



President's Message Winter 2012

It is exciting to take this opportunity to look back on the activities and growth of the specialty section last year. In March 2011 the specialty section sponsored four scientific sessions and a social reception. Since then we have sponsored a webinar and developed a draft document on "Consensus On Qualifications For Persons Conducting Toxicology Risk Assessments Under ISO 10993-1." With considerable effort from our membership committee, we have consistently grown in membership, peaking at 109 members at the end of 2011.

With all of the progress that has been made in 2011 we look forward to 2012 with eager anticipation of even more scientific content and membership growth. We are sponsoring a reception, a poster session, and a roundtable discussion at the Society's 51st Annual Meeting in San Francisco, California in March. The comment period on our document "Consensus On Qualifications For Persons Conducting Toxicology Risk Assessments Under ISO 10993-1" closed on February 5th, and we are currently addressing all of the comments and working with SOT to understand the future of this document. The program and awards committee has selected deserving recipients for the four awards that are given by the specialty section each year, and this committee has already begun planning for additional webinars through the rest of 2012. More detail on each of these topics is provided in this newsletter.

Lastly, the election process for new leadership of the specialty section is complete and the results have been announced. We are all excited to welcome these new members who will be leading the specialty section. At the same time, we want to recognize a few key members of the specialty section who were pivotal in the early days of the specialty section and will soon be rotating off the Executive Committee.

First, Dr. Lori H. Moilanen, who served as the first President of the Specialty section and was an inspirational leader before the specialty section was approved by SOT. Lori's leadership, energy, and inspiration were pivotal to the genesis of this specialty section and she will be missed.

Second, Dr. Edward E. Reverdy who has served as the Secretary/Treasurer for the specialty section since its inception. Ed has been instrumental in coordinating our efforts and managing the budget of the specialty section. Thanks to Ed's efforts, the specialty section is on firm financial footing, and thus able to support our numerous awards, social programs, and webinars.

And lastly, Dr. Esther Hope who has served as our webmaster from the beginning of the specialty section. She was the original designer of the webpage, and has maintained it. Since this is the most visible face of the MDSS to the outside world, we thank Esther for her efforts to make sure that we are prominently represented. Dr. Alan Hood will be succeeding Esther in this important role. Thank you Esther and Alan.

We are excited to share this newsletter with you, and we look forward to seeing you in San Francisco, California next month.

Richard W Hutchinson, DVM, PhD, DABT
MDSS President

SAVE THE DATE!
TUESDAY, MARCH 13,
MDSS MEETING &
RECEPTION, MARRIOTT
MARQUIS, WILLOW ROOM,
6-7:30 PM

Officers

President

Richard Hutchinson

Vice President

Ron Brown

Vice President-Elect

Jon Cammack

Treasurer/Secretary

Edward Reverdy

Councilors

Molly Ghosh
Lori Moilanen
Greg Erexson

Newsletter Editors

Jon Cammack
Molly Ghosh

Table of Contents

Membership & Treasury Update	2	ISO/AAMI TC 194 San Diego Meeting Update	5
2012 MDSS Program and Awards at SOT	3	MDSS Membership Update	5
2012 MDSS Program and Awards at SOT (con't)	4	MDSS News and Member Updates	6

Membership & Treasury Update

The MDSS Treasury is in good standing with more than \$10,000 in the treasury to start 2012. As our member numbers have grown this year so has the potential for our income from member dues. This is extremely vital to the operations of the specialty section along with donations from others. We thank Boston Scientific Corporation for their donation of \$1000 and The Science Cooperative, LLC for their donation of \$500. We look to other companies to also provide donations of any amount to help support the activities of the MDSS.



Medical devices range from sutures and bandages to imaging technologies. Consider sponsoring the MDSS to further the efforts of science and education for these life-sustaining and life-saving products.

Expenses for 2011 are anticipated from two primary areas. One is the addition of awards from the MDSS. Along with cash prizes for the Student Travel awards, MDSS will incur expenses for plaques and awards to be issued for the Best Abstract and Best Paper Awards. The second primary expense will be for conducting the meetings at the 51st SOT Annual Meeting in San Francisco. These fees will be assessed of the MDSS following the meeting.

Balance – 2011		\$10,088
Income -	Corporate Sponsors	<u>1,500</u>
	Total	\$ 11,588
Expenses -	Awards (2)	(2000)
	Plaques (4)	(242)
	Meeting Expenses – 2012	<u>(2,680)</u>
Anticipated Balance April 2012		\$ 6,666

Donations Are Important for Our Bottom Line

Annual donations provide funds for operating costs within the SOT as well as the annual business meeting and reception at the annual SOT meeting. We welcome continued donations from our members through corporate contributions and will post these donations and pledges both on the SOT website page and future newsletters. The process for submitting donations is simple, and checks can be made out and mailed to SOT at:

Society of Toxicology
1821 Michael Faraday Drive
Suite 300
Reston, VA 20190

There should be an indication - on the check itself if possible, that it is a donation for the Medical Device Specialty Section. This helps to ensure that the check is processed correctly. Spelling out the Specialty Section name will help to avoid any potential confusion with other sections.

If you would like to make a credit card payment and/or need an invoice for your records, please contact Kim von Brook at SOT HQ (Kimberly@toxicology.org) with the donor's name and contact information and the amount of the donation.

SOT will notify the President/Secretary when a donation is received.

*Tell a colleague about
the MDSS – the process
for joining is simple!*

2012 MDSS Program and Awards

The MDSS Program and Awards Committee has continued to develop and promote three different distinctions to be presented each year at the SOT Annual Meetings. Descriptions and winners of the awards follow:

- **Medical Device SS Best Overall Abstract Award** - Any abstract submitted to SOT for the Annual Meeting that indicates a medical device focus or impact is eligible for this Best Abstract Award. Winner receives a 5x7 inch Award Plaque.

2012 Award Winner: KP Coleman, JW Casas, GM Lewerenz, EA Rankin, JA Willoughby, Sr., LC Blakeman and JM McKim, Jr. *Evaluation of an In Vitro Human Skin Irritation Test for Use With Medical Device Extracts.*
- **Medical Device SS Best Published Paper Regarding Medical Devices Award** - Any paper published in a peer-reviewed journal between January 2011 and December 2011. Papers should illustrate techniques or approaches that are likely to significantly advance the science and/or application of medical devices. Winner receives a 5x7 inch Award Plaque.

2012 Award Winner: DR Doerge, NC Twaddle, M Vanlandingham, RP Brown, JW Fisher. *Distribution of bisphenol A into tissues of adult, neonatal, and fetal Sprague-Dawley rats.* Toxicol Appl Pharmacol. 2011 255(3):261-70.
- **Medical Device SS Student Travel Award** – The Medical Device Specialty Section’s Student Travel Award provides travel awards to one or more graduate students to participate in the Annual Meeting of the SOT. Recipients of the Award will be selected by a committee jointly appointed by the leadership of the Medical Device Specialty Section. The MDSS Travel Award Recipient(s) will be selected based on the scientific quality of the abstract of a presentation that applies mechanistic toxicology to risk assessment and that has been accepted for presentation at an Annual Meeting of the SOT. The abstract and presentation should be based on the student's research. To be eligible, the student or postdoctoral fellow must be first author and the abstract must have been accepted by the Program Committee. Winner(s) receive a Travel Award of \$1,000 (each) and a 5x7 inch Award Plaque.

No nominations were received for this award this year.

Remember to check out the Medical Device Poster Session at the SOT Annual Meeting in San Francisco. There were outstanding submissions and winners will be identified and recognized at the meeting.

2012 MDSS Program and Awards Con't.

In conjunction with the development of the awards, the Program Committee has adopted the following Conflict of Interest Recusals for the Awards:

- a. **Committee Chairpersons and Committee Members** can have abstracts in the competition. However, they should not score the abstracts on which they are co-authors.
- b. **Collaborators:** If a committee member has collaborated in work described in an abstract, s/he should not score the abstract. Any past or present collaborative/funding relationships with the authors are not considered to be relevant to this committee work.
- c. **Supervisors:** If the committee member is the current supervisor of one or more co-authors of an abstract being evaluated, s/he should not score the abstract.
- d. **Institution:** Best judgment will be applied in recommending refusal when a colleague from the same institution is nominated. The decision regarding refusal will take into account the size of the institution and the proximity in the management structure. The final decision regarding refusal due to institutional conflict of interest will be made by the committee chair (who is a member of the MDSS executive committee), unless the committee chair's institution is involved, in which case the decision will be made by the MDSS President.
- e. **Multiple awards:** The same abstract cannot receive more than two awards.
- f. **Winner:** The winner of the Best Abstract Award is based on the average score among all who scored the abstract, not the total numerical score.

Visit our website for more information on the MDSS:

<http://www.toxicology.org/ISOT/SS/mdss/Index.asp>

2013 MDSS Program

In looking ahead to the 2013 Annual Meeting of the SOT, please forward any ideas or suggestions you may have for scientific sessions. The Program and Awards Committee looks forward to a wonderful SOT meeting and the inaugural presentation of the MDSS awards!

ISO/AAMI TC 194 San Diego Meeting Update

From April 16-20, 2012, ISO/AAMI Technical Committee (TC) 194 will hold a full meeting at the Westin Gaslamp Quarter Hotel in San Diego, California. ISO/AAMI TC 194 is responsible for the ISO/AAMI 10993 medical device testing standards. The standards provide guidance on how potential risks to patients can be minimized during medical device use when following a risk management approach.

The following working groups will meet in San Diego:

ISO/TC 194 / WG5 (Cytotoxicity)
ISO/TC 194 / WG6 (Mutagenicity, carcinogenicity, and reproductive toxicity)
ISO/TC 194 / WG7 (Systemic toxicity)
ISO/TC 194 / WG8 (Irritation and sensitization)
ISO/TC 194 / WG9 (Effects on blood)
ISO/TC 194 / WG10 (Implantation)
ISO/TC 194 / WG11 (Allowable limits for leachable substances)
ISO/TC 194 / WG15 (Strategic approach to biological assessment)
ISO/TC 194 / WG16 (Pyrogenicity)
ISO/TC 194 / WG17 (Nanomaterials)
ISO/TC 194 / WG 6, 11, and 14 (Material characterization), Joint meeting
ISO/TC 194 Plenary Meeting

In Memoriam

It is with deep sadness that we announce the death of Mr. Barry Page earlier this year. Barry was one of the original members of the United States Technical Advisory Group (TAG) to ISO TC 194, and was instrumental in developing key ISO 10993 standards, especially ISO 10993-7, Ethylene Oxide Sterilization Residuals. He was a medical device industry “beacon”, having spent time at several companies including Becton-Dickenson, and Medtronic, as well as HIMA/AdvaMed, and as a private consultant. Barry will be fondly remembered as a devoted scientist and passionate advocate of practical standards that were use-able by industry and regulators alike. He was a “gentle giant” of a man, with a kind heart who listened to all sides of a discussion, and worked to find middle-ground solutions all parties could accept. All who knew Barry agree he will be deeply missed, and we will commemorate his achievements in the area of medical device standards at the meeting in San Diego.

ISO10993 standards are available through country accredited organizations. In the U.S., it's AAMI.

Membership Update

Contact: Kelly Coleman (Chair) and Lori Moilanen (Vice Chair)

Demographics: The MDSS was formed in 2009 with 51 founding members; we have grown to 109 members as of January, 2012. Our members come from industry, government, consulting, and academia. Educational backgrounds range from BS degrees, to those with multiple doctorates, doctors of veterinary medicine, and MBAs.

Recruitment: We achieved our goal of 100 members by 2012. Also, we're beginning to have a more diversified mix of members, including academic members. It is worth noting a distinguished new member, Dr. James Anderson. Dr. Anderson, MD, PhD, is professor of pathology, macromolecular science and biomedical engineering at Case Western Reserve University's School of Medicine. He joined SOT and MDSS in 2011 and is a member of the National Academy of Sciences, an AAAS Fellow, and Editor-in-Chief of the Journal of Biomedical Materials Research, A. He is also Chairman, of Working Group 1 in ISO/AAMI TC194 responsible for ISO 10993-1 Standard on Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management System. New members will be listed in future newsletters.

MDSS News and Member Updates

Activities Sponsored by the Medical Device Specialty Section Society of Toxicology 51st Annual Meeting San Francisco March 11-15, 2012

Reception/Business Meeting: Medical Device Specialty Section
TUESDAY, March 13, 6:00-7:30 PM
Marriott Marquis, Willow Room

Poster Session: Medical Devices
MONDAY, March 12, 9:30 AM – 12:30 PM
Exhibit Hall (Convention Center)
Chair: Lori Moilanen

Roundtable: Bisphenol A Risks in a Human Exposure Context: Is Internal Exposure to Bioactive Bisphenol A in Humans Similar to Levels in Affected Rodent Test Species? Wednesday, March 14, 7:30-8:50 AM. Room 303 (Convention Center)

MEMBER UPDATES

- **KELLY P. COLEMAN, PhD, DABT** has been named a Distinguished Scientist at Medtronic, one of only ten such honorees in a company of 45,000 employees. He serves as Medtronic's chief toxicologist and is also an adjunct assistant professor of toxicology at the University of Minnesota.
- **ESTHER HOPE, DVM, DABT** to retire as MDSS Webmaster – The MDSS Executive Committee expresses our sincere thanks for her outstanding efforts that helped shape the identity of our specialty section!!
- **LORI H. MOILANEN, PhD, DABT** has been appointed to AAMI/BE Working Groups 10 (Implantation), 11 (Allowable Limits for Leachable Substances), 15 (Strategic Approach to Biological Evaluation), and 17 (Nanomaterials).

MEDICAL DEVICE NEWS

Interesting review article on device regulation

["Regulation of Medical Devices in the United States and European Union". NEJM, February 14, 2012.](#)

The FDA Center for Device and Radiological Health has released their 2012 Strategic Priorities

<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHVisionandMission/ucm288735.htm>

510(k) Guidance Footnote May Signal Greater FDA Oversight Of Preclinical Testing

<http://www.elsevierbi.com/publications/the-gray-sheet/38/04/510k-guidance-footnote-may-signal-greater-fda-oversight-of-preclinical-testing>

FDA Reproductive and Developmental Toxicity Testing Workshop

The U.S. FDA is hosting a workshop on Reproductive and Developmental Toxicity Testing at the FDA White Oak Campus in Silver Spring, Maryland on April 16, 2012. The workshop is co-sponsored by the National Institute of Environmental Health Sciences, the Center for Alternatives to Animal Testing, Johns Hopkins University and The Middle Atlantic Reproduction and Teratology Association.

Registration is free but space is limited. To register, please send your name, affiliation, and email to

OCSFDAWORKSHOP@fda.hhs.gov.