

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 at the Annapolis Waterfront Hotel

WEDNESDAY APRIL 23

OSMA BUSINESS MEETING

7:30 AM Breakfast is available outside the conference room.

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, *Accenture*; Jens Lauber, *Accenture*; Bassil Akra, PhD, *AKRA TEAM*
Panel Moderator: Suchitra Basu, PhD, *J&J MedTech*

WEDNESDAY APRIL 23

EDUCATIONAL MEETING

11:30 AM

Digitalization in Regulatory, Quality, and Clinical Documentation

- Methods Applied by the Medical Device Industry to Increase Efficiency. **Speaker:** Amra Racic, RAC, Veeva Systems
- From Application to Certification, the Value of Digital Methods. **Speaker:** Martin Witte*, TÜV SÜD
- Current Practices and Future Opportunities. **Speaker:** Jens Lauber, Accenture

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

7:30 AM **Breakfast is available outside the conference room.**

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*

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*

Moderator: Payman Afshari, PhD, *J&J*

12:30 PM **LUNCH**

THURSDAY APRIL 24

EDUCATIONAL MEETING

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: Dave McGurl, *MCRA*; Nima Akhlaghi, PhD, *MCRA*; Garrett O’Lochlainn*, *Medtronic*; Andrew Fields*, *Medtronic*

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, *J&J MedTech*; Diane Legere*, *DNV Product Assurance AS*

3:30 PM

Closing Remarks and Day 2 Meeting Adjournment

Note: An * indicates that a speaker is participating virtually