Standards:
The Ultimate Regulatory Weapon

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Inter-American Coalition for Regulatory Convergence,
Medical Technology Sector
External Stakeholder Session
March 14, 2024

U.S. FOOD & DRUG ADMINISTRATION
Center for Devices and Radiological Health
Division of Standards and Conformity Assessment

Topics

- Value of consensus standards
- FDA's Division of Standards and Conformity Assessment (DSCA)
- Standards Recognition Program
- Question and Answer Session

VALUE OF CONSENSUS STANDARDS

Benefits of Consensus Standards

- Improved quality thanks to the consensus process, tapping into a broad array of experts and expertise
- More efficient than lengthy legal or rule-making approaches
- Encourage innovation and competition among product developers
- Reduce burdens on manufacturers by harmonizing expectations across jurisdictions
- Promote regulatory science at national and international levels
- Streamline conformity assessment

CDRH strongly encourages the use of standards

Why?

- FDA-recognized standards have FDA's confidence that conformity will support device claims
- Using recognized standards with a declaration of conformity generally reduces documentation needed in the submission
- Fewer Additional Information questions
- Conformity assessment resource used by multiple jurisdictions

DIVISION OF STANDARDS AND CONFORMITY ASSESSMENT (DSCA)

CDRH's Division of Standards and Conformity Assessment (DSCA)

DSCA By the Numbers

1400+
Recognized standards

400+
CDRH staff contribute to standards development (20%)

3 dozen
Standards development organizations we work with

303
Years of standards experience among DSCA staff

DSCA Goals

Optimize	Increase	Enhance	Support	Practice	Increase
Optimize standards for regulatory use	Increase the appropriate use of FDA-recognized standards across the total product life cycle of devices	Enhance conformity assessment in device review	Support international harmonization through standards	Practice leadership to demonstrate the promise of standards in policymaking, regulatory science and device review priorities	Improve cross-cutting DSCA programs

DSCA’S STANDARDS RECOGNITION PROGRAM

FDA's Standards Recognition Program

'Recognition': FDA's formal identification of a standard after determining that it is appropriate for manufacturers to declare conformance (with a declaration of conformity) to meet relevant requirements

- We may recognize all, part or none of the standard
- We publish the decision rationale
- We regularly update databases
  - Recognized Consensus Standards Database
  - Non-recognized Consensus Standards Database
- We may withdraw recognized standards, as appropriate

FDA Recognized Consensus Standards Database

Searchable by:

- Standards Development Organization (SDO)
- Designation number
- FDA recognition number
- Keywords
- Inclusion in ASCA
- And more

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/search.cfm

Supplementary Information Sheets (SIS) include:

- Recognition number
- Date of entry into Recognized Consensus Standards Database
- SDO and designation number
- US identical adoption (if applicable)
- Scope of standard
- Extent of recognition
- Included in ASCA?
- Rationale for recognition or partial recognition
- Transition period (if any)
- Examples of applicable device product codes
- Relevant guidance documents or other publications
- Relevant FDA Specialty Task Group (STG)
- Name of contact person

Part B: Supplementary Information Sheet (SIS)

FR Recognition List Number 053 **Date of Entry** 12/23/2019

FR Recognition Number 5-125

Standard

ISO 14971 Third Edition 2019-12
Medical devices - Application of risk management to medical devices

Identical Adoption

ANSI AAMI ISO 14971: 2019
Medical devices - Applications of risk management to medical devices

Scope/Abstract

This International Standard specifies a process for a manufacturer to identify the hazards associated with medical devices, including in vitro diagnostic (IVD) medical devices, to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls.
The requirements of this International Standard are applicable to all stages of the life-cycle of a medical device.
This International Standard does not apply to clinical decision making.
This International Standard does not specify acceptable risk levels.
This International Standard does not require that the manufacturer have a quality management system in place.
However, risk management can be an integral part of a quality management system.

Extent of Recognition

Complete standard

Rationale for Recognition

This standard is relevant to medical devices and is recognized on its scientific and technical merit and/or because it supports existing regulatory policies.

Relevant FDA Guidance and/or Supportive Publications*

ISO/TR 24971 Second edition 2020-06 Medical devices - Guidance on the application of ISO 14971

AAMI/ISO TIR24971: 2020 Medical devices - Guidance on the application of ISO 14971

Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices - Guidance for Industry and Food and Drug Administration Staff, issued September 2018.

FDA Technical Contact

Melissa Torres
FDA/OC/CDRH/OCD/
301-796-5576
melissa.torres@fda.hhs.gov

Standards Development Organization

ISO International Organization for Standardization https://www.iso.org/

SIS Example
ISO 14971:2019
(complete recognition)

Note rationale for recognition

Note other relevant documents

Note FDA contact and SDO

Conformity Assessment Defined

"…demonstration that specified requirements relating to a product, system, process, person, or body are fulfilled." *- ISO/IEC 17000*

*** Testing, inspection and certification are all elements of conformity assessment ****

Conformity Assessment

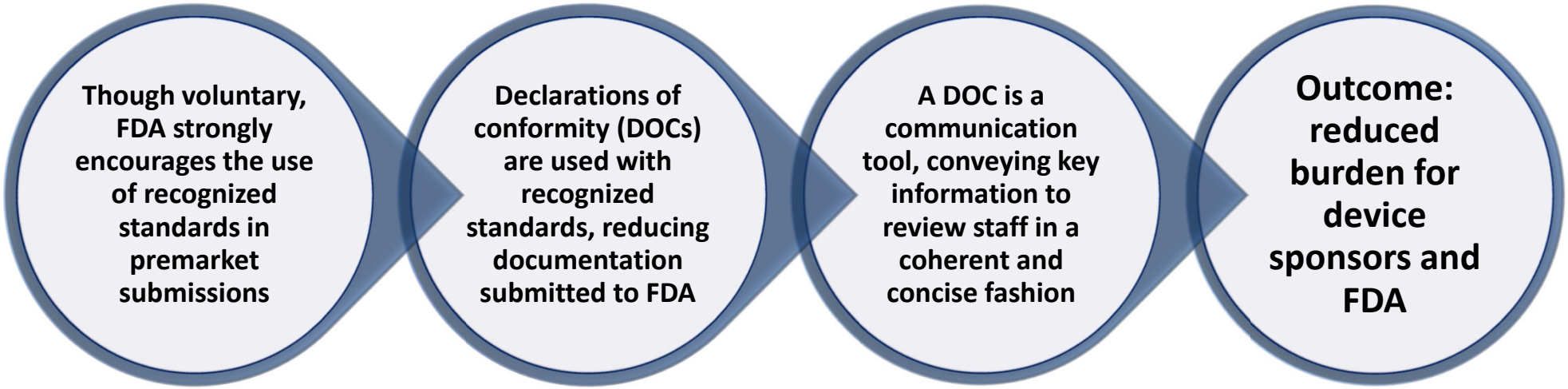
Device sponsors:

- Use standards to address regulatory requirements
- Support their submission with testing
- Work with the test lab to develop test plan
- Report results to FDA (for devices not exempt from such clearance/approval)

FDA:

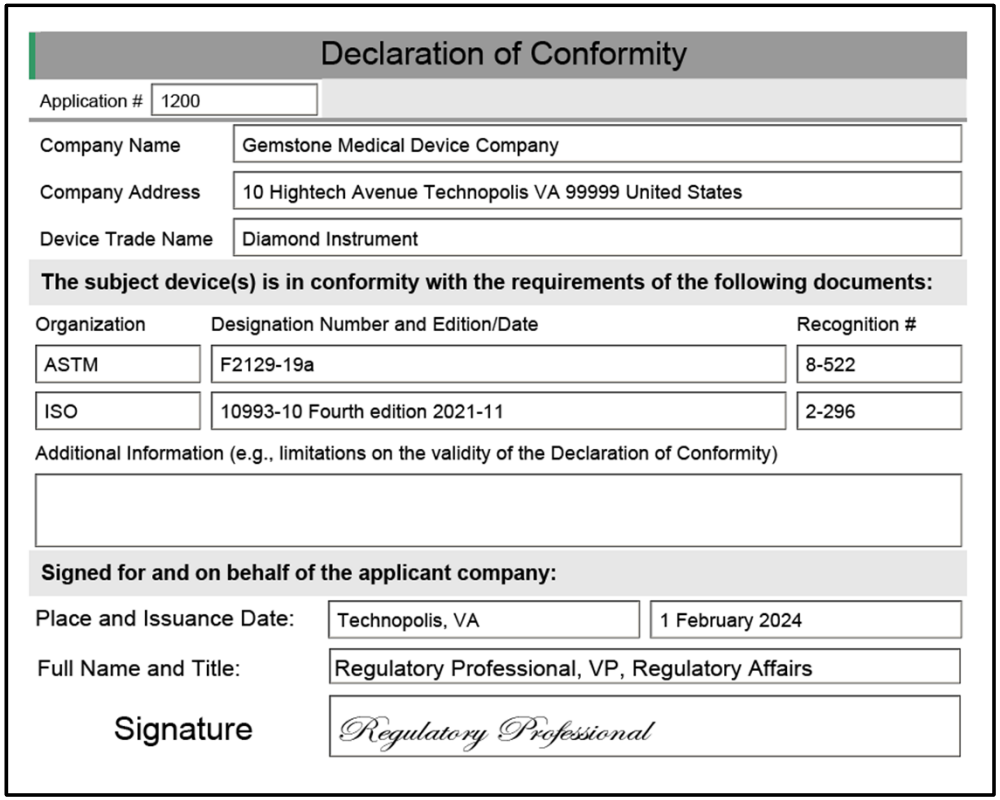
- Recommends that sponsors conform to consensus standards via recognition, conformity assessment programs and FDA Guidance and applicable regulations
- Reviews test methods and results and determines that reasonable assurance of safety and effectiveness or substantial equivalence is met
- For exempt devices, methods and results may be reviewed during a QMS inspection or if there are post market issues

Using FDA-Recognized Standards



Declaration of Conformity (DOC)

- Communication that the device conforms with the cited FDA-recognized standard
- If the manufacturer declares conformity with a recognized standard, a DOC accompanies the submission
- DOCs generally reduce the documentation needed to be included – ***and reviewed*** - in a submission
- Complete test reports generally not needed and should not be submitted with a DOC



Declaration of Conformity

Application # 1200

Company Name	Gemstone Medical Device Company
Company Address	10 Hightech Avenue Technopolis VA 99999 United States
Device Trade Name	Diamond Instrument

The subject device(s) is in conformity with the requirements of the following documents:

Organization	Designation Number and Edition/Date	Recognition #
ASTM	F2129-19a	8-522
ISO	10993-10 Fourth edition 2021-11	2-296

Additional Information (e.g., limitations on the validity of the Declaration of Conformity)

Signed for and on behalf of the applicant company:

Place and Issuance Date:	Technopolis, VA	1 February 2024
Full Name and Title:	Regulatory Professional, VP, Regulatory Affairs	
Signature	*Regulatory Professional*	

Above image is a DOC from eSTAR

‘General Use’ of Standards

For citing:

- Non-recognized standards
- A recognized standard where modifications have been made in testing
- A recognized standard without submitting a DOC

Complete test reports are needed - *and will be reviewed* - for ‘General Use’

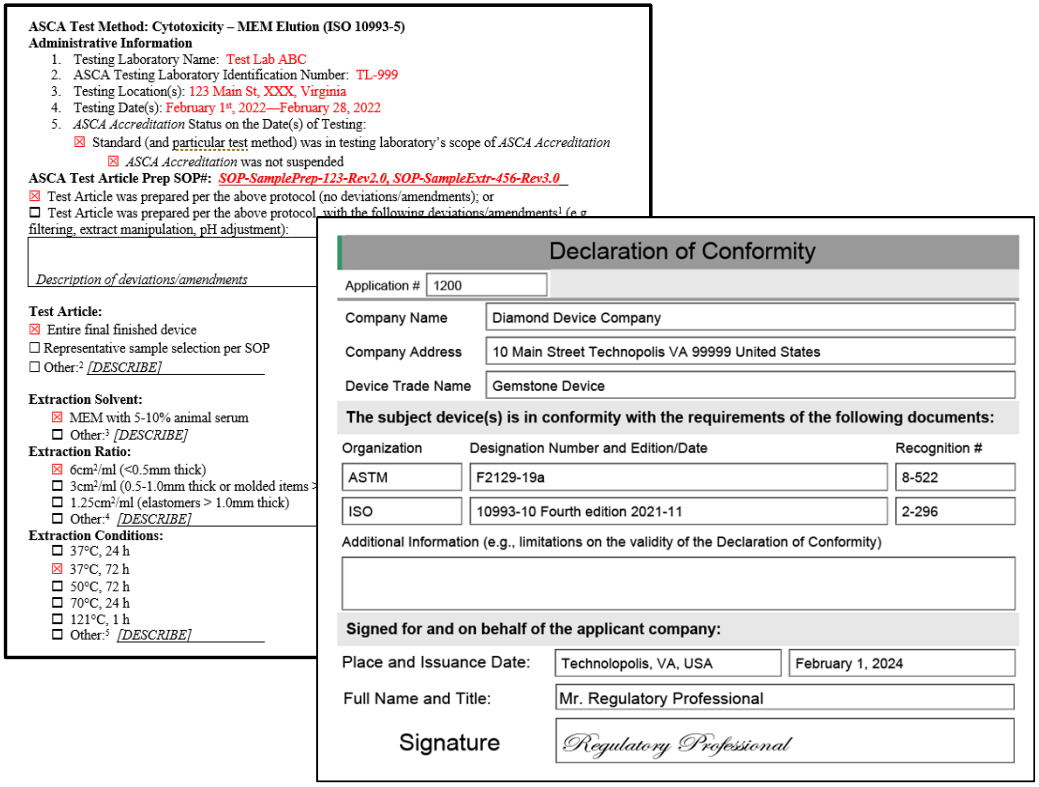
- Information that supports the declaration of conformity
- Needed when:
  - Standard does not feature test methods or acceptance criteria
  - Standard allows choices, e.g., for methods or criteria
- The ultimate goal: a standard that clearly outlines expectations for manufacturers and regulators

ACCREDITATION SCHEME FOR CONFORMITY ASSESSMENT (ASCA)

ASCA Goal: Streamline Conformity Assessment in Pre-market Review

Benefits of ASCA:

- Improves the quality of testing and reporting
- Removes the guesswork about supporting documentation needs
- Provides templates for the only documentation needed:
  - — ASCA Declaration of Conformity
  - — ASCA Summary Test Report



ASCA Test Method: Cytotoxicity – MEM Elution (ISO 10993-5)
Administrative Information

1. Testing Laboratory Name: Test Lab ABC
2. ASCA Testing Laboratory Identification Number: TL-999
3. Testing Location(s): 123 Main St, XXX, Virginia
4. Testing Date(s): February 1st, 2022—February 28, 2022
5. *ASCA Accreditation* Status on the Date(s) of Testing:
   - ☒ Standard (and particular test method) was in testing laboratory's scope of *ASCA Accreditation*
   - ☒ *ASCA Accreditation* was not suspended

ASCA Test Article Prep SOP#: *SOP-SamplePrep-123-Rev2.0, SOP-SampleExtr-456-Rev3.0*

☒ Test Article was prepared per the above protocol (no deviations/amendments); or
☐ Test Article was prepared per the above protocol, with the following deviations/amendments[1] (e.g. filtering, extract manipulation, pH adjustment):

Description of deviations/amendments

Test Article:
☒ Entire final finished device
☐ Representative sample selection per SOP
☐ Other:[2] *[DESCRIBE]*

Extraction Solvent:
☒ MEM with 5-10% animal serum
☐ Other:[3] *[DESCRIBE]*

Extraction Ratio:
☒ 6cm²/ml (<0.5mm thick)
☐ 3cm²/ml (0.5-1.0mm thick or molded items >
☐ 1.25cm²/ml (elastomers > 1.0mm thick)
☐ Other:[4] *[DESCRIBE]*

Extraction Conditions:
☐ 37°C, 24 h
☒ 37°C, 72 h
☐ 50°C, 72 h
☐ 70°C, 24 h
☐ 121°C, 1 h
☐ Other:[5] *[DESCRIBE]*

Declaration of Conformity

Application #	1200
Company Name	Diamond Device Company
Company Address	10 Main Street Technopolis VA 99999 United States
Device Trade Name	Gemstone Device

The subject device(s) is in conformity with the requirements of the following documents:

Organization	Designation Number and Edition/Date	Recognition #
ASTM	F2129-19a	8-522
ISO	10993-10 Fourth edition 2021-11	2-296

Additional Information (e.g., limitations on the validity of the Declaration of Conformity)

Signed for and on behalf of the applicant company:

Place and Issuance Date:	Technolopolis, VA, USA	February 1, 2024
Full Name and Title:	Mr. Regulatory Professional	
Signature	*Regulatory Professional*	

Above image is a DOC from eSTAR

ASCA Progress

- (56) submissions spanning 7 of 8 OHTs
- Easier and faster than traditional review
- **Only 6% required complete test reports**
- ASCA transition from pilot to permanent is complete
- Program improvements under consideration with guidance revisions; watch the *Federal Register* for commenting opportunity
- Expansion criteria to be explored at April 17, 2024 workshop
  - Watch this space for meeting details: https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops

World Health Organization

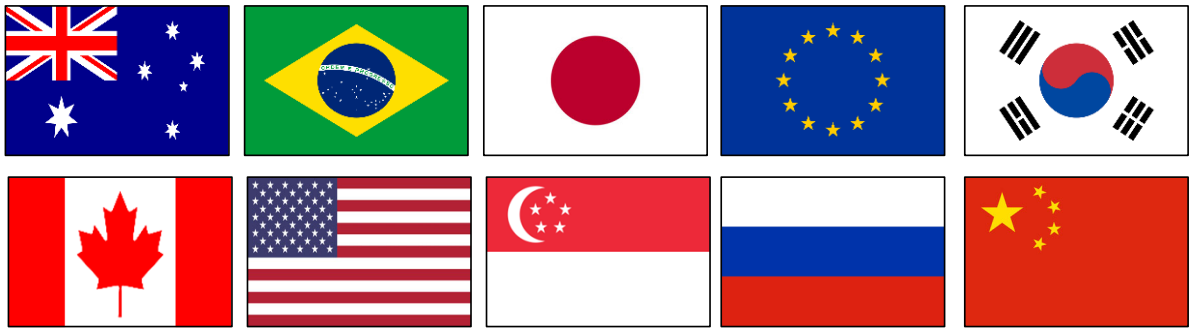
Official Observer

APEC
Asia-Pacific Economic Cooperation

Global Harmonization Working Party
GHWP Towards Medical Device Harmonization

Pan American Health Organization

Regional Harmonization Initiatives



Management Committee (MC) Members

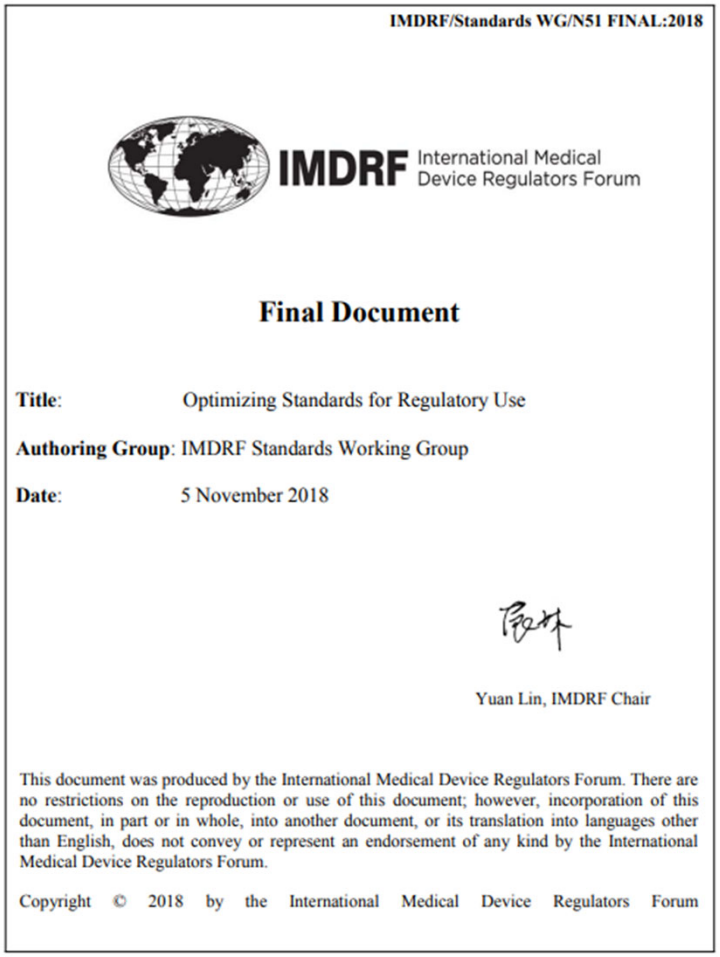
FDA

IMDRF
International Medical Device Regulators Forum

IMDRF International Medical Device Regulators Forum

Recommendations:

- Improve standards for regulatory use
- Enhance participation 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

IMDRF International Medical Device Regulators Forum

Improve Standards

Standards should feature:

- A strong rationale explaining the basis for the requirements in the standard that may assist in interpreting the meaning and/or purpose of the standard
- Clear scope
- Well-accepted and verified test methods (including for new or unfamiliar methods)
- Clear and quantitative acceptance criteria
- Means to assess clinical performance (if applicable) as part of the normative requirements
- Identification of risk and direction on how to address it
- An annex or table that cross references the standard's clauses to the IMDRF *Essential Principles*

Enhance Participation

- Regulatory Authorities and device firms should build a strong standards programs that encourage contributions to standards development
- Engagement with SDOs is essential
  - —On SDO Technical Committees
  - —Through national bodies and mirror committees
- Contribute your perspective and expertise
- Get involved early – at the New Work Item Proposal stage
- Consider leadership roles
- Help build conformity assessment and regulatory priorities into the standards (e.g., test methods, acceptance criteria)

IMDRF International Medical Device Regulators Forum

QUESTION AND ANSWER SESSION

Future

- Conformity assessment
  - Greater consideration given to testing needs
  - ASCA and ASCA-type expansion (more standardized reporting)
- Standards-driven international harmonization
  - Capacity-building
  - Fewer ‘national’ standards
- Optimizing standards initiatives
- Greater reliance upon consensus standards to reduce burden and enhance quality

Industry Updates and Education

1. **CDRH New**
   - Sign up at: https://public.govdelivery.com/accounts/USFDA/subscribers/qualify
2. **CDRH Learn: Multi-Media Industry Education**
   - Videos, audio recordings, power point presentations, software-based "how to" modules
   - www.fda.gov/CDRHLearn
3. **Device Advice: Text-Based Education**
   - Comprehensive regulatory information on premarket and postmarket topics
   - www.fda.gov/DeviceAdvice
4. **Division of Industry and Consumer Education (DICE)**
   - 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
5. **eSTAR Program**
   - https://www.fda.gov/medical-devices/how-study-and-market-your-device/voluntary-estar-program?utm_medium=email&utm_source=govdelivery
   - eSTAR Assistance: 510K_Program@fda.hhs.gov
   - Tech Questions/Feedback: eSubpilot@fda.hhs.gov

FDA Standards Resources

- **Division of Standards and 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

- **Non-recognized Standards Database**
  https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/nr_results.cfm

- **Email us at: CDRHStandardsStaff@fda.hhs.gov**

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

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**

THANK YOU

U.S. FOOD & DRUG ADMINISTRATION

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