Standards at FDA & CDRH

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Outline

- Federal Legislative & Policy Basis
- Evolution of Standards Use at CDRH
  - S-CAP: The Standards & Conformity Assessment Program
- Example: AM For Medical Use
- Questions

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CDRH Mission

- **Protect and promote the public health**
- Assure patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products.
- Provide consumers, patients, their caregivers, and providers with understandable and accessible science-based information about the products we oversee.
- Facilitate medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and assuring consumer confidence in devices marketed in the U.S.

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FDA Participation in Standards

- Federal Policy
  - Sets forth requirements for Agency participation in use & development of voluntary consensus standards and conformity assessment
  - Sets forth requirements for incorporation of standards into Agency regulations
- Goals:
  - Reduce Government costs
  - Provide incentives that serve national needs
  - Encourage long-term growth for the US
  - Promote economic competition

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Legislative Authority, Executive Branch Policy and FDA Participation

Congress	National Technology Transfer Advancement Act 1995	Federal agencies and departments shall use technical standards … developed or adopted by voluntary consensus standards bodies…to carry out policy objectives or activities
Executive Branch	OMB Circular A-119	Federal agencies will use voluntary consensus standards in lieu of government unique standards wherever appropriate
FDA Regulations	21CFR 10.95	60 FR 53078
FDA Staff Manual Guide	SMG 9100.1	FDA will preferentially use international harmonized standards where appropriate and when not in conflict with existing regulations

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Evolution of the use of standards at FDA/CDRH

Medical Device Amendments of 1976
- USC 514 – Performance Standards

1976

Safe Medical Device Act of 1990
- Promulgation of mandatory standards development at the Agency's discretion

1990

FDA Modernization Act (Sec 514(c))

Added ability to formally recognize a standard, "all or in part"

Added the ability to accept a formal Declaration of Conformity

1997

21st Century Cures Act: added to 514(c):

Transparency of regulatory decisions on use of standards

Training to employees

Focus on global harmonization

2016

ASCA Pilot Program 514(d)
- Conformity assessment - ISO/IEC 17025

2018

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Why FDA Supports Standards

- Ensures patient access to innovative products that are safe and effective
- Promotes international trade
- Expeditious to rely upon consensus-driven standards rather than lengthy legal or rule-making approaches
- Encourages innovation and competition among product developers
- Reduces burdens on device manufacturers by harmonizing expectations across national and *(possibly)* international jurisdictions
- Speeds the pre-marketing review process
  - Standardized conformance assessments and test reporting
  - Less time needed for 'one-off' evaluations and requests for additional information
- Promotes regulatory science at national and international levels

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S-CAP Vision

The Standards and Conformity Assessment Program (S-CAP) enhances consensus standards and their use in the design, development and evaluation of medical devices across their lifespans. Relying upon a collaborative approach to standards development and application, S-CAP draws upon expertise from across the medical device and standards communities to advance regulatory science, promote patient safety and support a least burdensome regulatory framework.

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S-CAP Mission

S-CAP supports CDRH's mission by driving the development, recognition, and appropriate use of regulatory-ready standards for medical devices throughout their lifecycles. S-CAP:

- Produces and implements clear policies to promote the appropriate use of standards in regulatory processes
- Anticipates the need for and leads development of national and international consensus standards
- Advances initiatives to enhance confidence in conformity assessment activities
- Fosters innovation and standardization in technologies that facilitate patient access to novel devices
- Provides leadership in standards quality and utilization through outreach and global harmonization

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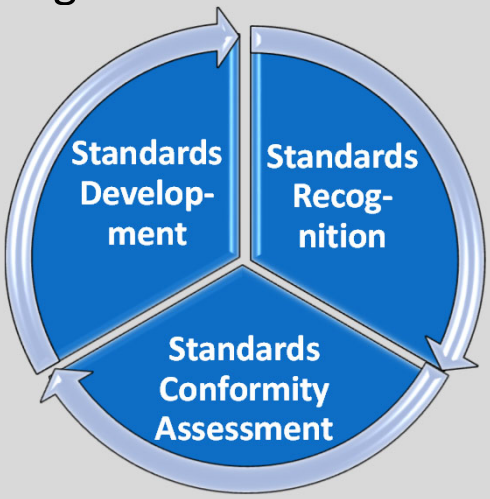
Leading the Standards Life Cycle

Standards Development

- **17** internal advisory Specialty Task Groups (STGs) in **23** device/scientific areas
- ~ **400** CDRH staff participating in ~ **600** standards committees across ~ **29** standards development organizations



Recognition Program

- **~1400** recognized standards
- 5-10% annual increase in new standards development activities
- Average of **7 (range of 1-35)** standards cited in each 510(k)

Standards Conformity Assessment

- Enhance the use of declarations of conformity in device submissions
- Accreditation Scheme for Conformity Assessment (ASCA) Pilot program

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Streamlining Regulatory Processes

Improved standards use and recognition	• Final guidance: Appropriate Use of Voluntary Consensus Standards (VCS) • Draft guidance: Recognition & Withdrawal of VCS • Redesigned Recognition Database to improve selection and use of VCS
Accreditation **S**cheme for **C**onformity **A**ssessment [ASCA] pilot program	• Enhancing regulatory efficiencies with increased consistency in FDA's approach to assessing conformance to standards
Regulatory reduction efforts	• Forthcoming guidance: *Medical X-ray Imaging Devices Conformance with IEC standards* • Transition to ISO 13485: *Medical devices - Quality management systems -- Requirements for regulatory purposes*

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The Ideal Relationship Between Regulatory Science and Standards

How to get there?

Communication and Hard Work -

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

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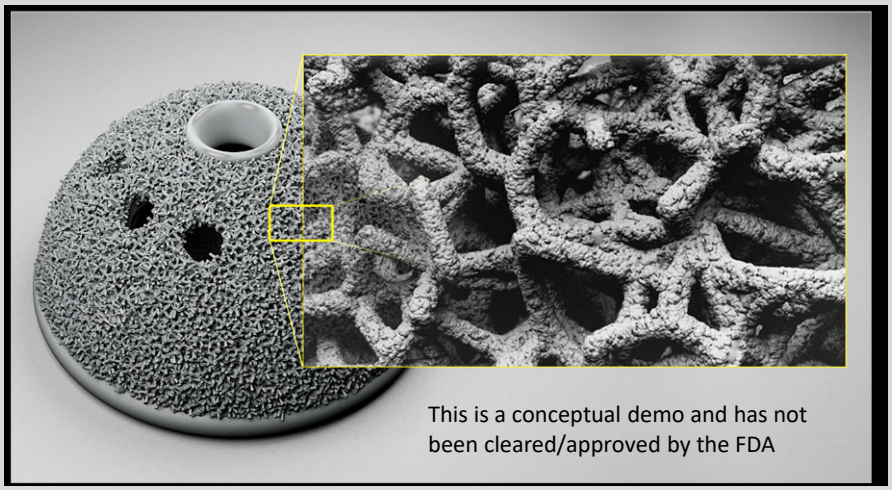
Example: AM For Medical Use



http://www.withinlab.com/case-studies/index13.php

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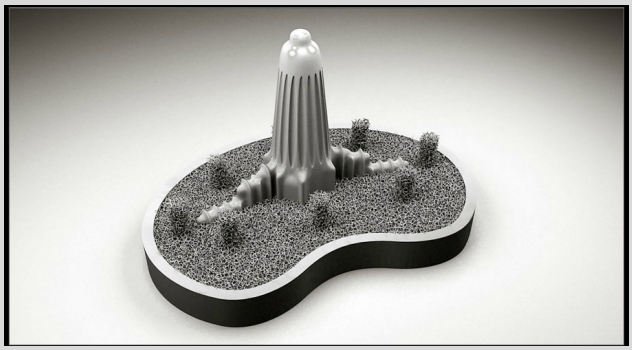
Complex Structures

- AM allows for complex architecture to be engineered, complex structures to be seamlessly integrated to solid components, and more organic designs for tissue in growth and reduced stress shielding
- While AM can be limited by system resolution, residual material removal, and the need for support structure; part complexity is not an inherent limitation



This is a conceptual demo and has not been cleared/approved by the FDA

http://www.withinlab.com/case-studies/index17.php

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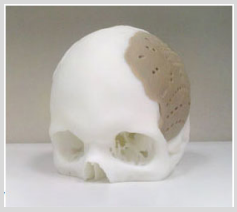
Patient Matched Devices

- Pairing 3D imaging (CT, MRI, optical scanning) with 3D printing allows for personalized medical devices
- Incorporating virtual surgical software allows for personalized cutting guide and tools

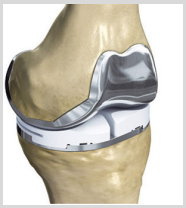
K133809: http://www.oxfordpm.com/news/article/2014-08-19_oxford_performance_materials_receives_fda_clearance_for_3d_printed_osteofab_patient-specific_facial_device.php

http://www.accessdata.fda.gov/cdrh_docs/pdf13/K133809.pdf



K121818: http://www.oxfordpm.com/news/article/2013-02-18_osteofab_patient_specific_cranial_device_receives_510k_approval_-_osteofab_implants_ready_for_us_market_and_beyond.php

http://www.accessdata.fda.gov/cdrh_docs/pdf12/K121818.pdf



K122870: http://www.conformis.com/customized-knee-implants/products/itotal/

http://www.accessdata.fda.gov/cdrh_docs/pdf12/K122870.pdf

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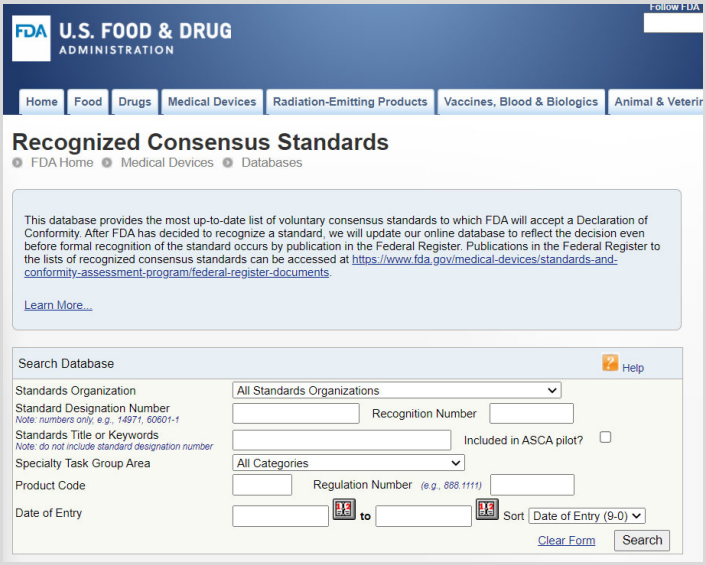
FDA Recognized Consensus Standards



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

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Recognized AM Consensus Standards (24)

- Design (6)
  - ISO/ASTM 52911-1, ISO/ASTM 52911-2, ISO/ASTM 52910, ASTM F3302, ASTM F3303, ISO/ASTM 52901
- Data (4)
  - ISO/ASTM 52950, ISO/ASTM 52915, ISO 17296-4, ASTM F2971
- Material – General (6)
  - ISO/ASTM 52903, ISO/ASTM 52912, ISO/ASTM 52907, ASTM F3301, ISO 17296-2, ASTM F3091
- Material – Specific (2)
  - ASTM F3001, ASTM F2924
- Assessment and Validation (4)
  - ISO/ASTM 52904, ASTM F3434, ASTM F3335, ISO/ASTM 52902
- General (2)
  - ISO/ASTM 52921, ISO/ASTM 52900

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AM Standard Use

- AM standards ideally provide industry tools to use to address the technical considerations of the AM Guidance and any device specific testing needs
- While several of the existing standards address aspects of technical concerns (e.g. AM file formats or AM material specification), standards don't yet address entire technical considerations
- ASTM F3001/F2924 have agreed upon minimum specifications, but there is no standard for addressing effect of build space or powder re-use on final performance variability
- This results in industry developing their own individual approaches to addressing FDA concerns and FDA having to assess each approach

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FDA AM Medical Standard Wishlist

- Better AM System Validation
  - Covering build space and powder re-use effects
  - Single and multiple AM systems
  - Correlation between coupon and final device properties
- Residual Powder Testing
  - Devices with lattices made by PBF often have some residual powder
  - Need a consistent way to assess how much residual powder is in a device
  - Need to better understand the maximum allowable amount of powder in a device
- AM Lattice Testing
  - Challenges applying the FDA porous coating tests to AM lattices
  - No AM lattice coupon for compression/tension testing
  - No standard way to measure AM lattice strut thickness

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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
- **CDRH Learn: How to Study and Market Your Device: Standards**
  www.fda.gov/training/cdrhlearn/default.htm

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Standards Resources

- **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
- **CDRH Learn: How to Study and Market Your Device: Standards**
  www.fda.gov/training/cdrhlearn/default.htm

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ASCA Resources

- **ASCA Pilot web page**
  www.fda.gov/medical-devices/standards-and-conformity-assessment-program/accreditation-scheme-conformity-assessment-asca
- **ASCA Pilot 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**

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Questions?

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