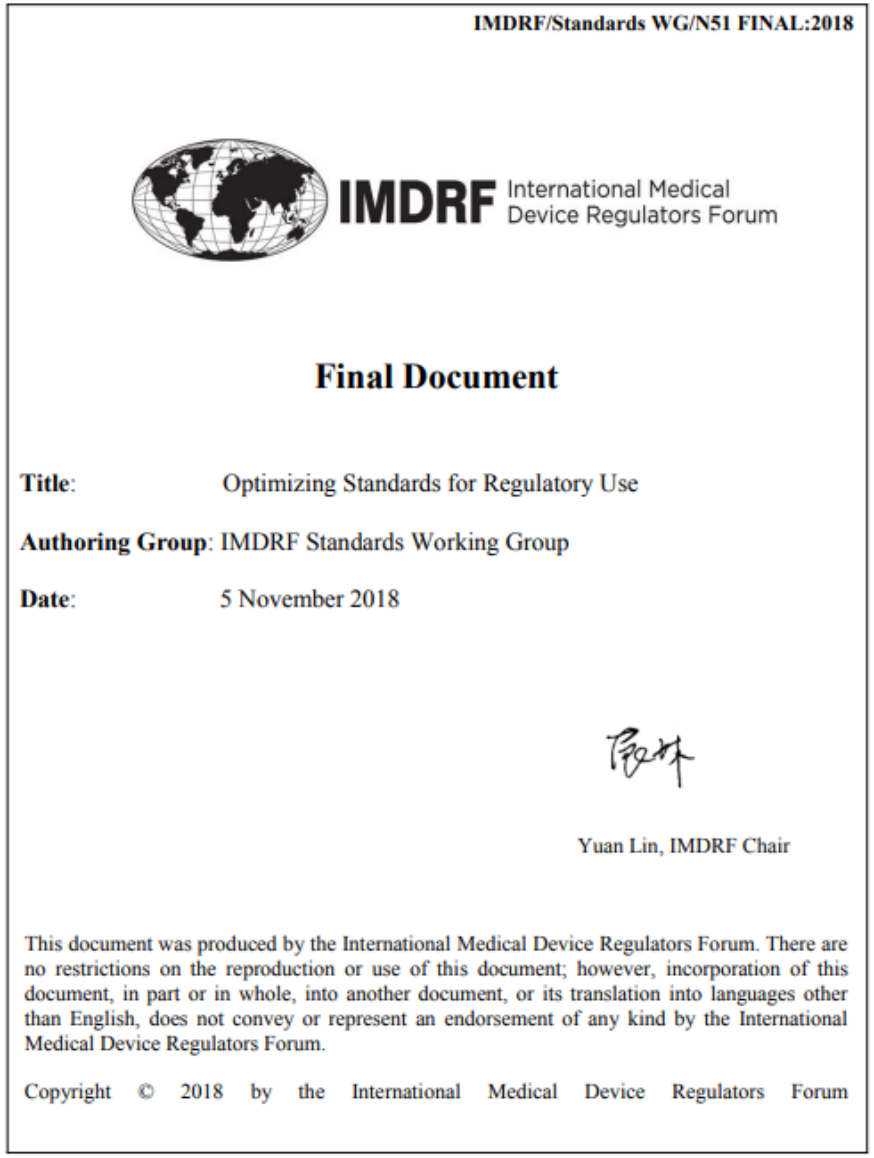
Challenges to Regulatory-ready Standards

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* → can render standards less useful as they may not adequately identify minimum requirements for quality, safety and/or effectiveness/performance.

Guidance Recommendations:

- Standards must be optimized for regulatory use
- IMDRF [RA] 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

Role of the Regulator in Standards:

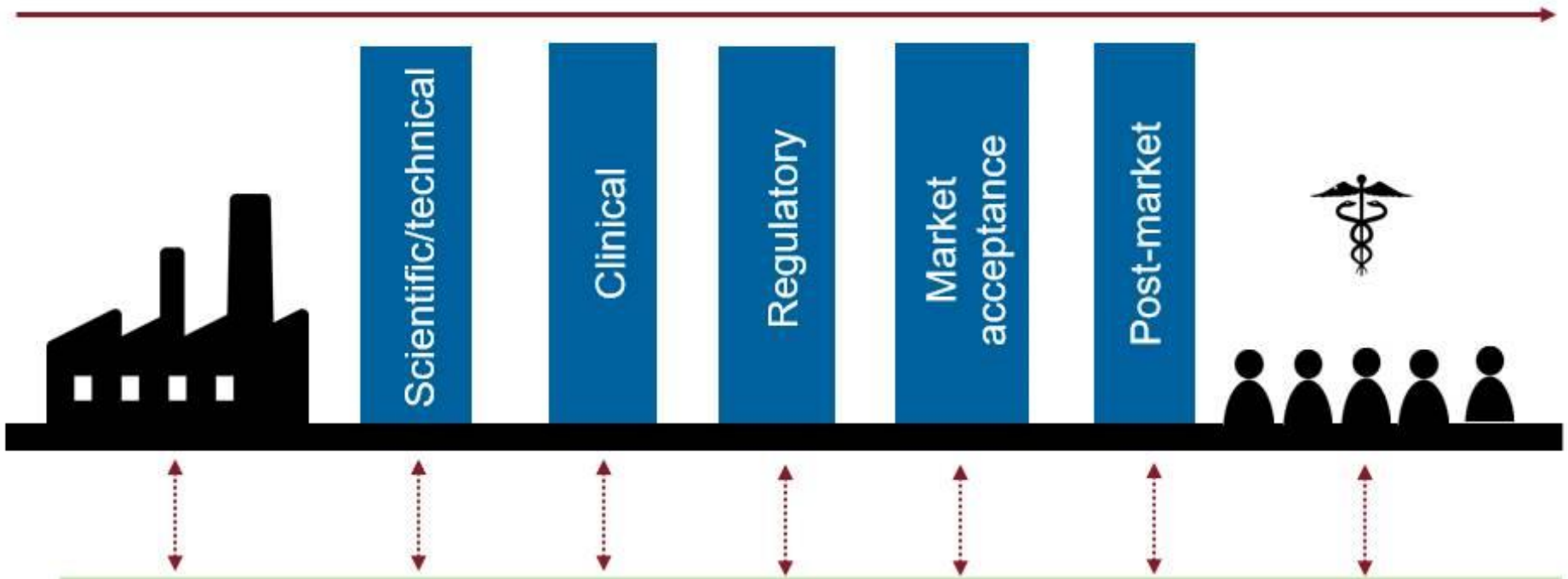
- Regulatory Authorities should build a strong standards program that encourages contributions to standards development
- Engagement with SDOs is essential
  - —Through national bodies and mirror committees
  - —On SDO Technical Committees
- Contribute regulatory perspective
- Get involved early – at the New Work Item Proposal stage
- Communicate national / regulatory needs
- Consider leadership roles

IMDRF International Medical Device Regulators Forum

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
  - Understand how to implement standards to meet jurisdictional needs

The connection between standards and regulations—Promoting safety, effectiveness, and access from conception through clinical use



Standards

Total Product Lifecyle Regulation

(Design to Disposal)

Essential Principles of Safety and Performance

(e.g., IMDRF [2018], EU, USA, Australia, etc.)

Benefit by Stakeholders

Patients, consumers, the public

- Assures device safety, effectiveness, quality
- Increases affordability
- Improves access to technology-enabled diagnosis and treatment

Clinicians, healthcare providers

- Assures device safety, effectiveness, quality
- Eases evaluation of devices (acquisition)
- Facilitates delivery of state-of-the-art healthcare

Medical Device Manufacturers

- Provides assessment of state-of-the-art
- Details product requirements
- Clarifies pathway for regulatory approval
- Provides presumption of compliance
- Limits unfair liability
- Promotes international trade

Medical Device regulators

- Provides assessment of state-of-the-art
- Provides consensus criteria for product evaluation
- Reduces review/approval times
- Facilitates of agile regulation
- Advances regulatory science

Stakeholders in Device Standards

- Regulators
- Clinicians/Healthcare delivery organizations
- Technology manufacturers, producers, vendors
- Patients and patient advocates
- Testing laboratories
- Consumers
- Health authorities

NOTE: For some international SDOs, like ISO and IEC, the stakeholders are often countries, rather than individuals

Different Types SDOs and Consensus

- **Regulatory**
  - Government developed standards and specifications
- **National Standard Bodies**
  - Consensus determined by national rules
- **Regional**
  - Consensus (voting) among member states (nations)
- **International NGOs (2 types)**
  - Consensus (voting) among stakeholders with a material interest
  - Consensus (voting) among member states (nations)

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

Relevant CDRH 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

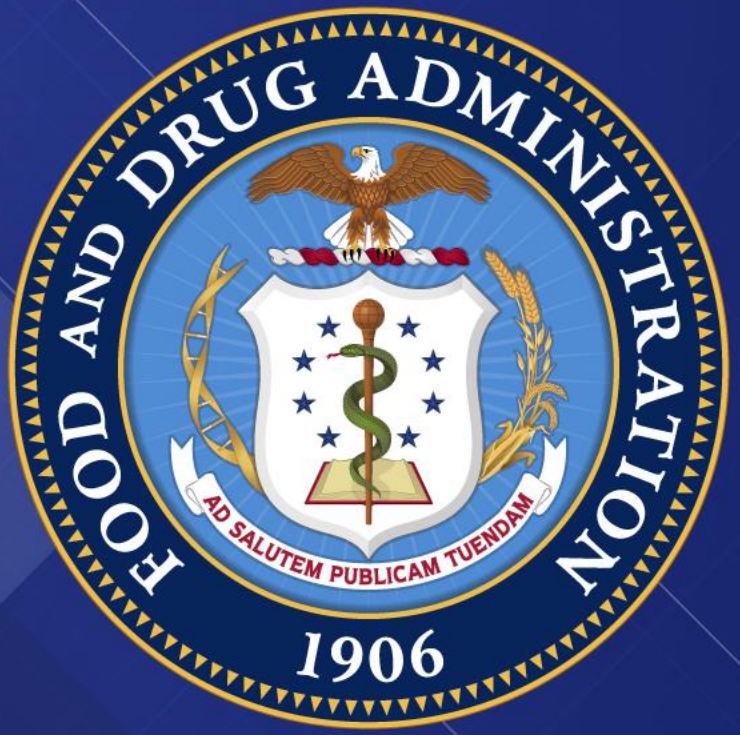
- **Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions: Guidance for Industry and Food and Drug Administration Staff**
  https://www.fda.gov/media/113230/download

CDRH Standards Resources

- **FDA/CDRH Division of Standards & Conformity Assessment**
  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

- **CDRHStandardsStaff@fda.hhs.gov**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