

## MDSS JUNE NEWSLETTER, 2013

### President's Message

I'm happy with the opportunity to say "hello" to everyone as I move into the role of President for the 2013-2014 term. As I look back on the activities and growth of the specialty section over the last 3-plus years, I'm so impressed by the outstanding efforts and leadership of past-Presidents. I certainly hope I can fill these very big shoes! 2012 was a resounding success: at the 2013 SOT annual meeting in San Antonio, we sponsored a technical and poster session, held our business meeting and awards ceremony, and we enjoyed time together at our social reception; we also hosted several exceptionally well-attended webinars during the past year. With considerable effort from our membership committee, we have consistently grown in membership, with 124 active members and 33 inactive members (that we're vigorously encouraging to re-engage!) as of May, 2013.

With all the progress in 2012/13, I look forward to the remainder of 2013/14 term, and anticipate even more scientific content and membership growth. We have proposed a workshop, and are sponsoring a CE Sunrise course at the 2014 SOT 53<sup>rd</sup> Annual Meeting in Phoenix next March, and will conduct our annual business meeting and reception, as well as hosting and sponsoring a poster session. The program and awards committee planned and hosted a webinar by Dr. Thomas Hartung in mid-May (the presentation deck can be accessed from our website), and is planning for at least one more in 2013-2014. In my reflections on what I hope we achieve this coming year, and in years after, there are several key areas I know the MDSS can have a large impact. We can build bridges and stronger relationships with other specialty sections, especially the Drug Development SS (DDSS), with areas of natural overlap like combination products (therapeutic and diagnostic products that combine drugs, devices, and/or biological elements). We can do more in leading initiatives in the area of *in vitro*

alternative methods as much interest was generated from Dr. Hartung's webinar on this topic. There are obviously other areas for our focus, and I would encourage each of you to consider and communicate ideas you may have to the EC.

At the same time that we look forward and shape our longer-term strategy for the MDSS, I want to recognize a several key members of the specialty section who have devoted considerable time and mental energy over the last term. First, Ron Brown, who served as President this last term; Ron is an inspirational leader, and was an original member of the group that conceived of our specialty section. Ron's ideas and energy drove us this past year, and thankfully he's already proven to be an active past-President and Councilor! Secondly, Taylor Builee, who has served as Secretary/Treasurer for the last two years. I have not seen someone as dedicated, responsive, and effective as Taylor in coordinating actions and managing the budget of a specialty section. Thanks to her efforts, the MDSS functions like a "well-oiled machine", and is on very firm financial footing, allowing us to support our numerous awards, social programs, and webinars. And lastly, Dr. Alan Hood (our VP-elect), who has served as our webmaster for the last year. Alan has re-designed and updated the site, and since this is the most visible face of the MDSS to the outside world, our thanks to Alan for his expert efforts to make sure we are prominently represented.



Jon Cammack, PhD, DABT  
MDSS President

I'm excited for this coming term, and look forward to hearing from members with ideas and thoughts on how we can continue to improve and create value for our community of science, and especially the SOT.

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# Treasury Updates

-By Taylor Builee

The MDSS treasury reports funds at an amount of \$10,987, following the 2013 SOT Annual Conference activities in San Antonio, TX.

Balance from January 2013	\$12,317
2013 Conference & Awards Expenses	
Student Travel Award	-1,000
MDSS Grad Student Travel Award	-350
Plaque Awards	-197
Luncheon, Executive Meeting and MDSS Social	-3,701
Income :	
Sponsorship	3,073
SOT meeting registration	843
Balance as of May 23, 2013	\$10,987

Please consider making a tax-deductible donation of any amount to support MDSS. MDSS accepts donations by check or credit card. Checks can be sent to SOT HQ. Credit card transactions can be completed by email or by phone directed to Raul A. Suarez at SOT HQ (raul@toxicology.org) (703) 438-3115 x1461.

All donations should have the minimal information, donor's name, contact information, amount of donation and payment information directed to the Medical Device Specialty Section.  
Society of Toxicology  
1821 Michael Faraday Drive  
Suite 300  
Reston, VA 20190

When the donation is completed a receipt will be sent to the donor and SOT will notify the MDSS President and Treasurer.

## Officers

### President

Jon Cammack

### Past- President

Ron Brown

### Vice President

Greg Erexson

### Vice President-Elect

Alan Hood

### Treasurer/Secretary

Taylor Builee

### Councilors

Kelly Coleman

Kavita George

Ron Brown

### Student

### Representative

Forrest Jessop

### Post-Doctoral Representative

Amber Nagy

### MDSS Website

Alan Hood

### Newsletter Editor

Sharmilee Sawant

***Dues Reminder – Please Keep Your Membership Current!***

# MDSS Awards

The MDSS Program and Awards Committee has continued to develop and promote different distinctions to be presented each year at the SOT Annual Meetings. The Executive Committee would like to thank the Awards Committee for reviewing the applications and selecting the winners- Jon Cammack, Greg Erexson, Kelly Coleman, Rich Hutchinson, Forrest Jessop and Taylor Builee

## *Congratulations to the 2013 Award Winners*

### *Medical Device SS Best Overall Abstract Award*

Ron Brown, Harshini Dinesdura, Jennifer Goode, Molly Ghosh, US  
FDA

*“Evaluation of sample preparation methods in the ISO 10993-12  
standard: Implications for toxicity testing of medical devices”*



## **Medical Device Student Travel Award**

Mo Dan, University of Kentucky

**“Superparamagnetic iron oxide loaded cross-linked nanoassemblies improve tumor accumulation and magnetic resonance imaging *in vivo*”**



### **Activities/Events Sponsored by the Medical Device Specialty Section at the Society of Toxicology 52<sup>nd</sup> Annual Meeting, San Antonio**

March 11, 2013:

- Poster Session 9:30-12:30pm @ Board #357 – 366
- Meet the Leaders Session 3-4pm @ ToxExchange Pavilion
- Social Hour/Networking 6:30-8 pm @ Guadalajara Grill Restaurant

March 12, 2013

EC brainstorming 2014 Conference Planning meeting 4-5pm @ Achiote Restaurant

March 13, 2013:

- Luncheon Reception and Awards Ceremony 12-1:30 pm, @ Conference Center Meeting room

March 14, 2013:

- Ocular Toxicity Specialty Section co-sponsored workshop, 9-11:45am @ Conference Center R207 “Ocular Medical Devices and Ocular Drug Delivery Systems: Challenges and Opportunities”

## 2013 MDSS Poster Presentations at the Annual Meeting, San Antonio

- By Alan Hood

MDSS posters kicked off the meeting this year. The well-attended poster session is testament to the excellent scientific work by MDSS members. MDSS members applied numerous toxicological scientific principles and methods to conduct characterization, biocompatibility testing, and risk assessment of medical device materials.

Material characterization of medical devices includes exhaustive and leachable extraction. Moilanan *et al.* (#201) demonstrated the utility of methanol as an exaggerated solvent for many polymeric dental devices. Hsia *et al.* (#198) used acetone as an exaggerated solvent to maximize the extraction of four colorants from short-term blood contacting catheter device. Pryzgoda *et al.* (#203) performed exhaustive extraction (Soxhlet) with isopropanol and demonstrated potential bisphenol A (BPA) exposure from medical device grade polycarbonate is less than automotive and consumer grade polycarbonate. Cho *et al.* (#202) demonstrated repeated clinically relevant extractions are necessary to accurately determine the total leachable BPA from porous polysulfone membranes used in hemodialyzers and hemoconcentrators. Brown *et al.* (#200) reported rigorous extraction conditions (50% ethanol or acetone at 37°C for 24 hrs) to correctly differentiate between toxic and non-toxic materials.

MDSS members applied novel and standard biocompatibility tests to investigate the biocompatibility of original medical devices. Malek *et al.* (#199) demonstrated *in vitro* cytotoxicity test results (MEM and colony formation) are not predictive of *in vivo* irritation, sensitization, or systemic toxicity; and 84% agreement between MEM with serial dilution and colony formation test methods. Shirwaiker *et al.* (#197) used two human cell lines (human epidermal keratinocytes and human dermal fibroblasts) and demonstrated an *in vitro* non-toxic response of a novel prophylactic surface treatment system (silver ions released by low intensity direct electric current stimulation). Yoon *et al.* (#204) and Cho *et al.* (#205) found innovative polymer-based microelectrodes (silicone-based platinum, polyimide-based gold, and liquid crystal polymer-based gold) to be biocompatible in a 12 week rabbit implant and 13 week systemic toxicity studies.

In addition to toxicity testing, risk assessment of medical device materials is becoming an important step in the biocompatibility assessment process. Hsia *et al.* (#198) applied the threshold of toxicological concern (TTC) to demonstrate acceptable chemical safety risk for colorants extracted from a short-term blood contacting catheter. Pryzgoda *et al.* (#203) found the amount of BPA extracted from consumer, automotive, and medical device polycarbonate to be 58, 704, and 1,300 times less than food consumption US FDA allowable daily intake (ADI) and EU tolerable daily intake (TDI) values. Nascarella *et al.* (#206) assessed potential patient exposure to copper (up to 219 µg Cu/patient procedure) from an ingestible medical device to be well below the Institute of Medicine (IOM) acceptable daily intake value (10 mg/day) for the general population, and applied a novel software approach that indicated the ingestible medical device would not elicit a cytotoxic response.

# Ocular Medical Devices and Ocular Drug Delivery Systems: Challenges and Opportunities at the Annual Meeting, San Antonio

- *By Molly Ghosh*

A Workshop entitled, “Ocular Medical Devices and Ocular Drug Delivery Systems”, that was co-sponsored by the Ocular Toxicology Specialty Section and the Medical Device Specialty Section was held during the morning of March 14, 2013 to an audience of approximately 100 attendees. Since the eye is a unique organ that is composed of many different structures, there were diverse topics focused on the therapeutic, safety and regulatory challenges of developing ocular medical devices and drug delivery systems. Dr. Chandramallika (Molly) Ghosh from the Office of Device Evaluation, Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA) presented a seminar entitled “Regulatory considerations in ocular medical device development.” Ocular medical devices encompass a wide variety of products including solid devices (such as intraocular lenses, surgical instruments and contact lenses) and devices that are liquid-based (such as viscoelastics and contact lens solutions). Dr. Ghosh provided an overview of the regulatory pathways for marketing ocular medical devices in the United States and discussed the premarket assessment process.

## Membership Update

-*By Kelly Coleman (Chair)*

**Demographics:** The MDSS was formed in 2009 with 51 founding members. As of June 2013 MDSS membership had grown to 126 active and 35 inactive members. Our members come from industry, government, consulting, and academia. Educational backgrounds range from BS degrees to those with multiple doctorates and MBAs.

**Recruitment:** Our goal now is to have 150 members by 2014. To diversify our ranks, the Membership Committee would like to continue our focus on recruiting student, academic, and international members. To that end we would like each of you to ask any of your friends or colleagues who might be interested to consider joining the MDSS. Also, if you have any recruitment suggestions, please let us know, we’re interested in your ideas.

## MDSS Website Updates

The MDSS community is invited to submit medical device toxicology job/career positions to MDSS leadership team for posting on the MDSS website. Submissions should be sent to Alan Hood, [hooda@bsci.com](mailto:hooda@bsci.com) and include job title, brief description, contact name/phone/email, open/close date.

## NEWS

### *Abstracts are Requested for the MDSS Poster Session*

- *By Ron Brown*

Please consider submitting an abstract for the MDSS Poster Session at the SOT Annual Meeting in Phoenix. Presenting a poster at the Annual Meeting is a great way to share your work with other medical device toxicologists and to get feedback from colleagues. Over the past two years, the poster session has been very well attended and has seen a number of excellent posters with a medical device focus, including ones on development of improved biocompatibility test methods, characterization of the biological response to biomaterials, and quantification of the exposure of patients to compounds released from device materials. Posters have also been submitted on non-lab projects, including ones involving computational toxicology modeling and the development and application of new risk assessment approaches. All of these applied topics are appropriate for the poster session along with basic science work that provides a scientific basis for improved decision making in medical device toxicology. Also keep in mind that abstracts with a medical device focus are eligible to receive the MDSS Best Overall Poster Award (separate application process). The SOT abstract submission site opens on August 15 and the deadline for abstract submission is October 7, 2013. When you submit your abstract, please remember to list “medical devices” as a keyword, so the abstract can be placed more easily into the MDSS poster session.

### *Medical Device Toxicologist Elected as SOT Vice President Elect*

- *By Ron Brown*

The MDSS is very proud to announce that a medical device toxicologist and member of our specialty section, Dr. Peter Goering, has been elected by the SOT membership to serve as Vice President Elect for 2013-2014. He will assume the SOT President position during the 2015-2016 term. Peter is currently a research toxicologist and leader of the Laboratory of Toxicology and Biocompatibility at the FDA Center for Devices and Radiological Health. He earned his PhD from the Kansas University Medical Center, and did a postdoctoral fellowship at the NIEHS, RTP, North Carolina, focusing on the toxicology of metals and metal defense mechanisms. At the FDA, his research interests include nanotoxicology, evaluating liver and kidney toxic injury, elucidating new biomarkers of toxicity, and understanding mechanisms of metal toxicity. Dr. Goering is a Diplomate of the American Board of Toxicology and was named a Fellow of Academy of Toxicological Sciences. In addition to being one of the founding members of the MDSS, Peter has served as President of the National Capital Area Chapter regional chapter, President and Councilor of the Metals Specialty Section, and a member of various SOT-level committees. Please join us in welcoming our fellow specialty section member as the new Vice President Elect and future SOT President.

# NEWS

## *ISO/AAMI TC 194 Pavia, Italy Meeting Update*

- *By Jon Cammack*

From April 21-26, 2013, ISO/AAMI Technical Committee (TC) 194 held a full meeting in Pavia, Italy. 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 met in Pavia



*Breaking  
News*

ISO/TC 194 / WG2 (Degradation aspects related to biological testing)

ISO/TC 194 / WG4 (Clinical investigations of medical devices in humans)

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 / WG13 (Toxicokinetic study)

ISO/TC 194 / WG14 (Material Characterization)

ISO/TC 194 / WG15 (Strategic approach to biological assessment)

ISO/TC 194 / WG17 (Nanomaterials)

ISO/TC 194 Plenary Meeting

**MDSS Sponsored  
CE Sunrise Course  
on Combination  
Products was  
Accepted for 2014  
SOT Annual  
Meeting.**

**We hope to see you  
all at the CE  
Sunrise Course!**

There were no controversial proposals or resolutions. Of note, WG 11 proposed, and ISO/TC 194 resolved to initiate, a New Work Item Proposal (NWIP) for a Technical Specification on the development of a Threshold of Toxicological Concern (TTC) approach for compounds released from medical devices. Additionally, ISO/TC 194 resolved to inform members about the new FDA Draft Guidance on the use of ISO 10993-1 "Biological evaluation of medical devices — Part 1: Evaluation and testing" and be aware that comments should be sent to FDA by 2013-07-22 at the latest.



# **THANK YOU SPONSORS**

The MDSS treasury would like to acknowledge and thank our corporate and personal donors who have provided financial contributions in 2013.

**Dr. William Wustenberg**

**Medtronic's Corporate Technology**

**MedImmune, LLC**

**Ethicon, Inc.**

**3M**

We would also like to thank those who are intending and have planned contributions to the Specialty Section.

**Boston Scientific**

**Kimberly-Clark Corporation**

**AbbVie**

**THANK YOU !!!!**

# Job Opportunities



## Senior Toxicologist - Consumer Products

Our services have been engaged by a large manufacturer of consumer products. The company is looking to expand their product safety program by seeking an experienced toxicologist. A graduate degree with five or more years of experience is required. DABT certification is preferred. For this specific opening, someone with medical device materials or related product experience is sought

Principal responsibilities will include establishing and growing the company's ingredient and material safety and risk assessment processes, while working closely with regulatory colleagues to support safety assessment requirements globally. The position reports to a Toxicology Group Leader in a department of approximately fifteen scientists.

The position will work from the company's offices in the Southeast U.S.

Confidential information about this opportunity is available from Mr. Terry Leyden, President, The Leyden Group, Inc. Phone (303) 865-2897. E-mail: [terry@leydengroup.com](mailto:terry@leydengroup.com)