

OSMA FALL MEETING AGENDA

20 25



OCTOBER 22-23, 2025
BETHESDA NORTH MARRIOTT
FDA WHITE OAK CAMPUS

ADVOCATE



EDUCATE



FACILITATE

WEDNESDAY, OCTOBER 22

7:30 AM Breakfast is available in the foyer of Brookside AB

OSMA BUSINESS MEETING-BROOKSIDE AB

The OSMA Business Meeting is for members only.
Speakers and guests are invited to join us at 11:25 for lunch.

8:00 AM Reading of the Meeting Minutes and Virtual Housekeeping

8:10 AM Opening Remarks and New Member Introduction
Ryan Belaney, OSMA President

8:20 AM OSMA Board Updates and Officer Reports

9:00 AM OSMA Team Building

9:20 AM Policy Updates

9:35 AM OSMA Process Changes

9:50 AM BREAK

10:05 AM Working Group Update

10:35 AM Voting for Open Board Positions

OSMA EDUCATIONAL MEETING

OSMA MEMBERS, SPEAKERS, AND GUESTS ARE INVITED TO ATTEND

11:25 AM LUNCH

12:15 PM Navigating FDA Submissions in a Changing Environment: Janice Hogan, *Hogan Lovells*

12:45 PM Your Standards Snapshot: What's New and Key Insights in ASTM and ISO Standards: Jason Steffens, *Endolab* and Leah Guenther

WEDNESDAY, OCTOBER 22

EDUCATIONAL MEETING- BROOKSIDE AB

1:45 PM	Innovation in Clinical Study Design: Nick Giokas, <i>MCRA</i>
2:30 PM	BREAK
2:45 PM	Reimbursement strategies: John D. McDermott, Jr., MBA, <i>MCRA</i>
3:30 PM	Clinical Data in 510(k)s: Michael Coladonato, <i>MCRA</i>
4:00 PM	Unboxing Orthopedics: Why Packaging Can Make or Break Safety: Christina Mendat, PhD, <i>Eurofins</i>
4:45 PM	Closing Remarks and Wednesday Meeting Adjournment

GROUP DINNER AT FOGO DE CHAO

We invite all attendees and speakers to join us in the lobby at 6:15pm to head to our private dinner just a short walk away.

THURSDAY, OCTOBER 23

TRANSPORTATION TO FDA

We will be meeting in the lobby at 7:00am to board the charter bus that will take us to the FDA White Oak Campus. You are also welcome to drive your own vehicle. If you are leaving directly from FDA, you may store your luggage in the green room just off of the Great Room where we will hold the meeting.

Please ensure you have the proper ID on you:

US Citizens: Valid (REAL ID compliant) government-issued PHOTO identification

Green Card Holders: Valid Lawful Permanent Resident card (no photocopies)

Foreign Nationals: Passport used on your FN Visitor Data Request Form

THURSDAY, OCTOBER 23

FDA WHITE OAK GREAT ROOM

8:00 AM	Breakfast is available in the Great Room Foyer
8:30 AM	Reading of the Meeting Guidelines and Virtual Housekeeping
8:40 AM	Office of Orthopedic Devices OHT6 Opening Remarks RDML Raquel Peat, Ph.D., MPH, <i>FDA</i>
9:25 AM	Quality Culture: Keisha Thomas MS, MHS, CQA, RAC, <i>FDA</i>
9:55 AM	Building a Sustainable Quality Culture in FDA-Regulated Industries: Amra Racic, <i>Veeva Systems, OSMA</i>
10:25 AM	BREAK
10:40 AM	DHT6A Update: Jiping Chen M.D., Ph.D., <i>FDA</i>
10:55 AM	DHT6B Update: Ronald Jean Ph.D., <i>FDA</i>
11:10 AM	DHT6C Update: Laurence Coyne, Ph.D., <i>FDA</i>
11:25 AM	Additive Manufacturing: David Hwang, Ph.D. and Jay Kadakia, M.S.*, <i>FDA</i>
11:55 AM	TAP program: Cynthia Chang, <i>FDA</i>
12:25 PM	LUNCH
1:10 PM	Corrosion Testing for Orthopedic Devices: Stephanie Smith, Ph.D.*, <i>FDA</i>
1:40 PM	Use of AI within CDRH: S. Raymond Golish, M.D., Ph.D., MBA, <i>FDA</i>
2:10 PM	Quantifying an Art: Industry Use of Data & AI to Improve Spine Surgery: Andrew Fields, <i>Medtronic</i>
2:30 PM	BREAK

THURSDAY, OCTOBER 23

FDA WHITE OAK GREAT ROOM

2:45 PM

Biocompatibility Updates: Aprajita Garg, Ph.D. and Berk Oktem Ph.D., *FDA*

3:15 PM

When Change is the Only Constant: Updates to ISO 10993-1 and Other Hot Topics in Biocompatibility: Lindsey Borton, *Gradient Corp*

3:45 PM

Biocompatibility Panel Discussion

Moderator: Ron Brown, *Risk Science Consortium, LLC*

Panelists: Lindsey Borton, *Gradient Corp*, Aprajita Garg, Ph.D., Paul Turner, Ph.D., Carole Wolfe, Ph.D., Berk Oktem, Ph.D., *FDA*

4:45 PM

Closing Remarks and Day 2 Meeting Adjournment



**DAY 1
ATTENDANCE**



**DAY 2
ATTENDANCE**



**DAY 1 SPEAKER
QUESTIONS**



**DAY 2 SPEAKER
QUESTIONS**

Note: An * indicates that a speaker is participating virtually

ADVOCATE



EDUCATE



FACILITATE