The Orthopedic Surgical Manufacturers Association is a nonprofit organization whose membership consists solely of manufacturers of orthopedic surgical appliances, implants, instruments or equipment and orthobiologics. Since its inception in 1954, OSMA has continued to actively participate in standards and regulatory guideline development, educate our membership on regulatory matters and provide regulatory professionals a forum to collaborate, communicate, cooperate and interact with worldwide regulatory agencies and health care professionals on issues to improve the application of device law and promote collaborative interaction for appropriate regulation.
To Our Members

2018 Highlights

Over the past year, OSMA continued to make significant contributions to the orthopedic industry through its partnership with FDA and international regulatory bodies thanks to our dedicated membership. As 2018 has now come to a close, we reflect on the following highlights from the past year.

Board of Directors

In 2018, the OSMA Nominating Committee, Stacey Bonnell (J&J/DePuy Synthes), Kathy Reddig (ConMed) and Alicia Hemphill (OsteoMed), worked to develop a slate of candidates to serve on the OSMA Board of Directors for the 2019-2022 term. The slate was approved by the existing Board and put forth to the Membership for a vote at the 2018 OSMA Fall Business Meeting. As of January 1st, 2019, the following Board members began their 4-year term:

President: Ehab Esmail (DJO Global)
Vice President: Stacey Bonnell (Johnson & Johnson/DePuy Synthes)
Secretary: Lisa Boyle (Aesculap)
Treasurer: Lori Burns* (Globus Medical)
Past President and Industry Representative, FDA Orthopedic Advisory Panel: Sharon Starowicz (Johnson & Johnson/DePuy Synthes)
Board Members: Rod Parker (Stryker), Bradley Heil* (Smith & Nephew), Natalie Heck* (Zimmer Biomet)

(*) Denotes new members to the Board.

OSMA would like to acknowledge the efforts of the Board Members that served the organization from 2015-2018. Their efforts have continued to shape the legacy of OSMA and on behalf of the membership, we thank them for their time and dedication in serving OSMA and the industry. A special thanks to Susan Krasny (Stryker), Ed Chin (Medtronic), Carolyn Shelton (Medtronic) and Kathy Reddig (ConMed).

OSMA Strategic Priorities

Based on feedback obtained from OSMA members via the 2017 OSMA Strategic Priorities Survey, the Board of Directors worked to develop strategic goals that align with the mission and purpose of the organization, with a heightened focus on the global regulatory environment and the challenges facing
our industry. Each Strategic Priority has a dedicated Workstream, comprised of a Board Sponsor and members from participating companies. The following Strategic Priorities were identified for 2018 and beyond:

- Reconstitute Board for New 4 Year Term
- Enhance Communications
- Increase Task Force Visibility and Effectiveness
- Increase OSMA Visibility and Expand Networks
- Increase International Focus
- Assess Future of Orthopedics

The OSMA Strategic Priorities were presented to the membership at the 2018 Spring Business Meeting and are accessible via the OSMA website. The progress of these efforts will be shared with the membership at future quarterly meetings.

AAOS Orthopaedic Device Forum
The AAOS Orthopaedic Device Forum was formed in the 1990s with the intent of bringing together representatives from AAOS, FDA, ASTM, CMS, ORS, NIH and industry (OSMA) to discuss topics of mutual importance and to resolve regulatory matters of significance to orthopedics. OSMA has most recently held the following seats on the Forum: Past President (Susan Krasny, Stryker), President (Sharon Starowicz, J&J), Vice President (Ehab Esmail, Zimmer Biomet), Biologics Rep (Bob Spiro, Aesculap) and Biomaterials Rep (David Schroeder, Zimmer Biomet).

In 2018, it was announced that the AAOS Orthopaedic Device Forum would be discontinued. As the Forum has played a such pivotal role in engaging key stakeholder groups on topics of mutual importance, OSMA is investigating alternative engagement methods to continue the great foundation that was established through the efforts of the Forum.

New Website and Logo
OSMA unveiled a new logo and website in 2018. This effort was identified as an OSMA Strategic Priority to assist with membership solicitation efforts and improve the overall use and functionality of the website. Partnering with an independent website developer and graphic designer, OSMA was able to provide the membership with a new logo and website. The logo has already been utilized in a variety of venues (used in hotel banners at quarterly meetings), for new member solicitation efforts and incorporated into post cards distributed to meeting attendees at the 2018 ISO TC 150 meeting,
highlighting OSMA’s sponsorship of the meeting. A special thanks goes to Valerie Franck, OSMA Administrator, for her tireless work in leading these efforts and ensuring that the refreshed website and logo meets OSMA’s current and future needs.

Task Force Updates

Orthopedic Instrument Accessories
In 2018, OSMA took a proactive approach in working with FDA with the goal of appropriately classifying orthopedic instrument accessories based on their risk and intended use. This has involved ongoing communications with FDA to discuss reclassification efforts for orthopedic surgical instruments that have historically been considered by FDA to be class II or class III based solely on their use with higher classification implant systems. Per FDA’s Guidance Document, Medical Device Accessories – Describing Accessories and Classification Pathways (December 20th, 2017), FDA describes the process by which accessories may be classified separately from the systems they are intended to be used with, based on risk. Task Force members worked together to prepare a consolidated list of instrument accessories for FDA, reflecting their current classifications, and prepared comments in response to an August Federal Register notice, requesting reclassification of previously classified accessories, as mandated by the FDA Reauthorization Act (FDARA). The task force has engaged with FDA through multiple conference calls and face to face discussions at both the Spring and Fall quarterly meetings and will continue to work with FDA to ensure orthopedic instrument accessories are appropriately classified.

EU MDR (Spinal Devices) Task Force Supports MedTech Europe
OSMA’s EU MDR (Spinal Devices) Task Force drafted a proposal that outlines OSMA’s interpretation of the new proposed classification rule. The proposal maintains the rationale for Class IIb on the well-established technology platform which is supported via reference to its long history of clinical use and the substantial body of evidence available from published literature. The proposal was submitted to MedTech Europe for further discussions and is intended to support mutual alignment amongst Notified Bodies and industry.
OSMA’s FDA Performance Survey
The membership had the opportunity to participate in the annual survey to capture metrics on FDA submission reviews including:

- Type of submission
- Device type
- Number of submissions resulting in a request for further information
- Number of rounds of questions from FDA
- The type of information requested by FDA
- Overall elapsed review time and whether the submission received clearance or approval

These data have been a unique and invaluable source of information that has allowed OSMA to capture overall submission review trends that are specific to the orthopedic industry and have been helpful in assessing progress against FDA performance goals. The results of the survey were shared with FDA at OSMA’s Fall educational program.

Benefits of Membership
OSMA continues to provide its members with an educational forum that allows a unique opportunity for face to face contact with global regulators (such as ANVISA, PMDA and Health Canada), Notified Body representatives (both large and small) and FDA representatives (from CDRH’s Office of Device Evaluation, Office of Compliance and Office of Science and Engineering Laboratories, as well as CBER) through information sharing, round table discussions and networking opportunities. OSMA values its long-standing relationship with regulators around the world and attributes the success of the organization to the continued engagement our membership maintains with regulators through conference calls, interactive discussions and collaborative efforts.

Thank You
OSMA continues to provide significant support to your company’s regulatory activities and to be an effective interface with global regulatory agencies, largely due to the active participation of your employees on task forces and at meetings. OSMA’s work is performed by volunteers from its member companies and its effectiveness depends on your continued support. If you wish to directly contribute your thoughts on ways OSMA can become an even more effective advocate for our industry, please do not hesitate to contact me at sstarow1@its.jnj.com, or (508) 828-2867.
On behalf of the Officers, Board of Directors and representatives of OSMA, we extend our thanks for your support of this organization in 2018 and look forward to your continued support in the future.

Respectfully submitted,

Sharon Starowicz
OSMA President
OSMA Quarterly Meetings

OSMA hosts a quarterly member meeting with the Spring and Fall meetings positioned in the Washington, D.C. area to accommodate FDA staff participation. All quarterly meetings are two-day events, with one full day dedicated to education and the second to serve as a business meeting. These meetings provide an opportunity for industry members to stay abreast of current issues and to enable a forum to discuss strategy and impactful actions that affect the regulatory environment.

Educational Meeting
The educational meeting is dedicated to current areas of interest to the membership. This meeting provides unique opportunities for member interaction with invited guests such as FDA, Notified Bodies and regulatory and industry representatives from across the globe. The quarterly meetings serve as a forum of education for regulatory professionals and the information obtained is distributed amongst member companies by meeting attendees and through meeting minutes and presentations.

Business Meeting
The business meeting is dedicated to:
- Reports of other professional organizations’ meetings such as ASTM, ISO, AdvaMed and the AAOS
- Reports to the membership of task force activities
- Recognition of significant accomplishments
- Discussion of emerging regulatory issues affecting the industry and the actions OSMA can take to address them

In addition, at the Winter and Summer business meetings, OSMA participates in a conference call with FDA to obtain updates relevant to the orthopedic industry and address specific questions from the membership.

2018 Educational Programs
As we look back at the past year, OSMA recognizes the planning efforts that make the educational programs so impactful and beneficial to each member company. Agenda topics and keynote speakers for each quarterly meeting conducted throughout 2018 are included within this report.
### 2018 Winter Meeting ∙ January 11th & 12th ∙ St. Petersburg, Florida

<table>
<thead>
<tr>
<th>Affiliation</th>
<th>Speaker</th>
<th>Agenda Topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medtronic</td>
<td>Dr. Joachim Wilke</td>
<td>Patient Labeling (Implant Card/Information Provisions)</td>
</tr>
<tr>
<td>MEDCERT</td>
<td>Tina Lochner</td>
<td>CE Marking Requirements/Challenges for Orthopedic Class IIb, III and Class I Reusable Devices</td>
</tr>
<tr>
<td>DEKRA</td>
<td>Kate Moffa</td>
<td>Transition Provisions</td>
</tr>
<tr>
<td>TUV SUD</td>
<td>Dr. Matthias Fink</td>
<td>European Clinical Evaluations, Clinical Investigations (PMCF), Post Market Surveillance/Vigilance: Case Studies</td>
</tr>
<tr>
<td>Medtronic</td>
<td>Dr. Joachim Wilke</td>
<td></td>
</tr>
<tr>
<td>MEDCERT</td>
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<td></td>
</tr>
<tr>
<td>TUV SUD</td>
<td>Dr. Matthias Fink</td>
<td>EU MDR Group Discussion</td>
</tr>
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</table>

*Figure 1: OSMA Winter Educational Program*

*Figure 2: Dr. Matthias Fink*
<table>
<thead>
<tr>
<th>Affiliation</th>
<th>Speaker</th>
<th>Agenda Topic</th>
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</thead>
<tbody>
<tr>
<td>FDA</td>
<td>Mark Melkerson</td>
<td>DOD Overview</td>
</tr>
<tr>
<td>FDA</td>
<td>CAPT Raquel Peat, PhD, MPH</td>
<td>FDA CDRH TPLC Future Direction &amp; Strategic Priorities</td>
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<td>FDA</td>
<td>Constance Soves, PhD</td>
<td>ODE Update/FDARA</td>
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<tr>
<td>FDA</td>
<td>Jennifer Goode</td>
<td>Biocompatibility Update</td>
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<tr>
<td>FDA</td>
<td>Aprajita Garg, PhD</td>
<td>Biocompatibility of Orthopedic Devices</td>
</tr>
<tr>
<td>FDA</td>
<td>Elizabeth Gonzalez, PhD</td>
<td>Endotoxin Update</td>
</tr>
<tr>
<td>JOHNSON&amp;JOHNSON</td>
<td>Michelle McMurray-Heath, MD, PhD</td>
<td>The Future of Global Evidence Generation: Advancing the Role of Innovative Data and Methods</td>
</tr>
<tr>
<td>FDA</td>
<td>Josh Chetta, PhD</td>
<td>The Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices</td>
</tr>
<tr>
<td>NESTCC</td>
<td>Rachael Fleurence, PhD</td>
<td>NEST Overview and Future Vision</td>
</tr>
<tr>
<td>MEDTRONIC</td>
<td>Jing Xie, PhD</td>
<td>Innovation in Evidence Generation to Support Expedited Access to Medical Device Technologies</td>
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<tr>
<td>JOHNSON&amp;JOHNSON</td>
<td>Michelle McMurry-Heath, MD, PhD</td>
<td>Real World Evidence Panel Discussion</td>
</tr>
<tr>
<td>FDA</td>
<td>Josh Chetta, PhD</td>
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<td>NESTCC</td>
<td>Rachael Fleurence, PhD</td>
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<tr>
<td>MEDTRONIC</td>
<td>Jing Xie, PhD</td>
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</tbody>
</table>

Figure 4: CAPT Raquel Peat

Figure 3: Real World Evidence Panel Discuss (L to R: Dr. Vincent Devlin, Dr. Stephen Weber, Josh Chetta, Rachael Fleurence and Jing Xie)
### 2018 Summer Meeting ∙ July 19th & 20th ∙ Montreal, Canada

<table>
<thead>
<tr>
<th>Affiliation</th>
<th>Speaker</th>
<th>Agenda Topic</th>
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</thead>
<tbody>
<tr>
<td>ABHI</td>
<td>Phil Brown</td>
<td>Brexit Update</td>
</tr>
<tr>
<td>MEDEC</td>
<td>Diana Johnson</td>
<td>MEDEC RA Update: Key Priorities, Issues and Opportunities to Partner</td>
</tr>
<tr>
<td>HEALTH CANADA</td>
<td>David Boudreau</td>
<td>Medical Device Bureau Update</td>
</tr>
<tr>
<td>HEALTH CANADA</td>
<td>Frederic Hamelin</td>
<td>Health Canada Update: MDSAP</td>
</tr>
<tr>
<td>HEALTH CANADA</td>
<td>Chris Schmidt</td>
<td>Health Canada Update: Investigational Testing Authorization</td>
</tr>
<tr>
<td>JOHNSON &amp; JOHNSON</td>
<td>Sally Prawdzik</td>
<td>Clinical Data Transparency</td>
</tr>
<tr>
<td>JOHNSON &amp; JOHNSON</td>
<td>Sally Prawdzik</td>
<td>IMDRF and TOC Update</td>
</tr>
</tbody>
</table>

*Figure 5: OSMA Spring Educational Program*
Figure 8: Health Canada Guest Speakers (L to R: Chris Schmidt, David Boudreau and Frederic Hamelin)

Figure 7: Diana Johnson

Figure 6: Sally Prawdzik
<table>
<thead>
<tr>
<th>Affiliation</th>
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<th>Agenda Topic</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA</td>
<td>Mark Melkerson</td>
<td>Orthopedic Devices Overview</td>
</tr>
<tr>
<td>FDA</td>
<td>Laurence Coyne, PhD</td>
<td>RRDB Updates</td>
</tr>
<tr>
<td>FDA</td>
<td>Aric Kaiser, M.S.</td>
<td>Animal Performance Testing Considerations for Bone Void Fillers</td>
</tr>
<tr>
<td>FDA</td>
<td>Jesse Muir, PhD</td>
<td>Stereotaxic, Bone Growth Stimulator and Fracture Fixation Devices Team Pilot</td>
</tr>
<tr>
<td>FDA</td>
<td>CDR Michel Janda</td>
<td>Software in Orthopedic Devices</td>
</tr>
<tr>
<td>FDA</td>
<td>Theodore Stevens</td>
<td>CBER Update Biologic Initiatives (not covered by CDRH) and Changes Occurring in HCTP</td>
</tr>
<tr>
<td>FDA</td>
<td>Andrea Gray</td>
<td>Potency for Live-Cell Products</td>
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<tr>
<td>FDA</td>
<td>Constance Soves, PhD</td>
<td>Update on Orthopedic Instruments in the Proposed Accessories Reclassification List</td>
</tr>
<tr>
<td>FDA</td>
<td>Colin O’Neill, MBE</td>
<td>2018 SMART Orthopedic Devices Workshop</td>
</tr>
<tr>
<td>FDA</td>
<td>Matthew Di Prima, PhD</td>
<td>Advanced Manufacturing Innovation &amp; the FDA</td>
</tr>
<tr>
<td>JOHNSON&amp;JOHNSON/DEPUY SYNTHES</td>
<td>Sharon Starowicz</td>
<td>Results of OSMA’s FDA Performance Survey</td>
</tr>
<tr>
<td>FDA</td>
<td>Terrie Reed</td>
<td>Global UDI Update</td>
</tr>
</tbody>
</table>

Figure 9: Mark Melkerson

Figure 10: OSMA Fall Educational Program
Figure 11: OSMA Fall Reception (L to R: Ed Chin, Sharon Starowicz, Alicia Hemphill, Kathy Trier)

Figure 12: OSMA Fall Reception (L to R: Natalie Heck, Lisa Boyle, Rod Parker, Simona Voic)
Task Forces

The following task forces have been established and continue their work to address relevant topics impacting our industry. Task force chairs and members continue to make a significant impact on these initiatives and their work is greatly appreciated amongst the membership and the orthopedic industry. Many thanks to the member companies for the support they provide their valued employees as they devote their time and effort to making positive changes and improvements on behalf of the industry. OSMA workstreams have been identified to improve the OSMA organization.

2018 OSMA Task Forces:
- Additive Manufacturing
- Class I Accessories
- Cleaning and Sterilization
- EU Medical Device Regulation (Spinal Devices)
- FDA Performance Goals
- Meeting Planning
- Proposed Guidance and Regulations

2018 OSMA Workstreams:
- Reconstitute Board for New 4 Year Term (complete)
- Enhance Communications
- Increase Task Force Visibility and Effectiveness
- Increase OSMA Visibility and Expand Networks
- Increase International Focus
- Assess Future of Orthopedics
Operating Highlights

Benefits of Membership

OSMA continues to provide its regulatory professionals with a cost-effective meeting venue to collaborate, communicate, cooperate and interact with worldwide regulatory agencies and industry professionals. As an OSMA member company, annual dues are collected to support the following:

- Enable Task Force groups to engage with consultants, attend meetings and provide for effective collaboration to meet various goals and milestones
- Provide assistance to organizations within the orthopedic industry to maintain valued partnerships
- Assist the organization with operating expenses such as administrative support, website expenses and liability services
- Subsidize the overall expense of each quarterly meeting to provide OSMA members with a low meeting registration fee

Cost of a Meeting

Meetings are held four times a year, with the Spring and Fall meetings located in the Washington D.C. area to support FDA participation. In consideration of the location of OSMA member companies, generally, the Winter meeting is located in the south and the Summer meeting is typically held in the west or north. Oftentimes, member companies will take advantage of the meeting location by allowing several colleagues to attend, as travel costs are decreased.

While the cost of hotel venues and catering costs continue to rise, OSMA is highly subsidizing meeting expenses above the current registration fee ($100.00). In 2018, OSMA supplemented costs, on average, $145.63 per member, per meeting.
### Table 1: Cost of a Quarterly Meeting/OSMA Member Attendee in 2018

<table>
<thead>
<tr>
<th></th>
<th>Total Meeting Cost</th>
<th>No. of OSMA Member Attendees</th>
<th>Actual Cost of a Meeting per OSMA Member Attendee</th>
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<tbody>
<tr>
<td>Winter</td>
<td>$16,065.38</td>
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<td>$265.12</td>
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<tr>
<td>Spring</td>
<td>$16,290.55</td>
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<td>$278.85</td>
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<tr>
<td>Summer</td>
<td>$4,551.79</td>
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<td>$97.90</td>
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<tr>
<td>Fall</td>
<td>$18,948.03</td>
<td>43</td>
<td>$340.65</td>
</tr>
</tbody>
</table>

OSMA continues to provide an affordable and competitive registration rate offering a breath of information provided during each OSMA educational forum and the ability for attendees to network directly with global regulators, including FDA, Notified Body representatives, industry partners and colleagues facing the same experiences in the orthopedic industry.

### Going Forward

As the membership moves forward, the organization continues to support strategic initiatives that will bring value to the membership and align with evolving technologies. It is through the active participation of our members that OSMA continues to thrive, grow and gain the recognition of industry partners as a respected organization.
*Active Implants
Acumed, LLC
Aesculap Implant Systems, LLC
Amendia
Arthrex, Inc.
*BioPro Implants
CeramTec GmbH
ConMed Corporation
Corin USA
DePuy Synthes/Johnson & Johnson
DJO Global
Exactech, Inc.
*FX Shoulder
Globus Medical
Innovasis
K2M, Inc.
Medtronic, PLC

NuVasive, Inc.
Ortho Development, Inc.
Ortho MicroPort
OsteoMed
RTI Surgical, Inc.
SeaSpine Orthopedics Corporation
Smith & Nephew
Spinal Kinetics
Spine Wave, Inc.
Stelkast
Stryker
Total Joint Orthopedics
*Tyber Medical
TranS1
Wright Medical
Zimmer Biomet

(*) Designates new 2018 OSMA Members.
Board of Directors

PRESIDENT AND
INDUSTRY REPRESENTATIVE, FDA
ORTHOPEDIC ADVISORY PANEL
Sharon Starowicz
Johnson & Johnson/DePuy Synthes

VICE PRESIDENT
Ehab Esmail
Zimmer Biomet

SECRETARY
Lisa Boyle
Aesculap

TREASURER
Ed Chin
Medtronic

PAST PRESIDENT
Susan Krasny
Stryker

BOARD MEMBERS
Stacey Bonnell
Johnson & Johnson/DePuy Synthes
Carolyn Shelton
Medtronic

Kathy Reddig
ConMed

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Orthopaedic Surgical Manufacturers Association
Email secretary@osma.net
Website www.osma.net