Recognized Consensus Standards:

The Ultimate Weapon to Streamline Conformity Assessment and Advance Innovation

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Streamline ↔ Innovate ↔ Harmonize

Learning Objectives

- Identify benefits of using consensus standards in device development and FDA regulatory review
- Explain why using FDA-recognized standards may save time
- Describe conformity assessment and the ASCA program
- Cite standards in eSTAR

ASCA = Accreditation Scheme for Conformity Assessment
eSTAR = electronic Submission Template and Resource

Benefits of Consensus Standards

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- **Reduce burden on manufacturers**
  - — By harmonizing expectations across jurisdictions
- **Improve device quality**
  - — Due to consensus process
  - — Tap into a broad array of experts

Benefits of Consensus Standards

- **Encourage innovation and competition**
  - — Among product developers
- **Promote regulatory science**
  - — At national and international levels
- **Streamline conformity assessment**

Use of FDA-Recognized Standards

FDA Definition of “Recognition”

- FDA’s formal identification of a standard after determining that it’s appropriate for manufacturers to declare conformance to meet relevant requirements

FDA's Roles with Standards

- Encourages stakeholders to nominate standards for recognition
- Recognizes standard (all, part, or none)
- Publishes decision rationale
- Updates recognition decisions regularly
- Withdraws recognized standards, as appropriate

Recognized Standards Database

[Recognized Consensus Standards Medical Devices Database]

CDRH Strongly Encourages Use of Standards

- FDA-recognized standards have FDA's confidence that conformity will support device claims
- Regulatory submissions may have fewer deficiencies
- Multiple regulatory jurisdictions use standards for conformity assessment

Declaration of Conformity (DOC)

- **A communication tool**
  - — Coherently and concisely conveys key information to FDA review staff
- **Used with recognized standards**
  - — Reduces documentation submitted to FDA

“General Use” of Standards

- **Used for citing:**
  - Non-recognized standards
  - Recognized standards where modifications were made in testing
  - Recognized standards without submitting a DOC
- **Complete test reports are needed**
  - FDA will review

Conformity Assessment and ASCA

Conformity Assessment, Defined

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

- **Testing, inspection, and certification**
  - —Are all elements of conformity assessment

ISO = International Organization for Standards
IEC = International Electrotechnical Commission

Conformity Assessment Roles

Device Sponsor

- Use standards to address regulatory requirements
- Support their submission with testing
- Work with test lab to develop test plan
- Report results to FDA

Conformity Assessment Roles

FDA

- Recommend that sponsors conform to consensus standards
  - FDA-recognized standards (in particular)
- Encourage the use of recognized standards to address regulatory requirements
- Encourage participation in ASCA
- Review test methods and results in regulatory submissions
  - To assess safety and effectiveness

Accreditation Scheme for Conformity Assessment (ASCA)

- Capitalizes on FDA-recognized voluntary consensus standards in development and review
- Leverages international standards ISO/IEC 17011 and 17025
- “Puts standards to work” in conformity assessment

ASCA (Device Advice)

What *ASCA Accreditation* Means

- Determination from FDA to a qualified test lab
- FDA has confidence in lab methods and results
- FDA does not need to review test report in regulatory submission
- Uses least burdensome principles by only needing the minimum amount of information needed to support the appropriate use of a standard in a DOC

Advantages of ASCA

- Removes guesswork about how to appropriately use standards
- Reduces FDA time to review conformity assessment element
  - Fewer deficiencies
  - Fewer extensive internal FDA consults
  - No need for FDA review of complete test report
- Improves quality of testing and reporting
  - Increased confidence in device safety
  - Addresses common FDA issues with testing

Goal of ASCA

- To streamline conformity assessment in premarket review

- Specifies supporting documentation needs
  - ASCA Declaration of Conformity (DOC)
  - ASCA Summary Test Report

ASCA Premarket Submission Elements

Cover Letter

- States that submission has ASCA testing
- Name, location and IDs of test lab(s)
- FDA-recognized consensus standard(s) and test methods used

ASCA Declaration of Conformity (DOC)

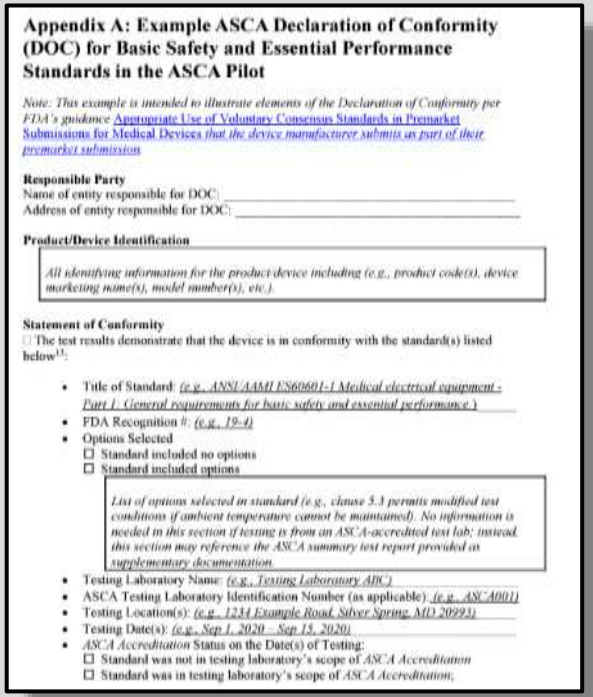
- Manufacturer provides
- *ASCA Accreditation* status for the test lab
- Example DOCs in ASCA guidances or eSTAR

ASCA Summary Test Report

- See standards-specific ASCA guidance documents for examples

- **Device sponsors are responsible for documenting how testing supports premarket submissions, even for ASCA submissions**

Example ASCA Declaration of Conformity



Appendix A: Example ASCA Declaration of Conformity (DOC) for Basic Safety and Essential Performance Standards in the ASCA Pilot

Note: This example is intended to illustrate elements of the Declaration of Conformity per FDA's guidance Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices that the device manufacturer submits as part of their premarket submission.

Responsible Party
Name of entity responsible for DOC: _____
Address of entity responsible for DOC: _____

Product/Device Identification

All identifying information for the product/device including (e.g., product code(s), device marketing name(s), model number(s), etc.).

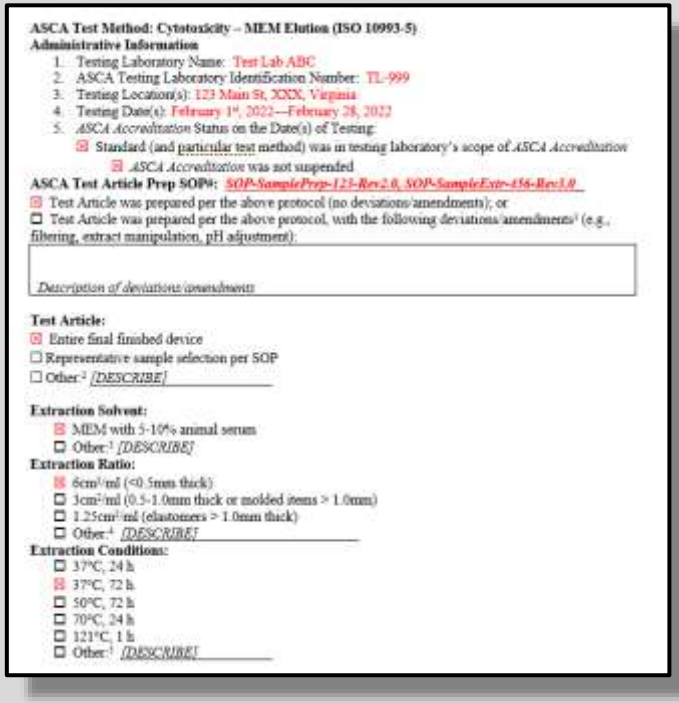
Statement of Conformity
☐ The test results demonstrate that the device is in conformity with the standard(s) listed below[1]:

- Title of Standard: *(e.g., ANSI/AAMI ES60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.)*
- FDA Recognition #: *(e.g., 19-4)*
- Options Selected
  - ☐ Standard included no options
  - ☐ Standard included options

  List of options selected in standard (e.g., clause 5.3 permits modified test conditions if ambient temperature cannot be maintained). No information is needed in this section if testing is from an ASCA-accredited test lab; instead, this section may reference the ASCA summary test report provided as supplementary documentation.
- Testing Laboratory Name: *(e.g., Testing Laboratory ABC)*
- ASCA Testing Laboratory Identification Number (as applicable): *(e.g., ASCA001)*
- Testing Location(s): *(e.g., 1234 Example Road, Silver Spring, MD 20993)*
- Testing Date(s): *(e.g., Sep 1, 2020 – Sep 15, 2020)*
- *ASCA Accreditation* Status on the Date(s) of Testing:
  - ☐ Standard was not in testing laboratory's scope of *ASCA Accreditation*
  - ☐ Standard was in testing laboratory's scope of *ASCA Accreditation*;

[Guidance: Basic Safety and Essential Performance…Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program]

Example 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 > 1.0mm)
☐ 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]*

[Guidance: Biocompatibility Testing… Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program]

Real World Example:
Wound Therapy Device Submission
Basic Safety and Essential Performance Assessment

- **Negative Pressure Wound Therapy Powered Suction Pump**
  - Promotes wound healing by the removal of excess exudates, infectious material, and tissue debris

- **Basic Safety and Essential Performance ASCA testing:**
  - IEC 60601-1
  - IEC 60601-1-2
  - IEC 60601-1-6
  - IEC 60601-1-8
  - IEC 60601-1-11

ASCA Wound Therapy Device Submission:
Comparing Non-ASCA and ASCA Reviews

60601-1 and all collaterals	Complete Test Reports (not needed but provided with ASCA Summary Test Reports)	ASCA Testing: ASCA Summary Test Reports
Review staff	Consult may be needed	No need for consult
Page count	407 pages total	20 pages total
Estimate of review time	~ 10 hours	~ 1 hours
Deficiencies identified	N/A	0

ASCA Lancet Submission: Biocompatibility Assessment

Contact type

- Limited skin-contacting devices (<24 h)

ASCA Biocompatibility Assessment

- Intracutaneous Reactivity Irritation
- Guinea Pig Maximization Sensitization
- MEM Elution Cytotoxicity

ASCA Lancet Submission: Biocompatibility

Comparing Non-ASCA and ASCA Reviews

Biocomp testing 3 methods	Complete Test Reports	ASCA Summary Test Reports
Number of pages	~ 60 pages	8 pages
Review time	~ 5 hours	45 min
Deficiencies identified	Deficiencies more likely	0

Citing Standards in eSTAR

What is eSTAR

- A dynamic PDF submission template for medical device submissions
- Features automation, guides, integrated databases, policies and procedures
- Guides applicant step by step through device submission process

eSTAR Template Options

- Non-In Vitro Diagnostic (nIVD) eSTAR (Version 5*)
- In Vitro Diagnostic (IVD) eSTAR (Version 5*)
- Early Submission Requests eSTAR (PreSTAR) (Version 1*)

***NOTE = These versions are current as of May 16, 2024. Please check eSTAR Device Advice page periodically to ensure you have current version.**

Documenting Standards in eSTAR

Documenting Standards in eSTAR

Documenting Standards in eSTAR: DOC

Declaration of Conformity

Application #

Company Name	Gemstone Medical Device Company, Inc.
Company Address	555 Hightech Avenue Technopolis VA 99999 United States
Device Trade Name	Diamond Instrument (1000-2)

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

Organization	Designation Number and Edition/Date	Recognition #
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	29 May 2024
Full Name and Title:	Regulatory Professional, VP, Regulatory Affairs	
Signature	*Regulatory Professional*	

Knowledge Check

Why should manufacturers cite FDA-recognized standards in device submissions?

1. Recognized standards have FDA's confidence that compliance with them will fulfill a regulatory expectation
2. Citing recognized standards adds time to the review process
3. Recognized standards are written in English
4. None of the above

Knowledge Check

Why should manufacturers use the ASCA program?

1. Improves the quality of testing and reporting
2. Fewer deficiencies related to testing
3. Complete test reports are generally not needed
4. All of the above

Resources

Slide Number	Cited Resource	URL
10	Recognized Consensus Standards: Medical Devices Database	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
18	ASCA (Device Advice)	www.fda.gov/medical-devices/division-standards-and-conformity-assessment/accreditation-scheme-conformity-assessment-asca
22	Guidance: Basic Safety and Essential Performance…Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program	www.fda.gov/regulatory-information/search-fda-guidance-documents/basic-safety-and-essential-performance-medical-electrical-equipment-medical-electrical-systems-and
22	Guidance: Biocompatibility Testing… Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program	www.fda.gov/regulatory-information/search-fda-guidance-documents/biocompatibility-testing-medical-devices-standards-specific-information-accreditation-scheme

Resources

Slide Number	Cited Resource	URL
24	Guidance: Infusion Pump Total Product Life Cycle	www.fda.gov/regulatory-information/search-fda-guidance-documents/infusion-pumps-total-product-life-cycle
31	Non-In Vitro Diagnostic (nIVD) eSTAR	www.fda.gov/media/174458/download?attachment
31	In Vitro Diagnostic (IVD) eSTAR	www.fda.gov/media/174459/download?attachment
31	Early Submission Requests eSTAR (PreSTAR)	www.fda.gov/media/169327/download?attachment
31	eSTAR Device Advice page	www.fda.gov/medical-devices/how-study-and-market-your-device/estar-program

For More Information

- **Division of Standards and Conformity Assessment (DSCA)**
  - www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program#intro

- **Email Us!**
  - DSCA: CDRHStandardsStaff@fda.hhs.gov
  - ASCA: ASCA@fda.hhs.gov

Summary

- Consensus standards offer advantages in device development and FDA review
- Use of FDA-recognized standards may save time
- We reviewed conformity assessment and ASCA program and with some examples
- Standards may be easily cited in eSTAR

Questions

Your Call to Action

- **Become familiar with consensus standards**
  - —They are an important resource to build in quality and promote innovation
- **Cite FDA-recognized standards in device submissions**
  - —Less documentation is needed than “General Use”
- **Participate in the ASCA program**
  - —It streamlines conformity assessment review