Boosting Bioethics & Bioprinting

The Role of Standards in Facilitating Bioprinting Technology:
Inroads Made, More Work to be Done

Katrina Wells
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Advanced Regenerative Manufacturing Institute (ARMI)
December 5, 2024

KATRINA WELLS

- Regulatory Affairs Specialist at ARMI | BioFabUSA
- Implements standards initiatives
- Champions standards
  - Facilitated the ASTM Committee F04 project for F3659: Standard Guide for Bioinks Used in Bioprinting
  - Co-Chaired the IEEE-SA Three-Dimensional (3D) Bioprinting of Tissue-Engineered Medical Products (TEMPs) Working Group
  - Participated in the ASME Bioprinters Standards Committee that focused on bioprinter hardware

Regulatory 101

FDA MISSION (abridged)

U.S. FOOD & DRUG ADMINISTRATION

- Protect PUBLIC HEALTH by ensuring the **safety**, **efficacy**, and security of drugs, biological products, and medical devices
- Advance PUBLIC HEALTH by facilitating innovations that make medical products safer and more effective

PRODUCTS THE FDA REGULATES

Human Medical Products:

Medical Devices

- Simple technologies (toothbrush)
- Complex technologies (heart pacemakers, ventilators)
- Dental devices (bone void fillers)
- Surgical implants

Drugs

- Prescription drugs
- Over-the-counter drugs

Biologics

- Vaccines
- Blood products
- Cell Therapies
- Gene therapies
- Tissue products

Other products:

Foods

- Bottled water
- Food additives
- Infant formulas
- Food products

Cosmetics

- Color additives
- Skin cleansers
- Nail polish
- Perfume

Veterinary Products

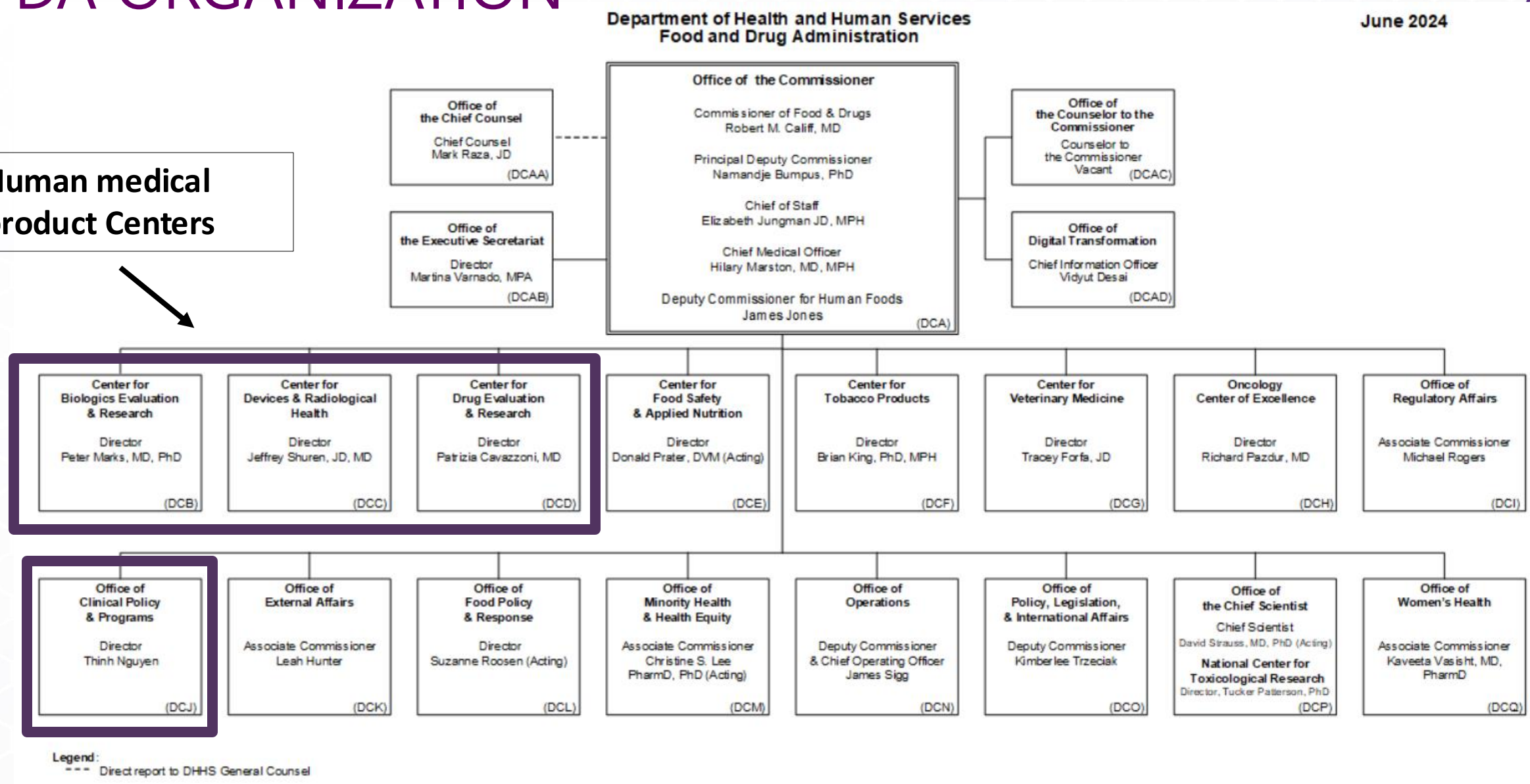
- Livestock feeds
- Pet foods
- Veterinary drugs and devices

Tobacco Products

- Cigarettes
- Cigarette tobacco
- Roll-your-own tobacco

FDA ORGANIZATION

Human medical product Centers



https://www.fda.gov/about-fda/fda-organization-charts/fda-overview-organization-chart

FDA REGULATORY AUTHORITY

Three-tiered system:

1. **Statutes** – Laws, as passed by Congress and signed by the President
2. **Regulations** – Agency's interpretation of the statutes
3. **Guidance Documents** – Agency's interpretation of the regulations

RELEVANT REGULATIONS

21 CFR 600s = Biologics

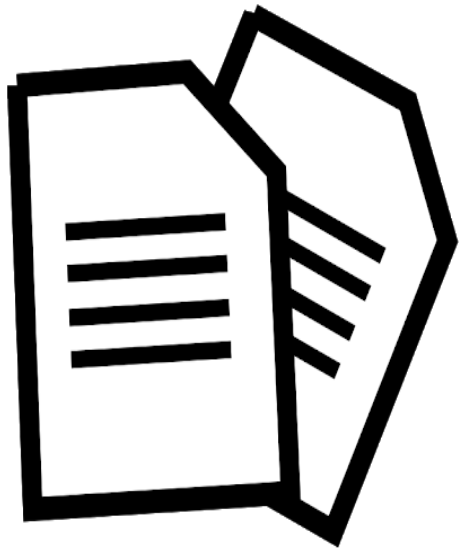
21 CFR 1271 = Human Cells, Tissues, and Cellular and Tissue-based Products

21 CFR 210s and 211s = Good Manufacturing Practice (GMP)

21 CFR 312 = Investigational New Drug (IND) applications

21 CFR 11 = Electronic Records; Electronic Signatures

REGULATIONS CAN BE BROAD



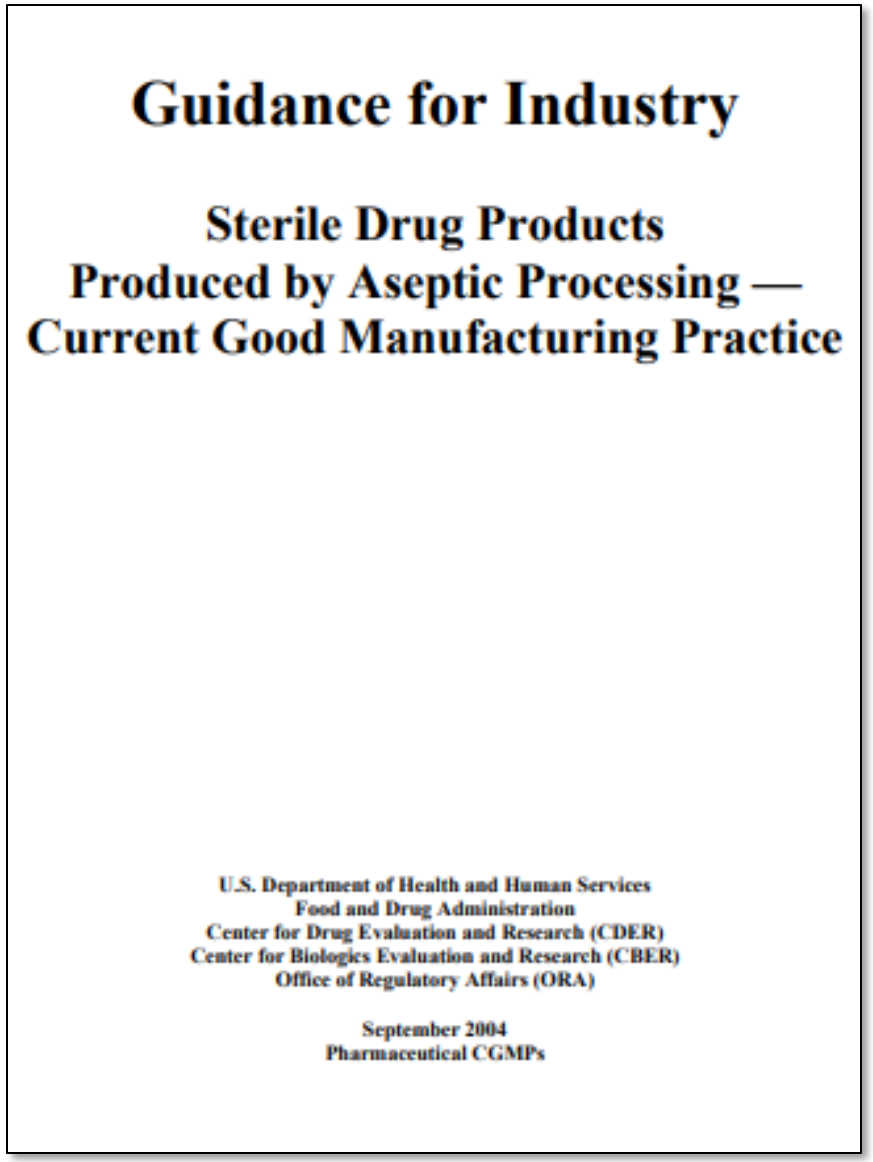
21 CFR 211.44 Lighting.

Adequate lighting shall be provided in all areas.

21 CFR 211.113 Control of microbiological contamination.

(b) Appropriate written procedures, designed to prevent microbiological contamination of drug products purporting to be sterile, shall be established and followed. Such procedures shall include validation of all aseptic and sterilization processes.

INTERPRETING THE REGS



Guidance for Industry

Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Office of Regulatory Affairs (ORA)

September 2004
Pharmaceutical CGMPs

1. Study Design

A media fill program should incorporate the contamination risk factors that occur on a production line, and accurately assesses the state of process control. Media fill studies should closely simulate aseptic manufacturing operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations. FDA recommends that the media fill program address applicable issues such as:

- Factors associated with the longest permitted run on the processing line that can pose contamination risk (e.g., operator fatigue)
- Representative number, type, and complexity of normal interventions that occur with each run, as well as nonroutine interventions and events (e.g., maintenance, stoppages, equipment adjustments)
- Lyophilization, when applicable
- Aseptic assembly of equipment (e.g., at start-up, during processing)
- Number of personnel and their activities
- Representative number of aseptic additions (e.g., charging containers and closures as well as sterile ingredients) or transfers
- Shift changes, breaks, and gown changes (when applicable)
- Type of aseptic equipment disconnections/connections
- Aseptic sample collections
- Line speed and configuration
- Weight checks
- Container closure systems (e.g., sizes, type, compatibility with equipment)

21

Contains Nonbinding Recommendations

- Specific provisions in written procedures relating to aseptic processing (e.g., conditions permitted before line clearance is mandated)

Standards 101

WHAT ARE STANDARDS?

U.S. National Technology Transfer and Advancement Act of 1995:

*Standards are the **common and repeated use** of rules, conditions, guidelines or characteristics for products or related processes and production methods, and related management systems **practices**.*

WHY ARE STANDARDS BENEFICIAL?

Resource: https://www.standardscoordinatingbody.org/standards-101

WHO CAN PARTICIPATE IN STANDARDS DEVELOPMENT ACTIVITIES?

Anyone!

HOW ARE STANDARDS DEVELOPED?

Standards Development Organizations (SDOs)

- Voluntary Consensus Bodies
  - ASME
  - ASTM
  - IEEE-SA
  - ISO
- Professional & Scientific Organizations
  - ICH
  - ISSCR
- Certification / Accreditation Bodies
  - AABB
  - FACT
- Pharmacopeia
  - P. Eur.
  - USP

Consensus Standards Development Process

Resource: https://www.standardscoordinatingbody.org/standards-101

STANDARDS vs REGULATIONS

	Regulations	Standards
Created by	Federal regulatory agencies (e.g., FDA)	Typically produced by non-government entities or standards development organizations
Mandatory?	**Yes:** Can be enforced by regulatory authorities	**No**: Use of a standard is voluntary unless mandated by regulation or statute
Purpose	Set out specific requirements for regulated products that must be met by the supplier of the product	An organization can adopt standards to make a process safer, more efficient, or better aligned with the practices of other organizations in their industry
Availability	In the United States, regulations are written in the Code of Federal Regulations and published in the Federal Register	Some standards are available for purchase from the publishing organization, while others are freely available to the public

Resource: https://www.standardscoordinatingbody.org/standards-101

STANDARDS COORDINATING BODY (SCB)

STANDARDS
COORDINATING
BODY

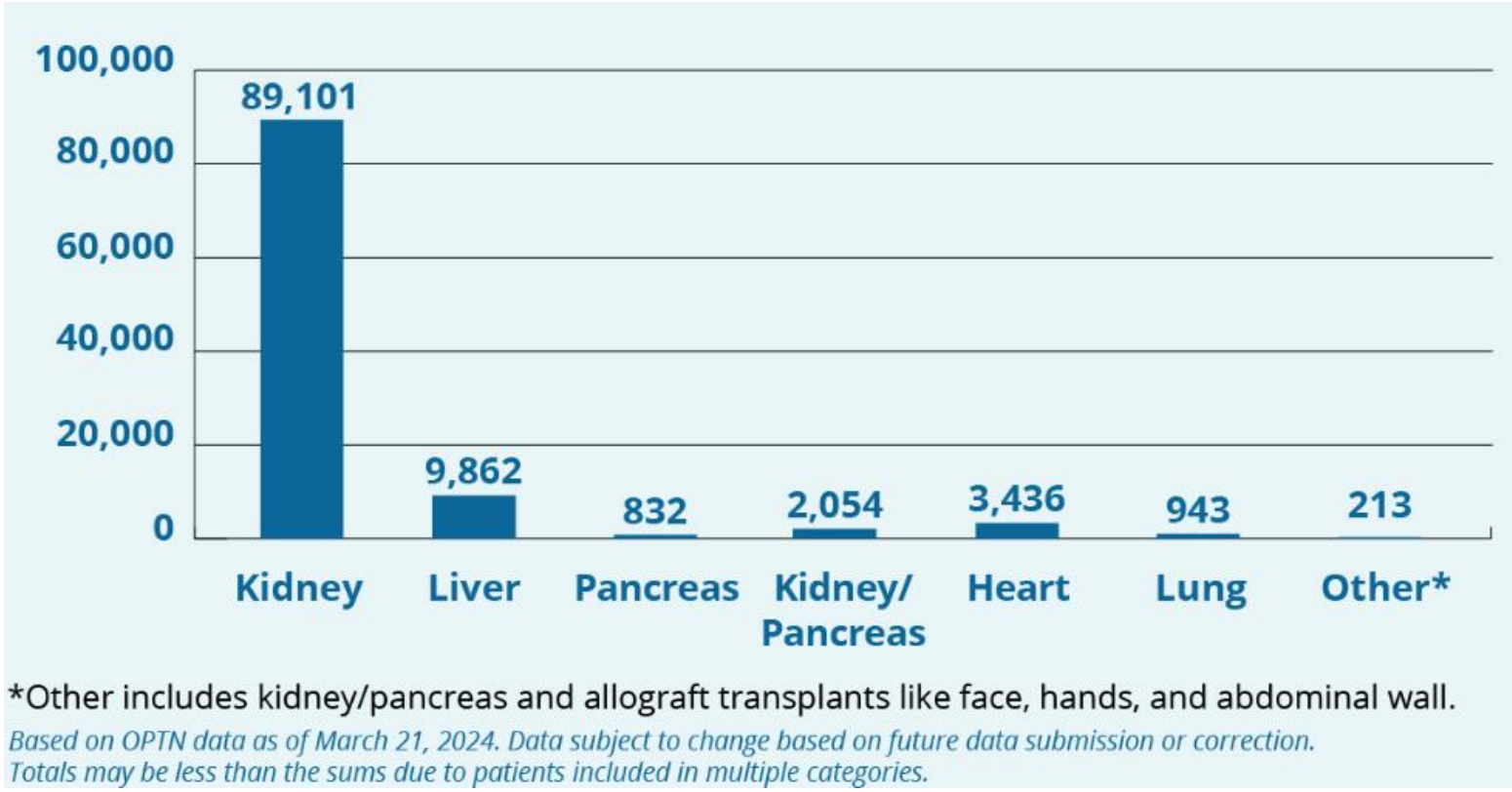
REGENERATIVE MEDICINE

Resource: https://www.standardscoordinatingbody.org/standards-101

The Role of Standards in Facilitating Bioprinting Technology

Patients on the Waiting List by Organ

Organ	Needed
Kidney	89,101
Liver	9,862
Pancreas	832
Kidney/Pancreas	2,054
Heart	3,436
Lung	943
Other*	213

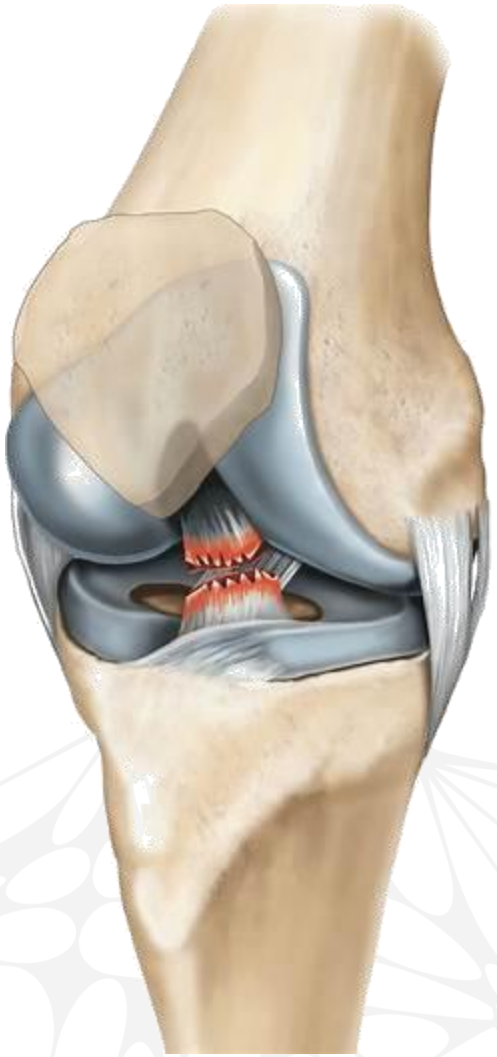


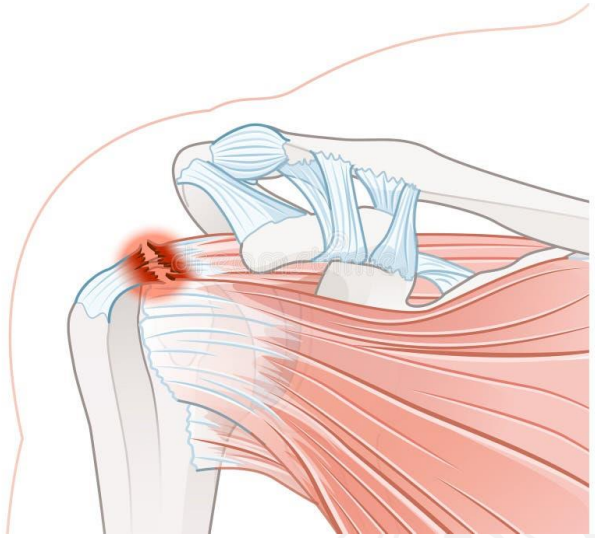
*Other includes kidney/pancreas and allograft transplants like face, hands, and abdominal wall.

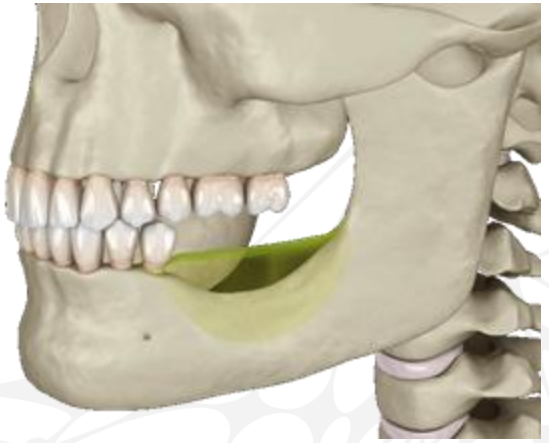
Based on OPTN data as of March 21, 2024. Data subject to change based on future data submission or correction.
Totals may be less than the sums due to patients included in multiple categories.

Figures and data from March 2024: https://www.organdonor.gov/

Debilitating Orthopedic Indications







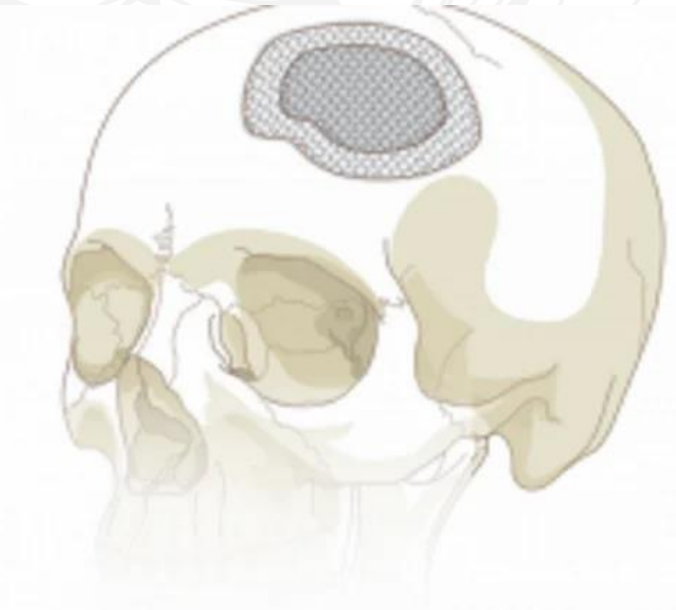
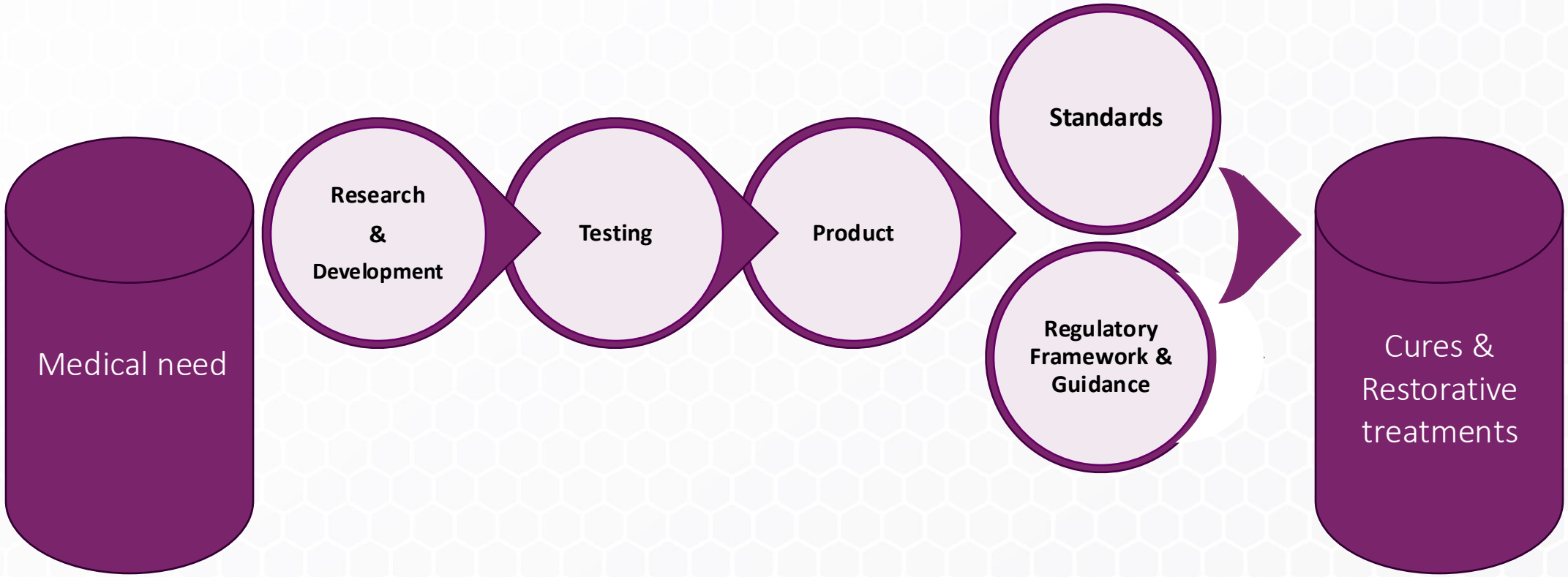


Image from: https://www.dreamstime.com/illustration/acl-anterior-cruciate-ligament.html

Bridging the Gap



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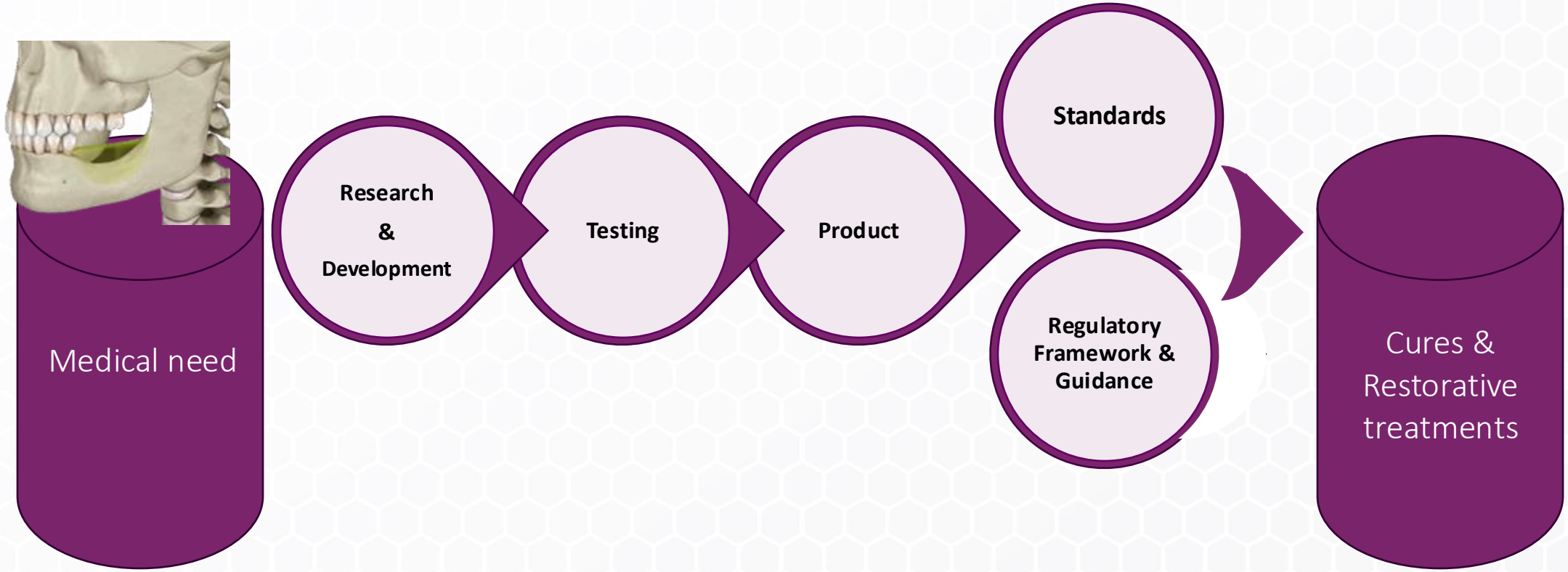

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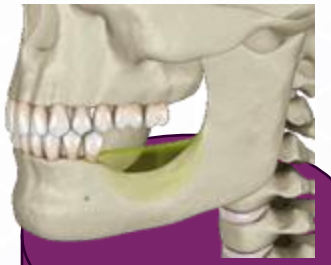


Medical need

Research & Development

Testing

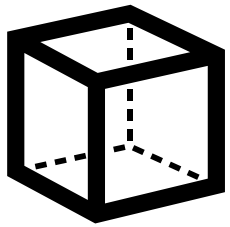
Product

Standards

Regulatory Framework & Guidance

Cures & Restorative treatments

R&D Challenges in Bioprinting



What bioprinting modality fits best for my purpose?

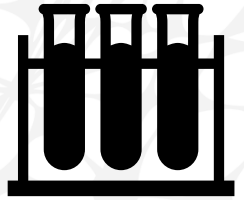
What characteristics should by bioink or biomaterial have?

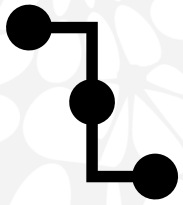
How can I maintain cell viability throughout the bioprinting process?

What bioink viscosity is best for my purpose?

What printing temperature is optimal?

What's the ideal post-bioprinting incubation time?



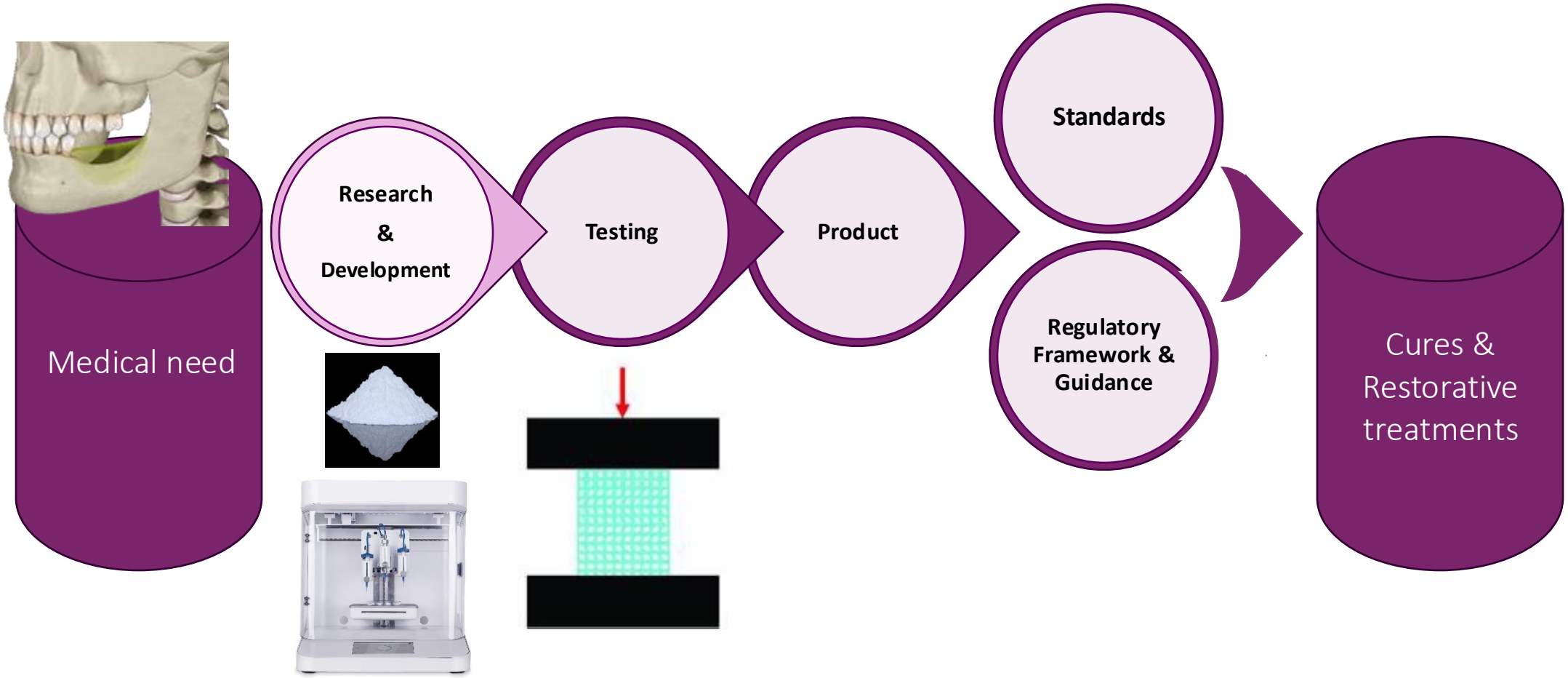


What methods of cross-linking exist to choose from?

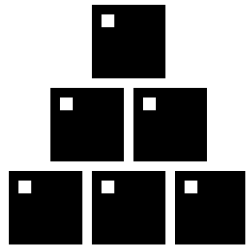
What types of cross-linkers could I use?

Do I need to use a support material?

Bridging the Gap

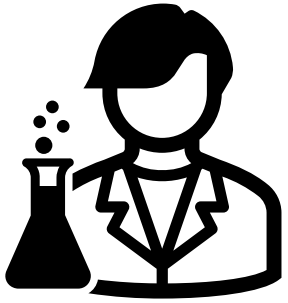


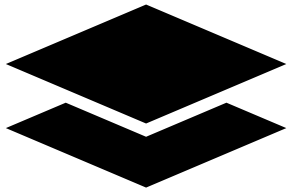
Testing Challenges in Bioprinting



How do I assess printability?

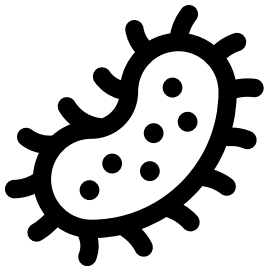
How can I test cell viability?





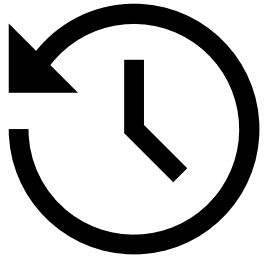
How should I assess sedimentation?

What other characteristics should I consider assessing?



How do I print aseptically and test for contaminants?

What characteristics should be assessed pre-print vs post-print?



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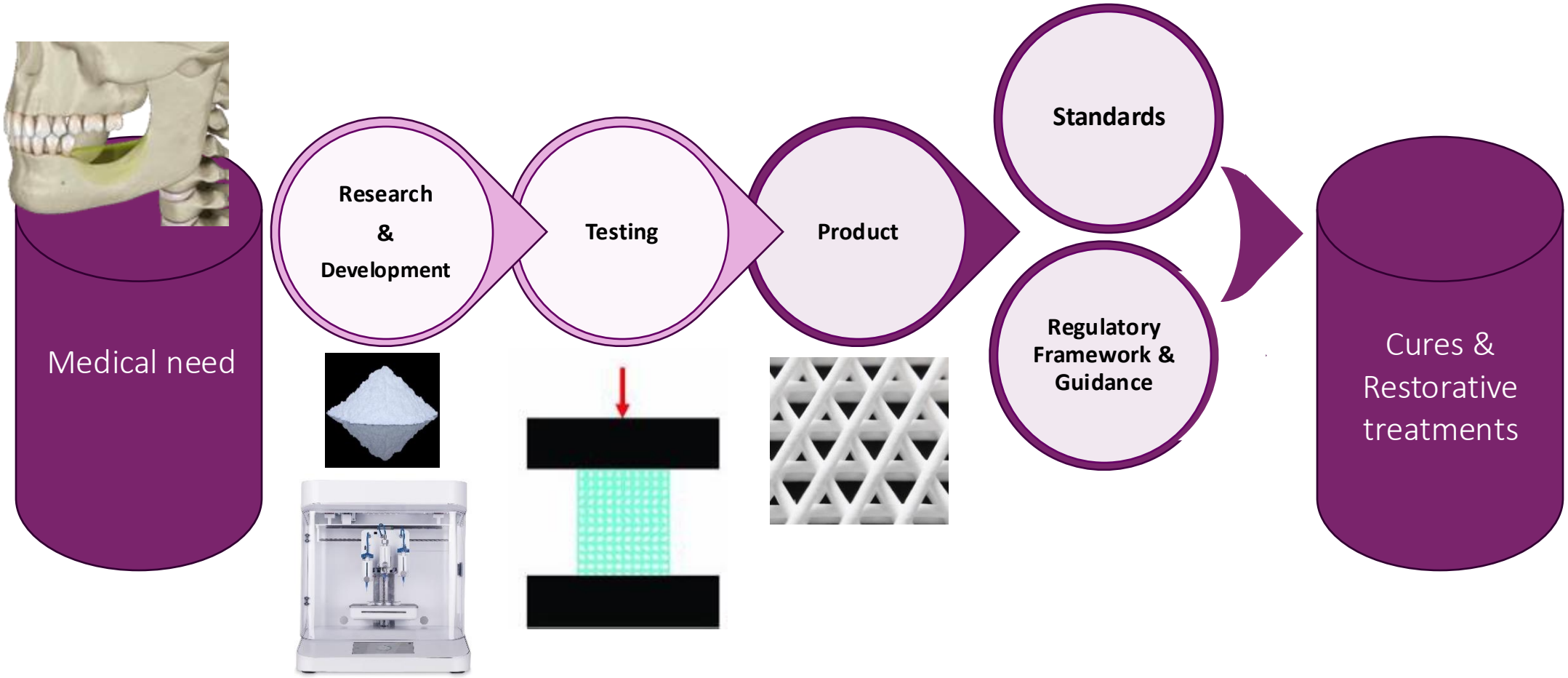


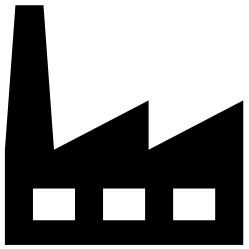
Regulatory Challenges with Bioprinted Products

What regulatory guidance can I leverage from classic AM devices?

What regulatory pathway will my bioprinted construct take?

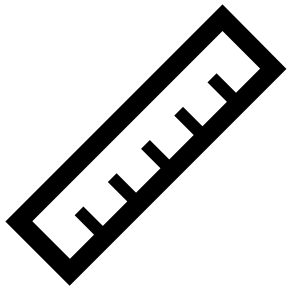
What are testing recommendations for bioprinted constructs or components?

What type of information should be included in my marketing application?



What are some manufacturing considerations I should consider?

What are some technical aspects I should consider through the phases of product design, production, and testing?



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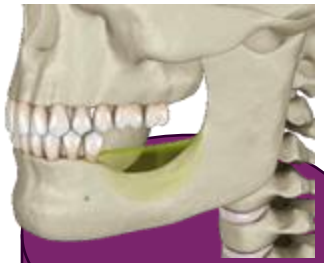
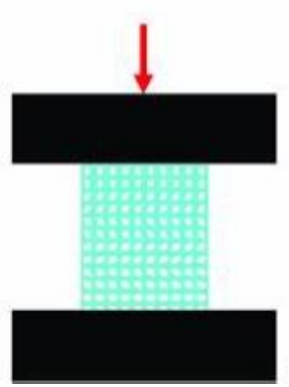


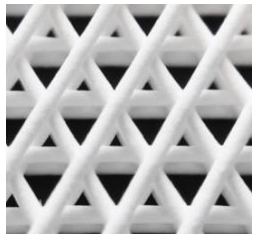
Medical need

Research & Development

Testing

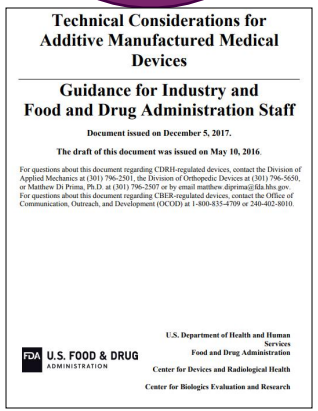


Product



Standards

Regulatory Framework & Guidance



Technical Considerations for Additive Manufactured Medical Devices

Guidance for Industry and Food and Drug Administration Staff

Document issued on December 5, 2017.

The draft of this document was issued on May 10, 2016.

For questions about this document regarding CDRH-regulated devices, contact the Division of Applied Mechanics at (301) 796-2501, the Division of Orthopedic Devices at (301) 796-5650, or Matthew Di Prima, Ph.D. at (301) 796-2507 or by email matthew.diprima@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010.

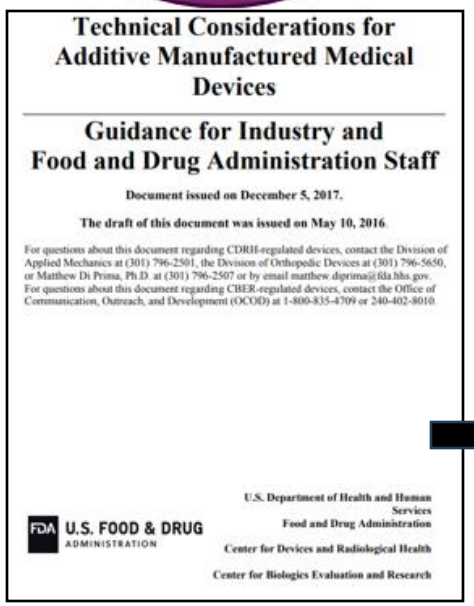
U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

FDA U.S. FOOD & DRUG ADMINISTRATION

Cures & Restorative treatments

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H - MEDICAL DEVICES

Regulatory Framework & Guidance



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U.S. FOOD & DRUG ADMINISTRATION

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TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H - MEDICAL DEVICES

PART 872 -- DENTAL DEVICES

Subpart D - Prosthetic Devices

Sec. 872.3930 Bone grafting material.

(a) *Identification.* Bone grafting material is a material such as hydroxyapatite, tricalcium phosphate, polylactic and polyglycolic acids, or collagen, that is intended to fill, augment, or reconstruct periodontal or bony defects of the oral and maxillofacial region.

(b) *Classification.* (1) Class II (special controls) for bone grafting materials that do not contain a drug that is a therapeutic biologic. The special control is FDA's "Class II Special Controls Guidance Document: Dental Bone Grafting Material Devices." (See § 872.1(e) for the availability of this guidance document.)

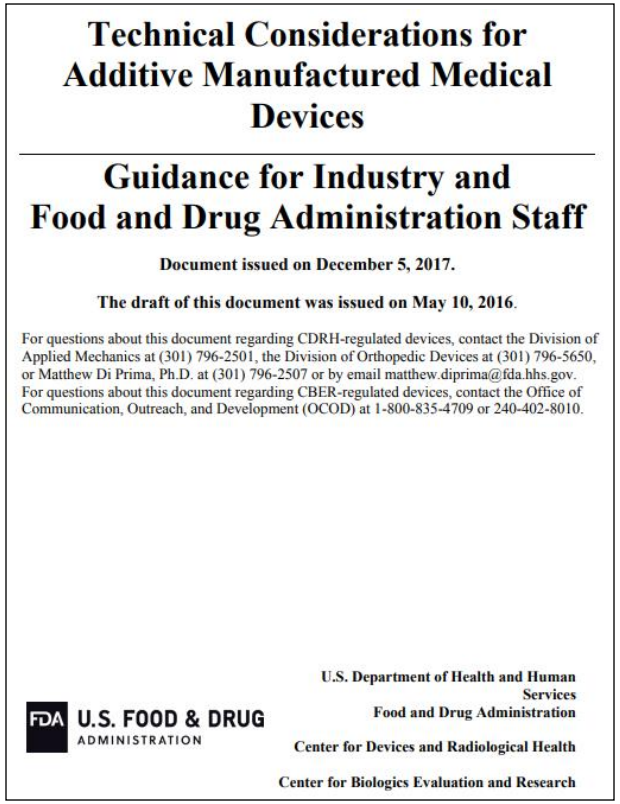
(2) Class III (premarket approval) for bone grafting materials that contain a drug that is a therapeutic biologic. Bone grafting materials that contain a drug that is a therapeutic biologic, such as biological response modifiers, require premarket approval.

(c) *Date premarket approval application (PMA) or notice of product development protocol (PDP) is required.* Devices described in paragraph (b)(2) of this section shall have an approved PMA or a declared completed PDP in effect before being placed in commercial distribution.

[70 FR 21949, Apr. 28, 2005]

The regulations are broad and focus on product identification and pathway rather than manufacturing considerations…

….and AM-related guidance is currently largely non-biological in nature, so only some considerations may be leveraged for TEMPs and related products



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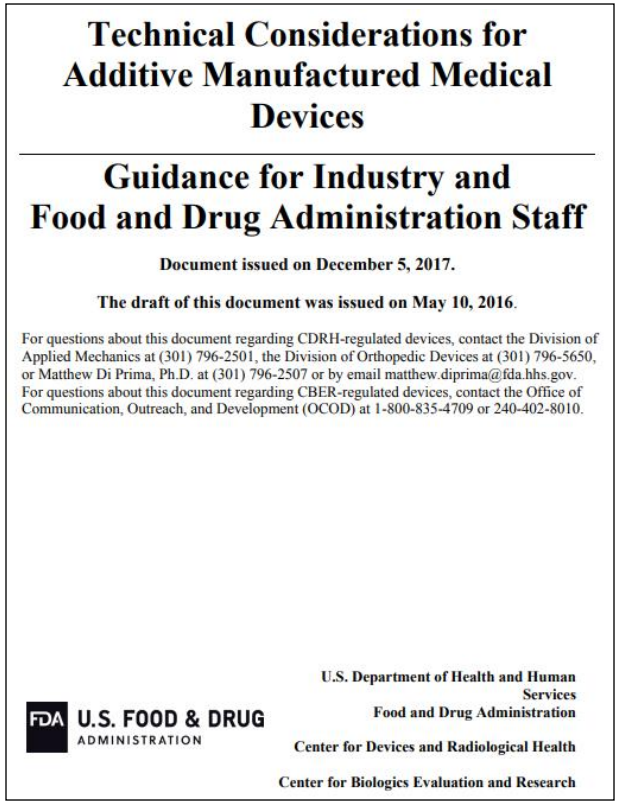
U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration

Center for Devices and Radiological Health

Center for Biologics Evaluation and Research

Resource: Technical Considerations for Additive Manufactured Medical Devices



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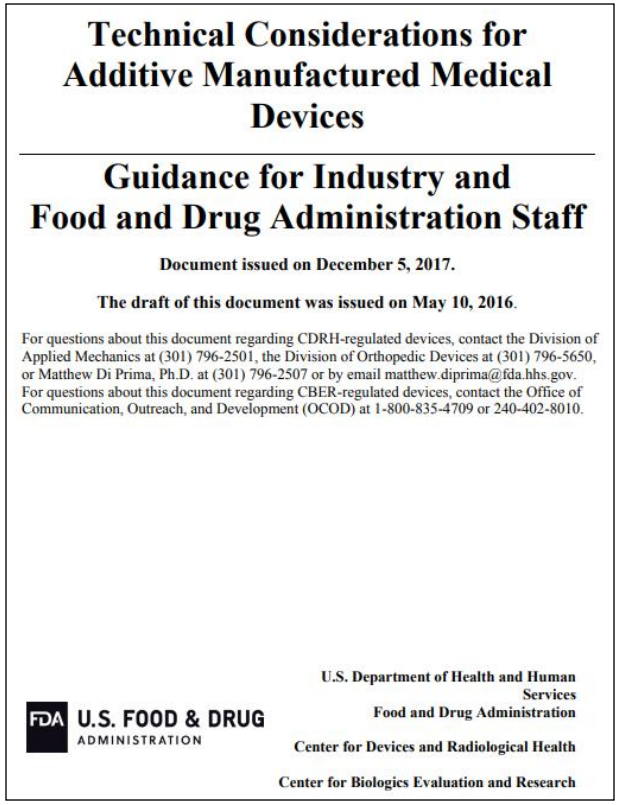
FDA U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

Scope:

- Does not address biological, cellular, or tissue-based products in AM
- Biological AM products may "*necessitate additional regulatory and manufacturing process considerations*"
- Questions pertaining to biological products still must be directed to CBER

Resource: Technical Considerations for Additive Manufactured Medical Devices



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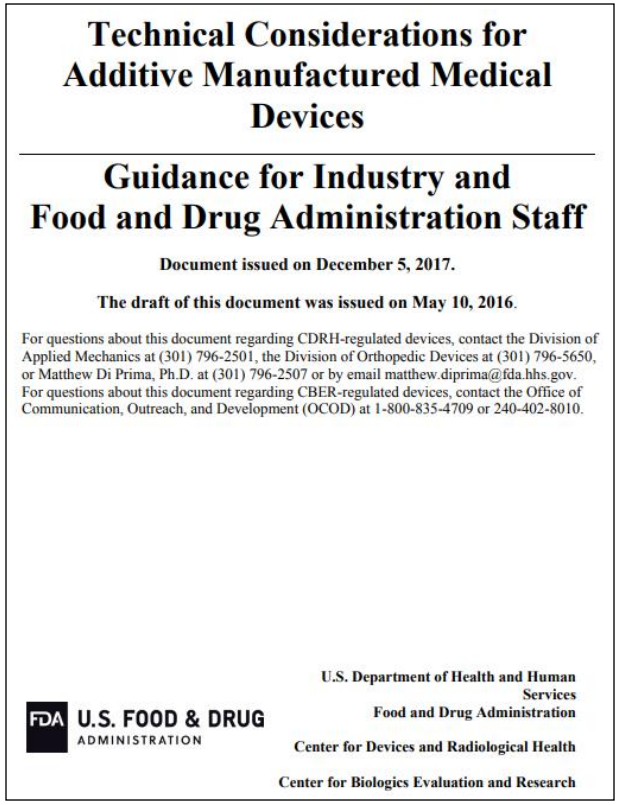
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

Scope:

- Does not address biological, cellular, or tissue-based products in AM
- Biological AM products may "*necessitate additional regulatory and manufacturing process considerations*"
- Questions pertaining to biological products still must be directed to CBER

Resource: Technical Considerations for Additive Manufactured Medical Devices



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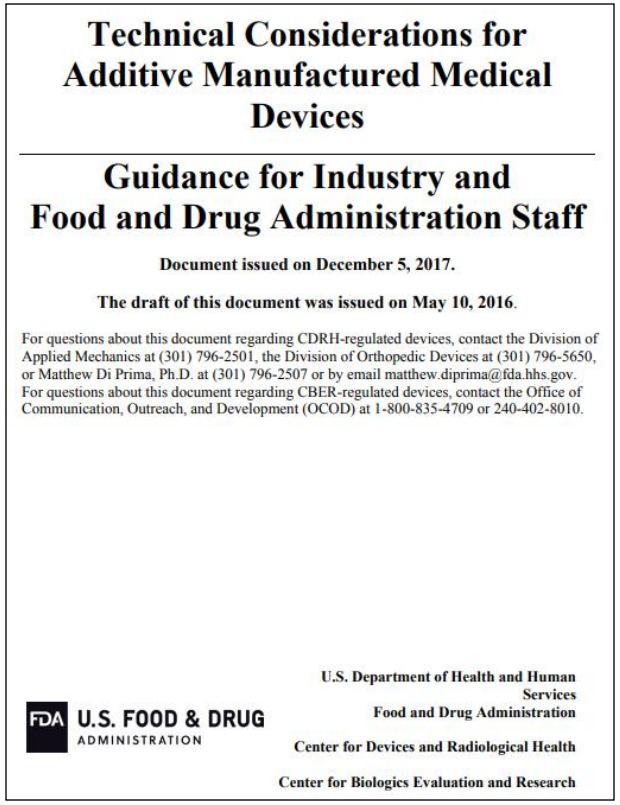

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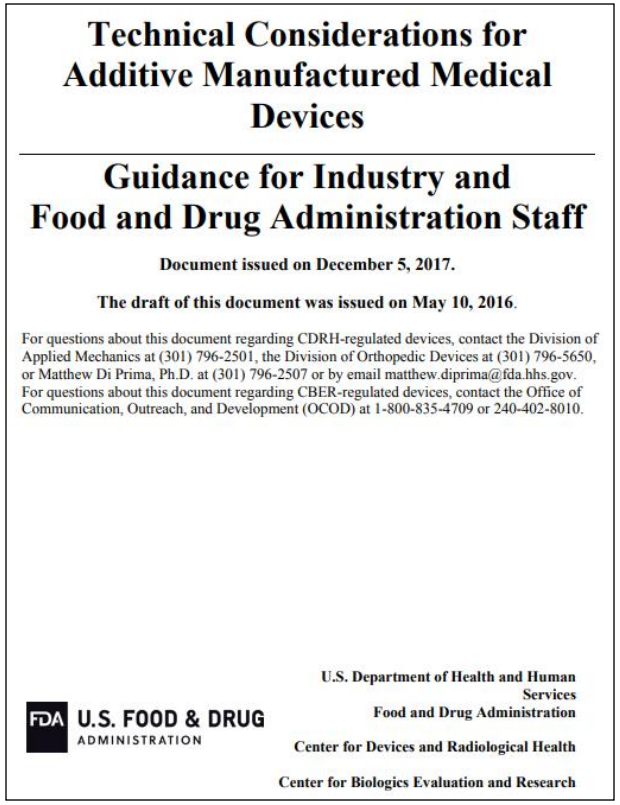

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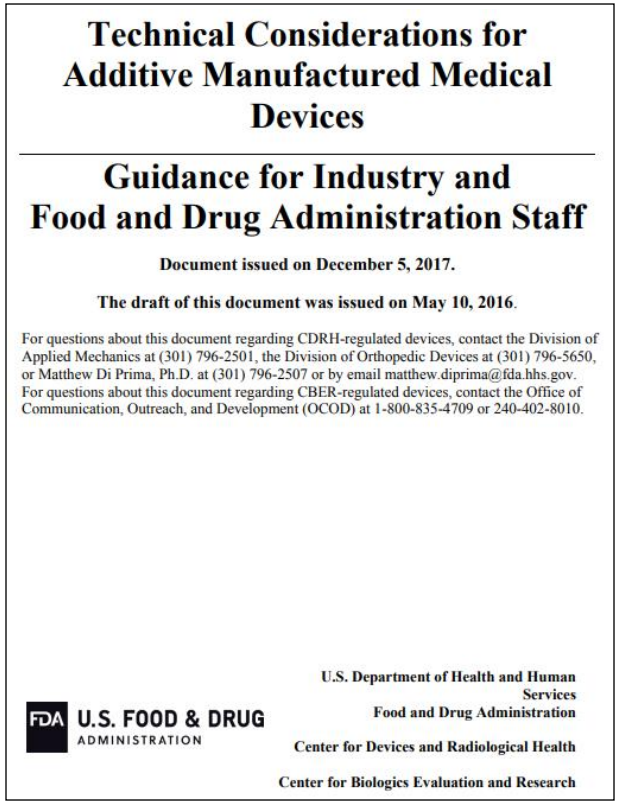

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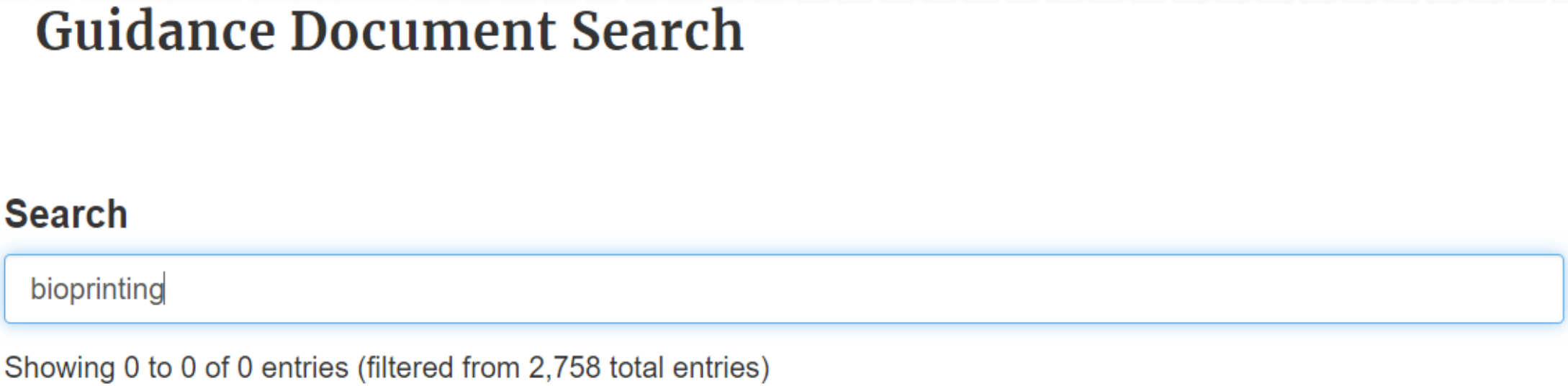
Search for FDA Guidance Documents



Resource: https://www.fda.gov/regulatory-information/search-fda-guidance-documents#guidancesearch

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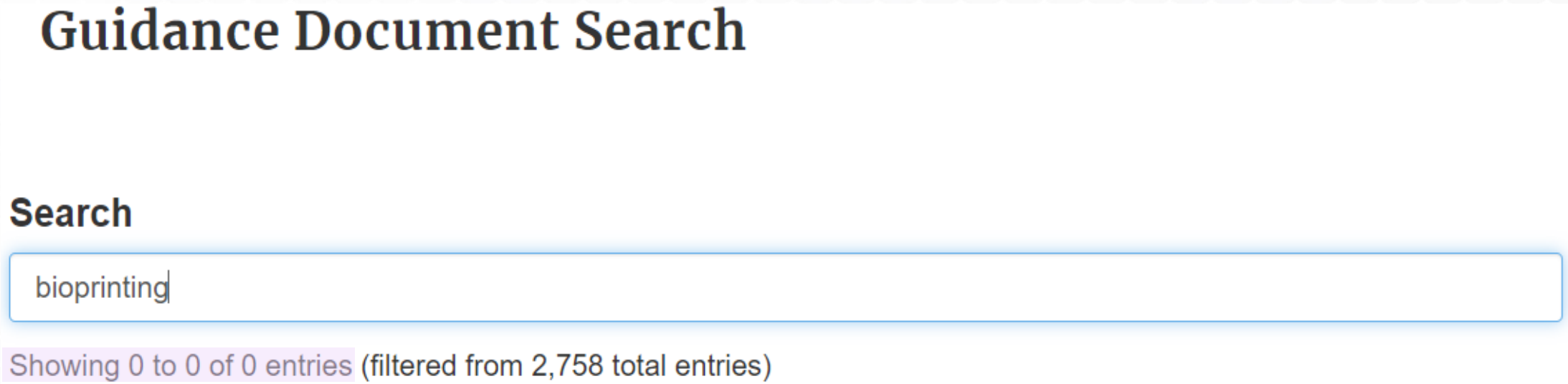

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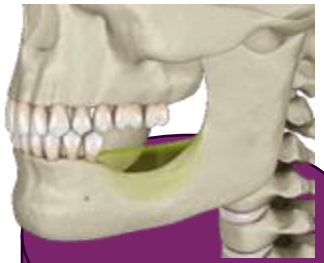
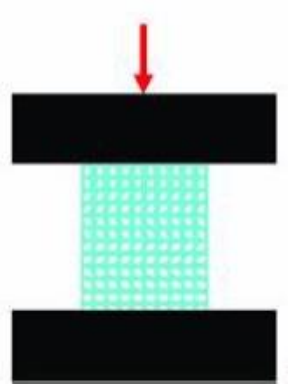
Bridging the Gap



Medical need

Research & Development

Testing



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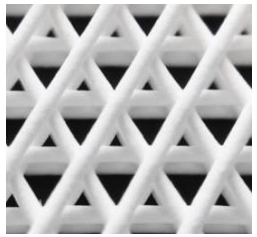
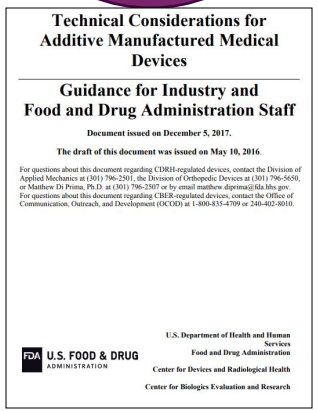


Standards

Regulatory Framework & Guidance



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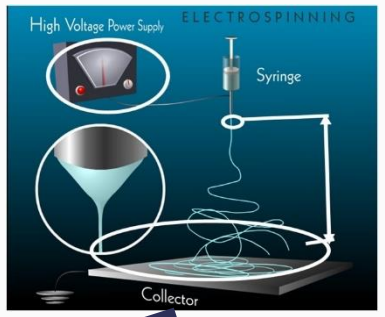
U.S. FOOD & DRUG ADMINISTRATION

Cures & Restorative treatments

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H - MEDICAL DEVICES

Standards Streamline Development

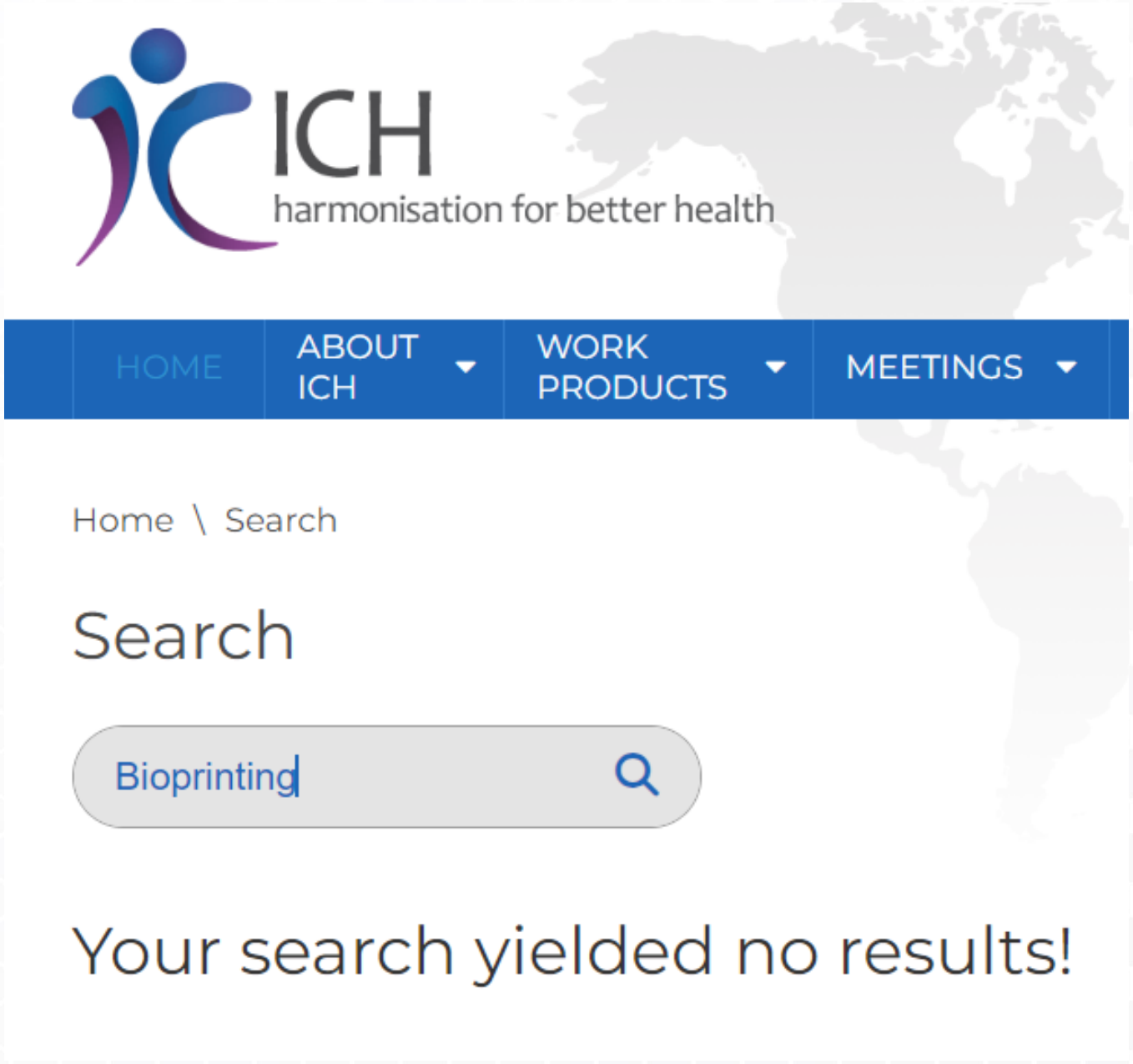
Before Standards



Crosslinking

Standards

After Standards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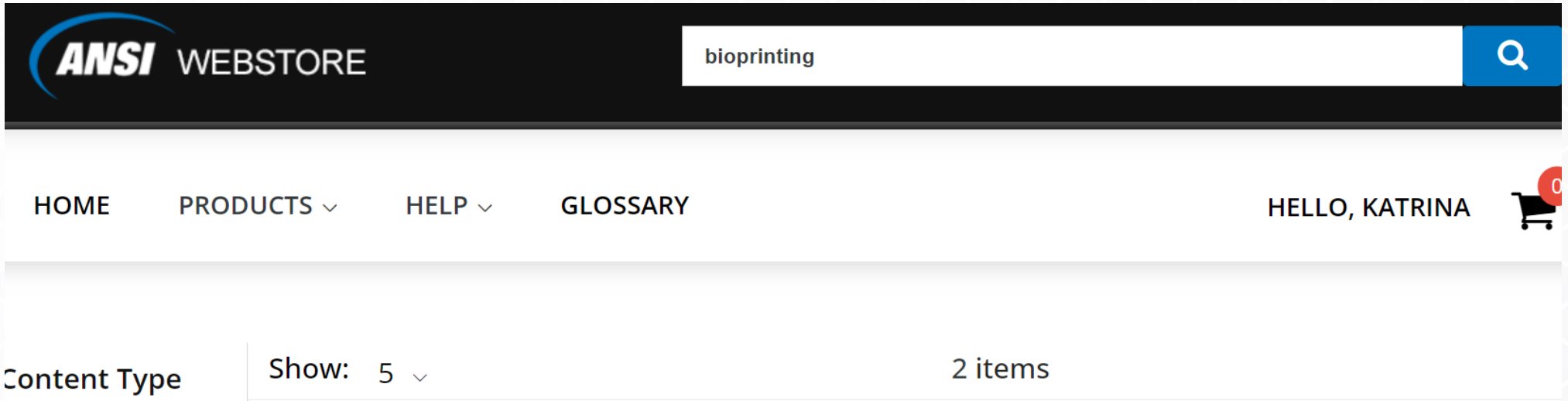
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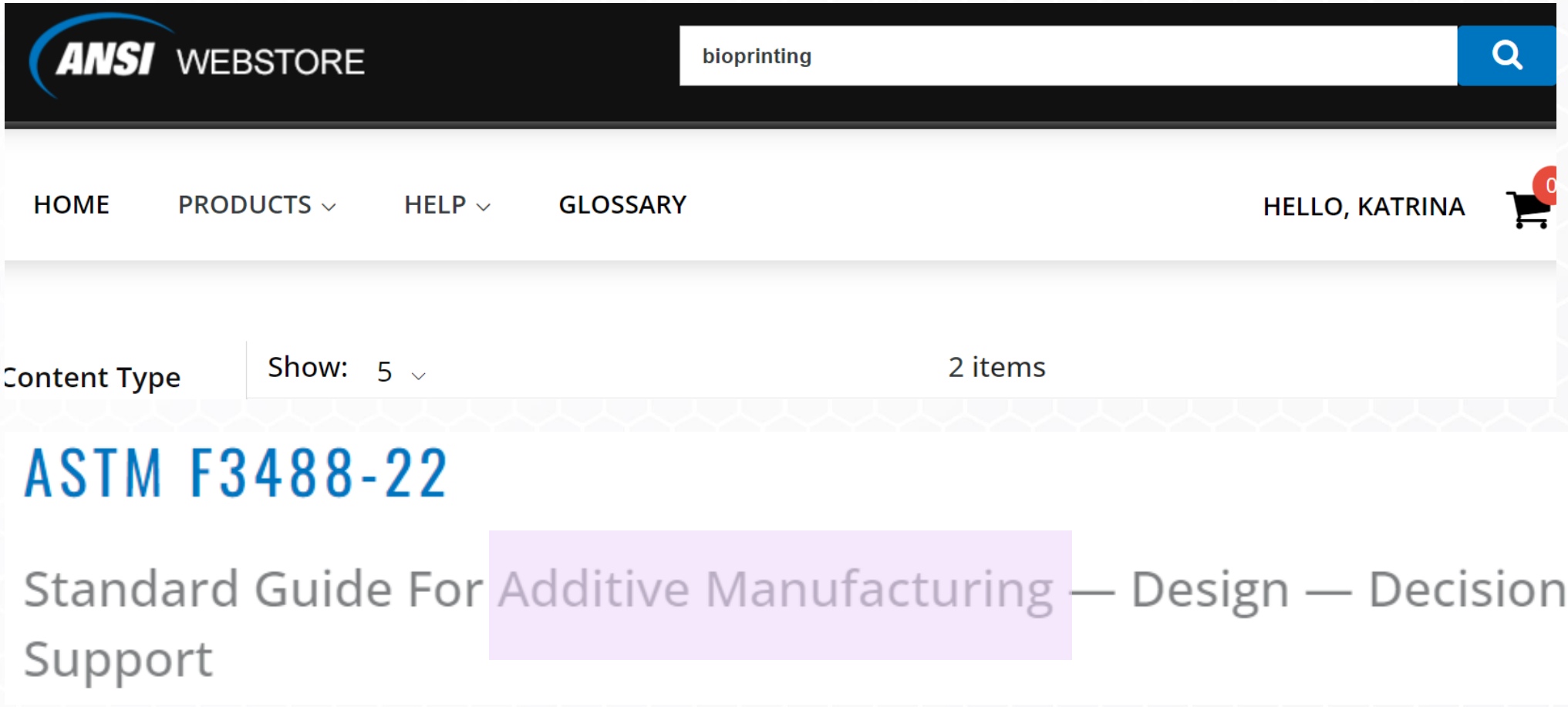
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ASTM F3488-22
Standard Guide For Additive Manufacturing — Design — Decision Support

NEED: Bioprinting-Specific Standard

ASTM F3659: Standard Guide for Bioinks Used in Bioprinting

6

Published in April 2024 after six years of work

Facilitated by SCB and ARMI

35+

Created by 35+ SMEs across industry, academia, and government

Contains broad considerations that lay the groundwork for future standard development efforts in this area

ASTM INTERNATIONAL
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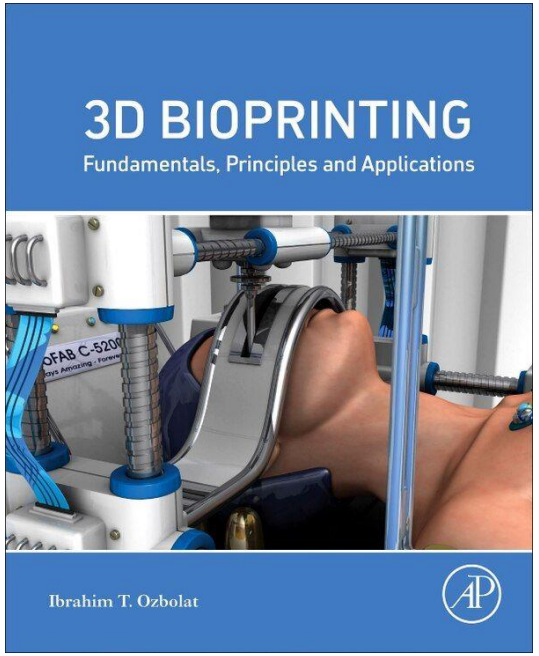


ASTM F3659-24

Standard Guide For Bioinks Used In Bioprinting

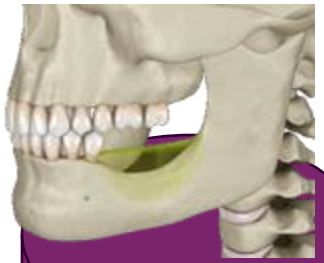
1.1 This guide is a resource **for bioprinting tissue-engineered medical products (TEMPs) with bioinks and biomaterial inks**. There are existing standards that cover biomaterials and scaffolds in a more general fashion (Guide F2150, Guide F2027, ISO 10993 series). This guide focuses **specifically on extrusion bioprinting utilizing bioinks** and biomaterial inks with inherent or inducible fluidic properties **with or without encapsulated cells** used to construct TEMPs. For the remainder of this guide, both bioinks and biomaterial inks will be collectively referred to as bioinks.

1.6 This guide will address **assessments** regarding the sterility and cytocompatibility of bioinks, including chemical and physical benchtop tests, as well as **measures of post-printing cell viability**.

“Best Practices” Taken Away from the Standard Development Process

- Leverage Information from Existing Standards
- Working Group Diversity Leads to Valuable Discussions
- Order of Actions and Discussion Topics Matter
- Streamline Administrative Tasks
- Utilize resources (i.e., Standards Coordinating Body) for Assistance

Bridging the Gap



Medical need

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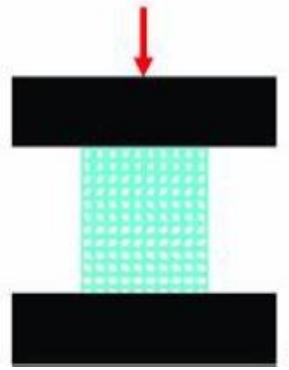

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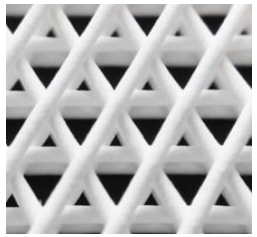

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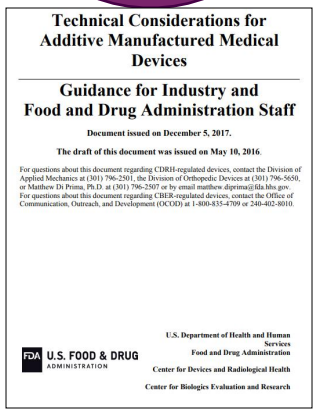

➡ Bioprinting-specific resources

Cures & Restorative treatments

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‘Inroads Made’ with Bioprinting Standardization

Completed Efforts

ASTM F3659-24: Standard Guide for Bioinks Used in Bioprinting

In Progress Efforts

ASME: Extrusion Bioprinter Hardware

ASTM WK72274: New Test Method for Printability of Bioinks for Extrusion-based Bioprinting

IEEE-SA P2864: Guide for a Software Change Control System for Three-Dimensional (3D) Bioprinting of Tissue-Engineered Medical Products (TEMPs)

Resource: https://portal.standardscoordinatingbody.org/search

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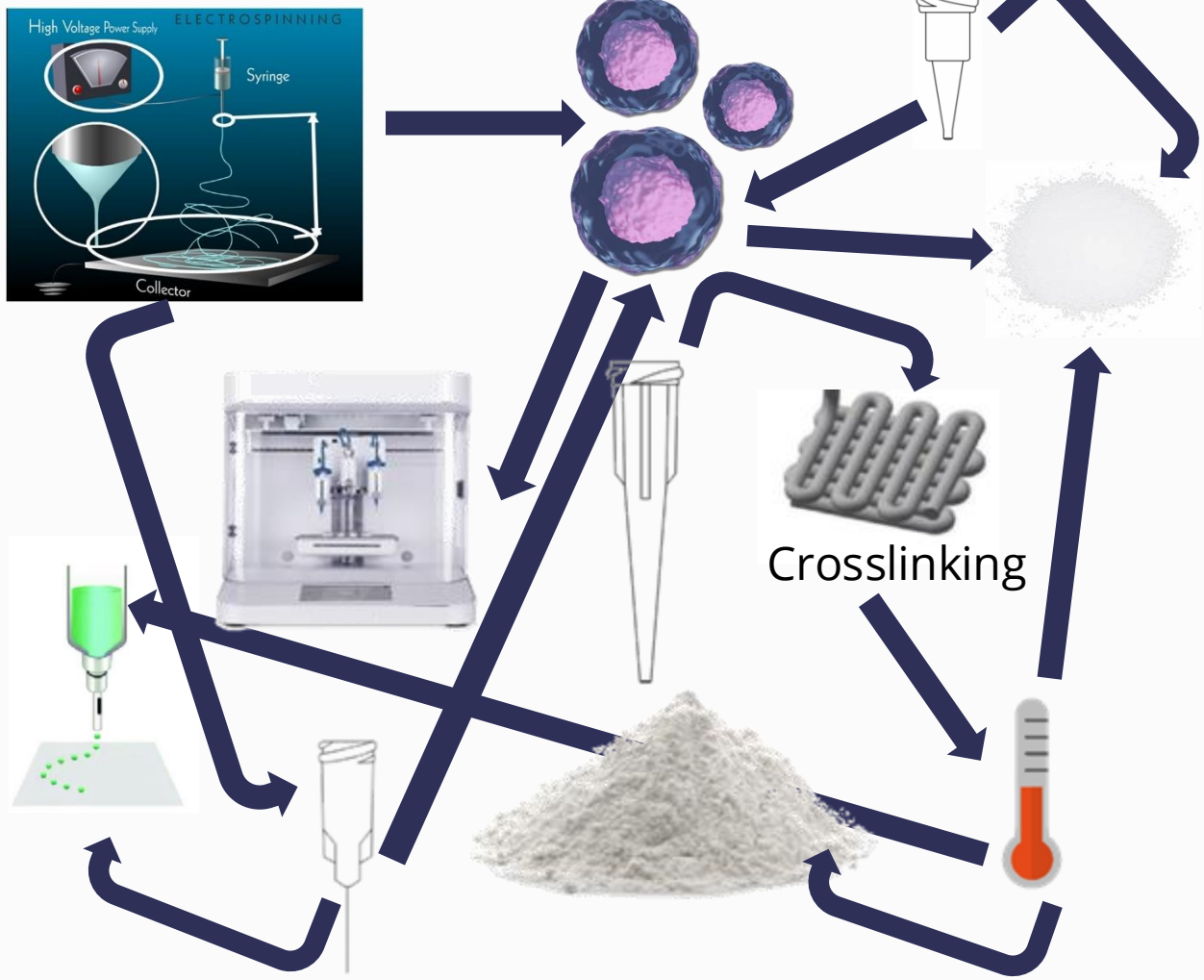


Standard Active Last Update

ASTM F3659-24

Standard Guide for Bioinks Used in Bioprinting

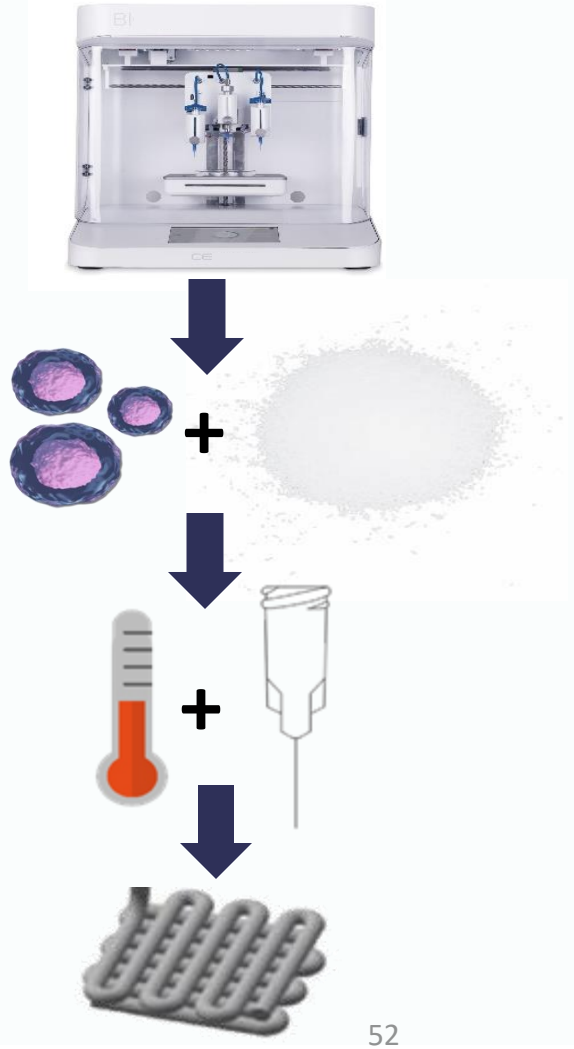
Standards

Standard Historical

ASTM F2312-11

Standard Terminology Relating to Tissue Engineered Medical Products

After Standards



‘More Work to be Done’ with Bioprinting Standardization

What are some best practices I should utilize?

What bioprinting-related assays and test methods have been standardized?

What data should I be measuring and documenting?

What environmental controls should I have in place to prevent contamination?

Areas of Need

Determining and Interpreting Cell Viability

Bioprinting Specifications

And more…

What construct characteristics affect strength and stability?

What are the optimal printing parameters for my purpose?

What characteristics should I consider assessing?

What printing parameters (e.g., temperature) should I control to maintain cell viability?

Resource: https://portal.standardscoordinatingbody.org/search

Join us in Building an Industry!

Get involved!
Easily search through and learn more about impactful standards development efforts through the **Standard Coordinating Body's (SCB's)** Regenerative Medicine Standards Portal.

Join us in Building an Industry!

SCB Survey: Needed Standards for the Regenerative Medicine Field

- Under 15 minutes to complete
- Identify standards that can promote product development
- Helps to establish the impact and urgency of the standards needs in the regenerative medicine community
- Reflected in the Regenerative Medicine Standards Portal
- Informs the selection of topics for SCB-coordinated standards advancement efforts

Join us in Building an Industry!

Thank you!

Questions?

Please feel free to reach out to me at kwells@armiusa.org!