# OSMA WINTER MEETING AGENDA

# 2025


## JANUARY 21-23, 2025

## RENAISSANCE ORLANDO AT SEAWORLD
## ORLANDO, FLORIDA

**ADVOCATE • EDUCATE • FACILITATE**

# TUESDAY JANUARY 21
## WELCOME RECEPTION

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| **7:00 PM** | **Please join us for a Networking Reception on the Upper Deck in the Renaissance Orlando at SeaWorld** |

# WEDNESDAY JANUARY 22
## OSMA BUSINESS MEETING

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| **8:00 AM** | **Breakast is available in the Tarpon Room** |

The OSMA Business Meeting is for members only.
Speakers and guests are invited to join us at 12:00pm for lunch.

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| **8:30 AM** | **Reading of the Meeting Minutes and Virtual Housekeeping** |
| **8:40 AM** | **Opening Remarks and New Member Introduction**<br>Ryan Belaney, OSMA President |
| **8:50 AM** | **OSMA Board Updates and Officer Reports** |
| **9:20AM** | **Working Group Breakout Sessions** |
| **10:00AM** | **BREAK** |
| **10:30AM** | **Working Group Updates** |
| **11:00AM** | **Working Group Revitalization Update and Discussion** |
| **12:00PM** | **LUNCH (OSMA Members and Guest Speakers)** |

# WEDNESDAY JANUARY 22
## EDUCATIONAL MEETING

Join us for a comprehensive examination of the evolving medical device regulatory landscape, where we'll explore the impact of EU MDR implementation and analyze regulatory developments in key markets including the UK, Switzerland, Canada, and Australia.

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| **1:00 PM** | **Regulatory Landscape Session Introduction**<br>Bassil Akra, PhD, *AKRA Team GmbH* |
| **1:15 PM** | **UKCA Update**<br>Andrea Pietsch, PhD, *TÜV SÜD* |
| **1:45 PM** | **Impact of MDR in Switzerland**<br>Ibim Tariah, PhD, *SGS* |
| **2:15 PM** | **BREAK** |
| **2:30 PM** | **Canadian eSTAR Pilot Program**<br>Daniel Yoon, *Health Canada* (remote) |
| **3:00 PM** | **MedTech Europe Update: 2025 Strategic Priorities**<br>Merlin Rietschel, *MedTech Europe* (remote) |
| **3:30 PM** | **Orthopedic Device Registration in Australia**<br>Rebecca Gaudin, *J&J MedTech* (remote) |
| **4:00 PM** | **Australia Regulatory Landscape: Clinical Evidence Requirements**<br>Dr. Adina Hayek *(TGA)* (remote) |
| **4:30 PM** | **Q&A Session**<br>Moderator: Bassil Akra, PhD, *AKRA Team GmbH* |
| **5:00 PM** | **Closing Remarks and Wednesday Meeting Adjournment** |

# GROUP DINNER
## SEAWORLD SHARKS UNDERWATER GRILL

We invite all attendees and speakers to join us at 6:30pm for a private dinner at SeaWorld, offering an exclusive opportunity to dine among sharks.

# THURSDAY JANUARY 23
## EDUCATIONAL MEETING

**8:00 AM** — **Breakast is available in the Tarpon Room**

**8:30 AM** — **Reading of the Meeting Guidelines and Virtual Housekeeping**

**8:35 AM** — **Welcome and Opening Remarks**
Ryan Belaney, OSMA President

The Team NB Code of Conduct has received its first major update in nearly 5 years with version 5.0, released in September 2024. This new version brings important additions, including guidelines for Structured Dialogue and specific timeframes for reviewing Technical Documentation and Corrective Actions. Let's explore how these changes reflect Notified Bodies' increasing collaboration to create consistent standards under the Medical Device Regulation (MDR).

**8:45 AM** — **Code of Conduct Session Introduction**
Bassil Akra, PhD, *AKRA Team GmbH*

**9:00 AM** — **Team NB Code of Conduct: What's New**
Purvi Patel, PhD, Team NB Representative

**9:30 AM** — **Code of Conduct Panel Session with Notified Body Members**
Moderator: Bassil Akra, *AKRA Team GmbH*;
Panel Members: Marie Abdallah, *GMED*; Ehab Amen, *GMED*; Andrea Pietsch PhD, *TÜV SÜD*; Ibim Tariah, PhD, *SGS*; Balazs Bozsik, *SGS*; Purvi Patel, PhD, *Team NB*

**10:15 AM** — **BREAK**

Join us for a comprehensive overview of the EU MDR Structured Dialogue initiative, followed by an expert panel discussion exploring its impact on industry stakeholders, current implementation challenges, and strategies for effective engagement with regulatory authorities.

**10:45 AM** — **Structured Dialogue**
Balazs Bozsik, *SGS*

**11:15 AM** — **Structured Dialogue Panel Session**
Moderator: Bassil Akra, *AKRA Team GmbH*;
Panel Members: Marie Abdallah, *GMED*; Ehab Amen, *GMED*; Andrea Pietsch PhD, *TÜV SÜD*; Ibim Tariah, PhD, *SGS*; Balazs Bozsik, *SGS*; Purvi Patel, PhD, *BSI Group*

# THURSDAY JANUARY 23
## EDUCATIONAL MEETING

**12:00 PM** **LUNCH**

After lunch, join us for a unique panel discussion where representatives from multiple notified bodies will share their perspectives on orthopedic device submissions, addressing what's working well and areas for improvement. This interactive session invites members to pose questions directly to notified body experts, fostering open dialogue and providing valuable insights into optimizing the submission process.

**1:00 PM** **Expert Notified Body Panel on Orthopedic Submissions: What's Working and What is Not**
Moderator Bassil Akra, PhD, AKRA Team GmbH,
Panel Members: Chris Brodrick *GMED*; Andrea Pietsch PhD, *TÜV SÜD*; Ibim Tariah, PhD, *SGS*; Balazs Bozsik, *SGS*; Daniel Hoehn, *BSI Group*

**1:30 PM** **Renewals and Transfers**
Andrea Pietsch PhD, *TÜV SÜD;* Daniel Hoehn, *BSI Group*

**2:00 PM** **BREAK**

After intense pressure from industry and the European Parliament, and with approval of the Council, the European Commission is working on short-term and longer-term initiatives to amend the MDR. The short-term changes will focus on reduction of bureaucracy and making the notified body process run smoother, while the longer-term changes will include among other things centralization of governance and changes to certification cycle. This means that manufacturers of medical devices will be faced with additional changes before the current legacy device translational regime is over. Join us as we address the changes to be expected and how to prepare for them, from the perspective of someone deeply involved in drafting and engineering of EU MDR regulatory concepts for the coming decades.

**2:30 PM** **What Changes Can We Expect to the MDR in 2025**
Erik Vollebregt, *Axon Lawyers*

**3:30 PM** **Future Legislation Panel Discussion**
Moderator: Bassil Akra, *AKRA Team GmbH*;
Panel Members: Marie Abdallah, *GMED*; Ehab Amen, *GMED*; Andrea Pietsch PhD, *TÜV SÜD*; Ibim Tariah, PhD, *SGS*; Balazs Bozsik, *SGS*; Purvi Patel, PhD, *BSI Group*

**4:30 PM** **Closing Remarks and Day 2 Meeting Adjournment**

# OSMA WINTER MEETING 2025


DAY 1 ATTENDANCE

DAY 2 ATTENDANCE

DAY 1 SPEAKER QUESTIONS

DAY 2 SPEAKER QUESTIONS

WORKING GROUP REGISTRATION

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