MDCPSS FALL NEWSLETTER

Volume 15 / Issue 2

MDCPSS OFFICERS

President
Ju Young (Julie) Park

Vice President
Sharlee More

Past President
Xiaoling (Sharlene) Dai

Vice President-Elect
Kimberly Ehman

Secretary/Treasurer
Bhavesh Ahir

Councilors
Rachel Chang
Deniz Emul

Student Representative
Postdoctoral Representative
Positions not filled – contact committee for application.

Newsletter Editors
Deniz Emul
Xiaoling (Sharlene) Dai
Ju Young (Julie) Park

Contents

Above: MDCPSS Reception Attendees;
Below: MDCPSS Officers 2024-2026 [Absent: Ju Young (Julie) Park]

PRESIDENT’S MESSAGE

Dear MDCPSS Members,

Greetings and welcome to Medical Device and Combination Product Specialty Section’s (MDCPSS) fall newsletter. It’s an honor to serve as your 2025–2026 MDCPSS President with our new Executive Committee members: Xiaoling (Sharlene) Dai (Past President), Sharlee More (Vice President), Kimberly Ehman (Vice President-Elect), Bhavesh Ahir (Secretary/Treasurer), Rachel Chang (Councilor), and Deniz Emul (Councilor). I also would like to thank the following previous MDCPSS Executive Committee members who provided significant contributions to the MDCPSS-organized and -sponsored activities during their terms: Mansi Krishan (Past President), Xiaoling (Sharlene) Dai (President), Sharlee More (Vice President-Elect), Bhavesh Ahir (Secretary/ Treasurer), William Wustenberg (Councilor), Rachel Chang (Councilor), Qiran Chen (Postdoctoral representative), and Ishita Virmani (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 a focus on sharing emerging toxicological science via webinars, membership communications, SOT Annual Meeting activities, growing our membership, providing valuable mentoring, and developing opportunities for early career toxicologists in the medical device and combination products area.

We are very proud of a successful 2025 SOT Annual Meeting and were very excited to greet MDCPSS members at the poster session and annual reception! Congratulations to all the 2025 MDCPSS award winners. Please see details below to learn more about the award winners and their cutting-edge research. MDCPSS, together with the *In Vitro* and Alternative Methods Specialty Section, hosted a joint mentoring event at SOT with 10 mentors from various backgrounds and experience. For more details on the mentoring event, please see below.

As we kicked off a new term in May, we received a total of four session proposals for pre-review and endorsement, and two have been accepted by the SOT Program Committee for presentation at the 2026 SOT Annual Meeting. We thank Dr. Sharlee More, Chair of the MDCPSS Program Committee, for leading the work on pre-review/formal review and recommendation process as well as for compiling detailed feedback.

We also had a successful webinar in August on material-mediated pyrogenicity for medical devices. I want to thank Dr. Sharlee More for her dedication for organizing and moderating the webinar as well as our speakers for their scientific contributions. If you missed it, please visit our MDCPSS website or SOT reference files. Please continue to check the MDCPSS website and e-Blasts for updates and information on additional upcoming webinars in 2026.

A big THANK YOU to MDCPSS Executive Committee members for your leadership, hard work, and commitment, including all the contributions toward this newsletter. I am thrilled to be a part of this wonderful team. Also, thanks to all the existing and new members and sponsors for their continued support.

Please continue to check the MDCPSS website and e-Blasts for upcoming events and award deadlines. If you have any thoughts and suggestions for MDCPSS programs, outreach, webinars, or suggestions for improvement, please feel free to contact me or any of the Executive Committee officers.

I am looking forward to the upcoming 65th Annual Meeting in San Diego, California, and hope to see you in person! Happy holidays!

Sincerely,

Ju Young (Julie) Park, PhD, DABT

MDCPSS President (2025–2026)

NEW OFFICER INTRODUCTION

Welcoming our new officers: incoming *Vice President-Elect* Kimberly Ehman, and *Junior Councilor* Deniz Emul.

Kimberly Ehman, PhD DABT
Head of Regulatory Toxicology
Eurofins Medical Device Services

VP-Elect

Kimberly Ehman leads the biocompatibility consulting and toxicological risk assessment (TRA) services for the US Medical Device Program. She has over 20 years of toxicology and medical device experience, with expertise in toxicological risk assessments (TRAs) for medical devices, food and beverage products, and electronic nicotine delivery systems. Prior to joining Eurofins, she was the Director of Regulatory Toxicology and Consulting at WuXi AppTec and has also held positions at Altria Client Services (Head of Regulatory Toxicology), Toxicology Regulatory Services (Consulting Toxicologist and Program Manager), and RTI International (Research Toxicologist for Developmental and Reproductive Toxicology and Neurotoxicology). She received her PhD from McGill University in Montréal, Canada, and conducted her postdoctoral research at the US EPA, with a focus on developmental neurotoxicology. She has been a Diplomate of the American Board of Toxicology since 2009, and an active member of the Society of Toxicology (SOT) since 2005, and the American College of Toxicology (ACT) since 2010. She is currently the VP-Elect for the Medical Device and Combination Product Specialty Section (MDCPSS) of SOT, and serves as an expert on several US working groups for the ISO 10993 series of standards, including ISO 10993-1 (Evaluation and testing within a risk management process), ISO 10993-3 (Tests for genotoxicity, carcinogenicity and reproductive toxicity), and ISO 10993-17 (Toxicological risk assessment of medical device constituents).

Deniz Emul, MS(PharmTox)
Senior Biocompatibility Engineer
Resmed Pty Ltd

Junior Councilor

Deniz Emul is a senior member of the biocompatibility and toxicology branch, evaluating respiratory medical devices under global risk and regulatory frameworks. She completed her Master's in Pharmacology and Toxicology at Michigan State University, with a focus on the development of new alternative methods (NAMs) in inhalational toxicology. She has been a member of SOT since 2018, and several Component Groups, including MDCPSS, IVAMSS, RASS, IRSS, RSESS, CSS and WIT. She spoke on the "Design of Clinically-Relevant Leachable Studies for Medical Devices with Replacement Schedules" at SOT 2023, co-authoring a poster of the same title, and on "Root Cause Analysis on Extract Color Change for Polymeric Medical Device Evaluation" at SOT 2025 (see Page 6). She is involved in ISO standard working groups, currently holds the role of Treasurer within the IVAMSS executive committee, and previously served in the role of Graduate Student Representative of MDCPSS.

SOT 2025 RECAP

SOT MARCH 16–20 ORLANDO

Hope you were able to attend the various medical device related events!

Event	Date/Time
Medical Device and Combination Product Specialty Section Meeting/Reception	**Monday Mar 17th 6:00pm – 7:30pm**
Medical Devices Poster Session	**Wed Mar 19th 9:15am – 11:45pm**
Joint Mentoring Event IVAMSS & MDCPSS	**Mon Mar 17th 5:00pm – 6:00pm**
Continuing Ed. Course: Roadmap for Safety Evaluation of Emerging Consumer Products: Application and Adaptation of Existing Practices	**Sun Mar 16th 8:15am – 12:00pm**
Workshop Session: How Can We Use Alternative Approaches to Move Safety Evaluation of Medical Devices Forward?	**Wed Mar 19th 1:30pm – 4:15pm**
Symposium Session: Emerging Approaches in Chemical Analysis and Toxicological Risk Assessments of Extractables Data for Medical Device Evaluations	**Tues Mar 18th 11:00am – 12:30pm**
Informational Session: A Cross-Industry Perspective on Exposure-Driven Human Safety Evaluation on Polymer Chemical Additives	**Mon Mar 17th 12:10pm – 1:30pm**
Tiny Tox Talk: Hazards and Heroes: The Life of a Medical Device Toxicologist	**Mon Mar 17th 2:00pm – 2:20pm**

2025 SOT MDCPSS Awards

At this year's Reception event, SOT MDCPSS was pleased to present awards in four categories.

Best Overall Abstract Award

1st Place:

X. Dai, J. R. Hakimi, S. Zhang, R. F. Shulfer, J. Weng, S. A. Citrowske, S. Wu, and M. Kamberi. (Abbott Laboratories)

"Characterizing and Refining Toxicological Safety Risks of Tissue Valve Devices Under Clinical Conditions: A Case Study Using Exhaustive and Clinical Simulating Extractions."

2nd Place:

N. R. Bronson, M. Hendershot, H. Izadi, J. Plaskey, A. J. Wyen, K. Sedlmeier, P. G. Smiraldo, L. Swanson, C. E. Reiter, and C. M. Ruch. (NAMSA)

"Rethinking Cytotoxicity: Do Cytotoxicity Results Predict *In Vivo* Outcomes?"

3rd Place:

E. Fesl, J. Caldwell, A. Whitnall, and L. Frankart. (Johnson & Johnson MedTech)

"Extraction Conditions for Chemical Analysis of Surgical Instruments"

Best Poster Award

(Reviewed during MDCPSS Poster Session)

1st Place:

L. Borton and K. Coleman (Gradient, Medtronic)

"Material-Mediated Pyrogens in Medical Devices: Myth or Reality?"

2nd Place (Honorable Mentions)

C. Jamison, S. Parker, K. Ehman. (WuXi AppTec, SParker Toxicology Consulting LLC)

"Biological Evaluation Gaps for Tampon Products – What Have We Missed and How Do We Move Forward?"

E. N. Rodgers, K. Cross, J. Bettis, S. Gad, and S. C. Gad. (Gad Consulting Service)

"Case Studies Using the Updated ISO 10993-17 Guidance."

Best Published Paper Award

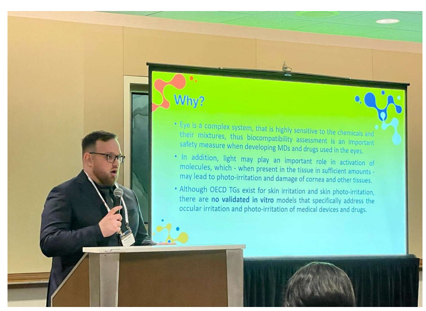
P. Pobis, J. Kubalcova, T. Milasova, and H. Kandarova. (IEPT and CEM within Slovak Academy of Sciences, Institute of Biochemistry and Microbiology of Slovak University of Technology)

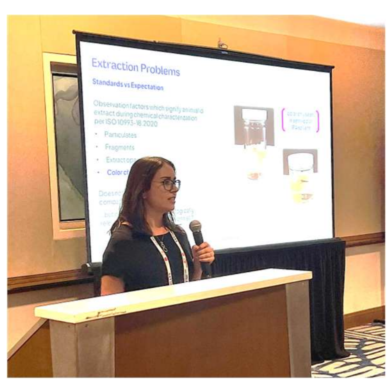
"Development of Sensitive *In Vitro* Protocols for the Biocompatibility Testing of Medical Devices and Pharmaceuticals Intended for Contact with the Eyes: Acute Irritation and Phototoxicity Assessment."

Early Career Achievement Award

D. Emul. (Resmed Pty Ltd)

"Root Cause Analysis on Extract Color Change for Polymeric Medical Device Evaluation."





We also had the opportunity to thank and present **Service Awards** to our outgoing officers:

- **Mansi Krishan**, Presidential Chain (2021-2025)
- **William Wustenburg**, Councilor (2023-2025)
- **Qiran Chen**, Postdoctoral Representative (2024-2025)
- **Ishita Virmani**, Graduate Student Representative (2024-2025)

Finally, thank you to the SOT MDCPSS community for your attendance!

For more information on awards, see our website.

Joint Mentoring Event: IVAMSS & MDCPSS

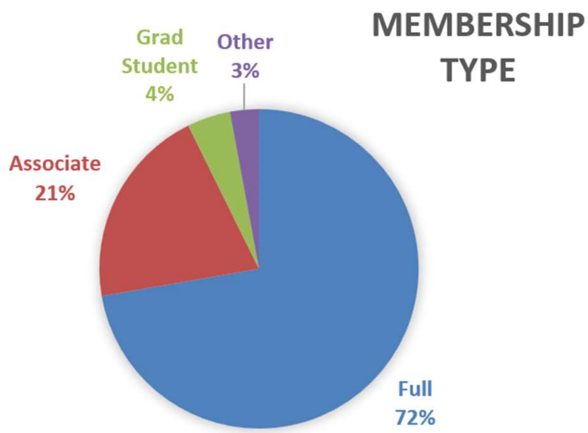
This year, MDCPSS co-hosted a popular mentoring event with *In Vitro* and Alternative Methods Specialty Section (IVAMSS). The event is designed to stimulate interest in medical devices and combination products and provide career insights in a social, friendly environment to undergraduate students, graduate students, postdoctoral scholars, and early-career scientists.

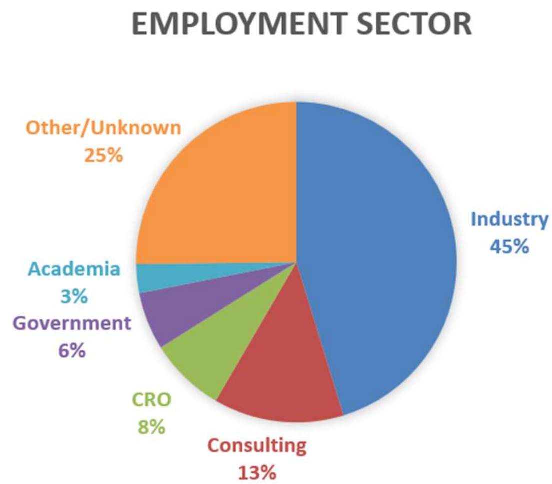
Mentees were provided the opportunity to network with expert mentors from diverse job backgrounds, and learn more about the variety of potential career paths and skills required to advance as toxicologists in this field.

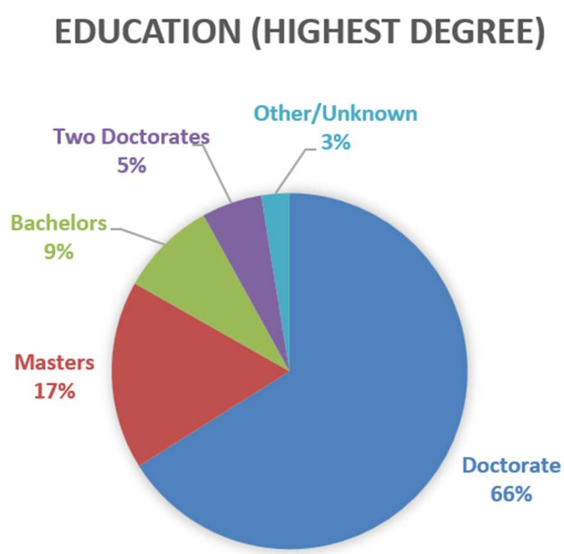
MEMBERSHIP UPDATES

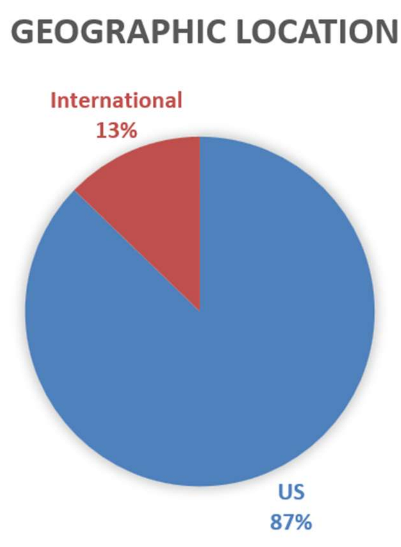
The MDCPSS was formed in 2009 with 51 founding members. Since then we've grown steadily and now have 277 members.

The figures below offer insight into the background of the MDCPSS community. Our members include representatives from industry, government, consulting, CROs, and academia. Our membership includes Full SOT Members, followed by Associate, Student, and Other member categories. Educational backgrounds range from BS degrees to those with MBAs, MPHs, PhDs, DVMs, and MDs. While the majority of MDCPSS is US-based, 13% of the community are non-US-based.









SPONSORS UPDATE

To support MDCPSS activities, please consider making a tax deductible donation. If you would like to donate, the MDCPSS EC will gladly facilitate your donation and recognize your support at the annual meeting event and in our MDCPSS SOT communication webpage. MDCPSS accepts donation through the SOT Component Group Donation Form Site.

For additional information regarding donations to MDCPSS, please contact the MDCPSS Secretary/Treasurer, Bhavesh Ahir (bhavesh.me@gmail.com or Bhaveshkumar.Ahir@fda.hhs.gov), or Rosibel Alvarenga (rosibel@toxicology.org) at SOT Headquarters.

Our MDCPSS members sincerely appreciate the generous sponsorship we received in 2024-2025. Invaluable financial support from our sponsors has been instrumental in making our specialty session a resounding success. Thank you for your invaluable support.

RECENT WEBINARS

Title: Material-Mediated Pyrogens: Myth or Reality? A Risk-Based Approach to Addressing the Endpoint of "Material-Mediated Pyrogenicity" for Medical Devices

Date and Time: August 12th, 2025
Speakers: Lindsey Borton, MPH, Gradient
Kelly Coleman, PhD, DABT, ERT, ATS, RAC, Medtronic
Ron Brown, PhD, DABT, Risk Science Consortium LLC

Webinar slides and recording are available on ToXchange:
https://toxchange.toxicology.org/viewdocument/material-mediated-pyrogens-myth-or

Title: Designing for Sustainable Sterilization and Its Impact on the Biological Safety of Medical Devices

Date and Time: April 30th, 2025
Speaker: Vu Lekate, Abbott
Zengmin Xia, Abbott

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

MEDICAL DEVICE STANDARD AND REGULATION UPDATES

Upcoming Changes in ISO/DIS 10993-3

Kimberly Ehman, PhD DABT and Bob Przygoda, PhD

ISO 10993-3 was last updated in 2014. Over the last 11 years, there have been considerable shifts in the way biological endpoints can be addressed, particularly with respect to the use of chemical characterization and toxicological risk assessment. As such, the updates to the revised version of ISO 10993-3, which is currently a DIS (Draft International Standard), reflect these different approaches for the evaluation of genotoxicity, carcinogenicity, and developmental and reproductive toxicity (DART).

In April 2025, ISO/DIS 10993-3 was released for comment, and voting occurred in June 2025. There was an interim meeting in mid-July (Berlin) to discuss the comments. An official summary of the meeting in Berlin will be released in the fall, including comments and a revised document. The delegates will review for accuracy, and if no additional technical comments are made, the document will proceed to FDIS.

ISO 10993-3 is applicable when the need to evaluate a medical device for potential genotoxicity, carcinogenicity, reproductive toxicity, and developmental toxicity has been established. The current version of the standard (2014) is titled "Biological evaluation of medical devices – Part 3: <u>Tests</u> for genotoxicity, carcinogenicity, and reproductive toxicity." In the ISO/DIS 10993-3, the title has changed to "Biological evaluation of medical devices – Part 3: <u>Evaluation</u> of genotoxicity, carcinogenicity, reproductive toxicity, and developmental toxicity." The updated title reflects several changes throughout the standard that focus on evaluation of genotoxicity, carcinogenicity and developmental and reproductive toxicity (DART) using chemical characterization (ISO 10993-18) and toxicological risk assessment (ISO 10993-17) to address these endpoints. One of the main reasons for the shift in terminology from "test" to "evaluation," particularly with carcinogenicity and DART endpoints, was due to the limitations and challenges that medical devices (or extracts) present in these biological assays.

In addition to changes in the normative portion of the standard, the main changes compared to the previous version are as follows:

- Deletion of the Annex on Cellular Transformation;
- Restructuring of Annex A on Guidance on selecting an appropriate test sample preparation procedure for genotoxicity testing;
- Moving ISO 10993-33 into this standard as a normative Annex (Annex B) on genotoxicity test methods;
- Addition of Annex C on *in vivo* carcinogenicity assays that includes the Annex on solid state carcinogenesis;
- Addition of Annex D on Genotoxicity assessment of nanomaterials;
- Addition of Annex E on Recipe for S9 mix;
- Addition of Annex F on Endocrine Disruptors;
- Addition of Annex G on the evaluation of reproductive and developmental toxicity;
- Update of normative references and bibliography.

Genotoxicity

- For genotoxicity, options are presented to address this endpoint using chemical characterization and risk assessment, or by performing genotoxicity testing, and in certain circumstances (e.g., a material which has not been used in a legally marketed device), both approaches may be appropriate.
- There is also guidance around devices that contain identified genotoxicants that are not easily detected using non-targeted chemical characterization approaches (e.g., glutaraldehyde, formaldehyde). In these cases, targeted approaches should be considered.
- Additional guidance around nanomaterials with respect to genotoxicity is provided in Annex D.
- The revised standard discusses circumstances where *in vivo* genotoxicity should be considered as well as options for mitigating a positive *in vitro* result.

Carcinogenicity

- It is strongly recommended that this endpoint be addressed using chemical characterization and risk assessment. If the TRA demonstrates unacceptable risk of carcinogenicity, it is suggested that the risk shall be managed according (ISO 14971).
- The toxicological risk assessment should address both genotoxic and non-genotoxic carcinogenicity per ISO 10993-17.
- The revised standard points out that recent publications indicate that TTCs (Thresholds of Toxicological Concern) based on Cramer Class are protective for non-genotoxic carcinogens (Batke et al., 2021 *Threshold of Toxicological Concern—An Update for Non-Genotoxic Carcinogens*. Front. Toxicol. 2021, 3:688321. https://doi:10.3389/ftox.2021 .688321).

Reproductive and Developmental Toxicity

- This section of the standard has been revised to include developmental toxicity in addition to reproductive toxicity. For each, there is a summary of when developmental or reproductive toxicity evaluations should be considered.
- The inclusion of "indirect" contact is something to consider since it will likely expand the types of devices where these endpoints should be considered.
- Similar to genotoxicity and carcinogenicity evaluations, chemical characterization and toxicological risk assessment are highlighted as an appropriate approach for these evaluations considering that current biological methods for both developmental and reproductive studies were developed for single substances and are not validated for mixtures.
- Although these sections of ISO/DIS 10993-3 point to IS0 10993-17, additional guidance is provided on tools (e.g., CMR, endocrine disruptor, and SVHC screens) and available DART study designs (summarized in Annex G) that could help address these endpoints the toxicological risk assessment.

Updates on Recent Activities from AAMI and TUV SUD on PFAS

Sharlee More, PhD, DABT

In May 2025, AAMI and TUV SUD co-hosted a PFAS Scientific Exchange in Arlington, VA. Throughout the 2-day meeting, various stakeholders in the medical device industry, including toxicologists, regulators, industry, and clinicians, discussed the challenges of PFAS regulation in medical devices. Solutions to address these challenges and regulatory gaps were proposed. It was a very successful meeting with a lot of great ideas exchanged between the attendees. Thank you to all who participated!

TREASURY UPDATE

The MDCPSS Executive Committee would like to thank our sponsors for helping to make MDCPSS 2024-2025 activities possible.

MDCPSS had a successful year in member registrations and net assets, with modest expenses.

2025-2026 Net Assets

January	$23,177
February	$22,099
March	$17,660
April	$18,160
May	$18,160
June	$27,489

MDCPSS MISSION

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