



osma

**Orthopaedic Surgical
Manufacturers Association**

2024 WINTER MEETING

**Grand Bohemian Hotel
Charleston, SC**

January 29-31, 2024

Monday, January 29

Time (EST) OSMA Fellows Recognition and Networking Reception

7:00 PM **Networking Reception:** Join us for a reception to honor our inaugural OSMA Fellow inductees and network with our colleagues (*Location TBD*)

Tuesday, January 30

Breakfast available at 7:30 am in the meeting room

Time (EST) Topic/Presenter

OSMA BUSINESS MEETING – MEMBERS ONLY

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 Board Updates and Officer Reports:** OSMA
9:05 AM **Biocompatibility, MR, RWE, and Anti-infection working group meetings:** OSMA

10:05 AM **Break**

10:20 AM **Working Group Updates - Accomplishments from past 6 months, future 12-month plans:** OSMA
11:20 AM **OSMA Website Update:** Michael Thomas, *OSMA*
11:30 AM **2023 OSMA Performance Survey:** Ryan Belaney and Gabriela Parana, *OSMA*

11:50 PM **Lunch (OSMA Members and Guest Speakers)**

OSMA EDUCATIONAL MEETING

1:00 PM **The Regulatory Landscape in Europe:** Bassil Akra, *AKRA TEAM GmbH*
1:30 PM **MedTech Europe Update- 2024 Strategic Priorities:** Merlin Rietschel, *MedTech Europe (remote presentation)*
2:00 PM **UKCA Update and Comparison to MDR Process and Documentation Requirements:** Tim Marriott, *BSI Orthopaedic and Dental Team*

2:30 PM **Break**

2:45 PM **MDR Extension:** Jie Gao, *DEKRA*
3:15 PM **Regulatory Pathways for Custom Made/ Patient Matched Devices:** Andrea Pietsch, *TÜV SÜD*
3:45 PM **Q&A**

4:00 PM **Closing Remarks and Day 1 Meeting Adjournment:** *OSMA*

Please join us for a group dinner at 6:00 p.m.

Wednesday, January 31
Breakfast available at 7:30 am in the meeting room

Time (EST)	Topic/Presenter
8:30 AM	Reading of Meeting Guidelines and Virtual Housekeeping: OSMA
8:35 AM	Welcome/Opening Remarks: Ehab Esmail, <i>OSMA President</i>
8:45 PM	
	Clinical Session/Panel Discussion: Bassil Akra, <i>AKRA TEAM GmbH</i> , Moderator
8: 45 AM	Opening Remarks and Setting the Stage: Bassil Akra, <i>AKRA TEAM GmbH</i>
9:00 AM	Clinical Conformity Routes for Orthopaedic Devices – Article 61, MDCG 2020-6, Annex XV: Daniel Gulkin, MD, <i>TÜV SÜD</i>
9:30 AM	Key Clinical, SSCP and PMS/ PMCF Non-Conformities Raised by Notified Bodies: Matthias Fink, MD, <i>AKRA TEAM GmbH</i>
10:00 AM	Break
10:30 AM	Clinical Consultation Process- First Experience with the Expert Panel: Tim Marriott, <i>BSI</i>
11:00 AM	Use of Real World Evidence During EU Submissions- Amelia Hufford, <i>3Aware</i>
11:30 PM	Lunch
	Change Management: Chris Brodrick & Anne Le Rouzo, <i>GMED North America</i>
	☐ Impact of classification changes
12:30 PM	☐ What types of changes/updates to SSCP would trigger revalidation?
	☐ Guidance regarding substantial vs non-substantial changes under MDR (e.g., software)- When to submit for review?
1:00 PM	Clinical Q&A and Panel Discussion
2:00 PM	Closing Remarks and Day 2 Meeting Adjournment: <i>OSMA</i>