

MDSS FALL NEWSLETTER

President's Message



This year has been very active and productive for the Medical Device Specialty Section. A name change to our specialty section was proposed early in the year and the SOT Council officially changed our name this past July to "Medical Device and Combination Product Specialty Section" or MDCPSS.

The MDCPSS Executive Committee has been busy in 2014 with regular monthly teleconferences. At the annual SOT in March 2014 in Phoenix, AZ, we had our business meeting and reception with approximately 80 people in attendance. Dr. Jon Cammack called the meeting to order at 6 PM on Monday March 24, 2014 at the Sheraton Phoenix Hotel. The Business Meeting Speakers were Jon Cammack (chair); Greg Erexson (MDCPSS 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).

I would like to welcome each of our newly-elected MDCPSS executive committee members, Jim Kleinedler (Secretary/Treasurer), Barbara Henry (Councilor) and Kevin Trout (Graduate Student Leadership Committee Representative).

Below are the details of the 2014 Medical Device Specialty Section Awards that were awarded to the recipients at SOT in March.

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".

In addition, a service award (engraved plaque) was present to Taylor Builee for her years of excellent and dedicated service to our Specialty Section.

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 MDCPSS 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

Thus far, we have had two Webinars this year. Webinar 1: Thomas Hartung, Johns Hopkins, gave a webinar on Friday, May 24, 2014 from 12-1 PM entitled, "Medical Device Testing In Vitro-Pyrogenicity Testing and Beyond."

Webinar 2: The Medical Device & Combination Product Specialty Section (MDCPSS) hosted a lunchtime webinar presentation by Ron Brown on the topic "Use of

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President's Message (continued)

Computational Toxicology for the Biological Evaluation of Medical Devices" on June 23, 2014 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. Ron 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).

A third webinar was September 24, 2014 at 12 noon EDT entitled "Quantitative Risk Assessment of the Genotoxicity and Tumorigenicity of CoCr-Containing Hip Implants" by Dr. Whitney Christian of Cardno ChemRisk and well attended with about 50 participants.

We are very excited that SOT approved the MDCPSS-submitted proposal for our full (approximately 3 hour) Continuing Education (CE) course on Sunday March 22, 2015 starting at 8:15 AM. The CE course is entitled "Toxicology and Regulatory Considerations for Combination Products (CE Basic).

Please check the MDCPSS link on the SOT website for further information and updates. I look forward to seeing you in San Diego in March 2015!!

Greg Erexson, PhD
MDCPSS President

News

SOT Accepts TWO MDCPSS Sponsored CE Proposals for 2015 Meeting in San Diego!

AM08 "Toxicology and Regulatory Considerations for Combination Products - This course will provide in-depth detail on the evolving regulatory processes in developing a successful preclinical evaluation program. 

PM08 "Advances in Safety Assessment of Medical Devices" (Basic) - The aim of this course is to provide an outline of the various in vitro, in vivo, and in silico methodologies for the safety assessment of medical devices and to discuss how risk assessment approaches can be used in the biological evaluation process for medical devices. 

SOT Announces Match For Endowment Contributions

The Society announced that it will provide a 100% match for member contributions to the SOT Endowment Fund.

2014-2015 SOT Presidents Message

Norbert E. Kaminski, Ph.D. released the annual Presidents Message, click to read more. 

OFFICERS (2014-2015)

President

Gregory L. Erexson

Past- President

Jon Cammack

Vice President

Alan Hood

Vice President-Elect

Kelly Coleman

Treasurer/Secretary

Jim Kleinedler

Councilors

Kavita George

Barbara Henry

Student Representative

Kevin Trout

Post-Doctoral Rep

TBA

MDSS Website

MDCPSS EC

Newsletter Editors

Alan Hood

Greg Erexson

MDCPSS EC



Mark Your Calendar!
March 22-26, 2015,
San Diego, California



It's been nearly six months since the Phoenix meeting, and before we know it, the San Diego meeting will be upon us. Now is the time to plan for the next SOT Annual meeting.

Important Dates to Remember!

October 7, 2014 



October 9, 2014 



January 31, 2015 (early bird) 



February 19, 2015 



February 28, 2015 (regular) 



Treasury Update

2014 MDCPSS Sponsors

WL Gore & Associates
NAMSA
Medtronic
Alternet
MedImmune
Kelly Coleman

MDCPSS Financial Information 2014-2015

By James Kleindler: MDCPSS had a successful year in member registrations and net assets, with modest expenses. Income from annual meeting registration and completed donations totaled \$3,633. Thanks to a strong year of support from sponsors, MDSS net assets increased throughout the year.

The MDCPSS Executive Committee thanks all this years sponsors for helping to make MDCPSS 2014 activities possible. Please consider making a tax-deductible donation of any amount to support MDCPSS.

General Fund 2014-2015

Month	Net Assets
January	\$16,289
February	\$16,289
March	\$13,495
April	\$13,495
May	\$13,495
June	\$13,495

MDCPSS accepts donations by check or credit card. Checks can be sent to SOTHQ, and other forms of payment may be completed by email or by phone directed to Raul A. Suarez (raul@toxicology.org) at SOT Head Quarters (703) 438-3115 x1461. All donations should have the donor's name, contact information, donation amount and payment details. This information should be sent to the Medical Device & Combination Products 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 MDCPSS President and Treasurer.

Events

Progress Made on Tox21 SLC Webinar: Presented by Daniel Krewski

On October 1, 2014, the Scientific Liaison Coalition (SLC) will host a webinar, Progress Made on Tox21: A Framework for the Next Generation of Risk Science, presented by Daniel Krewski. The webinar will be held from 12:00 noon to 1:30 pm ET USA. You will need to register for this webinar. Space is limited.

September 24 MDCPSS Webinar

Quantitative Risk Assessment of the Genotoxicity and Tumorigenicity of CoCr-Containing Hip Implants - Whitney Christian, PhD, CARDNO CHEMRSK

Cobalt-chromium (CoCr) alloys have long been used in metal-containing hip implants. Like all implant materials, CoCr alloys undergo some degree of wear & corrosion in vivo, and as a result implant patients experience blood & tissue Co & Cr(III) concentrations higher than background levels associated with dietary intake. Although epidemiology studies do not indicate an increased incidence of cancer in patients with hip implants, questions continue to be raised about the potential cancer risk posed by CoCr-containing implants. To address these concerns, the scientific literature investigating the genotoxic and tumorigenic effects of Co particles & ions, Cr particles & ions, CoCr alloy particles, as well as CoCr alloy implants was gathered, and NOAEL/LOAEL values were compared with body burdens of Co/Cr particles/ions that were calculated to exist in systemic tissues of hip implant patients under normal & excessive wear conditions. This presentation will illustrate the quantitative methods used to evaluate the weight-of-evidence regarding a causative relationship between CoCr-containing hip implants and increased cancer risk to determine whether the existing toxicology data support epidemiological findings.

Membership

The MDCP specialty section currently has 149 members, which is a 16% increase from last winter. Our members work for a wide variety of employers, are well-educated and professionally certified. Membership dues for graduate students are now free!

Use of Computational Toxicology for the Biological Evaluation of Medical Devices

by Ron Brown, FDA

An MDCPSS Webinar Presentation

June 23, 2014

MDCPSS Executive Committee thanks Ron Brown for presenting one of the highest attended webinars in MDCPSS history. A total of 191 active lines listened to Ron's presentation. The total number of attendees is expected to have exceeded 200.

Abstract

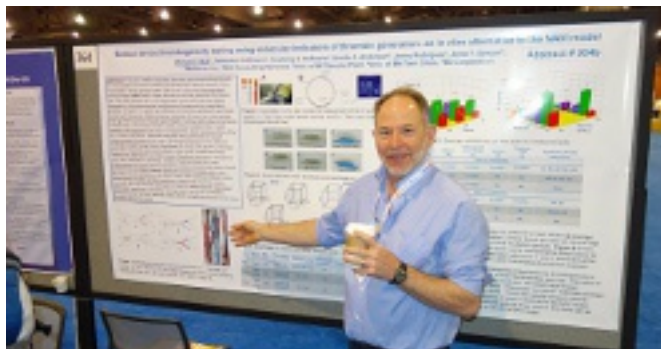
The biological safety of medical devices is typically assessed by conducting biocompatibility testing of an extract of the device or the device itself; however, there is growing interest in an alternate approach that involves characterizing the chemical composition of the device extract and conducting a risk assessment on the compounds identified in the extract. One limitation to the practical implementation of this chemical characterization/risk assessment approach is the lack of toxicity data for many compounds released from device materials. To address this need, computational toxicology models, such as Quantitative Structure-Activity Relationship (QSAR) models, are being increasingly used to predict the toxicity or carcinogenicity of compounds based on their chemical structure. Efforts are underway to validate the predictive ability of QSAR models for compounds that are known to be released from device materials. This webinar will describe the computational modeling approaches available to predict the toxicity, mutagenicity, and carcinogenicity of compounds released from device materials and will explore ways to use model-derived predictions as part of the biological evaluation of a device, notably, to determine when certain types of testing may not be necessary, download [webinar Recording](#) or [Slides](#).

FDA Workshop on Methods for Thrombogenicity Testing of Blood-contacting Medical Devices

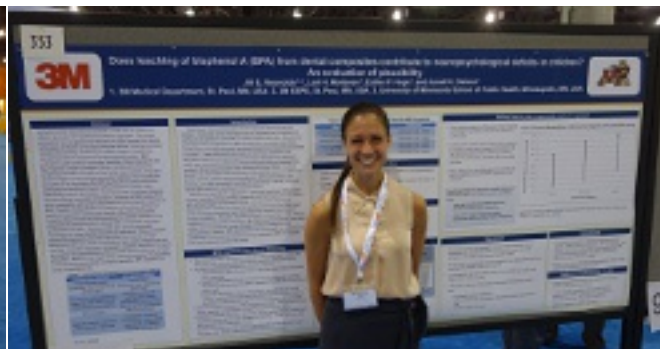
By James Kleindler: On April 14, 2014, the FDA Center for Devices and Radiological Health organized a workshop at the White Oak campus in Silver Spring, MD on methods used for thrombogenicity testing. This workshop brought together academia, industry professionals, and FDA regulators to discuss the advantages, limitations, and optimization of both in vivo and in vitro thrombogenicity test methods, and identified alternative in vitro tests that show promising clinical relevance. Access to the agenda, complete webcast, and presented slides can be accessed at [FDAWorkshops/Conferences](#).

2014 MDCPSS Posters Revisited

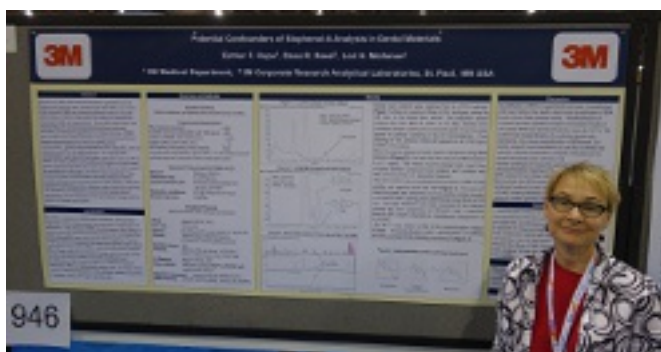
Photos provided by Kelly Coleman



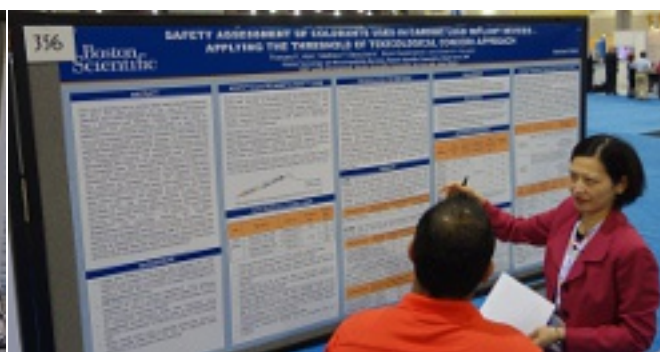
Michael Wolf



Jill Reynolds



Esther Hope



Frances Hsia



Nichole Soucy



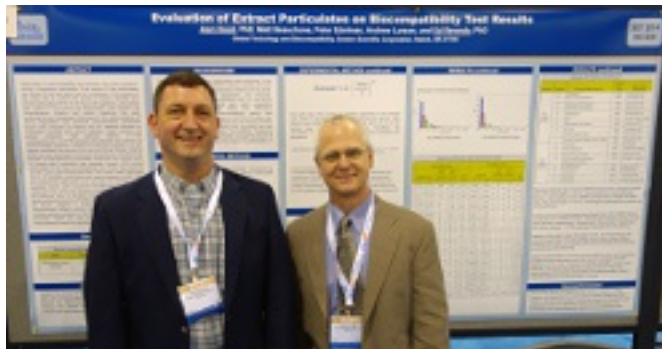
Randy White



Colleen Nycz and Anita Sawyer

2014 MDCPSS Posters Revisited

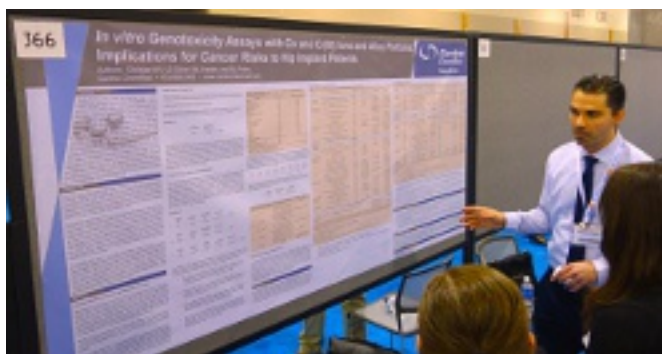
Photos provided by Kelly Coleman



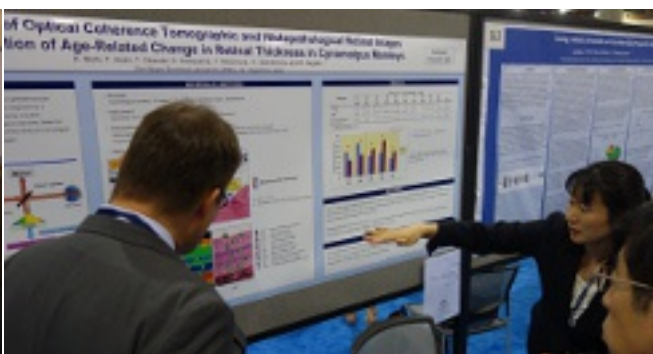
Ed Reverdy and Alan Hood



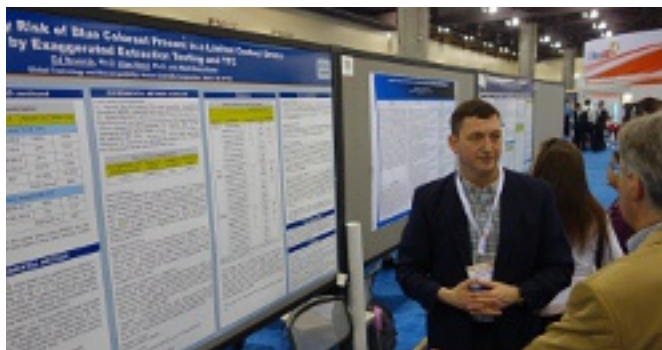
Amy Clippinger and Donald Keller



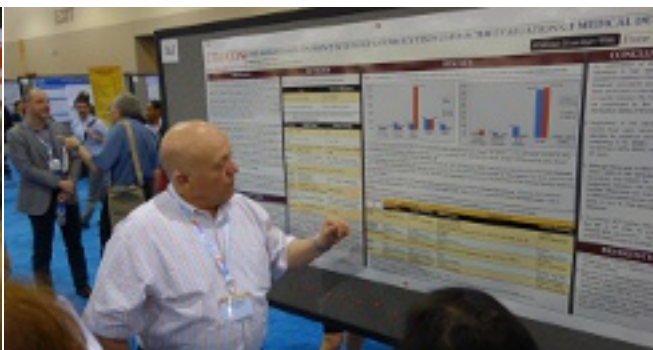
Whitney Christian



K. Nishi



Ed Reverdy



Bob Pryzgoda

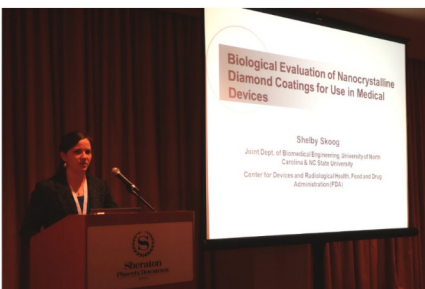


Kelly Coleman

Remembering 2014 MDCPSS Reception

A few photos of awardees and presentors from this years annual meeting in Phoenix, Arizona.

Photos provided by Kelly Coleman



Top Left: Greg Erexson, Taylor Builee, Jon Cammack

Top Center: Jon Cammack

Top Right: Jon Cammack, Anita Sawyer, Michael Wolf, Greg Erexson

Middle Left: Jon Cammack, Forrest Jessop, Greg Erexson

Middle Center: Greg Erexson

Middle Right: Jon Cammack, Kelly Coleman, Greg Erexson

Bottom Left: Michael Wolf, Kelly Coleman

Bottom Center: Shelby Skoog

Bottom Right: Jon Cammack, Shelby Skoog, Greg Erexson

Job Opportunities and Internships

Technical Director STP

WuXi AppTec, St Paul, MN (USA)

Position Description

The Technical Director is responsible for organizing, planning and performing duties related to genotoxicology assays in safety assessments. Daily activities include responsibility for the execution of genotoxicology assays, client interaction regarding the performance of genotoxicology, performing research for new assay designs and hands-on assay development work. Once studies have been validated, this person is responsible for transferring the assay into regular operational use. This will include training of appropriate operations personnel and development of documents.



More Information online

Head Of Preclinical Safety/Toxicology-Medical/Surgical Devices

Canton Technologies, LLC, Clearwater, FL (USA)

Position Description

Outstanding opportunity for a career-minded, Scientific, (R&D), professional who is seeking to take that next step in his/her career with a World Class, growing Medical Device Company. Company is an established and is one of the world's leading specialty medical device companies with a significant pipeline of healthcare products. Company is a global \$9+ billion, world class organization. Company offers a generous benefits package, including excellent 401(k), Medical, Dental, Vision, Life and disability coverage, fitness center and so much more! This is an IMMEDIATE Full-time, direct employee, position.



More Information online

MDCPSS Mission

The objectives of the Medical Device & Combination Products Specialty Section are to:

- Provide an international focus group for toxicologists working in the area of medical devices and combination products including a device component.
- Promote the development of new experimental methods for the evaluation of medical devices.
- Sponsor scientific and educational programs that emphasize current developments and issues in the toxicological evaluation of medical devices.
- Promote proactive communication and interactions among toxicologists in government regulatory agencies, regulated industry, and academia regarding current issues in medical device toxicology.
- Stimulate interest in medical device safety as a career path for new toxicologists.