OSMA BUSINESS & EDUCATION MEETING
Wednesday, October 23, 2024
Renaissance Baltimore Harborplace Hotel
Baltimore, MD

EXECUTIVE SUMMARY
Day One

OSMA marks its 70th year anniversary, and the Fall meeting provided an opportunity to celebrate this milestone and to reflect on OSMA's unique history and past accomplishments.

OSMA BUSINESS MEETING

OSMA BOARD UPDATES AND OFFICER REPORTS

OSMA's organization and structure were reviewed, including how the Committees are organized: **Advocate** (OAR Committee, Communication and Engagement Committee), **Educate** (Work Prioritization Committee) and **Facilitate** (Structure and Governance Committee). The OSMA website improvement accomplishments were highlighted and recognition given to Michael Thomas and the team. Work continues to standardize OSMA's financial policies and procedures. OSMA's bylaws were recently updated and now include a new non-voting Strategic Partner membership category. MED Institute and MCRA were welcomed as OSMA's first Strategic Partners, and a new OSMA member company (3Spine) was introduced. OSMA inducted four inaugural Fellows at the Spring meeting.

2025 OSMA meetings are planned and include the Winter meeting in Orlando, FL (January 21-23 or 28-30) focused on MDR, Canada, Australia, UK, and Switzerland; Spring meeting in the DC area (April 22-24) with topics TBD; Summer meeting to be held in conjunction with the OMTEC meeting in Chicago, IL (June 17-19) with educational topics focused on MDSAP as well as the potential for a virtual meeting in the July/August timeframe with topics TBD; and Fall meeting in the DC area (dates TBD) with an FDA-focused theme.

NEW BUSINESS

Two new business items were raised for OSMA's consideration, including Diversity/ Health Equity and Standardization of MDR Deficiencies Issued by Notified Bodies, Exploratory OSMA working groups were formed to address these topics.

WORKING GROUP BREAKOUT AND BRAINSTORMING SESSIONS

MR Labeling/ Testing

The focus has shifted to testing as labeling is less of a concern. MED Institute has been brought

in to lead the working group and offer expertise. The group will expand its scope to be more global in nature and explore taking a "envelope" approach to testing requirements.

Biocompatibility

Key takeaways were shared. Many chemical characterization deficiencies are not meeting the least burdensome threshold. The group is looking to connect with a panel of experts, perhaps holding a joint meeting of FDA and industry experts to understand FDA's perspective on the new guidance document.

Meeting Planning

Suggestions were to host virtual lunch and learn/ brown bag educational sessions and to include leadership topics on the agenda for future meetings.

Real World Evidence (RWE)

This working group will be reenergized and will be reaching out to outside experts to assist with efforts to develop a position paper and standards, while continuing to communicate with FDA.

Digital Health

It was proposed that OSMA consider starting a new working group for Digital Health. The process for initiating new working groups was discussed.

POLICY UPDATE (Angela Silvestri)

TAP (Total Product Lifecycle Advisory Program), a voluntary program intended to expedite patient access to innovative medical devices by providing early, frequent and strategic communications with FDA and other key parties, is funded by MDUFAV and will open up to OHT6 devices in January of 2025. The number of De Novos not granted continue to exceed those granted (45% granted in FY 2023), which is a concern of industry. An AdvaMed working group is looking at the main drivers for this and areas where industry can help. Digital Health is the hottest topic in the policy space, from a global perspective, and there is a need to educate regulators. FDA is collaborating with Health Canada and the UK MHRA on developing guidance. Other policy topics covered included recent data integrity issues, the status of current CDRH Q3 guidance documents and IMDRF.

ORTHOPAEDIC ALLIANCE ROUNDTABLE (OAR) UPDATE AND NEXT STEPS (Sharon Starowicz)

An overview of OAR was provided, including its background and legacy of the AAOS Orthopaedic Device Forum, OAR's stakeholder composition and mission, current status, future vision and the role that OSMA members can play to ensure OAR's future success. OAR's rebranding and role were discussed, along with its efforts to pursue CDRH Collaborative Community designation. The members and purpose of the OSMA OAR Committee were

introduced, as well as early OAR strategic priorities and feedback from OAR stakeholder interviews. There is general agreement on the value of an organization such as OAR- it is a unique opportunity to get multiple stakeholders around the table to tackle complex, cross-cutting challenges. The goal is to make the work actionable (whitepapers, exhibits, etc.) to make this useful for all stakeholders. In order to further OAR's efforts, it is important to seek new OAR participants and leadership. OAR is engaging in outreach to new stakeholders/champions to assess their interest and areas of mutual priority, including patient advocacy, clinician and specialty society groups and the standards community. Opportunities for future OAR engagement include a re-launch meeting (virtual) in Q1 2025 and a face-to-face meeting in conjunction with the OSMA Spring 2025 meeting. The goals for these meetings include appointment of an OAR Steering Committee, development of the OAR structure and governance process, and identification of work items, subject matter experts and resources. The update concluded with a discussion of the role of OSMA members and how they can contribute to OAR's success.

SURVEY RESULTS AND MEETING UPDATES (Ryan Belaney)

The OSMA performance survey, intended to capture insights from FDA and Notified Body review, working groups and performance metrics and satisfaction, was introduced. Survey respondents indicated a diversity of company size. The survey also captured the relative size of the regulatory teams, the types of submissions (highest number in spine and digital health), and types of deficiencies (most frequently cited were biocompatibility, MRI, additive manufacturing and cybersecurity). FDA deficiency trends noted new/change in reviewer and AIs for 510(k) summaries. On a positive note, the survey respondents were pleased with the level of interactive FDA communications, eSTAR and timely responses. The survey also captured experience with Notified Body performance, including overall satisfaction, positive trends and areas for improvement, highlighting the speed of review, cost effectiveness, transparency and communication, as well as degree of administrative burden. On a different note, the survey also solicited feedback on the OSMA working groups, quarterly meetings and degree to which OSMA is meeting the member company needs.

Ryan also provided insight into the CEO Roundtable, which began as informal discussions with FDA and a way for FDA to communicate trends and concerns. Ryan is leading the CEO Roundtable this year and all OSMA company CEOs are invited to participate. In the future, the intent is to afford the opportunity to participate to all orthopaedic company CEOs.

VOTING FOR OPEN BOARD POSITIONS (OSMA Voting Members)

Brianna Prindle (restor3d), Suchitra (Suchi) Basu (J&J MedTech) and David Rogers (Arthrex) were presented for ballot to fill three open untitled OSMA Board positions. Each candidate enthusiastically and thoughtfully presented their unique background and reasons why they are interested in joining the OSMA Board and all were voted in to fill these positions by the OSMA voting members. OSMA congratulates Brianna, Suchi and David and looks forward to their future contributions in serving on the Board.

UPDATE FROM CAPITOL HILL (Clayton Hall, *Medical Device Manufacturers Association, MDMA)*

Clayton opened with a Congressional update and House/Senate balance of power. Historically, this has been an unproductive Congress, marked by a decline in the number of bills placed. Key legislation includes the Biosecure Act, a bipartisan issue relating to concerns with Chinese biotech companies harvesting data on US patients, that would prohibit the US government from doing direct business in China. Also key is Medicare coverage for breakthrough devices (HR 1691) that would provide four years of automatic Medicare coverage for FDA-approved breakthrough devices, viewed critical to pass by the end of the year. Tax policy will be a driver next year. For FDA, a priority area is the quality of the deficiency letters. MDUFA V is a massive industry investment totaling $2B, with agreement to fund with leftover MDUFA IV carryover funds. Other areas of importance include AI/ML and emerging chemicals, prompted by new regulation for EtO and closure of sterilizer plants.

B1+RMS: WHAT IS IT AND HOW DOES IT IMPACT MRI SAFETY LABELING?
(Grant Baker, *MED Institute*)

Grant provided technical background on RF-induced heating, focusing on B1 (RF magnetic field) and RMS (root mean square). B1+RMS refers to the amplitude of the RF field. The Specific Absorption Rate (SAR)- a measure of power absorbed from the RF field- can contribute to temperature increases. There are different types of SAR, and SAR has been the precedent for MR conditional labeling for decades. The benefits, considerations and limitations of B1+RMS labeling were covered, as well as the physics of RF-induced heating. A simulation calculation of SAR and B1+SAR can result in an over exaggeration of heating that may not be clinically relevant. The presence of a metallic implant near the isocenter may skew the scanner-reported B1+RMS value; solution- publish on the topic to have more universal understanding for researchers, industry and regulators.

TRENDING TOPICS IN ORTHOPAEDICS
(Jemin Jay Dedania, Randy Prebula and Kelliann Payne, *Hogan Lovells*)

An overview of trending hot topics in orthopaedics was presented. This included digital trends, such as AI/ML-enabled devices, pre-determined change control plans (PCCPs), virtual and augmented reality devices, as well as relevant guidance documents and whitepapers. Other hot topics include biocompatibility (always consider a risk-based approach), additive manufacturing, and quality system changes (21 CFR 820 incorporation with ISO 13485 elements). FDA enforcement trends show a decrease in the number of FDA inspections post-COVID, although FDA is ramping back up. FDA is focusing on the proper use of AI/ML software and device modifications and labeling claims, with continued focus on recalls/communications at the patient level. Other noteworthy areas include registry data analysis and MDR review, and an increase in safety communications.

AAOS UPDATE FROM THE COMMITTEE OF DEVICES, BIOLOGICS. AND TECHNOLOGY (Daniel Saris, MD, *AAOS*)

Dr. Saris discussed AAOS' 2024-2028 strategic plan, with key enablers including advocacy, communication, partnerships and technology. He reviewed the AAOS Annual Meeting programming, including the AAOS Town Hall Meeting, focusing on the use of AI in orthopaedic surgery; *From Garage to Market*: *A Stepwise Approach to Creating an Orthopaedic Device*; AAOS/BA symposium on Orthobiologics in 2025 and Beyond; and OrthoPitch- an annual competition for novel orthopaedic products. Other AAOS efforts include a Biologics dashboard and a Devices Recall dashboard, searchable databases that facilitate quicker access to regulatory information, empowering clinicians with efficient decision-making support. Several technology overviews have been published in the Journal of AAOS (JAAOS), as well as publication of OrthoInfo patient-centered resources.

FDA QUALITY MANAGEMENT SYSTEM REGULATION: HOW SHOULD YOU PREPARE? (Timothy Gooch, *SGS*)

FDA published the final QMS Rule on February 2, 2024, with enforcement of the Final Rule occurring on February 2, 2026. The QMSR will be incorporated by reference in whole to ISO 13485 and harmonized with global regulators, with increased emphasis on risk management. Failure to comply with the QMSR will make your product adulterated and subject to enforcement action, with FDA having broadened authority. Specific areas of focus include CAPA vs. CA and PA, complaints and "secret records" (internal audit, supplier audit, management review) will now be subject to disclosure to FDA. MDSAP audits are designed to meet ISO 13485:2016 plus additional country-specific requirements (Australia, Brazil, Canada, Japan, USA). Audits are designed to meet ISO 13485 and the FDA QMSR requirements. Once engaged with MDSAP, a manufacturer is removed from the FDA inspection schedule. Advice to manufacturers is to focus on the BIG differences- i.e., take a risk-based approach, incorporate feedback from monitoring, measurement and analysis in the risk management system, and conduct robust quality planning.

UNDERSTANDING REQUIREMENTS FOR IN SILICO CLINICAL TRIALS (Marc Horner, Ph.D., *ANSYS*)

Traditional uses for computer modeling and simulation in orthopaedics include optimizing bench testing, MRI safety, AI, image-based modeling and materials intelligence. Traditional clinical trials are tightly controlled and have outcomes that may differ in real world use, often lacking use in underserved populations. The cost of these trials can stifle and large trials may expose patients to unproven technologies. Simulated trials can be beneficial in addressing these barriers. International support for CM&S is growing. The ASME V&V standard provides a risk-based framework for establishing the credibility of CM&S, along with the US FDA Credibility Guidance (2023)- *Assessing the Credibility of CM&S in Medical Devices.* In order to expand future recognition and adoption of CM&S, globally recognized standards and frameworks will be required for the healthcare industry.