



New President’s Message – Summer 2011

With the 2011 Annual Meeting only four months behind us, plans for the 2012 Annual Meeting are already under way by our program and awards committee. Two proposals were submitted and one was accepted. Congratulations to the entire committee, and special thanks to Committee Chair Ron Brown for overseeing this process.

Members of the Specialty Section are hard at work on several other initiatives:

- A new MDSS committee has been formed to address the needs of graduate students and postdoctoral scientists involved with medical device toxicology. We are very excited to see the involvement of these talented students and scientists in the specialty section.
- We are planning to develop a consensus statement or white paper on qualifications for a “Medical Device Toxicologist,” and have received extremely positive feedback on the need for this.
- We are also identifying webinar speakers that are of interest to the specialty section.
- Finally, we have committed to using ToXchange extensively to communicate this year.

The MDSS reception is scheduled for the evening of Tuesday, March 13, 2012, and I hope to see you there. If you are planning to submit a poster, please remember to include “medical device” as a keyword.

Lastly, I want to thank all of the specialty section members who volunteer their time and energy throughout the year. The Executive Committee and appointed committee members make this all possible.

I look forward to the next few months leading up to the 2012 SOT Annual Meeting.

As always, don’t hesitate to contact me or any of the Executive Committee members with your ideas, suggestions, and feedback.

HAVE NEW IDEAS FOR THE MDSS? SHARE NOW, AND WE’LL BE LOOKING FOR YOU AT OUR MDSS MEETING IN SAN FRANCISCO!

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Treasury Update

Financial Summary

From June 2010 – May 2011, our Section had almost \$1,000 income from dues and registrations, up from the previous year; however, we incurred \$3,500 in expenses. Most was due to the annual meeting and new awards that were granted at the 2011 Annual Meeting. Importantly, we provided three categories of awards showcasing the success of the MDSS scientists and students members. We're encouraging more postdoctoral fellows and graduate students to join the MDSS, but the first Specialty Section membership for Student and Post-doc members is at no charge, so no dues are collected unless they already belong to one or more Sections.



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.

Balance – January 2011	\$10,911
Income - Corporate Sponsors	<u>0</u>
Total	\$ 10,911
Expenses - Travel Awards (2)	(1000)
Plaques (4)	(237)
Executive Meetings	(170)
Annual Meeting Expenses – 2011	<u>(2,150)</u>
Total	(\$3,558)
Balance – May 2011	\$ 8,332

We are also thankful for the individual contributions from our corporate donations, and we encourage all to seek out donations from their companies, with funds directed to the MDSS if they choose. We also ask members to look into employer matching programs for individual donations to the MDSS.

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 individually and 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 relatively simple:

- 1) Request an invoice from SOT if desired through the membership office
- 2) Submit check written to the Society of Toxicology – Attention Medical Device Specialty Section
- 3) Email Ed Reverdy (MDSS Secretary/Treasurer) notice of your donation to ensure that the routing, acknowledgement, and posting are complete.
- 4) Funds may be submitted by check or credit card directly to the Society of Toxicology, but please include a note on the check or letter with the credit card payment indicating an MDSS donation for the payment to be processed correctly.

Contact Ed Reverdy about donations or any difficulties in contacting the SOT about your transactions. It is important to ensure that the money is directed to the MDSS and not the SOT general funds (if not specified properly at the time of payment / submission).

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

Recap of 2011 SOT Annual Meeting

The MDSS was very active at the 2011 Annual Meeting in Washington, DC. Activities included a Sunrise Continuing Education (CE) session on safety assessment of biodegradable materials given by John Fisher of the University of Maryland, a poster session on medical device toxicology chaired by MDSS President Lori Moilanen, and an informational session titled on application of the TTC concept to medical devices and combination drug-device products, -- not to mention our annual business meeting and awards ceremony.

Sunrise CE session

Despite the early hour, the Sunrise CE session sponsored by the MDSS was very well attended. Dr. John Fisher, leader of the Tissue Engineering and Biomaterials Laboratory at the University of Maryland, gave an interesting presentation titled, *Safety and Application of Biodegradable Materials for Tissue Engineering*. Dr. Fisher described the biodegradable materials that are commonly used in regenerative medicine, as well as some recently developed novel materials, and discussed the techniques to characterize the relationship between the physical properties of the materials and their tissue response. Since biodegradable materials are used in combination drug-device products, the course was of broad interest to scientists working in both the medical device and pharmaceutical fields.

Informational session: *The Application of the Threshold of Toxicological Concern Concept to the Preclinical Safety Assessment of Non-Pharmaceutical Medical Products, Including Medical Devices and Combination Drug-Device Products*

The MDSS sponsored and organized an informational session on the application of the Threshold of Toxicological Concern (TTC) concept for compounds released from non-pharmaceutical medical products, such as medical devices and combination drug-device products. The TTC approach can be used to estimate safe exposure levels for chemicals when experimentally obtained toxicological data are not available. Proposed TTC values are based on chemical structure and known safety data for structurally related chemicals and represent a low level of exposure with negligible risk to humans. In this session, Mitch Cheeseman from the FDA Center for Food Safety and Applied Nutrition (CFSAN) discussed the history of the TTC concept; Jon Cammack, now with The Science Cooperative, provided an overview of the ISO 10993-17 guidelines for setting tolerable exposure limits for compounds released from device materials (the approach to use when we do have toxicity data); Rich Hutchinson, J&J Ethicon, talked about application of the TTC concept to compounds released from medical devices (the approach to consider in the absence of relevant toxicity data), and Ron Brown from FDA's Center for Devices and Radiological Health discussed how computational modeling can be useful for implementation of the TTC approach.

Start considering topic submissions for medical device posters for SOT 2012. There were outstanding 2011 submissions and winners can be found on our MDSS website

HAVE NEW IDEAS? SHARE WITH MDSS EXECUTIVE COMMITTEE!

Awards

The MDSS was pleased to offer the following awards at the 2011 Annual Meeting:

Best Overall Abstract

Niranjan S. Goud and Edward E. Reverdy

Challenges in biocompatibility testing of medical devices.

Best Published Paper

James M. McKim, Jr., Don J. Keller III and Joel R. Gorski

A new in vitro method for identifying chemical sensitizers combining peptide binding with ARE/EpRE-mediated gene expression in human skin cells.

Student Travel Award

J. J. Kleinedler, LSU Health Science Center

Polyphenol-eluting stent coating, a novel approach for the prevention of restenosis with reduced side effects.

Congratulation to our 2011 award winners!

Planned MDSS Activities at the 2012 Annual meeting

We hope to see you at the 2012 Annual Meeting in San Francisco! The MDSS has endorsed a number of session proposals, and one has been tentatively accepted for the program, titled "Placing 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." Remember, the deadline for abstract submissions to SOT is October 3, 2011. If you are submitting a poster abstract on a topic related to medical device toxicology, please consider indicating on the submission form that you'd like it presented in the medical devices poster session.

It's not too early to start thinking about candidates for the awards offered by the specialty section at the 2012 Annual Meeting. The deadline for submission of the award nominations will be in the late January / early February timeframe (exact date will be announced). The awards and their requirements are listed below.

- **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 this award will be selected by a committee jointly appointed by the leadership of the Medical Device Specialty Section. The MDSS Student 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.
- **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.
- **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.

Visit our Web site
for more
information on the
MDSS:

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

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 88 members as of mid-July 2011. Our members come from industry, government, consulting, and academia. Educational backgrounds range from BS degrees to those with multiple doctorates and MBAs. Over half of MDSS's members are certified, with 9 having dual certifications, including 45 DABT, 4 RAC, 3 FATS, 2 DAVCP, 1 DACVPM, and 1 DABVT. SOT membership status includes 54 Full, 25 Associate, 5 Student, and 4 Full International members.

Recruitment: We're well on our way to achieving our goal of 100 members by 2012. To diversify our ranks, the Membership Committee has decided to focus on recruiting student, international, and academic members. As a first pass attempt, we're asking each of you to consider your friends and colleagues and ask any who might be interested to consider joining the MDSS. Other professional societies have successfully used this "Each One, Get One" approach to increase their membership. We hope it will work for us too. If not, we're open to other ideas. New members will be listed in future newsletters.

ISO/AAMI TC 194 2012 Meeting Update

In Spring 2012, ISO/AAMI Technical Committee (TC) 194 will hold a full meeting 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 last full ISO TC 194 meeting was Spring 2010 in Berlin, although several working groups (WGs) meet in Milan earlier this year for an interim meeting. The Milan meeting was hosted by Medtronic at its corporate headquarters in Milan, with Dr. Mike Wolf of Medtronic as the primary organizer for the interim meeting. The US has not hosted a full ISO TC 194 meeting since 2006, when the meeting was held in Chicago.

The final dates for the 2012 meeting have not been set, but organizers are targeting mid- to late April or early May. Currently, most working groups plan to meet, and AAMI is coordinating a meeting location as well as blocks of hotel rooms in, and/or near, the meeting location. Final meeting dates and logistics will be communicated to the MDSS as soon as the information is available.

AAMI Sponsored Biocompatibility Fall Webinar

On November 15, 2011, AAMI is sponsoring a webinar on ISO 10993 evaluation of medical devices. AAMI members that do not regularly participate in the standards process, but use the standards in some aspect of their professional roles, requested the webinar. Additionally, a number of members have expressed interest in a better understanding of ISO 10993 Part 17, Establishment of Allowable Limits for Leachable Substances. Based on these requests and the expressed needs, Dr. Molly Ghosh of FDA, and Dr. Jon Cammack of The Science Cooperative, LLC, have agreed to lead the Webinar.

- Dr. Ghosh will provide an overview of the non-clinical safety assessment of medical devices, including the testing strategy, sample preparation, and test methods recommended in ISO 10993 standards.
- Dr. Cammack will provide an overview of 10993 Part 17, including a practical example of how to apply the standard and the emerging concept of the Threshold of Toxicological Concern (TTC) in medical devices.

WILL YOUR EMPLOYER MATCH YOUR CONTRIBUTION TO THE MDSS?

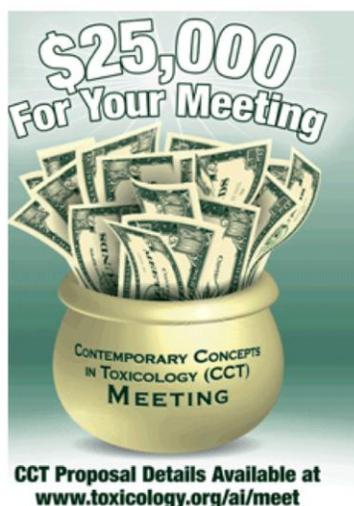
ISO10993 standards are available through country accredited organizations. In the U.S., it's AAMI.

Relevant and Important MDSS News

World Biomaterials Meeting

The 9th World Biomaterials Congress (WBC) will be held in Chengdu, China, June 1st-5th, 2012, <http://www.wbc2012.com/>

SOT CCT Meetings Eligible for Seed Money and Profit Sharing



SOT Sponsors two types of meetings outside of the SOT Annual Meeting: Contemporary Concepts in Toxicology (CCT) and Non-SOT meetings. CCT meetings are one- to two-day focused, open registration, scientific meetings in contemporary and rapidly progressing areas of toxicological sciences. Non-SOT meetings are sponsored by other not-for-profit organizations and SOT will either endorse or provide sponsorship money to toxicology-related meetings.

The Society will underwrite all the liabilities of the CCT meeting with the expectation that the meeting will at least break even financially. The goal of providing \$25,000 seed funds is to stimulate the creation of CCT meeting proposals.

For more information about CCT meetings, please visit the [SOT Web site](#).

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