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

DAY ONE- OSMA BUSINESS & EDUCATION MEETING

MEETING OPENING, GUIDELINES AND INTRODUCTIONS
Lindsay Stafford

Lindsay opened the meeting and read the meeting guidelines, followed by words of welcome and introductions. Ehab Esmail, *OSMA President*, noted that OSMA was celebrating its 70th year anniversary and shared a few historical milestones. He also thanked the Meeting Planning Committee for organizing an excellent educational program.

OSMA BOARD UPDATES AND OFFICER REPORTS

PRESIDENT'S REPORT (Ehab Esmail)

Ehab highlighted the OSMA website improvement accomplishments and recognized Michael Thomas and the team. He reviewed the OSMA organization and structure, and described how the Committees are organized: **Advocate** (OAR Committee, Communication and Engagement Committee), **Educate** (Work Prioritization Committee) and **Facilitate** (Structure and Governance Committee). He referred to the recent update of the OSMA bylaws and encouraged everyone to get involved.

VICE PRESIDENT'S REPORT (Ryan Belaney)

Ryan discussed OSMA's partnership and charter with ORTHOWORLD. He also introduced a new OSMA member (3Spine) and prospective new member (Hyalex). He noted that OSMA had inducted four inaugural Fellows at the Spring meeting, and outlined OSMA's new non-voting Strategic Partner membership category, including qualifications, responsibilities and restrictions. MED Institute and MCRA were welcomed as OSMA's first Strategic Partners.

SECRETARY'S REPORT (Lisa Boyle)

Lisa reviewed the 2025 meeting schedule: Winter (Orlando, FL- January 21-23 or 28-30, 2025; Topics-MDR, Canada, Australia, UK, Switzerland); Spring (DC area- April 22-24, 2025; Topics-TBD); Summer (Chicago, IL- June 17-19, 2025; OMTEC Meeting; Topic- MDSAP and potential for July/August virtual meeting (solicited ideas from group on topics of interest); Fall (DC area- Dates TBD; Topics- FDA and OHT6 Updates).

TREASURER'S REPORT (Angela Silvestri)

Angela highlighted a few noteworthy items, including the transition from Regions Bank to Bank of America and the work to standardize OSMA's financial policies and procedures. She explained that the increased meeting registration fees are a direct result of increasing hotel costs.

NEW BUSINESS ITEMS (Michael Owens)

Michael raised two new business items for OSMA's consideration. He proposed an industry effort to address FDA's Diversity Action Plan guidance document, including the development of background information on health equity in orthopaedics, such as a guideline or position paper, that could be used by reference to support individual company approaches. The second item raised was a proposal that the Notified Bodies adopt a guidance on issuing non-conformities to improve the clarity and understanding of MDR deficiencies. The names of those interested in forming working groups to explore these items were solicited.

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.

Diversity/ Health Equity

The group will open a thread on the OSMA web page, leveraging publications and sharing resources, including a list of potential clinical investigators who have access to diverse patient populations. Next steps include reaching out to external consultants.

Standardization of MDR Deficiencies

The plan is to survey OSMA members to get some structure and understanding of the issue. It will be important to articulate the selling point/ benefit to the Notified Bodies and identify who

needs to be engaged.

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 MDUFA V 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. Recent data integrity issues were discussed. FDA sent out a communication in February 2024 voicing concern over fraudulent test data (200 submissions confirmed, additional submissions on hold). FDA is employing enforcement tools, including withdrawing test lab accreditation, issuing warning letters and cautioning industry to avoid the use of test labs outside the United States. Angela reviewed the CDRH Q3 guidance documents, including their review status and which guidances are open for comment (e.g., Predetermined Change Control Plans (PCCPs) and Chemical Analysis for Biocompatibility Assessment). She noted several upcoming meetings, including the Patient Engagement Advisory Committee on October 30, 2024 (with focus on patient informed consent) and a meeting on AI to be held November 20-21, 2024. IMDRF was also discussed. The US is the chair and secretariat this year- next year this will move to Japan. The focus of the meeting in September was on maximizing the reliance on resources and leveraging requirements/ frameworks from multiple jurisdictions, as well as training and inclusion through membership expansion.

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

Sharon provided an overview of OAR, 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 is truly a unique opportunity for OSMA to not only remain connected with other critical stakeholders in a collaborative space, but also to tackle issues that might otherwise be challenging for industry to do on its own. 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. There is a need within the orthopaedic community at large for a cross-functional group sharing perspectives and coalescing on issues that will benefit the ecosystem. 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. One of these champions is Rita Roy, MD (*CEO, National Spine Health Foundation and Member of FDA Patient Engagement Advisory Committee*), who is a patient advocate and was introduced as an OSMA guest. 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)

Ryan reviewed the goals of the OSMA performance survey, intended to capture insights from FDA and Notified Body review, working groups and performance metrics and satisfaction. Sales demographics of survey respondents indicated a diversity of company size- large, small and in-between. 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. The Fall CEO Roundtable meeting was focused on MRI; however, company subject matter experts were not able to be present to enable in-depth discussions. Future topics include angel vs. investor funding, uncertainty in the FDA review process, encouraging use of the TAP program for early-stage products, OSMA performance survey results and the continuity of medical reviewers.

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. The path to 270 electoral votes remains key for the 2024 elections. The 2024 Senate map favors the GOP while the 2024 House is too close to call. 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- unleashing the full promise of AI tools while still protecting the public from risk. FDA approved the first AL/ML device in 1995. Since then, there have been nearly 1,000 devices cleared for market access (over 151 in last eight months that are SaMD and PCCP enabled). Additional focus is on 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. For AI as a medical device, FDA expects that the algorithm is frozen (locked) and that all testing has been performed with the locked algorithm. Clinical data are used to support most marketing submissions. The majority of AI devices are in radiology but they have also expanded to other fields, such as surgical navigation devices in orthopaedics. PCCP is a negotiation process with FDA and companies should only include a few specific modifications that can be verified and validated. From a compliance perspective, FDA has been looking at PCCPs. Other hot topics include biocompatibility (always consider a risk-based approach), with FDA publishing guidance for labs, combination products, including those with growth factors and antimicrobials, and resorbable metal technologies, where Mg and its alloys are considered next generation biodegradable biomaterial for orthopaedic applications. Additive manufacturing remains front and center in orthopaedic submissions and companies should follow FDA guidance and keep the manufacturing section consistent with eSTAR. Surface modifications should consider impact on biocompatibility, adhesion and durability of coatings. Quality system changes include 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 (undocumented significant modifications, defective packaging, risk of device failure). FDA is looking at PMA purchasing/ supplier controls during QSIT inspections.

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 QS regulation was last updated in 1996. 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 innovation (estimates of $ 1 M- feasibility study and $ 30 M- pivotal study), and large trials may expose patients to unproven technologies. Simulated trials can be beneficial in addressing these barriers. A case study was presented- *Reducing Clinical Trial Size Through Virtual Patients*. International support for CM&S is also 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.