



MDCPSS SPRING NEWSLETTER

Volume 16 / Issue 2

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PRESIDENT'S MESSAGE

Dear MDCPSS Members,

Hope everyone is staying warm and healthy in this freezing winter weather. As we prepare for the 2026 Society of Toxicology (SOT) Annual Meeting, we are pleased to share a summary of Medical Device and Combination Product Specialty Section (MDCPSS) events planned for 2026 SOT, along with a recap of our 2025-2026 accomplishments. Thanks to the dedication and exceptional contributions of our members, it has been a remarkably productive and successful year for MDCPSS.

Before diving into our 2025-2026 accomplishments and upcoming events, I want to express my sincere gratitude to the MDCPSS Executive Committee for their unwavering commitment and tireless efforts in reviewing scientific sessions, preparing newsletters, evaluating award applications, and organizing webinars and mentoring events. It has been an honor to work alongside this exceptional team. I also extend my thanks to our sponsors and all existing and new members for your continued support—you are the backbone of our success.

Recap of 2025-2026 Accomplishments and Membership Updates

Our continued growth and visibility have translated into impressive scientific contributions. This year, we have two workshop sessions accepted and a total of 64 medical device-related abstracts accepted for poster presentation (a notable increase from 47 last year!). We also hosted a well-attended webinar in August on material-mediated pyrogenicity for medical devices. Additionally, we shared important updates on medical device standards and regulations, specifically ISO 10993-1. These achievements underscore both the dedication of our members and outstanding scientific endeavors within our community.

I am also delighted to announce that our membership has grown to 274 members, up from 248 members last year, and we have received generous donations from various sponsors. Thank you for your continued support.

Upcoming Events at the 2026 SOT Annual Meeting

The annual SOT meeting is approaching quickly, and I am excited to share the MDCPSS events we have planned. I strongly encourage you to attend and participate in the events and sessions listed in this newsletter. On behalf of the MDCPSS Executive Committee, I cordially invite you all to the SOT MDCPSS annual reception, where we will network and celebrate the outstanding achievements of our members, including the recipient of our newly established Lifetime Achievement Award. For this year's mentoring event, we will be participating in NetworX Night hosted by the SOT Career Advancement, Mentoring, and Networking (CAMAN) Committee. Special thanks to Dr. Kimberly Ehman and Dr. Deniz Emul for coordinating this event with the CAMAN Committee.

Wish you all safe travels to San Diego, and I look forward to seeing you all at the 2026 SOT Annual Meeting and our upcoming events!

Sincerely,

Ju Young (Julie) Park, PhD, DABT, RAC

MDCPSS President (2025-2026)



ANNUAL MEETING 2026



We look forward to seeing you at the MDCPSS Events!

Medical Device and Combination Product Specialty Section Meeting/Reception	Wed Mar 25th 6:00pm – 7:30pm
NetworX Night SOT Joint Mentoring Event	Mon Mar 23rd 7:30pm – 9:00pm
Medical Devices Poster Session I	Mon Mar 23rd 9:15am – 11:45am
Medical Devices Poster Session II	Tues Mar 24th 9:15am – 11:45am
Workshop Session: Toxicological Risk Assessment of Medical Devices Used for Neonatal and Pediatric Populations	Mon Mar 23rd 2:00pm – 4:45pm
Symposium Session: <i>In Vitro</i> Testing for Skin Sensitization of Mixtures: Where Science Stands Today	Wed Mar 25th 8:00am – 10:45pm
Workshop Session: Optimizing Chemical Risk Assessment for Medical Device Biological Safety: Challenges, Progress, and Collaborative Opportunities	Wed Mar 25th 1:30pm – 4:15pm

2026 SOT MDCPSS Awards

Awards in five categories will be presented at SOT 2026:



Best Overall Abstract Award



Best Poster Award – [Apply Here!](#)

(Reviewed during MDCPSS Poster Session)



Best Published Paper Award



Early Career Achievement Award



Lifetime Career Achievement Award



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

Questions? Email [Rachel Chang](#) (2025-2026 MDCPSS Councilor) and [Sharlee More](#) (2025-2026 Vice President).

Joint Mentoring Event – Introducing NetworX

This year, MDCPSS joins 30+ component groups in partnership with the SOT Career Advancement, Mentoring, and Networking (CAMAN) Committee to host NetworX – a new initiative!

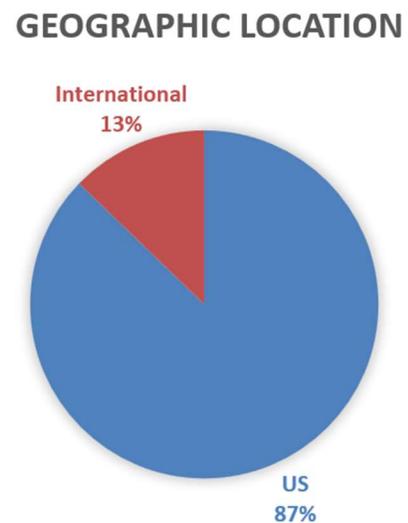
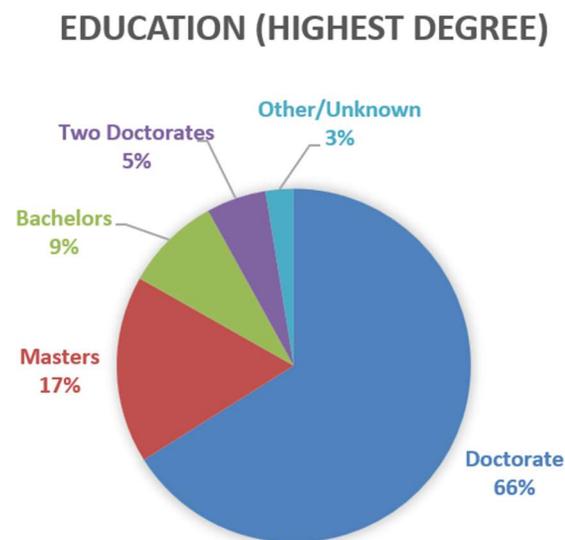
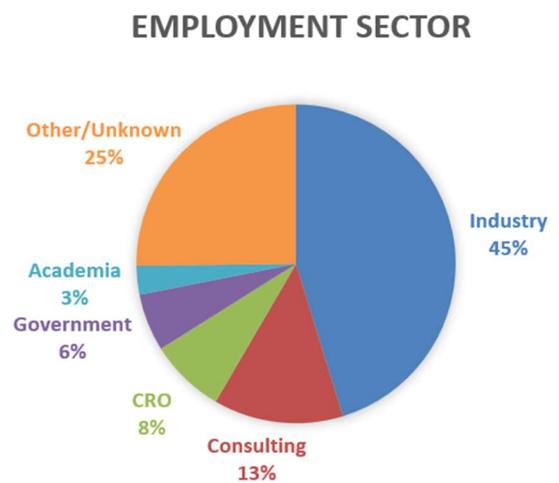
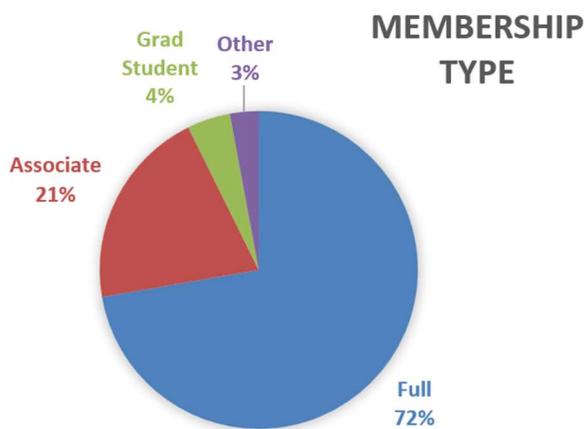
This speed-networking opportunity is for trainees to meet diverse professionals in toxicology, increase networks, and explore career paths and career-change options. Table hosts nominated by component groups will represent different career sectors (e.g., academic, industry, government, consulting). After a brief introduction to toxicology-related career resources, those who register will follow their assigned rotation to three tables, concluding with additional time to network freely with the table hosts.

Each participant will receive a drink ticket, and a cash bar will be available. Note: This is an Add-On Event on the registration form; there is no charge. Registration is limited and is on a first-come, first-served basis.

MEMBERSHIP UPDATES

The MDCPSS was formed in 2009 with 51 founding members. Since then we've grown steadily and now have 274 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 [GiveSmart platform](#).

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 would 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.

MEMBER RECOGNITION

Shortlist Selection of MDCPSS Members Kelly Coleman and Lindsey Borton for the Lush Prize

Congratulations to MDCPSS members **Kelly Coleman** (Medtronic) and **Lindsey Borton** (Gradient) for being shortlisted as candidates for the prestigious 2026 Lush Prize in the Political Advocacy Category (<https://lushprize.org/2026-prize/2026-prize-shortlist/>).

The selection recognizes their work to evaluate the relevance of material mediated pyrogenicity (MMP) as an endpoint for the safety assessment of medical devices. This work is discussed more fully in their recent paper in ALTEX (<https://www.altex.org/index.php/altex/article/view/2977>). In their article, Borton and Coleman used an evidence-based toxicology approach to determine whether MMPs exist in a medical device context, and whether the RPT could detect the presence of MMPs in or on a medical device. The implications have potential to reduce animal-based testing requirements. The selection not only recognizes their scientific efforts, but also acknowledges the regulatory impact of this work, notably, in support of changes to the new ISO 10993-1:2025 standard. Best of luck to Kelly and Lindsey as you enter the next phase of the selection process.

MEDICAL DEVICE STANDARD AND REGULATION UPDATES

ISO 10993-1 Has Arrived!

Kimberly Ehman, Rachel Chang, and Sharlee More

On November 18, 2025, the much-anticipated revision to ISO 10993-1 was released. Below are some of the notable changes compared to the 2018 version.

- Title change: ISO 10993-1:2025 is titled “Biological evaluation of medical devices- Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process”
- Device category and body contact site have been updated to the following four categories:
 - intact skin
 - intact mucosal membrane
 - breached or compromised surfaces (skin or mucosal membranes) or internal tissues other than circulating blood
 - circulating blood
- The term “effects after implantation” has been changed to “local effects after tissue contact” as some non-implanted devices also need this assessment
- Life cycle considerations are more prominent.
 - Characteristic change of the medical device during transport, storage or use should be considered in biological evaluation.
 - For reusable devices, reprocessing should also be considered.
- There may be additional considerations for “novel” materials.
 - Novel material as defined in the standard is: “material that has not previously been used in a medical device for which biological safety has been established relevant to the intended use”
- Changes to calculation of total exposure period (e.g., 5 min of contact is 1 contact day)
 - Adding up minutes or days to account for cumulative exposure is no longer acceptable
- Reasonably foreseeable misuse will need to be considered (e.g. longer duration of use, different than manufacturer expected patient population and body contact site) “where there is information available (e.g., post-market surveillance data, clinical literature) to suggest that the device can be used outside of its intended use, and this misuse is identified as being systematic.”
- Physical/chemical characterization has been removed from the table, but remains throughout the normative text as an important approach
- Material mediated rabbit pyrogenicity has been removed from the table of biological effects
 - Testing is still required when materials previously elicited a pyrogenic response or when the pyrogenic potential is unknown for novel materials.
- Systemic toxicity has been simplified in endpoint tables
 - Concept is the same in practice
- “Transitory” has been removed and replaced with “very brief contact”
 - Same rules apply (i.e., case-by-case assessment of test needs)

- Biological risk estimation is emphasized throughout the new version of the standard to consider severity and probability of occurrence of harm
 - Risk estimation can be qualitative or quantitative, but the approach using either needs to be documented.

WG1 experts are developing technical specifications and technical reports to provide more guidance around several concepts. The WG1 experts are likely to begin convening in early 2026; however, development of further guidance could take up to two years.

- Risk estimation
- Bioaccumulation and intermittent contact
- Biological equivalence
- Reasonably foreseeable misuse
- Life cycle requirements

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.

Visit the MDCPSS Website for regular updates: <https://www.toxicology.org/groups/ss/MDCPSS/index.asp>