



osma

Orthopaedic Surgical
Manufacturers Association

**2024 FALL MEETING
October 22-24
Agenda**



Tuesday, October 22

Time (EST)	OSMA Networking Reception
6:30 PM	Networking Reception: Join us for a networking reception at The Capital Grille: 500 E. Pratt Street, Baltimore, MD

Wednesday, October 23

Breakfast available at 7:30 am in The Kent Room

Time (EST)	Topic/Presenter
8:00 AM	Reading of Meeting Guidelines and Virtual Housekeeping: OSMA
8:10 AM	Welcome/Opening Remarks and Introduction of New Members: Ehab Esmail, OSMA President
8:20 AM	OSMA BUSINESS MEETING – MEMBERS ONLY OSMA Board Updates and Officer Reports: OSMA Board of Directors
9:00 AM	Working Group Breakouts and Brainstorming Sessions: Workgroup Leads and OSMA Members
9:45 AM	Break
10:00 AM	Working Group Updates - Accomplishments from past 6 months, future 12-month plans: OSMA Subcommittee and Working Group Leads
10:30 AM	Policy Update: Angela Silvestri
10:45 AM	OAR Update and Next Steps: Sharon Starowicz
11:00 AM	Survey Results and Meeting Updates: Ryan Belaney
11:20 AM	Voting for Open Board Positions: OSMA
12:00 PM	Lunch
1:00 PM	OSMA EDUCATIONAL MEETING Update from Capitol Hill: Clayton Hall, <i>Medical Device Manufacturers Association (MDMA)</i>
1:30 PM	B1+RMS: What is it and How Does it Impact MRI Safety Labeling?: Grant Baker, MSE, Program Manager, MRI Safety Evaluations, <i>MED Institute</i>
2:00 PM	Trending Topics in Orthopaedics: Jemin Jay Dedania, Randy Prebula, Kelliann Payne, <i>Hogan Lovells</i>
2:45 PM	Break
3:00 PM	AAOS Update from the Committee of Devices Biologics, Technology: Daniel B.F. Saris, M.D., Ph.D., <i>AAOS</i>
3:30 PM	FDA Quality Management SYSTEM Regulation: How Should You Prepare?: Timothy Gooch, <i>SGS</i>
4:00 PM	Understanding Requirements for In Silico Clinical Trials: Marc Horner Ph.D., <i>ANSYS</i>
4:30 PM	Closing Remarks: OSMA

Please join us for dinner at 6:15 at the Rusty Scupper Restaurant & Bar- 402 Key Highway, Inner Harbor Marina. Dining space is in the Topside Lounge.

Thursday, October 24

Breakfast available at 7:30 am in The Homeland Room

Time (EST)	Topic/Presenter
8:00 AM	Reading of Meeting Guidelines and Virtual Housekeeping: OSMA
8:10 AM	Welcome/Opening Remarks: Ehab Esmail, OSMA President
8:20 AM	OSMA Working Group Updates: OSMA
8:35 AM	Office of Health Technology (OHT) 6: Orthopedic Devices Director's Opening Remarks: RDML Raquel Peat, Ph.D., MPH, FDA
9:35 AM	Accreditation Scheme for Conformity Assessment (ASCA) Program Updates: Eric Franca, Ph.D., FDA
10:00 AM	Break
10:15 AM	Update on Magnetic Resonance Testing Requirements for Orthopaedic Devices: Vikansha Dwivedi, BSME, FDA
10:40 AM	MRI Safety Evaluations: Common Deficiency Questions: David Gross, PhD, PE, Director, MRI Safety Evaluations and Engineering Simulations, MED Institute
11:05 AM	Biocompatibility Update: Teresa Palacios Hernández, Ph.D, DABT, FDA
11:30 AM	International Organization for Standardization (ISO) and American Society for Testing and Materials (ASTM) Arthroplasty Update: John Goode, MS, FDA
11:55 AM	Lunch
12:40 PM	Division of Health Technology (DHT)6A, DHT6B, and DHT6C High Level Updates: Jiping Chen M.D., Ph.D., Ronald Jean Ph.D., and Laurence Coyne, Ph.D., FDA
1:10 PM	Experiential Learning Program (ELP) Update and Insight: Alan Myers, MA, FDA
1:35 PM	FDA Updates: Inspections and Compliance: Keisha Thomas, MS, MHS, CQA, RAC, FDA
2:00 PM	De Novo Decision Analysis: Peter Yang, FDA
2:25 PM	Break
2:40 PM	Digital Health Insights: Kathryn Drzewiecki, Ph.D., FDA
3:05 PM	Digital Health, Industry Perspective: Teal Bjoraker, Medtronic
3:30 PM	Table Topic Discussions
20 minute segments, three groups	Biocompatibility Moderators: Paul Turner, Ph.D., FDA and Ryan Belaney, OSMA
	Medical Device Development Tools (MDDT) Moderators: Jessica Mavadia-Shukla, Ph.D., FDA and Lisa Boyle, OSMA
	Custom Device Exemption and Expanded Access Requests Moderators: Christopher Ferreira, MS, FDA and Brianna Prindle, OSMA
4:30 PM	Wrap Up and Closing Remarks: OSMA
4:40 PM	Meeting Adjourn