The MDSS is a new SOT specialty section launched in September 2009 whose purpose is to provide an international forum where government, industry, consulting, and academic toxicologists can share state-of-the-art knowledge and develop new approaches for the evaluation of medical devices. The objectives for the MDSS are:

1) Provide an international focus group for toxicologists working in the area of medical devices and combination products including a device component;
2) Promote the development of new experimental methods for the evaluation of medical devices;
3) Sponsor scientific and educational programs that emphasize current developments and issues in the toxicological evaluation of medical devices;
4) Promote proactive communication and interactions among toxicologists in government regulatory agencies, regulated industry, and academia regarding current issues in medical device toxicology. Specific areas of interest include: plastics, metals, ceramics, materials of biologic origin, and validation of new/alternative toxicity assays for medical devices; and
5) Stimulate interest in medical device safety as a career path for new toxicologists.

Founding Members
Lori H. Moilanen, President
Richard W. Hutchinson, Vice President
Ronald Brown, Vice President-Elect
Edward E. Revery, Secretary/Treasurer
Jon N. Cammack, Councilor
Robert T. Pryzgoda, Councilor
Chandramallika Ghosh, Councilor
Albercht Poth, International Advisor

Table 1. FDA approvals of Medical Devices (PMA), Biologics Agents (BLA) and New Molecular Entity (NME)

<table>
<thead>
<tr>
<th>Year</th>
<th>PMA</th>
<th>BLA</th>
<th>NME</th>
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<tr>
<td>2000</td>
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<td>2004</td>
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</tr>
<tr>
<td>2006</td>
<td>2</td>
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Medical devices are an ever increasingly important part of the global healthcare industry, delivering life-saving and life-sustaining therapies. Additionally, devices are becoming even more critical in pharmaceutical research including diagnostic imaging, devices used to deliver drugs, and diagnostic tests used to assess whether a patient will respond to a particular therapy. Devices are different from pharmaceutical products in terms of the FDA approval process, the CDISC standards applied, and the types of studies needed for market clearance.

Innovations in the medical device industry are particularly noteworthy. Breakthrough technologies that range from miniature robots that can perform complex spinal surgery, to non-invasive devices for treating brain tumors with focused gamma irradiation, to delivery of light-activated drugs that specifically target diseased cells are just a few examples of technologies that have made the leap from medical fantasy to medical reality recently.

The global medical device market is expected to exceed $300 billion in 2011, and experience a growth rate in the range of 4.6% over the next several years, a comparable to slightly higher growth rate of that expected for the global pharmaceutical industry. PMA submissions are the type of regulatory filing required by FDA for new medical devices and BLA submissions are required for combination devices using biologics. In the U.S., the number of new devices approved by the FDA has increased by 52% in the past decade, compared to a decline in the approvals for new molecular entities (NME).

2011 Calendar
Sunrise CE Course (7:00-7:45 AM March 6, 2011)
Biodegradable Materials for Tissue Engineering: Applications and Safety Assessment
Medical Device Meeting/Reception Session (6:30–8:00 PM, March 6, 2011)
Medical Device Poster Session (1:00–4:30 PM, March 8, 2011)
Informational Session (6:30 AM–7:30 AM March 9, 2011)
The Application of the Threshold of Toxicological Concern Concept to the Preliminary Safety Assessment of Non-Pharmaceutical Medical Products, Including Medical Devices and Combination Drug-Device Products

Awards & Activates
MDSS Best Overall Abstract Award
Best Published Paper Award
MDSS Student Travel Award
Quarterly Newsletter