MDCPSS SPRING NEWSLETTER

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PRESIDENT'S MESSAGE

Dear MDCPSS Members,

As we welcome the spring season and prepare for the 2025 SOT Annual Meeting, I am excited to share with you the latest updates and events from our Medical Device and Combination Product Specialty Section (MDCPSS), highlighting our 2024-2025 accomplishments and excellent opportunities for networking with our medical device toxicology community colleagues and friends at 2025 SOT.

It has been an incredible year so far, and I am grateful for the dedication and exceptional contributions of our members.

Celebrating Increased Scientific Contributions

I am thrilled to announce that our scientific contributions have significantly increased this year. We have seen a remarkable rise in the number of Medical Device Section posters accepted by SOT, from 32 last year to 47 this year. Additionally, the number of scientific sessions has doubled, from 2 last year to 4 this year.

This growth is a testament to the hard work and dedication of our members in advancing the field of medical device toxicology. Furthermore, the Best Publication Award applications have tripled, from 2 last year to 6 this year. This increase highlights the outstanding research and innovation within our community.

Upcoming Events at the SOT 2025 Annual Meeting

The annual Society of Toxicology (SOT) meeting is just around the corner, and we have an exciting lineup of events planned for our MDCPSS members. I encourage you to attend and participate in these SOT 2025 MDCPSS events sessions listed in this newsletter. Especially, I would love to invite you to the SOT MDCPSS annual reception, a highlight of MDCPSS at SOT where we celebrate the outstanding achievements of our members in 2024-2025, and a mentoring event co-hosted by MDCPSS and IVAMSS, sparking interest in medical devices and combination products and offering career insights and networking opportunities for students and early-career scientists.

Webinars and Membership Updates

We have two upcoming webinars that you won't want to miss! Our membership continues to grow, and we now have 232 members from 15 countries, representing industry, government, consulting, and academia. Your involvement and support are what make our section thrive.

Medical Device Standard and Regulation Updates

The first update is to share the ISO TC194/ISO 10993 Meeting (Nov. 2024, Paris), which focused on the latest advancements and updates in medical device standards. Key discussions included the development of new guidelines to enhance the safety of medical devices.

The second update is about recent activities from U.S. Food and Drug Administration on chemical characterization of medical devices. The FDA has released new draft guidance on chemical characterization for the biocompatibility assessment of medical devices to provide detailed recommendations and unveiled a new public dataset to assist chemistry labs in ensuring the robustness of their chemical characterization methods.

Acknowledgments and Appreciation

I would like to extend my heartfelt thanks to our leadership committee members for their invaluable efforts in reviewing scientific sessions, evaluating award applications and qualifications, organizing the mentoring event, and promoting our MDCPSS by reaching out to graduate students, postdocs, and early career professionals. Your dedication and hard work are greatly appreciated and have been instrumental in our success. It's been an honor to serve as your 2024-2025 MDCPSS President.

I would like to extend my heartfelt thanks to our sponsors for their invaluable support. Your contributions have been instrumental in making our activities and events a success.

Looking Ahead

As we move forward, let's continue to foster collaboration, innovation, and excellence in the field of medical device toxicology. I look forward to seeing you all at the SOT 2025 Annual Meeting and our upcoming events.

Sincerely,

Xiaoling (Sharlene) Dai, MD, PhD, RAC, DABT

MDCPSS President

SOT 2025 MDCPSS EVENTS

Hope to see you there!

Continuing Education Course
Roadmap for Safety Evaluation of Emerging Consumer Products: Application and Adaptation of Existing Practices
Date/Time: Sun, Mar 16th, 8:15 am - 12:00 pm (Eastern)
Location: Room W204A, Convention Center

Informational Session
A Cross-Industry Perspective on Exposure-Driven Human Safety Evaluation on Polymer Chemical Additives
Date/Time: Mon, Mar 17th, 12:10 pm - 1:30 pm (Eastern)
Location: Room W304E, Convention Center

Tiny Tox Talk
Hazards and Heroes: The Life of a Medical Device Toxicologist
Date/Time: Mon, Mar 17th, 2:00 pm - 2:20 pm (Eastern)
Location: W Hall A2, Convention Center

Medical Device and Combination Product Specialty Section Meeting/Reception
Date/Time: Mon, Mar 17th, 6:00 pm - 7:30 pm (Eastern)
Location: Celebration Room 3, Hyatt Regency

Symposium Session
Emerging Approaches in Chemical Analysis and Toxicological Risk Assessments of Extractables Data for Medical Device Evaluations
Date/Time: Tue, Mar 18th, 11:00 am - 12:30 pm (Eastern)
Location: Room W203A, Convention Center

Medical Devices Poster Session
Date/Time: Wed, Mar 19th, 9:15 am - 11:45 am (Eastern)
Location: W Hall A2, Convention Center

Workshop Session
How Can We Use Alternative Approaches to Move Safety Evaluation of Medical Devices Forward?
Date/Time: Wed, Mar 19th, 1:30 pm - 4:15 pm (Eastern)
Location: Room W204A, Convention Center

2025 SOT MDCPSS Awards

We are thrilled to invite you to the reception and award ceremony, a highlight of our conference where we celebrate the outstanding achievements of our peers. This is an excellent opportunity to show your support and

appreciation for the hard work and dedication that has driven innovation and excellence in our field. Join us in congratulating the award winners and being inspired by their remarkable contributions. Your presence will make this event even more special.

- Best Overall Abstract Award
- Best Published Paper Award
- Early Career Achievement Award
- Best Poster Award – Reviewed at SOT Annual Meeting during Medical Device and Combination Product Poster Session and Announced after SOT.

MENTORING EVENT @ SOT 2025

The Medical Device and Combination Product Specialty Section (MDCPSS) is excited to co-host a popular mentoring event with *In Vitro* and Alternative Methods Specialty Section (IVAM) during the upcoming SOT 2025 meeting. It 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. This event will facilitate opportunities for mentees to network with expert mentors from diverse job backgrounds to learn more about the variety of potential career paths and skills required to advance as toxicologists in this field.

Location: Celebration Rm 3 Hyatt Regency

Date: Monday March 17th

Time: 5 pm – 6 pm

Please scan the QR code to sign up.

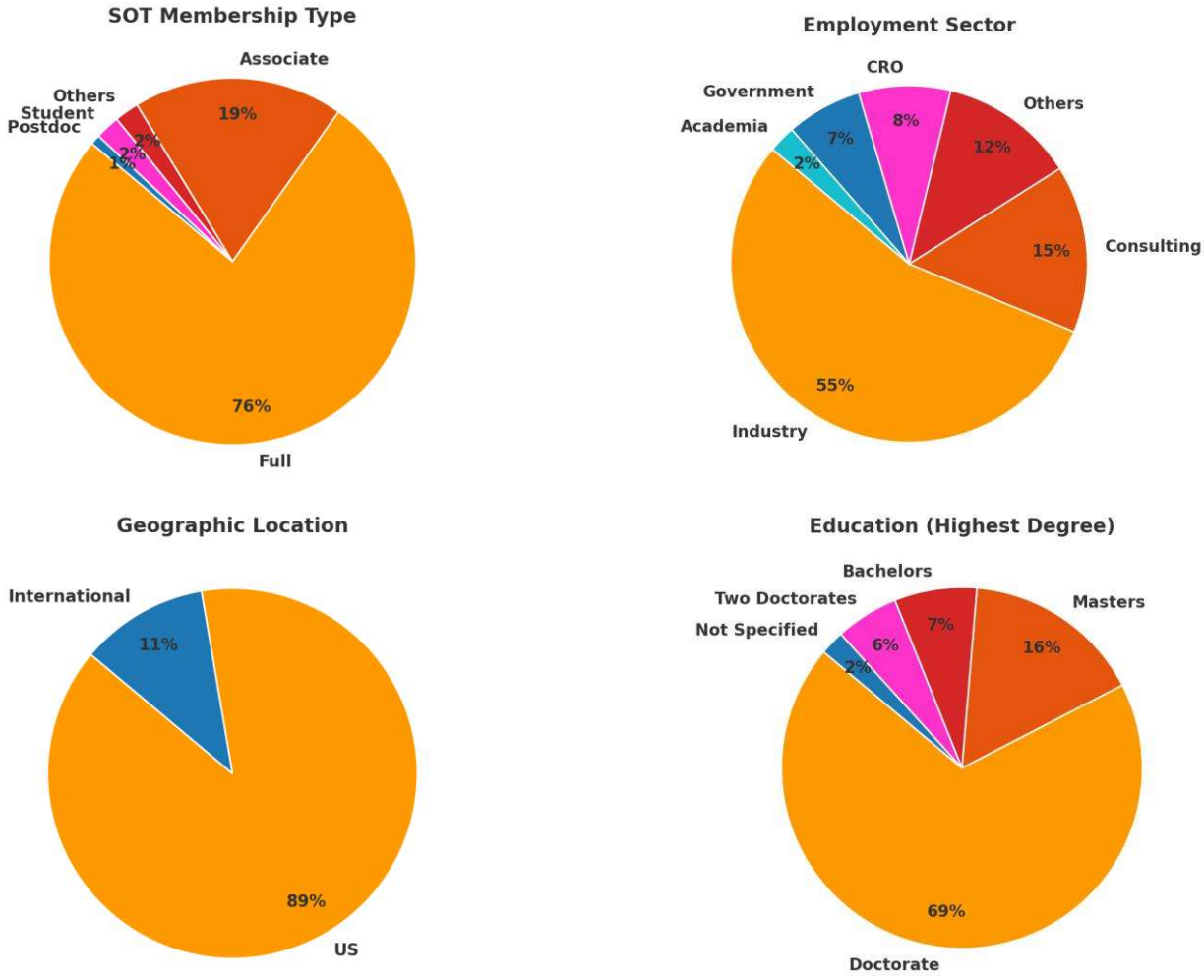
UPCOMING WEBINAR

Title: Designing for sustainable sterilization and its impact on biological safety
Date and Time: 11:00 AM, April 30th, 2025
Speakers: Vu Lekate, Zengmin Xia, Ph.D.

MEMBERSHIP UPDATES

The MDCPSS was formed in 2009 with 51 founding members. Since then we've grown steadily and now have 248 members.

Our members come from 15 countries and include industry, government, consulting, and academia representatives. Our membership comprises Full SOT Members, followed by Associate, Student, and Postdoctoral Members (see Figure below). Educational backgrounds range from BS degrees to those with MBAs, MPHs, PhDs, DVMs, and MDs.



MDCPSS 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 on our MDCPSS website. MDCPSS accepts donations 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 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.

MEDICAL DEVICE STANDARD AND REGULATION UPDATES

Key Takeaways from ISO/TC 194 (ISO 10993) – Working Group (WG) 1 Meeting

Daysi Diaz-Diestra, PhD, DABT, Senior Toxicologist, Gradient

In October of last year, the ISO technical committee (ISO/TC 194) held an in-person meeting in Saint Denis, France, from October 21-25. This committee is responsible for overseeing the ISO 10993 series of standards, along with ISO 22442 and ISO 14155. Nearly all of the committee's working groups participated, and the meeting saw strong engagement from the medical device industry, including regulators, manufacturers, laboratories, and consultants.

WG 1, Systematic Approach to Biological Evaluation and Terminology, is responsible for the most anticipated standard revision, ISO 10993-1. The group met daily to address comments on the Draft International Standard (DIS). After voting, WG1 members supported moving the revision to FDIS (Final Draft International Standard), but the US delegation did not support this move due to many last-minute changes affecting device categorization and biological risk estimation. Regardless, the final version is expected to be published later this year.

- Biological Effects vs. Biological Risk Assessment: A distinction is introduced between biological effects (the physiological impact of a substance/material) and biological risks (the potential for harm from those effects). This change aims to provide more clarity, but it may require additional interpretation and adaptation for those already familiar with the existing framework
- Changes to Device Contact Categories and Duration: The contact categories are refined into four distinct groups: intact skin, intact mucosal membranes, breached or compromised surfaces (excluding blood), and blood. Additionally, the duration categories have been split into limited exposure (< 24 hours), prolonged exposure (> 24 hours but ≤ 30 days), and long-term exposure (> 30 days) with the introduction of intermittent contact and bioaccumulation considerations. While these changes provide more specific classifications, they may also introduce additional complexity in categorizing devices, particularly those with multiple types of contact.
- Genotoxicity and Carcinogenicity Assessment: Genotoxicity testing is now applicable for all devices with prolonged contact, except those that only contact intact skin. This change reflects a broader approach but may increase the testing burden for manufacturers, particularly for devices that previously would not have required such assessments.
- Life Cycle Considerations: In line with MDR requirements and recently incorporated into the latest version of ISO 18562:2024 (*Biological Evaluation of Medical Devices — Part 2: Assessment of emission of airborne contaminants from patient contact materials*), this evaluation now requires assessing a device's biological safety not only at first use but also throughout its shelf life, service life, and post-production phases. While this offers a more comprehensive view of device safety, it may necessitate ongoing assessments and additional resources to maintain compliance. It is important to note that this evaluation does not include sustainability considerations.
- Biological Equivalence: The introduction of biological equivalence allows for the justification of exempting certain tests when a device undergoes changes in design, materials, or manufacturing. Based on the ISO 10993-18:2020 method, this approach could potentially reduce testing requirements in some cases. Still, it may require more documentation and justification to demonstrate that the changes do not significantly affect biological safety.
- Harmonization with ISO 14971: The revised standard emphasizes harmonization with ISO 14971, aiming to align biological risk assessments with broader risk management practices. While this could help create a more streamlined approach, it may also require adjustments in how biological risks and other device risks are managed together. For instance, there is still a lack of clarity regarding acceptability criteria.

- Elimination of Material-Mediated Pyrogenicity Testing: This change reflects the growing understanding that this biological effect is rare and occurs only with a few constituents. Instead of testing, a rationale stating that the device's composition (including processing aids and contaminants) does not pose a significant pyrogenic risk, along with adequate controls during manufacture, is deemed sufficient.

A summary of the takeaways from other working groups and ISO 10993 standards will be presented in a future issue.

Updates on Recent Activities from the U.S. Food and Drug Administration on the Chemical Characterization of Medical Devices

Siyi Zhang, Ph.D., Yan Jia, Ph.D., and Mikel Roe, Ph.D.

In September 2024, US Food and Drug Administration (FDA) released "Chemical Analysis for Biocompatibility Assessment of Medical Devices; Draft Guidance for Industry and Food and Drug Administration Staff". This highly anticipated document provides the FDA's recommendations on chemical analysis to assess the biocompatibility of medical devices. FDA requested comments from industry after the release of the draft guidance, and the comment period has ended on December 19, 2024.

This document details recommendations regarding information gathering, test article extraction, chemical analysis and data reporting. The appendices provide further considerations in these areas. These recommendations are generally consistent with the very conservative approaches that the FDA has taken in regulatory review processes since the release of ISO10993-18:2020. Key aspects of the document include:

- Exaggerated extraction with polar, semi-polar and non-polar solvents are recommended for long term contact (>30 days) devices
- Exaggerated extraction with polar and non-polar solvents, exceeding both clinical use time and temperature are recommended for limited contact (<24 hour) devices.
- Test article preparation mimics the clinical preparation of the device prior to extraction, if applicable, to account for the physical transfer of chemicals onto the test article
- If a compatible pure semi-polar solvent cannot be identified, then a polar/semi-polar mixture may be appropriate, with justification. Likewise, if a compatible pure non-polar solvent cannot be identified, then a semi-polar/non-polar mixture may be appropriate, with justification
- Select methods that ensure a wide range of analytes can be detected, identified, and quantified. At least 3 surrogate reference standards for direct injection GC-MS and at least 5 for each polarity of LC-MS.
- Any extract processing methodologies are accompanied with method qualification and verification information, which generally involves a spike and recovery report.
- Confident and confirmed identifications are recommended for TRA.

On November 6th, 2024, the FDA hosted a public workshop titled "Accreditation Scheme for Conformity Assessment (ASCA) and Use of Chemical Analysis to Support Biocompatibility of Medical Devices". FDA stated that this public workshop was to discuss with stakeholders the expansion of the ASCA program to include chemical analysis to support biocompatibility of medical devices. It was well attended in person and by webcast. There were four sessions in the workshop. The morning sessions were primarily presentations from FDA and industry stakeholders on current methods and challenges, as well as ideas on developing a coverage map for chemical analysis. The afternoon sessions were FDA-led panel discussions, focusing on considerations when developing a general approach to chemical analysis. Every step in the chemical analysis processing was discussed. FDA did not intend to use the workshop as a venue to collect feedback on the draft guidance. However, many similar feedback and comments were discussed and shared during the workshop.

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.

2024-2025 Net Assets

July	$21,177
August	$21,177
September	$21,177
October	$21,177
November	$21,427
December	$22,177

MDCPSS MISSION

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