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PRESIDENT'S MESSAGE

Dear MDCPSS Members,

Greetings and I hope everyone is enjoying a wonderful fall/early winter! I am grateful to serve as your 2022/2023 MDCPSS President with our new Executive Committee members: Jan Oberdoerster (Past President), Mansi Krishan (Vice President), Xiaoling (Sharlene) Dai (Vice President-Elect), Hiroimi Hosako (Secretary/Treasurer), Mercedes Salvador-Silva (Councilor), Bhavesh Ahir (Councilor), and Deniz Jade Emul (Graduate Student Representative). I also want to sincerely thank the following previous MDCPSS Executive Committee members who provided significant contributions to the activities of MDCPSS during their terms: Whitney Christian (Past President), Megan Hahn (Secretary/Treasurer), Xiaoling (Sharlene) Dai (Councilor), Kevin Trout (Postdoctoral Representative), and Christopher Pohl (Graduate Student Representative). Thank you for your service on the MDCPSS Executive Committee!

The MDCPSS Executive Committee is dedicated to continuing to improve MDCPSS through focus on growing our membership, providing valuable opportunities for mentoring, and sharing emerging toxicological science via webinars, membership communications, and SOT Annual Meeting activities.

MDCPSS-sponsored webinars in 2022 include:

- Nitrosamines: Evolving Regulatory Landscape and its Potential Impact on Medical Devices and Combination Products
- Integrating Mass Spectrometry Non-Targeted Analysis and Computational Toxicology to Characterize Chemicals

I want to thank Mansi and Jan for their dedication for organizing and moderating the webinars, as well as our speakers for their scientific contributions. We are coordinating additional webinars for early 2023 so please continue to check the MDCPSS website and e-Blasts for updates and additional information.

In this edition of the MDCPSS newsletter, we highlight the 2022 MDCPSS webinars, SOT 2022 Annual Meeting activities and MDCPSS award winners, member accomplishments, MDCPSS updates, and information for the upcoming SOT 2023 Annual Meeting. I want to thank Sharlene for organizing the newsletter as well as everyone who provided contributions.

The MDCPSS EC will be providing multiple communications in the upcoming months regarding webinars, award deadlines, and SOT Annual Meeting activities. We hope you participate in these upcoming events!

Please feel free to contact me or other Executive Committee officers with ideas for programs, outreach, webinars, or suggestions for improvement.

I am looking forward to the upcoming 62nd Annual Meeting in Nashville, TN and hope to see you in person!
Happy holidays!

Sincerely,
Shelby Skoog, PhD
MDCPSS President
Shelby.Skoog@fda.hhs.gov



MDCPSS Webinars



MDCPSS and CTSS Webinar: Integrating Mass Spectrometry Non-Targeted Analysis and Computational Toxicology to Characterize Chemicals

Date and Time: June 30, 2022

Speaker:

Antony Williams, US-EPA, Center for Computational Toxicology and Exposure

Webinar Organizer:

Ron Brown, Risk Science Consortium

Moderators:

Jan Oberdoerster, MDCPSS Past President

Nigel Green, CTSS President

Abstract: As part of its mission the Center for Computational Toxicology and Exposure (CCTE) in the US EPA's Office of Research and Development delivers access to chemicals related data via freely accessible online Dashboards. The CompTox Chemicals Dashboard (available at <https://comptox.epa.gov/dashboard>) provides access to >900,000 chemicals and associated data including experimental and predicted property data, in vivo hazard data, in vitro bioactivity data, exposure data, and various other data types. The application provides a set of flexible searches allowing for search, visualization, and downloads of the data to the desktop for further interrogation. The underlying chemical database offers a strong underpinning for structure identification using mass spectrometry. Cheminformatics approaches provide mass and formula-based searching, metadata ranking of tentative candidates and hazard profiling of the resulting chemicals. This presentation will provide an overview of the Dashboard with a focus on how the application could be used for the identification of leachables and extractables. This presentation will also introduce a number of proof-of-concept modules in development including a hazard module which allows profiling of chemicals based on toxicity types. This abstract does not necessarily represent the views or policies of the US Environmental Protection Agency.

This webinar slides and recording are available on the MDCPSS website:

<http://www.toxicology.org/groups/ss/MDCPSS/pastevents.asp>

SOT Annual Meetings



2022 SOT Annual Meeting Highlights

The following Medical Device and Combination Product Specialty Section events were held at the **2022 SOT Annual Meeting & ToxExpo**:

- **Medical Devices Poster Session** (Monday, March 28, 2022)
21 abstracts
- **MDCPSS Mentoring Event** (Monday, March 28, 2022)
Summary: Although this mentoring event provided opportunities for anyone to meet with medical device and combination product toxicologists and to share career insights, it was primarily held for undergraduate students, graduate students, postdoctoral scholars, and early-career scientists to network with expert mentors from diverse job sectors to learn more about the variety of potential career paths and skills required to advance as medical device and combination product toxicologists. A small, social-friendly environment provided ample opportunity for those who participated to learn career insights and network.
- **MDCPSS Reception** (Monday, March 28, 2022)
100+ Attendees
Summary: The reception included a presentation overview of the 2022 SOT Annual Meeting MDCPSS activities, MDCPSS officers, subcommittees, treasurer's report, membership report, 2021-2022 webinars, MDCPSS award winners, and upcoming opportunities.
- **Roundtable Session** (endorsed by MDCPSS - Tuesday, March 29, 2022)
“Harmonization of Approaches for the Biological Safety Assessment of Medical Devices and Pharmaceutical Packaging: Implications for Drug-Device Combination Products”

Chair:

Ron Brown, Risk Science Consortium LLC

Co-Chair:

Cheryl Stults, C&M Technical Consulting LLC

Abstract: Approaches used for the biological safety assessment of medical devices and pharmaceutical packaging/delivery systems share a number of common elements but differ in the pathways by which the approaches have been developed. Differing regulatory viewpoints on how to evaluate the toxicological safety of drug packaging/delivery systems and medical devices have

led to differences in the way these products are evaluated for safety. The lack of uniformity in methods for the safety evaluation of drug packaging and devices has resulted in confusion over regulatory expectations for the safety assessment of drug-device combination products. For example, overlapping requirements for material safety result when the drug container is the delivery device. With respect to assessment of biocompatibility, application of USP and ISO 10993-5 to the same assembly that functions both as a container closure and as a device (e.g., prefilled syringe or metered dose inhaler) results in redundant testing due to nonalignment of USP and ISO standards for cytotoxicity. With respect to toxicity assessment, emphasis is placed on chemical characterization with toxicological assessment for both packaging (USP, 1663, 1664, 1664.1) and devices (ISO 10993-1 and 10993-18). The recent update to ISO 10993-18 included the concept of an Analytical Evaluation Threshold (AET) for extractables developed from a dose-based threshold per ISO TS 21726, which is inconsistent with the PQRI approach. Therefore, the design of appropriate extractables studies for a combination product where the device is also packaging presents some unique challenges because the threshold concepts for a device are different from those for packaging. Additionally, differences exist in methods to evaluate potential patient risk following exposure to E&L compounds. The process for developing Tolerable Intake (TI) values, as described in ISO 10993-17, differs from that for the derivation of Permissible Daily Exposure (PDE) values for compounds released from packaging. In the absence of any guidance or standard, principles from ICH Q3C or ICH M7 have been applied to develop PDE values for packaging leachables. Also, differences exist in the way that nonclinical studies are used to evaluate the safety of devices or drug delivery systems undergoing clinical trials. This session will identify the similarities and differences in methods to conduct safety assessments of medical devices and pharmaceutical packaging/delivery systems and will propose harmonized approaches that may be useful for the safety assessment of drug-device or biologic-device combination products.

Congratulations to our 2022 MDCPSS Award Winners!!!



Best Abstract Award

Ju Young Park and Alan Hood

A Step Forward in the Preclinical Safety Assessment of Medical Devices: Evaluation Methods of Reproductive and Developmental Toxicity Endpoints



Best Published Paper Award

Bradford D. Bagley, Jordan N. Smith, and Justin G. Teegarden

Risk Assessment of Predicted Serum Concentrations of Bisphenol A in Children and Adults Following Treatment with Dental Composite Restoratives, Dental Sealants, or Orthodontic Adhesives using Physiologically Based Pharmacokinetic Modeling (Regulatory Toxicology and Pharmacology) <https://doi.org/10.1016/j.yrtph.2020.104839>



Best Poster Award

Rachel Chang, Alexander Alverson, and Joel Cohen

A Rubric for Identifying Potentially Genotoxic Polycyclic Amines and Derivation of a Chemical Class-Specific TTC



Malek Toxicology Delaware LLC Student Excellence Award

Yizhong Liu
Dynamic Evaluation of Vascular Endothelial Cell Toxicity of Silver Nanoparticles: Flow Rate, Concentration, and Size-Dependent Cellular Uptake, Inflammation, and Cytotoxicity

Executive Committee Service Awards



Past President – Whitney Christian

Secretary/Treasurer – Megan Hahn

Councilor – Xiaoling (Sharlene) Dai

Postdoctoral Representative – Kevin Trout

Graduate Student Representative - Christopher Pohl



The **SOT 62nd Annual Meeting and ToxExpo** will be held in-person on March 19-23, 2023 in Nashville, TN and will feature more than 70 Featured and Scientific Sessions, 2,000 presentations, 250 exhibitors, and 5,000 attendees. For more information, please see the 2023 [SOT Primary Program](#), the SOT [Online Planner](#), and the [SOT Annual Meeting website](#).

2023 MDCPSS Awards and Application Deadlines

Best Overall Abstract Award – January 6, 2023

Best Poster Award – Reviewed at SOT Annual Meeting during Medical Device and Combination Product Poster Session

Best Published Paper Award – January 6, 2023

Malek Toxicology Delaware LLC Student Excellence Award – January 6, 2023

Student Achievement Award – January 6, 2023

For more information on awards, see our [website](#).



2023 SOT Annual Meeting – MDCPSS Events

- **Workshop Session (MDCPSS endorsed) - Monday, March 20, 9:15 AM to 12:00 Noon**
“Biocompatibility Assessment of Absorbable/Degradable Materials Employed in Medical Devices: Challenges, Pitfalls, and Emerging Testing Methods”

Chairs: Daysi Diaz-Diestra, North American Science Associates LLC
Teresa Palacios-Hernandez, US FDA/CDRH

Abstract: The use of absorbable materials in medical devices has expanded over the last few decades. These materials are particularly attractive as they do not remain permanently in the body, do not require removal/revision surgeries, and may reduce or eliminate late-stage adverse responses. However, assessing the biocompatibility of these materials and/or risk they pose to patients can be quite challenging given their unique physicochemical properties. The main objective of this Workshop is to discuss some of these challenges (e.g., solvent incompatibility during chemical characterization, high variability in leachable profiles, and limitation of preclinical models to predict long-term biological effects). The Workshop will also consider ongoing efforts to develop and update methodologies for more comprehensive biocompatibility assessments in order to ensure patient safety and establish regulatory compliance. The first speaker will take a materials-based perspective and present an overview of absorbable materials development, degradation testing, and applications. The second speaker will discuss biocompatibility testing considerations in the regulatory approval process of absorbable-based medical devices. The third talk will review the challenges of biocompatibility evaluation of absorbable medical devices and efforts to improve our understanding of biological responses to these devices through degradation, which enables us to better predict long-term clinical outcomes. The next talk will provide an overview of the new changes introduced to ISO 10993-12 that are applicable to the preparation of absorbable/degradable test articles for biological testing; where applicable, examples of in situ polymerizing, biomaterial- or bioabsorbable-based devices will be presented for discussion. The fifth talk will provide an overview of the use of ISO 10993-18:2020 and key scientific aspects of an extractables study, such as information gathering, selection of extraction conditions, sample extraction, extract sample processing, system selection and qualification, quantification, and identification. Additionally, questions on how to test novel materials for chemical characterization will be discussed. The final speaker will highlight new approach methods for risk assessing extractable compounds from biodegradable medical devices. Also discussed will be best practices and potential pitfalls in applying and interpreting in silico predictions for mutagenicity and Cramer classification. This speaker will also present case studies demonstrating the application of in silico methods to connect structurally discrete polymer degradants to the device materials of construction and possibly to support a chemical category read-across approach.

- **Medical Devices Poster Session - Wednesday, March 22, 9:00 AM to 4:30 PM (display)**
(author attended 10:45 AM to 12:30 PM)
- **MDCPSS Mentoring Event - TBD**
- **MDCPSS Reception - Wednesday, March 22, 6:00 PM to 7:30 PM (Omni Nashville Hotel)**

The MDCPSS was formed in 2009 with 51 founding members. Since then we've grown steadily and now have 241 members.

Our members come from 17 countries and include representatives from industry, government, consulting, and academia. Our membership includes Full SOT Members, followed by Associate, Student, and Postdoctoral Members. Educational backgrounds range from BS degrees to those with MBAs, MPHs, PhDs, DVMs, and MDs.

MDCPSS Recommendations for SOT Speaker Directory submitted May 27, 2022.

1. Sherry Parker, PhD (SParker Toxicology Consulting LLC)
2. Alan Hood, PhD (FDA, CDRH/OSEL)
3. Molly Ghosh, PhD (FDA, CDRH/OPEQ)
4. Ron Brown (Risk Science Consortium)
5. Daniel Nazarenko, PhD (BD)

Officers Highlight



Dr. Hiromi Hosako is currently a Fellow Toxicologist in the Preclinical Safety Department at Alcon Laboratories. She leads the preclinical safety activities for Vision Care medical device candidates and products and develops global toxicology testing strategy and preclinical safety assessments. She is also currently serving Ocular Toxicology Specialty Section (OTSS) of the Society of Toxicology (SOT) as a Treasurer. While serving in the Presidential Chain of the OTSS recently, she has successfully collaborated with MDCPSS to cohost events such as a webinar in 2019 and a Virtual Career Panel in 2020. Prior to starting at Alcon 7 years ago as a Project Toxicologist II and holding a Senior Principal Scientist position before the current position, Hiromi was an Assistant Director in General Toxicology Department at Charles River Laboratories (former WIL Research) and served as a study director conducting a broad range of preclinical studies for a variety of industry clients. She received her Ph.D. in Toxicology, with an emphasis in Developmental Toxicology, from Texas A&M University in 2008 and her B.S. in Biochemistry from Texas State University. Hiromi is a board-certified toxicologist since 2012 and has been a member of SOT since 2008 and the American College of Toxicology since 2011. She has authored /co-authored multiple peer-review articles encompassing *the* neurotoxicity of a pharmaceutical drug, food safety, and investigative toxicology.

For our annual newsletters, MDCPSS EC requests highlights (e.g., publication, presentation, award) from MDCPSS members to share. If you have a highlight that you would like to share with MDCPSS membership in the future, please submit them to the MDCPSS EC for inclusion in the MDCPSS newsletter.

Frances Hsia, Alessia Stornette and Nicole Soucy from Global Toxicology & Biocompatibility from Boston Scientific recently published a paper in “Frontiers in Medical Technology, section Diagnostic and Therapeutic Devices” – “A Case Study: Re-evaluating the Biological Risk Following a Processing Aid Change on a Marketed Cardiovascular Implant Device”.

<https://www.frontiersin.org/articles/10.3389/fmedt.2022.1006984/abstract>

Treasury Update

The MDCPSS Executive Committee would like to thank our sponsors for helping to make MDCPSS 2021-2022 activities possible. MDCPSS had a successful year in member registrations and net assets, with modest expenses.

2022 Net Assets

January	\$25,831
February	\$25,190
March	\$17,797
April	\$17,789
May	\$19,072
June	\$24,645
July	\$24,645
August	\$24,645
September	\$24,645

2022 MDCPSS Sponsors

Kelly P. Coleman
Medtronic
WL Gore & Associates Inc.

To support MDCPSS activities, please consider making a tax deductible donation. If you would like to donate, the MDCPSS EC will gladly facilitate your tax free donation and recognize your support at the annual event and in our communication. MDCPSS accepts donations by check or credit card. For additional information regarding donations to MDCPSS, please contact the MDCPSS Secretary/Treasurer, Hiromi Hosako (Hiromi.Hosako@sunovion.com), or Rosibel Alvarenga (rosibel@toxicology.org) at SOT Headquarters.

The mission of the Medical Device and Combination Product Specialty Section is 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.

Don't forget to visit the MDCPSS Website for regular updates:

<https://www.toxicology.org/groups/ss/MDCPSS/index.asp>