OSMA BUSINESS & EDUCATION MEETING
Wednesday, January 22, 2025
Renaissance Orlando at Sea World
Orlando, FL

EXECUTIVE SUMMARY
Day One

READING OF MEETING MINUTES AND VIRTUAL HOUSEKEEPING

Lisa Boyle, OSMA Secretary, opened the meeting and welcomed all attendees. The meeting logistics were reviewed and the meeting guidelines read.

OPENING REMARKS AND NEW MEMBER INTRODUCTION

Ryan Belaney, OSMA President, welcomed everyone and introduced an ice breaker activity to get things started. Members introduced themselves and the following organizations were welcomed as new Strategic Partners- AKRA Team GmbH (regulatory consulting), Veeva MedTech (product lifecycle management), Element Materials Technology (testing firm) and MRC Global (regulatory consulting).

OSMA's Mission - to facilitate the timely availability of orthopedic technologies - is accomplished through three foundational pillars: *Advocate, Educate, Facilitate*. Quarterly educational meetings, established working groups, guidance documents and website enhancement contribute to OSMA's mission and focus.

Highlights from the OSMA Board of Directors meeting agenda were shared, including the Treasurer's report, 2025 calendar of meetings (Spring- Digital Health), Summer (virtual meeting), Fall (OHT6 at FDA offices), Working Group processes, Communications (LinkedIN, emails and web resources) and the establishment of two voting member meetings/year (virtual).

OSMA BOARD UPDATES AND OFFICER REPORTS

Treasurer's Report- *Angela Silvestri*

OSMA's total 2024 revenue was $264,000, offset by $280,000 total expenses. Meeting expenses continue to be the biggest expenditure. Other expenses include office expenses, consultant expenses, and professional fees (e.g., legal- bylaws update). There remains a continued focus on process improvements and noteworthy 2024 accomplishments include establishing a national bank (Bank of America), online QuickBooks account, office expenses on autopay, and an OSMA credit card. 2025 will focus on fine tuning processes.

Secretary's Report- Lisa Boyle, *Secretary*

The planned calendar for upcoming 2025 meetings was shared, along with areas of educational focus:

Spring (April 22-24, 2025)- Annapolis Waterfront Hotel, Digital AI/FDA- Suchi Basu is taking the lead on meeting planning, with topics covering the **orthopedic digital revolution** (enabling technologies, imaging technologies, miniature robotics, personalized medical devices and 3D, EU AI Act, lessons from pharma submissions utilizing AI tools that could be leveraged in orthopedic submissions, AI in digital health (regulatory, business and legal considerations), lessons from imaging /radiological companies on utilizing AI/ML in their devices, cybersecurity, global perspective (FDA, EMEA, other HAs, IMDRF, possibly a panel session), and lifecycle management.

Summer (June/July- Dates TBD)- virtual meeting, possibly spanning across two weeks for a few hours each day - MDSAP and ASPAC/Japan, IMDRF, regulatory focus from key markets: Australia, US, Brazil, South Korea, etc.

Fall (October 21-23, 2025)- Bethesda North Marriott- to be held at FDA campus (Thursday)- agenda TBD.

WORKING GROUP BREAKOUT SESSIONS
Working Group Updates

Ryan Belaney presented an overview of the OSMA working group survey results. MR testing/labeling reflected the highest level of interest among respondents. Feedback included the suggestions to widen RWE to include clinical evidence needed for non-conformities, global regulatory requirements (Japan, Brazil, UK, etc.), health technology reimbursement, and diversity action plan (currently tabled). Future working group resources and tools will address hosting a kick-off meeting, establishing a cadence of meetings, engaging new/interested members, and engaging a broader sphere of SMEs within the companies.

MR Testing/Labeling- *Grant Baker (MED Institute)*

The working group is focusing on MR safety evaluations- gaps/inconsistencies between requirements listed in standards/guidance/regulatory expectations- leading to deficiencies, delays and added costs. A position/ best practices paper could help to bridge the gap. Topics for the paper are being discussed, starting with generating a common list of deficiency types, along with specific product examples. The voice of the surgeon will be important to consider, as well as the voice of regulators (US and global), to add to the strength/acceptance of publication. Worst case scenarios vs physiologic relevance should also be addressed. The working group will need to decide how prescriptive the position paper should be (general vs specific). There are opportunities to comment on FDA MR guidance and to possibly leverage efforts related to the ASTM 2182 revision. Other opportunities include hosting an MR workshop comprised of regulators, SMEs and test labs, and publishing proceedings from the workshop, as well as including MR-focused educational sessions during OSMA quarterly meetings.

Proposed New Working Groups

Digital Health/AI/ML (led by Suchi Basu)- The Spring meeting will help to set goals for the working group.

Standardizing Notified Body Responses (led by Michael Owens)- The model in EU (where there is more independence) is different from FDA ("4 part harmony"), creating stream of consciousness deficiencies that are often nice-to-knows but not real non-conformities, as well as inconsistent communication of deficiencies/non-conformities. There is potential to survey the OSMA members to solicit feedback and collect specific examples. It will also be important to seek the best avenue to pursue further efforts- possibly through Team NB?

Standards and Guidance (TBD)- OSMA used to have routine standards updates but no longer- how can we bring this back? OSMA also used to have a working group that commented on guidance documents. Jamie MacDougall will monitor and flag relevant guidance documents for awareness and potential OSMA commenting efforts.

WORKING GROUP REVITALIZATION UPDATE AND DISCUSSION (*David Rogers*)- In order to foster advocacy and establish a track record of OSMA accomplishments, working groups will be provided tools/templates to define roles and responsibilities (leader, member, etc.), set expectations on cadence of meetings, establish milestones, communicate clear goals and objectives, and to make the working groups' goals and progress accessible to all OSMA members.

WEBSITE RESOURCES (*Michael Thomas*)- New member companies/individuals and strategic partners (individuals and principals) have been included on the OSMA website. Michael provided a demo on navigating the website and where to find specific information- Executive Summaries, Member Contact Information, Events (meetings- current and previous), etc. Future enhancements include a searchable database of all presentations, based on topic, a working group discussion page, and enhanced public-facing content. The number of posts/activity on LinkedIn continue to be tracked.

NEW BUSINESS, NEW MEMBERS, NEW STRATEGIC PARTNERS (*Ryan Belaney*) There is a continued call to solicit new strategic partners, and OSMA members are encouraged to reach out with suggestions. Ryan also noted that custom/ compassionate use devices remain a global issue and may be a potential area for OSMA working group exploration.

REGULATORY LANDSCAPE SESSION INTRODUCTION
Bassil Akra, PhD*, AKRA Team GmbH*

Dr. Akra provided a high-level overview and noted that there is interest in leaner processes and digital solutions. It is important for regulators to balance their mandate to protect the public while still supporting innovation. The MDR is continuously being updated as a result of rushing through a regulation and not thinking through implications before implementation. Industry must contribute early on. While there is potential future legislation in the EU, it is unlikely that

the current MDR regulation will go away. Since its implementation, there have been 27,000 applications, with less than 7,000 certificates issued since 2019. There are 50 MDR Notified Bodies (NBs) in comparison to 86 under AIMDD and MDD. Collaboration is important!! The NBs need to learn from industry and vice versa.

UKCA UPDATE
Andrea Pietsch, PhD, TÜV SÜD

The UK MDR 2002 (current regulation) is based on three directives (MDD, AIMDD, IVDD) amended by the EU exit legislation (Schedule 2A). The 2023 regulations reflect legislation defining CE transition periods. The EU NBs become UK-approved NBs. The manufacturer can no longer self-certify Class I devices. Provisions are made for custom made devices. Amendment 2024- PMS requirements for Great Britain (GB)- is applicable to medical devices placed on GB market via CE marking (MDR and Directives) and UK MDR 2002 (UKCA). Different PSURs are required by countries in different formats. This becomes very labor intensive for industry, and the UK is specifically looking for UK-specific data on patients/ #s of devices sold, AEs, etc. The UK Medical Devices Regulatory Reform addresses the following: pre-market (increase some medical device classifications, introduce UDI requirements, implant cards and requirements around claims made in public, etc.), international recognition of requirements, AI, innovative devices access pathway (IDAP)- a special pathway to promote the introduction of innovative devices in the UK first (currently in pilot phase with 8 technologies), MHRA Consultation, international reliance, UKCA marking, and IVD devices. **There are three different conformity routes: 1-UKCA only application, 2- initial combined application (UKMDR + EU MDR), 3- initial application with existing CE (UKMDR plus EU MDR or UKMDR plus EU MDD/AIMDD).**

IMPACT OF MDR IN SWITZERLAND
Ibim Tariah, PhD, SGS

The Swiss Medtech industry (approximately 1400 medtech companies) is robust and important for the Swiss economy. Its GDP is greater than the US and UK. According to a Swiss Medtech industry survey- 75% of Swiss companies are calling for opening of the market to non- CE marked devices. You cannot introduce products in Switzerland first- must go through US or EU (impact to innovative products!). The MDR implementation is leading to supply shortages for both existing and new products. Swiss manufacturers like FDA approval pathways- fast, regulated and monitored procedures. ***Swiss parliament motion 20.311 requires that medical devices with FDA certification can also be placed on the Swiss market- Swiss national law must be changed to permit this.*** There is no mutual recognition agreement (MRA) agreement between EU and Switzerland- considered a different country. Manufacturers outside EU must appoint a Swiss Authorized Representative and have their QS certified to Swiss requirements- with Swiss-specific labeling, Swiss vigilance reporting, Swiss fees and taxes and database for registration of economic operators.

<u>Summary</u>: In absence of an EU mutual recognition agreement (MRA), Switzerland has implemented its own MDR. Manufacturers entering Switzerland with CE marked devices need to register with Swissmedic and report incidents. Manufacturers coming to Switzerland

for the first time must undergo a conformity assessment process and comply with Swiss regulations. Parliament instructed the Federal Council to allow FDA-certified devices in Switzerland. Swiss national law must now be changed accordingly.

CANADIAN ESTAR PILOT PROGRAM
Daniel Yoon, Health Canada (remote)

The eSTAR program was originally developed by FDA. It adds a user-friendly façade to the Table of Contents (ToC) structure and is intended to be a dynamic pdf. In 2023, Health Canada (HC) and the FDA announced a joint pilot to test the use of eSTAR to submit premarket applications to both HC and FDA. HC gathered feedback from pilot participants (15), as well as HC reviewers and screeners, and has added the façade to the ToC structure. Users found eSTAR to be user friendly and intuitive, but would like to see clearer alignment between IMDRF/ToC section numbers in the template. The next phase will be to integrate feedback into eSTAR templates/processes and incorporate ToC updates from recent IMDRF N9 and N13 updates, as well as evaluate areas for expansion (e.g., IVDD submissions). IMDRF is working on developing a dynamic template to streamline and harmonize medical device submissions across multiple jurisdictions. HC and FDA are assessing the results of the initial eSTAR pilot with plans to conduct additional pilots in the future.

MEDTECH EUROPE UPDATE: 2025 STRATEGIC PRIORITIES
Merlin Rietschel, MedTech Europe (remote)

MedTech Europe is an EU trade association that includes medical devices, diagnostics and digital health technologies, and is comprised of 50 medical device manufacturers and 145+ multinational corporations. A survey on EU QMS certification under MDR found little difference between small and large companies regarding timelines- 19.5 mos. to achieve EU QMS certification, on average: Prereview (28%), Review (49%), Issuance (23%). ***There was a significant disparity in timelines reported by industry and NBs. Cost under the MDR has increased about 100% for certification and for technical documentation assessment.*** For QMS certification: Approximately 137,000 Euros NB certification fees; 491,000 Euros manufacturer's FTE costs; For Technical Documentation Assessment: 176,000 Euros NB costs; 3.4 million Euros manufacturer's FTE costs and Yearly Maintenance Costs for all classes of devices subject to NB certification: 100,000 Euros. Before MDR, manufacturers preferred an EU launch first, now other markets (e.g., US) are seen as preferable. The EU Commission for Targeted Evaluation of IVDR/MDR (Q3 2024- Q4 2025)- could lead to EU Commission legislative proposal in 2026 (seen as too late)- need this reform today! Propose Three Phases- 1- Short-term fixes within current IVDR/MDR through guidance and other tools, 2-targeted "bridging" measures with legal weight (add predictability to timelines and costs, provide an accelerated pathway for breakthrough devices, adapt certification to follow a lifecycle approach (renewals)), 3- (Systemic) Legislative reform of IVDR/MDR (comprehensive). There is strong consensus that the EU Commission needs to deliver reforms. The EU Commission recognizes the challenges and will step up its work, both short term and after targeted evaluation; however, there is a lack of consensus on the timeline for reform and what changes are necessary. There are other interested parties besides the EU Commission- EU Parliament, EU 27 member states,

HCPs and patient advocacy groups. Suggested actions include continuing to engage with Competent Authorities, reaching out to encourage all stakeholders to engage (especially patients and doctors) and contributing to EU and national level initiatives to gather evidence.

ORTHOPEDIC DEVICE REGISTRATION IN AUSTRALIA
Rebecca Gaudin, J&J MedTech (remote)

The regulatory framework in Australia is generally aligned with the EU MDR requirements. Key components include- Legal Manufacturer, GMDN, Classification, and Sponsor (legal entity). The medical device must be included on the Australian Register of Therapeutic Goods (ARTG). The classification of devices (implants) list all components separately on the ARTG (not as systems). Certifications from HC, Japan, US and EU can be leveraged in Australia (abridged requirements for ARTG); however, the device must still meet TGA Essential Principles and Clinical Evidence is required per TGA guidance. TGA may also conduct an application audit.

AUSTRALIA REGULATORY LANDSCAPE: CLINICAL EVIDENCE REQUIREMENTS
Dr. Adina Hayek, TGA (remote)

The focus of clinical evidence is on Class III implants. There is a new risk-based application audit framework and guidance- *Case Management and Selection for Non-Mandatory Audit* (comment period open until Feb 17, 2025). This proposed guidance describes the criteria the TGA uses to select applications to audit. The agency will select applications if it has "ongoing concerns about the device that may have been raised during preliminary assessment." Clinical evidence requirements are outlined in Essential Principle 14. Clinical evidence = Clinical data + clinical evaluation. Substantial equivalence considerations specify that comparative devices are most similar to the device under evaluation to such an extent that there would be no clinically significant difference in safety or performance. Claims of equivalence should include detailed (tabulated) comparison between clinical, technical and biological characteristics, and all differences should be addressed as to their impact to safety and performance by a clinical expert. **Clinical characteristics to consider for orthopedic implants** include intended purpose, indications for use, intended patient population, anatomic location, intended user, user environment and expected implant lifetime. **Technical characteristics** include, for example, design and geometry, method of fixation, dimensions, materials and surgical implantation technique. **Biological characteristics** include biocompatibility, degradation profile and biological response. Clinical data may include manufacturer-conducted clinical investigations, literature review, post-market experience and real world evidence. **Key Points**: ***Clinical Evidence*** is a key part of demonstrating compliance with many of the Essential Principles, Acceptable ***Substantial Equivalence*** claims does not itself provide clinical evidence, but allows use of indirect clinical evidence, ***Benefit-Risk*** balance should consider the current standard of care, and ***Patient Information Leaflets*** should assist patients in understanding the medical device and not be promotional.

Follow-On Questions:

For biological equivalence- EU vs. Australia- Can different materials be compared for equivalence? EU- No. Must be the same material.
Substantial equivalence- Is expectation to do a detailed side-by-side comparison to equivalent device? Yes.
Collection of clinical data- Would preference/weighting be toward Australian registry data? The limitations of other registries would need to be considered.
How is long term evidence defined? Minimum of 2 years.
Are there efforts to harmonize labeling requirements with other jurisdictions? Australia participates in and supports IMDRF.

Q&A SESSION
Moderator: Bassil Akra, PhD, AKRA Team GmbH

Value Proposition

There are business considerations in introducing products in the EU and/or continuing to sell products in EU. Need a cost benefit analysis- both initial costs and lifetime maintenance considerations. Postmarket clinical evidence generation should be closely considered if you want to reintroduce device to EU down the road (e.g., may be challenging to reestablish MD relationships later on for data collection purposes). If other manufacturers withdraw from the EU market, could increase market share for those remaining.

Other considerations- CE mark is passport to other jurisdictions.

Need to find a balance between regulatory requirements and what is beneficial to patients.