Realizing the Promise of Regenerative Medicine Therapies: Strengthening the Standards Development Process

Many promising regenerative medicine therapies that could help manage and even cure many conditions and diseases become stalled on the path to commercialization. Coordinated standards development can target common industry needs and reduce the timeline for moving therapies from the laboratory to commercial scale. Standards development benefits the regenerative medicine community by:

Reducing barriers to innovation by replacing costly and time-consuming trial-and-error processes with researched best practices

Increasing the safety and reliability of therapies by defining testing and processing parameters throughout the product life cycle, from raw materials sourcing to clinical administration

Allowing more efficient review processes by eliminating the need for regulatory bodies to re-validate common operational steps for each new product

Decreasing costs of therapies with the efficiency gains from standardizing equipment, methodologies, processes, and testing protocols

What are standards?

Standards ensure that something is fit for its purpose. They may be created by the government, or they may be developed by non-governmental standards developing organizations (SDOs).

Documentary standards for regenerative medicine therapies set consistent protocols, methodology, technical specifications, or terminology that ensure a high level of product quality and safety.

Physical reference materials with known properties are used to calibrate equipment and provide consistency and quality in measurement processes.

The Standards Coordinating Body for Gene, Cell, and Regenerative Medicines and Cell-Based Drug Discovery (SCB) complements the current SDO processes for standards development by engaging regenerative medicine stakeholders to ensure that new or revised standards provide the greatest benefits to the broad regenerative medicine community. To keep up with the fast-paced growth of regenerative medicine and advance standards specific to the field, SCB:

ENGAGES
the broader regenerative medicine community in the identification, prioritization, and advancement of potential standards to incorporate a range of perspectives and expertise

COORDINATES
and communicates about standards activities across the regenerative medicine community to accelerate standards advancement

EDUCATES
the community about available standards and their benefits, standards development processes, and standards implementation

STANDARDS COORDINATING BODY
REGENERATIVE MEDICINE

NEXIGHT GROUP

How SCB Supports the Standards Advancement Process

Pre-Development Process

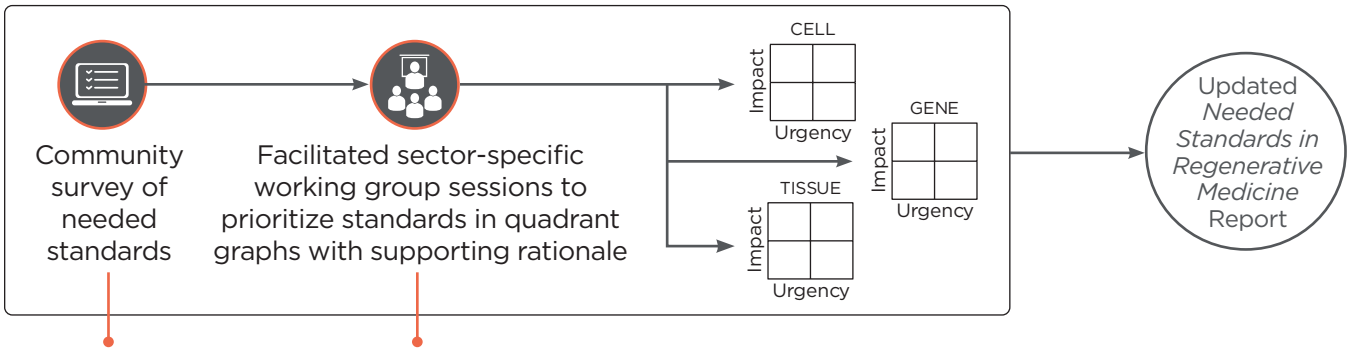
● = SCB supporting activity

1 Define the standards landscape and identify needs

Allows stakeholders to more easily identify gaps and ways to move the field forward

2 Prioritize needed standards

Allows resources to be focused on the standards that will have the greatest impact



3 Conduct feasibility assessment

Ensures that the standards selected are ready for development and likely to be adopted by the regenerative medicine community

Development Process

● = SCB supporting activity

4 Coordinate and support standard development

Drives efficiency and allows stakeholders from across the regenerative medicine community to make their voices heard

GET INVOLVED by participating in these activities

Post-Development Process

● = SCB supporting activity

5 Educate and build awareness of standard

Encourages adoption of the standard and helps stakeholders understand the benefits it can bring their organization

Educational materials that convey benefits of a specific standard, stakeholders impacted, relevant regenerative medicine sectors, and product development processes

- Case studies
- Fact sheets
- Blog posts
- Website content
- Social media
- Quarterly newsletter

Materials disseminated through:

- Educational webinars
- Annual regenerative medicine conference
- Facilitated workshops
- Regenerative medicine media channels
- Teleconferences and targeted meetings
- Networking at community events

GET INVOLVED by participating in these activities

How to get involved in the standards development process

Identify and prioritize needed standards

Participate in **surveys, phone interviews, and workshops** to identify and prioritize needed standards

Participate in **regular sector calls** to stay informed on standards in development

Submit a **project proposal idea** to SCB

Contribute to the ***Landscape of Regenerative Medicine Standards*** report

Provide feedback on the ***Community Perspectives: Needed Standards in Regenerative Medicine*** report

Draft and develop new or updated standards

Participate in **SCB project working groups** and **SDO technical committees**

Provide **subject matter expertise** to help develop and review drafts of standards and best practices

Educate the broad community on new standards and the development process

Contribute to a **case study** on your participation in standards development efforts, or on the value of a standard to your organization

Participate in **community events** and network with other attendees

Share information on the development process or on new/updated standards through **regenerative medicine media channels**

Attend or present during an **SCB webinar***

Attend the **annual regenerative medicine conference***

Follow SCB's efforts

Join the **SCB mailing list** to get the latest news and updates about regenerative medicine standards (**SCB: www.standardscoordinatingbody.org/contact**)

Follow SCB on **Twitter** (**@scbregenmed**) and **LinkedIn** (**company/standards-coordinating-body**)

*Dependent on additional resources

About the development of the improved process

In September 2017, the U.S. Food and Drug Administration awarded a contract to Nexight Group and SCB to engage with experts and recommend a process and plan to strengthen the development of standards for regenerative medicine and advanced therapies. In 2018, more than 300 experts from industry, academia, government, SDOs, and accreditation bodies provided their perspectives on how the process could be improved through interviews, during meetings and workshops, and through participation in an online survey. Nexight Group and SCB thank those who participated for their time and input.