

OSMA SPRING MEETING AGENDA

20 25



APRIL 22-24, 2025
ANNAPOLIS WATERFRONT HOTEL
ANNAPOLIS, MARYLAND

ADVOCATE • EDUCATE • FACILITATE

TUESDAY APRIL 22

WELCOME RECEPTION

7:00 PM

Please join us for a Networking Reception in Ballroom III at the Annapolis Waterfront Hotel

WEDNESDAY APRIL 23

OSMA BUSINESS MEETING- BALLROOM II

7:30 AM

Breakfast is available in the foyer of Ballroom II

The OSMA Business Meeting is for members only.
Speakers and guests are invited to join us at 10:00am for the Education Meeting

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 Teambuilding

8:45 AM

OSMA Board Updates and Officer Reports

9:15 AM

Working Group Updates

9:30 AM

BREAK

OSMA EDUCATIONAL MEETING

OSMA MEMBERS, SPEAKERS, AND GUESTS ARE INVITED TO ATTEND

To kick off our education meeting, join us for a comprehensive examination of the key trends shaping the MedTech evolution. Topics include **embracing a digital core** (exploring the significance of a robust digital foundation and digital degrees of freedom as pathways to transformation); **strategic responses to challenges** (how MedTech companies are adapting to navigate evolving pressures); **segment-specific focus** (insights from orthopedics with lessons applicable across various MedTech sectors); **emerging reimbursement models** (examining advancements in leading areas such as radiology and the importance of collaboration over solitary efforts); and **AI's growing role** (discussing the rise of AI and agentic AI, and their implications for the orthopedic landscape).

10:00AM

Digital Health Revolution- Key Trends Shaping the MedTech Evolution

Speakers and Panelists: Oliver C. Richards, PhD, Accenture; Jens Lauber, Accenture; Bassil Akra, PhD, AKRA TEAM

Panel Moderator: Suchitra Basu, PhD, J&J MedTech

WEDNESDAY APRIL 23

EDUCATIONAL MEETING- BALLROOM II

11:30 AM

Digitalization in Regulatory, Quality, and Clinical

Documentation: Methods Applied by the Medical Device Industry to Increase Efficiency, Value of Digital Methods from Application to Certification, Current Practices and Future Opportunities

Speaker: Amra Racic, RAC, *Veeva Systems*; Martin Witte*, TÜV SÜD; Jens Lauber, *Accenture*; Conor Hogan*, *BSI Group*

12:30PM

LUNCH

1:30 PM

Unlocking AI Innovations- Navigating FDA's Guidance Documents for AI/ML Enabled Devices.

- Regulatory Insights on Lifecycle Management of AI-enabled devices
- Introduction of AI-DSF into clinical workflows
- R&D of AI-enabled devices – development, data, and interoperability
- PCCP – Background and Expectations

Speakers and Panelists: Ganesh Saiprasad*, PhD, *Focal One*; Diane Johnson, *Johnson & Johnson*; Manan Hathi, MS, RAC, *Stryker*; Anupama Govindarajan, PhD, *J&J MedTech*

3:00 PM

BREAK

Join us for a comprehensive examination of the regulatory requirements for patient-specific implants and surgical planning software. Discussion includes **navigating FDA submissions** and **recent guidance updates**; FDA expectations for **mechanical testing, biocompatibility, and software validation**, including AI/ML-based applications; and evaluating the benefits and challenges of **separating pre-operative planning software as SaMD**.

3:30 PM

Precision in Practice: Navigating Regulatory Requirements for Patient-Specific Implants & Surgical Planning Software.

Speakers: Dave McGurl, *MCRA*; Nima Akhlaghi, PhD, *MCRA*

4:30 PM

Closing Remarks and Wednesday Meeting Adjournment

GROUP DINNER AT CHOPTANK

We invite all attendees and speakers to join us at 6:30pm for our private dinner on the waterfront at the Choptank Annapolis.

THURSDAY APRIL 24

EDUCATIONAL MEETING- BALLROOM II

7:30 AM **Breakfast is available in the foyer of Ballroom II**

8:00 AM **Reading of the Meeting Guidelines and Virtual Housekeeping**

8:10 AM **Welcome and Opening Remarks**
Ryan Belaney, OSMA President

We will start the day with an insightful session on emerging European trends for AI/ML medical devices. Topics include **navigating the EU AI Act** requirements and their intersection with MDR/IVDR frameworks; addressing **enhanced cybersecurity requirements** for connected medical devices; implementing **cybersecurity/QMS integration** strategies to meet regulatory expectations; and preparing for the **evolving compliance landscape** as European regulators refine their approach to AI/ML technologies in healthcare.

8:15 AM **Emerging European Regulatory Trends for AI/ML Medical Devices.**

Speakers and Panelists: Erik Vollebregt*, *Axon Lawyers*; Jens Lauber, *Accenture*; Conor Hogan*, *BSI Group*; Manan Hathi, *MS, RAC, Stryker*; Anupama Govindarajan, PhD, *J&J MedTech*
Moderator: Bassil Akra, PhD, *AKRA Team*

10:15 AM **BREAK**

After the break we will explore the use of **in silico evidence in orthopedic device evaluation**. This session will examine how computational modeling and simulation are transforming the medical device industry. Topics include: **integration of simulation into product development** with examples of in silico clinical trials; **regulatory advancements** in computational modeling standards and harmonization; **transitioning from benchtop to in silico evidence**; and approaches to **generating synthetic patient data** for both patient-specific and population analyses. The session will conclude with a roundtable discussion on future opportunities in this field.

10:45 AM **Revolutionizing Orthopedic Device Evaluation with In-Silico Evidence**

Speakers and Panelists: Luca Emili*, *InSilico Trials*; Marc Horner, PhD, *Ansys*; Cheryl Liu, PhD, *Stryker*; Payman Afshari, PhD, *J&J*; Mathieu Rimaud, *Twinsight Medical*
Moderator: Payman Afshari, PhD, *J&J*

12:30 PM **LUNCH**

THURSDAY APRIL 24

EDUCATIONAL MEETING- BALLROOM II

After lunch, join us for an informative presentation and panel discussion on the regulatory landscape surrounding the latest smart implants and sensor technology. Topics include an introduction to **sensor technology and smart implants** and their regulatory challenges; considerations for **active implantable medical devices** (radio, battery, software, hazardous substances); **regulatory considerations for sensors** in medical devices; and **wearable sensors** in the orthopedic space.

1:30 PM

Smart Implants: New Generational Implants, Devices, and Sensor Technology

Speakers and Panelists: Garrett O'Lochlainn*, *Medtronic*; Andrew Fields*, *Medtronic*; Dave McGurl, *MCRA*; Nima Akhlaghi, PhD, *MCRA*;

For our final session of the meeting, our expert speakers will discuss the challenges and opportunities in post-market surveillance considering changing regulations and advancing technologies. You can expect topics including: **evolving regulatory requirements** (MDR/IVDR, FDA active surveillance, IMDRF harmonization); **technology enablement** through AI/ML, automation, and NLP; **strategic use of real-world data** for evidence generation and predictive risk management; and shifting from compliance-focused to **patient-centered surveillance approaches**.

2:30 PM

Post-Market Surveillance: Challenges and Opportunities in an Era of Regulatory Change and Technological Advancement

Speakers: Jens Lauber, *Accenture*; Heather Colvin, MPP, *J&J MedTech*; Diane Legere, RN, BScN, MSc, APCCN, *DNV Product Assurance AS*

3:30 PM

Closing Remarks and Day 2 Meeting Adjournment

Note: An * indicates that a speaker is participating virtually

OSMA SPRING MEETING

20
25



ADVOCATE



EDUCATE



FACILITATE



**DAY 1
ATTENDANCE**



**DAY 2
ATTENDANCE**



**DAY 1 SPEAKER
QUESTIONS**



**DAY 2 SPEAKER
QUESTIONS**



**WORKING GROUP
REGISTRATION**



**OAR- PATIENT
SPECIFIC DEVICE
SURVEY**