

## TERMIS-AM 2025 Workshop: Innovation and Oversight: Navigating FDA Regulatory Pathways in Tissue Engineering and Regenerative Medicine toward Industry Scale

**Workshop Date & Hour:** Sunday, November 9, 2025 from 1:00 PM – 4:00 PM

### Workshop Organizers:

Advanced Regenerative Manufacturing Institute (ARMI) and Standards Coordinating Body for Regenerative Medicine (SCB)

### Workshop Overview:

Join us for a dynamic gathering to explore the latest advancements and challenges at the intersection of tissue engineering and FDA regulation. This symposium will offer insightful presentations, and collaborative discussions focused on fostering innovation within a regulatory by pre-competitive standardization and competitive product development in this multi-disciplinary field. Join us for an opportunity to engage with thought leaders, share knowledge, and envision the future of tissue-engineered products within the regulatory landscape. Don't miss this chance to be at the forefront of transforming healthcare and advancing medical technology.

### Workshop Speakers

	<p><b>Richard McFarland, PhD, MD</b>          Chief Regulatory Officer of the Advanced Regenerative Manufacturing Institute (ARMI). Prior to ARMI he was Associate Director of Policy for FDA/CBER's Office of Tissues and Advanced Therapies and its predecessor office, the Office of Cellular, Tissue and Gene Therapies. In this position, he was heavily involved in policy development for tissue engineering, regenerative medicine, and alternatives to animal use in regulatory decision making. He also serves as the President of the Board of the Standards Coordinating Body for Regenerative Medicine (SCB).</p>
	<p><b>Dawn Henke, PhD</b>          Executive Director of the Standards Coordinating Body. Experienced in leading field experts in developing standards for regenerative medicine including a range of tissue-engineered medical products and related technologies. Dawn has a PhD in genetics and genomic sciences which is useful in standards development considerations and understanding how to implement standards necessary for manufacturing and development of regenerative medicines. She also helps educate experts on what standards currently exist, how to get involved in standards development and how to implement standards into manufacturing processes appropriately.</p>
	<p><b>Kelly Morbey, RAC</b>          Director of Quality Assurance at Advanced Regenerative Manufacturing Institute. RAC-credentialed Regulatory Affairs and Quality professional with 13 years of FDA-facing industry experience, specializing in leading teams involved in the preclinical-through-commercial development and manufacture of complex drugs, devices, and biologics, as well as the efficient, compliant generation of associated quality system and regulatory submission documentation.</p>
	<p><b>Katrina Wells, RAC</b>          Regulatory Affairs Specialist at ARMI   BioFabUSA responsible for creating and implementing regulatory strategies for BioFabConsulting clients across a range of tissue-engineered medical products and related technologies. With a background in biotechnology and years of experience focused on medical device and combination product compliance, Katrina provides expertise in development considerations, testing needs, and regulatory submissions. Katrina also leads standards implementation initiatives within ARMI and assists with standards development activities across various standards development organizations, including ISO and ASTM.</p>

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### Workshop Agenda

1:00pm – 1:05pm	<b>Welcome</b>
1:05pm – 1:35pm	<b>History of Tissue Engineering and Regenerative Medicine over the Last Three Decades</b> <i>Richard McFarland, Ph.D., M.D.</i>
1:35pm – 2:05pm	<b>Fundamentals of the Regulatory Pathways for Regenerative Medicine Products from Ideation to Cure</b> <i>Katrina Wells, RAC</i>
2:05pm – 2:30pm	<b>Coffee Break</b>
2:30pm – 2:55pm	<b>Phase Appropriate Quality Management Systems: The Choreographer of the Dance Among Product Development, Regulatory Submissions and the Patient</b> <i>Kelly Morbey, RAC</i>
2:55pm – 3:20pm	<b>The Standards Outlook for Tissue Engineering and Regenerative Medicine: Anything but Standard!</b> <i>Dawn Henke, Ph.D.</i>
3:20pm – 3:45pm	<b>The Dawning of the Age of Widespread Curative Therapies</b> <i>Richard McFarland, Ph.D., M.D.</i>
3:45pm – 4:00pm	Q&A + Discussion