

Last Updated on May 5, 2026

**AGENDA: AIMBE Biomedical Engineering Multidisciplinary Alliance
(BEMA) Roundtable Meeting on “Regulatory, Technical, and Scientific Frontiers in
Combination Products”**

Monday, May 18, 2026 | 8:00 AM – 4:30 PM (Eastern Time)

Venue:

American Association for the Advancement of
Science (AAAS)
1200 New York Ave NW
Washington, DC 20005

AIMBE Staff Contact Information:

Dawn Beraud, AIMBE Executive
Director, policy@aimbe.org

Jason Marvin, AIMBE Director of
Partnerships and External
Relations, partnerships@aimbe.org

This meeting will focus on regulatory and technical challenges for combination products, a topic spanning drug, device, and biologic interfaces. Advances in combination products are rapidly reshaping how therapies are designed, regulated, and delivered, while introducing new regulatory, technical, and translational challenges. This roundtable will provide participants with actionable insights on FDA regulatory pathways, technical and manufacturing integration, product classification strategies, and emerging scientific frontiers. Discussions will examine how these factors influence development timelines, safety and performance, and regulatory decision-making, while identifying best practices to streamline development, reduce inefficiencies, and accelerate translation to market. As an invite-only forum, the event is designed to foster candid cross-sector dialogue on pressing issues facing the combination products and broader biotechnology community.

Thank you to our BEMA Roundtable sponsors and contributing organizations:



7:30-8:20 AM

Breakfast Available

8:00-8:20 AM

Opening Remarks by **Dawn Beraud**, Ph.D. (AIMBE Executive Director) and **Utkan Demirci**, Ph.D. (AIMBE Industry Council Chair)

8:20-10:25 AM

Session 1. Regulatory Considerations and Challenges for Combination Products

This session will explore FDA regulatory pathways and oversight considerations for combination products, including how product design, delivery duration, and intended use influence regulatory strategy and approval processes. Speakers will share perspectives from both regulatory agencies and industry on navigating evolving guidance and compliance requirements.

Three speakers will each present for 20 minutes, followed by 10 minutes of Q&A, concluding with a 30-minute discussion panel.

- **James Bertram**, Ph.D., Director, FDA Office of Combination Products
- **Elijah Wreh**, DMin, Senior Manager of Regulatory Affairs, Boston Scientific Corporation
- **Megan Robertson**, JD, Partner, Epstein, Becker & Green, P.C.

Moderator: **Rebecca Bergman**, Former President of Gustavus Adolphus College and Medtronic Executive

10:25-11:50 AM

Session 2. Technical Considerations and Challenges for Combination Products

This session will examine key technical challenges in developing combination products, including delivery modalities, device–drug integration, quality control, and manufacturing considerations. Case examples will highlight how engineering and design choices impact performance, safety, and scalability.

Two speakers will each present for 20 minutes, followed by 10 minutes of Q&A, concluding with a 25-minute discussion panel.

- **James Glover, Ph.D.** Head of Devices Centre of Excellence, Pfizer
- **Lesley Crookall**, Preclinical Advisor, Medtronic, Inc.

Moderator: **Dawn Beraud**, Ph.D., Executive Director, AIMBE

11:50 AM-12:40 PM Lunch

12:40-2:10 PM

Session 3. Classification of Combination Products: Therapies and Applications

This session will discuss how combination products are classified across therapeutic areas and applications, emphasizing common technology platforms applied to diverse clinical needs. Speakers will share case studies illustrating how classification decisions shape regulatory pathways and development strategies.

Two speakers will each present for 20 minutes, followed by 10 minutes of Q&A, concluding with a 25-minute discussion panel.

- **James Bertram, Ph.D.**, Director, FDA Office of Combination Products
- **Rumi Young**, Director of Regulatory Policy, Novo Nordisk

Moderator: **Utkan Demirci, Ph.D.**, Professor of Radiology, Stanford University

2:10-3:35 PM

Session 4: New Scientific Frontiers: Research Driving the Future of Combination Products

This session will spotlight the latest scientific advances and research directions shaping the next generation of combination products. Speakers will highlight cutting-edge technologies, basic science breakthroughs, and translational research poised to transform the future of combination products.

Two speakers will each present for 20 minutes, followed by 10 minutes of Q&A, concluding with a 25-minute discussion panel.

- **Alex Abramson, Ph.D.**, Assistant Professor of Chemical and Biomolecular Engineering, Georgia Institute of Technology
- **David Grainger, Ph.D.**, Distinguished Professor and Chair of Biomedical Engineering, University of Utah

Moderator: **Phil LeDuc, Ph.D.**, Professor of Engineering, Carnegie Mellon University

3:35-4:30 PM

Wrap-Up, Discussion, and Closing Remarks

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AIMBE BEMA Roundtable Organizing Committee:

Dawn Beraud, Ph.D., Executive Director, AIMBE

Rebecca Bergman, Former President of Gustavus Adolphus College and Medtronic Executive, AIMBE Fellow and NAE Member

Joseph Delaney, Ph.D., Senior Science Fellow, Boston Scientific Corporation, AIMBE Fellow

Utkan Demirci, Ph.D., Professor of Radiology at Stanford University, AIMBE Fellow, and AIMBE Industry Council Chair

Chetan Goudar, Ph.D. Vice President of Manufacturing and Clinical Supply at Amgen, Inc., AIMBE Fellow and NAE Member

Philip LeDuc, Ph.D., William J. Brown Professor of Engineering, Carnegie Mellon University, AIMBE Fellow

SuPing Lyu, Ph.D., Senior Distinguished Scientist, Medtronic, Inc., AIMBE Fellow

Jason Marvin, Ph.D., Director of Partnerships and External Relations, AIMBE

Terry Woods, Ph.D., Director - Division of Standards & Conformity Assessment, FDA, AIMBE Fellow

AIMBE BEMA Roundtable Participants Represent the Following Organizations:

- Association for the Advancement of Medical Instrumentation (AAMI)
- American Institute for Medical and Biological Engineering (AIMBE)
- Amgen, Inc.
- Boston Scientific Corporation
- Brown University
- Carnegie Mellon University
- Daikin America
- dsm-firmenich
- Epstein, Becker & Green, P.C.
- FDA Center for Devices and Radiological Health (CDRH)
- FDA Office of Combination Products
- Georgia Institute of Technology
- Georgia Institute of Technology NSF Engineering Research Center for Cell Manufacturing Technologies (CMaT)
- Lubrizol
- Medtronic. Inc.
- Merck, Inc.
- National Institutes of Health (NIH)
- North Carolina State University / North Carolina Viral Vector Initiative in Research and Learning (NC-Viral)
- Novo Nordisk
- Pfizer
- Sanofi
- Stanford University
- The Chemours Company
- University of Illinois Chicago
- University of Maryland School of Pharmacy / Center for Research on Complex Generics
- University of Massachusetts Chan Medical School / Massachusetts Medical Device Development Center (M2D2)
- University of Utah

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Hotel Accommodations Within Walking Distance

- Courtyard by Marriott Washington, DC/U.S. Capitol
- Hampton Inn Washington-Downtown-Convention Center
- Washington Plaza Hotel
- Kimpton Hotel Monaco Washington DC
- The Westin Washington, D.C. City Center
- Eaton DC
- Hamilton Hotel