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Voluntary Consensus Standards Recognition Program for Regenerative Medicine Therapies

Workshop 2022
August 24th
12 PM - 2 PM EST

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Senior Scientific Program Manager

STANDARDS COORDINATING BODY
REGENERATIVE MEDICINE

Agenda

1. Welcome
2. Regulatory viewpoint on standards
3. Introduction to FDA guidance
4. Discussion on guidance and commenting
5. Next Steps

Welcome and Expectations

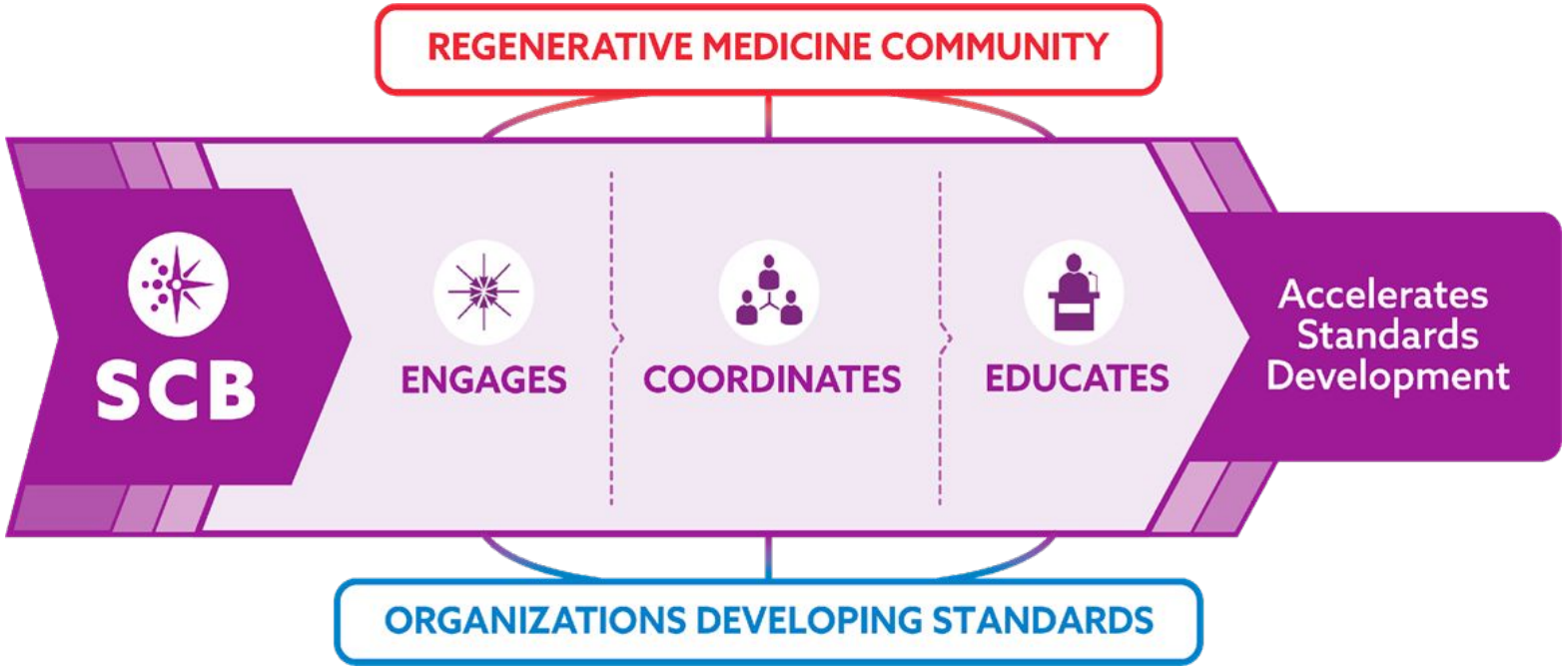
Welcome

Welcome and thank you for your involvement and participation in this workshop.

All participation and views are welcome and appreciated.

This an exciting opportunity for us to come together and incorporate our various viewpoints.

The Standards Coordinating Body (SCB)



Established in 2016 and launched in January 2017, SCB is an **independent 501(c)(3)** organization

Occupies unique niche within field with **no vested interests in specific scientific, commercial, clinical or policy approaches**

SCB is **not an SDO**, but rather **coordinates** the standards development process

Serves as **communication vehicle** among all stakeholders, including government agencies, critical to the development of standards

Goals of the Workshop

The goal of the FDA standards guidance workshop is to bring together organizations involved in regenerative medicine in order to introduce the new guidance and provide a forum for discussion.

Expectations

- Everyone has the opportunity to share their organization's role and viewpoints
- Participation is voluntary and to the level of comfort for the organization
- Discussions are conducted in the spirit of cooperation
- Please mute yourself when you are not speaking
- Please put any comments in the chat or raise your hand (if you would like to send a question privately please send it to Katie Zander)

Regulatory Viewpoint on Standards

Benefits of Standards

Documentary Standards

- Written document containing technical specifications or other criteria
- Written rules, guidelines, or definitions of characteristics

Examples

- ASTM F2944-12 Standard Test Method for Automated Colony Forming Unit (CFU) Assays – Image Acquisition and Analysis Method for Enumerating and Characterizing Cells and Colonies in Culture
- ISO 23033:2021 Biotechnology — Analytical methods — General requirements and considerations for the testing and characterization of cellular therapeutic products

Consensus Standards Process

- Openness
- Balance of Interest
- Due Process
- Appeals Process
- Consensus

Legal Basis for the Use of Standards in the Regulatory Process

The legal basis of the federal use of consensus standards is found in the:

1. National Technology Transfer and Advancement Act (NTTAA)
2. Federal Food, Drug, and Cosmetic Act (FD&C)

It is further clarified in multiple FDA guidances,

1. *Standards Development and the Use of Standards in Regulatory Submissions Reviewed in the Center for Biologics Evaluation and Research*
2. *Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices*

This stance across the federal government is well summarized by the Office of Management and Budget (OMB) as follows:

> *"Agencies shall use existing voluntary consensus standards, both domestic and international, in their regulatory and procurement activities as a means of carrying out policy objectives or activities determined by the agencies, unless use of such standards would be inconsistent with applicable law or otherwise impractical.* ***Agencies shall use such voluntary consensus standards for test methods, procurement guidelines, management systems, sampling procedures, or protocols to determine whether established regulatory limits or targets have been met."***

Regulations, Guidances, and Standards

Regulations:
Have the force and effect of law and are usually mandatory, setting out specific requirements that regulated products and organizations must meet. In the United States, regulations are written in the Code of Federal Regulations and published in the Federal Register.

Guidances:
Formal documents issued by a government agency **to clarify** the agency's **thinking on existing laws or regulations** and offer guidelines for how industry **can comply with these regulations**.

Standards:
Voluntary rules, conditions, characteristics, or physical materials that an organization can adopt to make a process safer, more efficient, or better aligned with the practices of other organizations in their industry.

Different standards types include:

- **Documentary Standards**
- Standard Reference Material
- Standard Reference Data

What is an FDA guidance

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in Agency guidance means that something is suggested or recommended, but not required.

Previous FDA guidance on standards usage

Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices

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Guidance for Industry and Food and Drug Administration Staff

Document issued on September 14, 2018.

Previous FDA guidance on standards usage

This guidance describes the appropriate use and documentation of both FDA-recognized and nonrecognized consensus standards for premarket submissions and how FDA staff intends to rely on consensus standards during the review process. This guidance provides further clarity and explanation about the regulatory framework, policies, and practices regarding the appropriate utilization of consensus standards for premarket submissions.

Previous FDA guidance on standards recognition

Recognition and Withdrawal of Voluntary Consensus Standards

Guidance for Industry and Food and Drug Administration Staff

Document issued on September 15, 2020.

Previous FDA guidance on standards recognition

This guidance describes the procedures that FDA follows, and the actions FDA may take during its review and evaluation of requests for standards recognition or the withdrawal of recognition. This guidance provides further clarity and explanation about the regulatory framework, policies, and practices regarding FDA's recognition and withdrawal of recognition of voluntary consensus standards.

Guidance for Discussion

Voluntary Consensus Standards Recognition Program for Regenerative Medicine Therapies

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Draft Guidance for Industry

This guidance document is for comment purposes only.

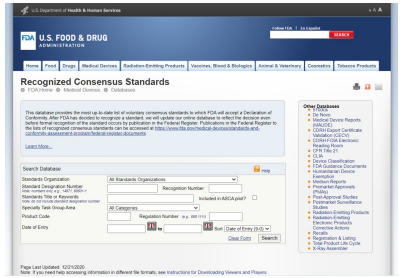
Key Information

Date released: June 16th

Comment Period Open through : September 14th

Publishing Center: CBER

Overall purpose/scope of guidance



This program is modeled after the formal standards and conformity assessment program or S-CAP for medical devices

This guidance describes a program at CBER for recognition of VCS relevant to RMT products regulated in CBER. This guidance also describes how CBER intends to review VCS for recognition in the SRP-RMT. This program will not apply to: statutory and regulatory standards that are legally binding, such as certain provisions of the FD&C Act (21 U.S.C. 301-et seq.) and PHS Act (42 U.S.C.); to standards developed by SDOs that do not follow consensus mechanisms; or to electronic data exchange standards for submissions to CBER.8

The SRP-RMT is expected to facilitate product development by:

- Using Agency expertise to evaluate and recognize voluntary consensus standards related to RMT products that are potentially useful to industry and CBER staff. Specifically, this process will allow CBER to:
  - Receive a candidate VCS, with relevant information (e.g., the scope of the standard and the purpose), from internal or external parties for informal recognition.
  - Determine whether to recognize a standard in whole or in part following an internal scientific evaluation.
  - List the recognized standards in a publicly searchable database on CBER's website, accompanied by an information sheet describing the scope and the extent of CBER's recognition of that standard and any other relevant information about the standard.
- Providing transparency to industry and other stakeholders regarding CBER's thinking about a particular method or approach, thereby increasing regulatory predictability.
- Promoting the visibility and use of standards applicable to its public health mission.

FDA evaluation of standards

- The standard does not conflict with the FD&C Act, the PHS Act, applicable regulations, or current policies;
- The standard is scientifically sound;
- The standard can assist in the assessment of a regulatory submission for RMT products; and;
- Use of the standard may facilitate the ability of a sponsor to meet regulatory requirements for RMT products reviewed in CBER.

Information to include for suggested standard

1. Name and electronic or mailing address of the requester;
2. Name of the SDO;
3. Title of the VCS;
4. The VCS reference or SDO designation number and publication date (e.g., Q1234-2019);
5. Proposed list of products for which the standard could apply routinely;
6. Rationale for request; and
7. A brief description of the testing, performance, or other characteristics of the RMT product(s) or process(es) that would be addressed by the proposed standard.

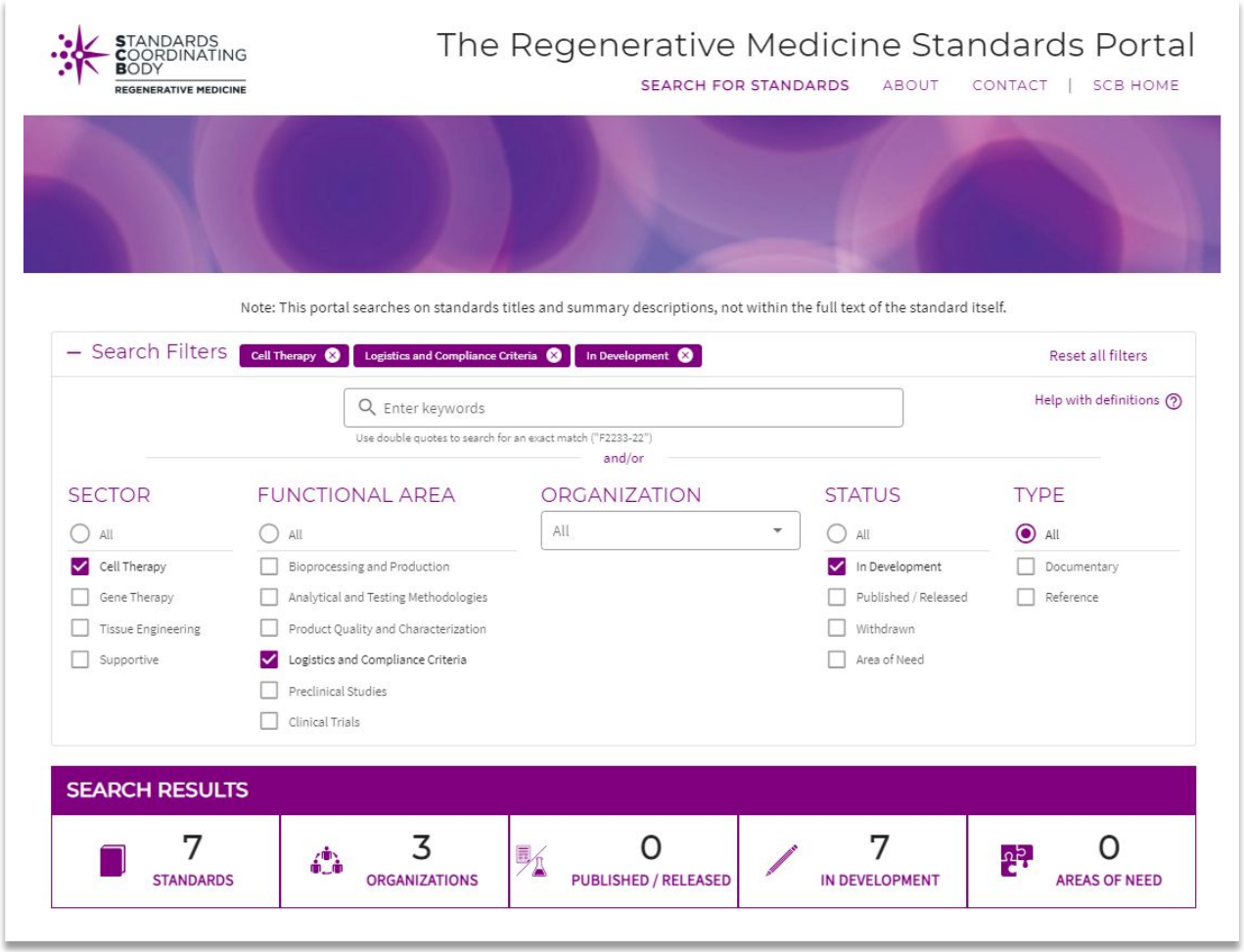
Discussion

Portal Highlights

Easily **searchable and filterable database** of more than 280 regenerative medicine standards and 42 areas of standards need

Custom search by

- Keywords
- Sector
- Functional area
- SDO
- + more



Discussion on FDA Guidance

Any questions on the guidance or how it will be implemented?

Discussion on FDA Guidance

What existing regenerative medicine therapy standards do you think should be suggested for the recognition program?

Discussion on FDA Guidance

Any concerns/questions with how this recognition program will approach the differences between typical standards for medical devices versus typical standards currently used for regenerative medicine?

Discussion on FDA Guidance

Any issues with the process outlined in the guidance?

Discussion on FDA Guidance

Are there any points that should be addressed in the guidance that are absent?

Discussion on FDA Guidance

Is this guidance likely to increase your organization's use of voluntary consensus standards? Why or why not?

Next Steps

Share with your stakeholders

Please share this guidance with your stakeholders and colleagues https://www.fda.gov/regulatory-information/search-fda-guidance-documents/voluntary-consensus-standards-recognition-program-regenerative-medicine-therapies

Any comments should be turned in to the FDA by September 14th

Discussion on FDA Guidance

- SCB is sending a short letter of general support
- SCB will draft a detailed letter and submit it to the FDA outlining the main comments and discussions had during this workshop
- You are encouraged to review and comment on the guidance through your organization
- SCB will keep all registrants updated on the progress of this guidance

Questions?

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For information on how to support SCB's mission, please contact Justin Barch, at JBarch@regenmedscb.org

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Follow us on social media to stay up to date on news surrounding regenerative medicine standards, including webinars, FDA guidance documents, NIST consortium opportunities, open ballots, and new working groups.

Linkedin: https://www.linkedin.com/company/standards-coordinating-body

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Thank you!