STANDARDS COORDINATING BODY
REGENERATIVE MEDICINE

Food and Drug Administration

10903 New Hampshire Ave WO71-3128

Silver Spring, MD 20993-0002

[RE: Voluntary Consensus Standards Recognition Program for Regenerative Medicine Therapies: Docket No. FDA-2022-D-0745]

To whom it may concern,

This response represents the shared perspective of standards development organizations, regenerative medicine therapies (RMT) stakeholders, and RMT subject matter experts working within academia, industry, and patient advocacy.

We strongly support the Voluntary Consensus Standards Recognition Program for Regenerative Medicine Therapies: Docket No. FDA-2022-D-0745 as written in the draft guidance. We appreciate FDA's acknowledgment of the importance of Voluntary Consensus Standards (VCS) as demonstrated in the creation of this standards recognition program, as well as their continued input and feedback within the consensus standards development and review processes. By continuing to support the drafting of, and by formally recognizing VCS, FDA is strengthening the RMT standards community and spurring the involvement of additional subject matter experts. We're in agreement with FDA that this dedication paired with added regulatory predictability will "facilitate the overall development of safe and effective RMT products"[1].

[1] Voluntary Consensus Standards Recognition Program for Regenerative Medicine Therapies: Docket No. FDA-2022-D-0745

However, RMT products are inherently variable and complex as a consequence of the inherent variability and complexity of the biological systems from which they are produced. In contrast to the standards within the S-CAP program for medical devices that was used as the template for the VCS Recognition Program, standards most useful to the RMT community emphasize processes, methods, and quality systems, and acknowledge clinical implications of the RMT products. We believe the acknowledgment of these differences within the guidance will encourage the success of the program.

Finally, we are grateful for the creation of the VCS recognition program and the Standards Coordinating Body, standards development organizations, RMT stakeholders, and RMT subject matter experts working within academia, industry, and patient advocacy are looking forward to collaborative activities on future RMT VCS with the FDA and other stakeholders.

Signed,

Justin Barch, CAE
Executive Director
Standards Coordinating Body

Linda S. Barnes, DrPH, MHA, RAC
Vice President
Biotherapies
AABB
32 years of experience in blood and biotherapies

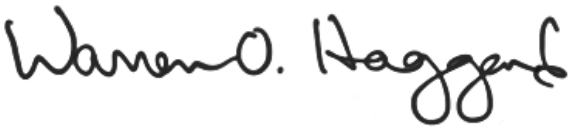
Linda S Barnes

Digitally signed by Linda S Barnes
Date: 2022.09.13 08:14:18 -07'00'

STANDARDS COORDINATING BODY
REGENERATIVE MEDICINE

Michael Lehmicke
Vice President
Science and Industry Affairs
The Alliance for Regenerative Medicine
23 years in the field

Richard McFarland, PhD, MD
Chief Regulatory Officer
Advanced Regenerative Manufacturing Institute (ARMI) / BioFabUSA
25 years in the field



Warren O. Haggard, PhD
Chair, ASTM International Committee F04 on Medical and Surgical Materials and Devices Experiences
Biomedical Engineering
The University of Memphis
25+ years in tissue engineering and related fields

Katherine Donigan, Ph.D.
Senior Director
Science and Regulatory
Biotechnology Innovation Organization

Phyllis I. Warkentin, MD

Chief Medical Officer

Foundation for the Accreditation of Cellular Therapy

43 years in the field

Professor of Pathology/Microbiology and Pediatrics University of Nebraska Medical Center, Omaha, NE. Medical Director, Biologics Production Facility University of Nebraska Medical Center

Michael Mendicino, PhD

President and Chief Consultant

Hybrid Concepts International, LLC

23 years in the field

Worked at FDA, in biotech companies and established and run niche consulting firm focused on cell & gene. Co-founded SCB out of ARM. Current SCB BoD member

Karen Moniz

Technical Director

Technical

ICCBBA

37 years in the field

Karen Moniz Digitally signed by Karen Moniz Date: 2022.09.09 07:09:52 -06'00'

Gene Schaefer

Senior Fellow

NIIMBL

37 years in the field

Christine Roberts
Standards Manager
Parenteral Drug Association
8 years in the field

Dr. Clarice Hitchens
Sr. Director
GCMC Regulatory
Pfizer
30 years in the field

Lina Jamis
Senior Regulatory Affairs Specialist
Quality Assurance / Regulatory Affairs
Synthego Inc.
5 years in the field
Formerly RA at Genentech