REALIZING *THE* BENEFIT *OF* 21st CENTURY CURES *THROUGH* STANDARDS DEVELOPMENT

A Workshop Convened by FDA, NIST, SCB, and Nexight Group

Draft High-level Agenda

Monday, March 18 – Tuesday, March 19, 2019
NIST National Cybersecurity Center of Excellence
9700 Great Seneca Highway, Rockville, MD 20850

WORKSHOP OBJECTIVES

- **Increase participation in the standards development process**
- **Promote use of standards in product development and regulatory approval**
- **Increase awareness of the reference material development process**

TARGET AUDIENCE

This workshop is intended for individuals from the regenerative medicine community who can drive the development and adoption of standards based on their role within their organization. These individuals should be strongly focused on improving the quality and safety of regenerative medicine products throughout the product development process, including research and development, manufacturing, and clinical translation. Targeted stakeholders include:

- RM manufacturers
- Clinical trial sponsors
- Contract manufacturers
- Academic institutions
- Raw material providers
- Logistics delivery providers

At the workshop, representatives from Standards Development Organizations (SDOs) and industry organizations that actively support standards advancement will provide information on recent efforts that highlight the benefits of standards and of participating in the standards development processes. Participants will also learn about current regenerative medicine standards efforts that need community support and participate in discussions to support their advancement.

DRAFT AGENDA

Monday, March 18, 2019

Time	Session
8:30-9:00 am	**Networking and Registration**
9:00-9:30 am	**Welcome**
9:30-9:55 am	**Key Note: title TBD**
9:55-10:20 am	**Building the Foundation for Regenerative Medicine Innovation**
10:20-10:45 am	**The Standards Evolution of Regenerative Medicine**
10:45-11:00 am	*Break*
11:00-11:30 am	**"Fireside" chat: Documentary standards and reference materials**

Time	Session	
11:30 am-12:30 pm	*Lunch & Learn with SDOs*	
12:30-12:50 pm	**Case Studies: Starting with Success in Mind**	
12:50-1:20 pm	**Panel: Starting with Success in Mind**	
1:20-1:40 pm	**Case Studies: Moving from Idea to Innovation**	
1:40-2:10 pm	**Panel: Moving from Idea to Innovation**	
2:10-2:20 pm	**Introduction to Breakout Sessions: Kicking-off and Advancing Development**	
2:20-2:35 pm	*Break and Transition to Breakout Groups*	
2:35-3:15 pm	**Breakout Sessions: Kicking-off and Advancing Development**	
	2 parallel groups on: **Cell Characterization**	2 parallel groups on: **Transportation**
3:15-3:45 pm	**Report Outs: Kicking-off and Advancing Development**	
3:45-4:15 pm	**How to Get Involved**	
4:15-4:30 pm	**Thank you and wrap up**	
4:30 pm	**Adjourn**	

Tuesday, March 19, 2019

Time	Session	
8:30-9:00 am	**Networking and Registration**	
9:00-9:15 am	**Welcome**	
9:15-9:40 am	**Key Note: title TBD**	
9:40-10:25 am	**Panel: Common Questions about Standards, Demystified**	
10:25-10:35 am	**Introduction to Prioritizing Areas for Standards**	
10:35-10:45 am	*Break and Transition to Prioritization Areas*	
10:45-11:45 am	**Breakout Sessions: Prioritizing Areas for Standards**	
11:45 am-12:30 pm	*Lunch*	
12:30-12:45 pm	**The Importance of Reference Materials**	
12:45-1:00 pm	**Case studies: Reference Materials**	
1:00-1:30 pm	**Panel: Reference Materials**	
1:30-1:50 pm	**Introduction to Breakout Sessions: Standards Advancement Projects**	
1:50-2:00 pm	*Break and Transition to Breakout Sessions*	
2:00-2:50 pm	**Breakout Sessions: Priority Standards Advancement Projects** (Identified by regenerative medicine community and workshop participants)	
	Topic TBD	**Topic TBD**
	Topic TBD	**Topic TBD**
2:50-3:30 pm	**Report out: Standards Advancement Projects**	
3:45-4:00 pm	**What's next, thank you & closing**	
4:00 pm	**Adjourn**	