Medical Device and Combination Product Specialty Section

MDCPSS FALL NEWSLETTER

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PRESIDENT'S MESSAGE

Dear MDCPSS Members,

Welcome to the Medical Device and Combination Product Specialty Section's (MDCPSS) fall newsletter!

It's an honor to serve as your 2026–2027 MDCPSS President alongside our outstanding Executive Committee: Ju Young (Julie) Park (Past President), Kimberly Ehman (Vice President), Rachel Chang (Vice President-Elect), Mark Cabonce (Secretary/Treasurer), Deniz Emul (Councilor), Clarissa Shaffer (Councilor), and Nicole Akers (Graduate Student Representative).

I would also like to recognize and thank our outgoing Executive Committee members: Xiaoling (Sharlene) Dai (Past President), Bhavesh Ahir (Secretary/ Treasurer), and Rachel Chang (Councilor), for their dedication and many contributions to the Specialty Section. We greatly appreciate your service and leadership.

As we move into the end of 2026, I would like to thank our members, volunteers, sponsors, and Executive Committee for their continued support of the Medical Device and Combination Product Specialty Section. The 2026 SOT Annual Meeting provided a fantastic opportunity for our community to reconnect, share scientific advancements, and celebrate the accomplishments of medical device and combination

product toxicologists. Through our receptions, networking events, awards program, and scientific sessions, we saw firsthand the continued growth and impact of our specialty section. Congratulations to our 2026 award recipients, whose innovative work continues to advance our field.

Looking ahead, the Executive Committee remains focused on increasing member engagement, expanding educational opportunities through webinars, and preparing for an exciting 2027 SOT Annual Meeting in San Antonio. This year, we received 10 session proposals for review, and we are proud that four were accepted by the SOT Program Committee, reflecting the strength and relevance of the science being conducted throughout our community. A special thank you to Dr. Kim Ehman for leading the MDCPSS Program Committee and coordinating the review and recommendation process.

We are also excited to introduce a new Student Travel Award this year. In addition, MDCPSS will recognize excellence through monetary awards for the Best Overall Abstract, Best Poster, Best Published Paper, Early Career Achievement, and Lifetime Career Achievement categories. Thank you to Rachel Chang and the Awards Committee for their leadership in expanding these opportunities for recognition.

Finally, we are pleased to offer two webinars this fall and winter on topics of interest to medical device and combination product toxicologists. Be sure to register and join us for these upcoming events.

Please continue to watch for MDCPSS e-Blasts and visit our website for updates on events, award deadlines, and opportunities to get involved. We always welcome your ideas and feedback, so please don't hesitate to reach out to me or any member of the Executive Committee with suggestions for future programs, webinars, or initiatives.

Thank you for helping make MDCPSS a vibrant and growing professional community. I look forward to seeing many of you at the 66th Annual Meeting in San Antonio, Texas!

Sincerely,

Sharlee More, PhD, DABT

MDCPSS President (2026-2027)



SOT 2026 MDCPSS EVENTS



The MDCPSS Executive Committee would like to thank all members who attended MDCPSS events during the 2026 SOT Annual Meeting in San Diego.

The annual reception provided an opportunity for members from industry, academia, consulting organizations, regulatory agencies, and contract research organizations to reconnect, establish new collaborations, and celebrate accomplishments within the medical device toxicology community.

MDCPSS Scientific Programming Highlights

The MDCPSS community was well represented throughout the Annual Meeting through workshops, posters, mentoring events, and scientific discussions on topics including:

- Pediatric and neonatal medical device risk assessment
- Medical device biological safety and chemical risk assessment
- *In vitro* approaches to safety assessment
- Emerging biocompatibility challenges





MDCPSS members during the 2026 SOT Annual Meeting reception

2026 SOT MDCPSS Awards

Overall Abstract:

1st: L. M. Harrington, M. Giffin, S. M. Street, K. L. Pacholke, E. K. Long, and K. A. Chaffin. (Medtronic Inc). PFAS in Chronically Implanted Cardiac Leads.

2nd: K. D. Shimshock, D. Buchanan, R. Nguyen, M. Stang, and J. Wong. (Philips Respironics). Chemical Class Emission Trends of Volatile Organic Substances Emitted from Breathing Gas Pathway Devices under ISO 18562-3:2024.

3rd: A. Bettmann, J. Brown, and A. J. Clippinger. (PETA Science Consortium International). Scientific Confidence in the Monocyte Activation Test: A Human-Relevant Pyrogenicity Test for Medical Devices.

Best Poster:

1st: N. Akers, A. Harmon, M. R. Smith, C. E. Astete, C. Sabliov, and T. R. Dugas. (Louisiana State University School of Veterinary Medicine; Lousiana State University). Novel, hemocompatible nanoparticles with unexpected pharmacological properties.

2nd: S. Zheng, R. Nguyen, and D. Faulk (Philips Respironics). Temporal Profiling of VOS Emissions: Accelerated Aging and Reprocessing of Breathing Gas Path Medical Devices for Biological Safety Assessments.

3rd: K. Godlewska, C. Graham, M. Frohbergh, S. Kalyan, R. Viswanadha, and P. Hasgall. Zimmer and Exponent). Passivation, Electropolishing and Anodization as Surface Residue Mitigation Steps for Biocompatibility Risk Management in Medical Device Manufacturing—A Retrospective Analysis.

Best Published Paper:

Borton, L., & Coleman, K. Material-mediated pyrogens in medical devices: Myth or reality?. *ALTEX*, 43(1), 78-97 https://doi.org/10.14573/altex.2504231.

Early Career Achievement Award:

Cassandra J. Meakin (Gradient). "Identification of Chemicals of Endocrine and Reproductive Concern in Medical Device Extractables and Leachables Datasets"

Lifetime Achievement Award: Ron Brown (Risk Science Consortium)

Mentoring and Networking

MDCPSS participated in the inaugural NetworX event organized through the SOT Career Advancement, Mentoring, and Networking (CAMAN) Committee. The event provided trainees and early-career professionals with opportunities to engage with experienced toxicologists across a variety of sectors. The initiative was considered successful and discussions are underway regarding a similar activity for the 2027 SOT Annual Meeting.

MEET YOUR 2026-2027 EXECUTIVE COMMITTEE

The MDCPSS Executive Committee welcomed several new officers beginning May 1, 2026. The current leadership team includes:

Position	Officer
President	Sharlee More
Vice President	Kimberly Ehman
Vice President-Elect	Rachel Chang
Secretary/Treasurer	Mark Cabonce
Past President	Ju Young (Julie) Park
Senior Councilor	Deniz Emul
Junior Councilor	Clarissa Shaffer
Graduate Student Representative	Nicole Akers

WELCOME NEW EXECUTIVE COMMITTEE MEMBERS

Rachel Chang, Vice President-Elect



Rachel Chang is the new Vice President-Elect of MDCPSS. Rachel is a board-certified toxicologist at Gradient with extensive experience supporting medical device biological safety and risk assessment in accordance with ISO 10993 and ISO 18562. Rachel is a member of AAMI working groups WG02, WG06, and WG18. She received her PhD in Toxicology, with an emphasis in Neurodevelopmental Toxicology, from University of Washington.

Mark Cabonce, Secretary/Treasurer



Mark Cabonce, MS, DABT, is a board-certified toxicologist with more than 20 years of experience spanning agricultural chemicals, pharmaceuticals, medical devices. He is an ISO 10993 biocompatibility and toxicology SME who has directed GLP and non-GLP toxicology studies and authored numerous BEPs, BERs, and TRAs supporting US FDA, EU MDR, and global submissions. His background includes human exposure toxicological risk assessments, mechanistic modeling (PBPK, BMD), and broad pre-clinical safety expertise. He is currently a Principal Scientist at Abbott and has been a Diplomat of the American Board of Toxicology since 2005.

Clarissa Shaffer, Junior Councilor



Clarissa Shaffer is the new Junior Councilor for MDCPSS. She is a board-certified toxicologist, and is currently a manager in the Global Toxicology, Biocompatibility, and Chemical Characterization organization at Boston Scientific. She received her PhD in Molecular and Environmental Toxicology from the University of Wisconsin-Madison in 2014. Clarissa currently serves as a committee member for multiple AAMI BE working groups, and she previously served 6 years on the board for the Northland Regional chapter of the Society of Toxicology (NLSOT).

Nicole Akers, Graduate Student Representative



Nicole Akers is a third-year DVM/PhD student in the Department of Comparative Biomedical Sciences at the Louisiana State University School of Veterinary Medicine. Her current research focuses on the development of nanomaterials as coatings for medical devices. As the Graduate Student Representative, she is eager to promote student engagement within MDCPSS.

AAMI BIOLOGICAL EVALUATION WEEK REPORT

Kim Ehman and Megan Hahn

The US working groups (WGs) for the ISO 10993 series are managed by the AAMI (Association for the Advancement of Medical Instrumentation) biological evaluation (BE) committee. Each year AAMI hosts a BE week, which serves as a forum for US experts involved in the development and revision of the ISO 10993 series.

AAMI BE Week was held as a hybrid event from May 11–15, 2026. During the meeting, US members of the ISO 10993 working groups participated both onsite in Arlington, Virginia, and remotely to discuss recent developments, ongoing activities, and proposed updates across multiple standards within the ISO 10993 series.

Notable Highlights from AAMI BE Week

Within **WG01**, which supports the ISO 10993-1 standard, extensive discussion focused on several projects that are planned to follow the recent revision of Part 1, including: (1) guidance on biological risk estimation; (2) consideration of bioaccumulation and intermittent contact; (3) product life cycle considerations; (4) biological equivalence; (5) reasonably foreseeable misuse; and (6) the use of clinical data.

The majority of discussion during AAMI BE Week centered on the proposed guidance for biological risk estimation, as well as how bioaccumulation and intermittent contact can impact device duration categorization. The topics generated significant engagement from participants, and the project leads indicated that draft documents are expected to be available for review during the summer, ahead of further discussion at the ISO meeting in the fall. Both working groups are targeting early 2027 for completion of draft guidance documents in the form of Technical Specifications (TS).

Product life cycle considerations and reasonably foreseeable misuse were also discussed extensively. Additional updates on the scope and timelines for these projects are expected following the fall ISO meeting.

In **WG02**, there was extensive discussion around degradable materials, including extractable and leachable challenges, support for improved histopathology guidance, and recognition for greater harmonization across the ISO standards addressing degradable devices. Action items included development of additional guidance, decision-tree approaches, mechanism-based testing strategies, and standardized evaluation methods for degradable and absorbable materials.

WG06 supports ISO 10993-3, which addresses genotoxicity, carcinogenicity, and developmental and reproductive toxicity. During BE Week, much of the discussion focused on the definition of "indirect" contact in relation to reproductive and developmental toxicity assessments. Participants expressed concern that the current wording could be interpreted too narrowly and potentially exclude devices that may result in systemic exposure through extractables and leachables. This topic was identified for further discussion at the ISO meeting in the fall. Future revisions may also address assessment of non-genotoxic carcinogenicity, particularly for situations where traditional extractables testing is difficult. With respect to genotoxicity testing, there was recognition of the need for additional guidance on interpretation of equivocal genotoxicity results, including historical control data and borderline responses, and consensus that further discussion is needed before pursuing harmonization of S9 metabolic activation systems across laboratories. The final version of ISO 10993-3:2026 was released in August, incorporating the related ISO /TR 10993-33:2015 technical report into the main ISO 10993-3 standard.

One of the main topics of discussion in **WG11**, which supports ISO 10993-7 and -17, including ISO/TS 21726, was TTC harmonization (µg/day vs. µg/kg/day). There was no consensus reached during this meeting, but the

implications for pediatric and neonatal populations, analytical evaluation thresholds (AETs), and toxicological risk assessments (TRAs) were extensively discussed. Additional discussions on this topic will continue at the ISO level in the fall with a follow-up AAMI WG meeting.

Highlights from **WG16** included more discussion to phase out the rabbit pyrogen test for material mediated pyrogenicity. Potential flow charts based on a materials assessment may be incorporated into the upcoming revision to ISO 10993-11 to help determine the risk of an actual pyrogenic effect from a device. However, some regulators are still reluctant to waive this test when there are significant limitations in screening methods for this endpoint and tests (such as the Monocyte Activation Test) are not currently validated for medical devices.

The above summary provides some key takeaways from a few sessions; however, numerous additional working group meetings were held during BE Week. Overall, BE Week 2026 highlighted a shift toward more risk-based, mechanism-driven biological evaluation approaches, greater reliance on chemistry and modeling tools, and increased harmonization across standards to support evolving medical device technologies.

MEMBER ACCOMPLISHMENTS AND RECOGNITION

The MDCPSS Executive Committee would like to recognize the accomplishments of our members.



Congratulations to MDCPSS members **Kelly Coleman** and **Lindsey Borton**! They have been awarded the 2026 Lush Prize for Political Advocacy for their work championing non-animal alternatives to the evaluation of material-mediated pyrogenicity. The Lush Prize is a collaboration between cosmetics company Lush and research group Ethical Consumer. The £250,000 prize fund is the biggest prize in the non-animal testing sector, and they were selected from 60 nominations across all award categories. Please join us in congratulating Kelly and Lindsey on this incredible accomplishment!

RECENT & UPCOMING WEBINARS

MDCPSS have two webinars planned for the 2026-2027 year!

"Particulate Risk Assessment Strategies for Medical Devices Manufacturers" featuring Dr. Shahid Parvez (Intuitive Surgical) and Dr. Sharlee More (MCRA) was held on Monday October, 26 2026 at 11:00 AM to 12:00 Noon (US EDT)

Slides to be made available on the SOT Learning Library.

"Medical Device Design Changes: Bridging Chemical and Biological Equivalence in a Changing Regulatory Landscape" featuring features Dr. James Kleinedler (Medtronic), Adam Kozak (Lifesciences), Dr. Kevin Trankler (Eurofins, Medical Device Services), Dr. Sherry Parker (Sparker Toxicology Consulting LLC) and Dr. William Wustenberg on January 27, 2027 at 1:00 PM to 2:30 PM (US EST)

SOT 2027 PROGRAMMING

MDCPSS-related proposals receiving acceptance for SOT 2027 include:



- Navigating PFAS in Medical Device Safety (Informational Session)
- Clearing the Air: Challenges and Strategies for Analyzing Breathing Gas Pathway Devices (Informational Session)
- Advancing Medical Device Safety with Human-Relevant New Approach Methodologies (Scientific Session)
- On the Nerve: From Implantation Studies to Risk Assessment of High-Risk NeuroTech Medical Devices (Continuing Education Course)

MDCPSS Awards

MDCPSS Executive Committee would like to announce the addition of a student travel award for the upcoming year. See our website for award descriptions and eligibility requirements.

In addition, monetary prizes will be awarded for the Best Overall Abstract Award, Best Poster Award, Best Published Paper Award, Early Career Achievement Award, Lifetime Career Achievement Award, and our newly added Student Travel Award. The award application deadline is January 15, 2027.

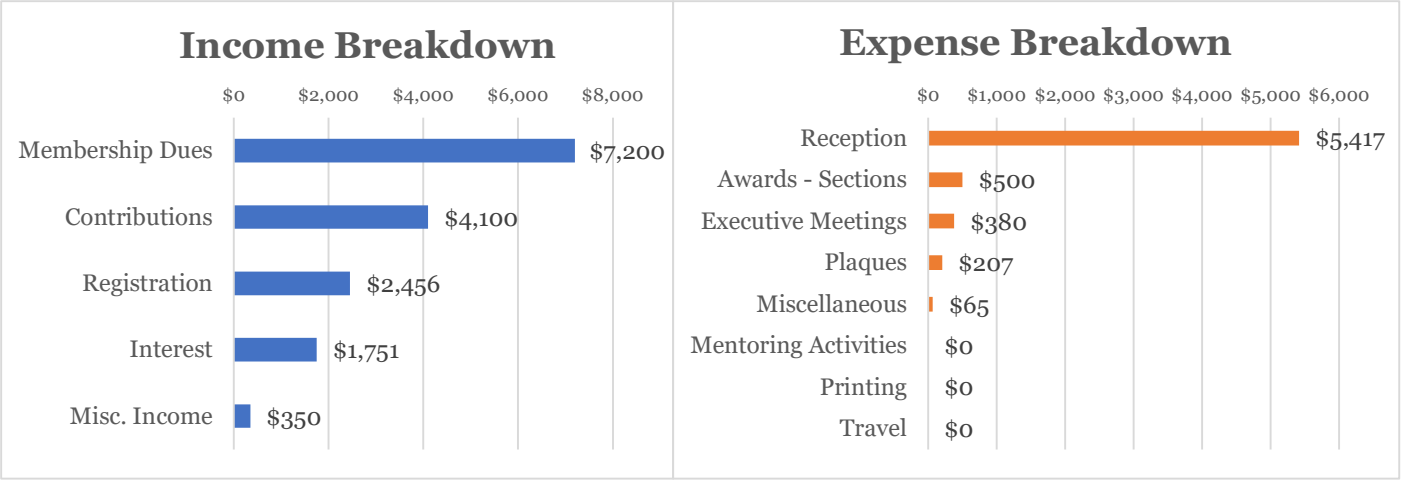
TREASURY UPDATE

The Executive Committee sincerely thanks all organizations and individuals who support MDCPSS through sponsorship and donations. Sponsorship support helps fund student and early-career activities, awards,

networking events, and future educational programming. Sponsorship outreach for the 2026-2027 year is currently underway.

TOTAL INCOME	TOTAL EXPENSES	OPERATING SURPLUS	ENDING NET ASSETS
$15,857	$6,569	$9,288	$36,777

MDCPSS FINANCIAL OVERVIEW



MDCPSS OBJECTIVES

MDCPSS Mission

1. Provide an international focus group for toxicologists working in the area of medical devices and combination products including a device component
2. Promote the development of new experimental methods for the evaluation of medical devices
3. Sponsor scientific and educational programs that emphasize current developments and issues in the toxicological evaluation of medical devices
4. Promote proactive communication and interactions among toxicologists in government regulatory agencies, regulated industry, and academia regarding current issues in medical device toxicology
5. 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