

NAME OF SPECIALTY SECTION ____Medical Device and Combination Product____

ANNUAL REPORT: 2013-2014

May 1, 2013 to April 30, 2014

I. Officers/Committees:

Officers	2013-2014	2014-2015
President:	Jon N Cammack	Greg Erexson
Vice President:	Greg Erexson	Alan Hood
Vice President-Elect:	Alan Hood	Kelly Coleman
Secretary/Treasurer:	Taylor Builee	James Kleinedler
Past President	Ron Brown	Jon N Cammack
Councilors:	Kelly Coleman	Kavita George
	Kavita George	Barbara Henry
PDA Representative:	N/A	N/A
GSLC Representative:	Forrest Jessop	Kevin Trout

Committees:

- 1) Nominating Committee,
Jon Cammack, Chair
- 2) Program and Awards Committee
Alan Hood, Chair
- 3) Mentoring Committee
Jon Cammack, Chair
- 4) Membership Committee
Kelly Coleman, Chair
- 5) Outreach Committee
Kelly Coleman, Chair
- 6) Graduate Student and Postdoc Committee
Kevin Trout, Chair
- 7) Newsletter
Alan Hood, Chair and Jill Reynolds (3M)
- 8) Budget
Jim Kleinedler

II. Activities:

2014 SOT Annual Meeting Medical Device Specialty Section Reception was held in Phoenix, Arizona Monday March 24, 2014.

- Approximately 80 people were in attendance.
- Dr. Jon Cammack called the meeting to order at 6PM on Monday March 24, 2014 at the Sheraton Phoenix Hotel in Phoenix, AZ.

- Business Meeting Speakers: Jon Cammack (chair); Greg Erexson (MDSS awards and award presentations); membership update (Kelly Coleman); budget update (Taylor Builee); newsletter update (Alan Hood) and graduate student representative/post-doc representative updates (Forrest Jessup and Kevin Trout).
- Meeting Minutes: (see Attachment I)

Medical Device Specialty Section Awards for 2014:

Medical Device SS Best Overall Abstract Award for 2014: Michael F. Wolf et al. “Medical device thrombogenicity testing using molecular indicators of thrombin generation: An *in vitro* alternative to the NAVI model”.

Medical Device SS Best Published Paper in 2013 Regarding Medical Devices Award: Jesus Casas et al. (Medtronic, Inc. and CeeTox). “In vitro human skin irritation test for evaluation of medical device extracts” *Toxicology In Vitro* 27:2175-2183 (2013).

Medical Device SS Student Travel Award for 2014: Shelby Skoog (Joint dept. of Medical Engineering, UNC-NCSU, Raleigh, NC). “Biological Evaluation of Ultrananocrystalline and Nanocrystalline Diamond Coatings”.

2014 SOT Annual Meeting Courses/Sessions: (at the Convention Center)

- 1) Poster Session: Medical Devices, Wednesday March 25, 2014 at 9:30AM, Phoenix, AZ
- 2) Meet the Leaders Session: Wednesday March 25, 2014 at 1PM,, Phoenix, AZ
- 3) Social Hour/Networking: Monday March 24, 2014 at 8PM after the MDSS business meeting/reception, Phoenix, AZ
- 4) Sunrise CE Course: Combination Products: Toxicology and Regulatory Challenges Sunday March 23, 2014 from 7-8AM at the Convention Center, Phoenix, AZ

Endowment Fund Details: None.

Newsletters:

Teleseminar 1: Thomas Hartung, Johns Hopkins, gave a webinar on Friday, May 24, 2013 at 12-1 pm titled, *Medical Device Testing In Vitro—Pyrogenicity Testing and Beyond*.

Teleseminar 2: The Medical Device Specialty Section (MDSS) hosted a lunchtime webinar presentation by Ron Brown on the topic “Use of Computational Toxicology for the Biological Evaluation of Medical Devices” on June 23, 2013 from 12-1PM EDT. Ron Brown is a toxicologist at US FDA Center for Devices and Radiological Health (CDRH), where he coordinates CDRH’s efforts in toxicological risk assessment and computational toxicology. Dr. Brown is a founding member and former President (2012-2013) of the MDSS and recently served as author of the chapter on toxicological risk assessment in, *Biocompatibility and Performance of Medical Devices* (J-P Boutrand, ed., Woodhead Publishing).

Contributions to SOT website: The MDSS website was maintained and updated.

Other Specialty Section 2013-2014 Activities:

- Submitted a proposal for a CE course for the 2015 Annual Meeting that was accepted as a full CE course (Toxicology and Regulatory Challenges in Developing Preclinical Evaluation Programs for Combination Products)
- The MDSS decided to add a new position which would have an international/cross-functional purpose. The proposal for this Liason position is being drafted by Jon Cammack (MedImmune-Astra-Zeneca). Xin Tang from Medtronics., Inc. expressed interest in this type of role for the executive committee.
- MDSS sponsored the sunrise continuing education course at the Phoenix, Az SOT annual meeting on Sunday March 23, 2014 from 7-8AM entitled “Combination Products: Toxicology and regulatory Challenges”. Chairpersons were Jon Cammack (MedImmune-Astra Zeneca) and Chandramallika (Molly) Ghosh (U.S. FDA). The speakers were Thinh Nguyen (U. FDA), Jon Cammack and Molly Ghosh. Approximately 215 attendees which was the second highest of any CE course at the SOT annual meeting in 2014.

Attachment I – Annual Meeting Minutes

Medical Device Specialty Section Executive Committee
Minutes
Monday, March 24, 2014 1130-1pm Arizona Time
1130 Restaurant, Phoenix, AZ

1. EC Member Roll Call
 - a. Jon N. Cammack, President 2013-14
 - b. Greg Erexson, Vice President 2013-14
 - c. Kelly Coleman, Councilor 2012-14 (incoming Vice President-Elect 2014-2015)
 - d. Taylor Builee, Secretary 2012-2014
 - e. Forrest Jessop, Graduate Student Representative 2012-14
 - f. Alan Hood, Vice President- Elect 2013-14
- Absent
 - g. Kavita George, Councilor 2013-14
 - h. Ronald Brown, Past President/Councilor 2013-14
 - i. Invited incoming EC Barbara Henry – Councilor 2014-2016
 - j. Invited incoming EC Student Representative Kevin Trout 2014-2016
 - k. Invited incoming EC Jim Kleinedler – Secretary 2014-2016
2. Corium Present - Yes
3. Truncated agenda focused on meeting activity only. Request for additions to the agenda – None
4. Motion to accept agenda by Jon, Second by Alan
5. Annual meeting activities.
 - a. Grad Student/Post Doc involvement – (Grad. Student Rep. Forrest)
Mixer March 25th 730-930 had low attendance with low recruitment potential for MDSS. Low attendance suspect to program planed.
 - b. Sunrise CE had 215 attendees, 2nd highest of all CE's this year. Mark verbally agreed it would be a good idea expand topic to a full CE session next year.
2015 CE proposals are due April 30, 2014. (Kelly, Greg, Alan and Jon will work on this) Molly Ghosh expressed interest in participating as a speaker.
Potential ideas for organization are:
 1. 2 session with a panel discussion between
 2. Sessions to be organized as regulatory and industry
 - c. Jon proposed changing the SS name to: Medical Devices and Combination Products SS. EC provided a preliminary vote and agreed (Alan, Kelly, Greg, Taylor) to investigating the follow up.
 1. EC vote to be collected/confirmed
 2. Membership to vote to a change to the bylaw with the new name
 3. SOT HQ to vote provide blessing on the bylaw change. Upcoming SOT HQ meetings are 2014May 20, 2014July 22, 2014Nov 5, 2015Jan 13 and 2015March 21.
 4. Next step is to send proposal to EC Kavita and Ron. Draft the bylaw proposal send vote to membership and include as an agenda item for next SOT HQ meeting.
 - d. Membership (Kelly)
 1. The targeted recruitment campaign to attract former members has had a low response.
 2. The proposed MDSS name change could include members in the Drug Discovery Group. Kelly proposed use of the targeted recruitment approach.
 - e. Finances (Taylor)
 1. Use SOT meeting to connect with Industry and gain interest in sponsors. Kelly is meeting WuXi on Tuesday evening. Taylor invited

Yvonne Leonard from WuXi to the annual reception to see program layout and open opportunities for WuXi involvement.

6. Other activities
 - a. Next Meeting scheduled on April 11, 2014 (10-1130am)
7. Close meeting Motioned to Close by Jon, Second by Alan.