MDCPSS FALL NEWSLETTER

Volume 15 / Issue 1

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2023-2024 MDCPSS Executive Committee Members at the 2024 SOT 63rd Annual Meeting (Dr. Hosako not shown in the picture)

PRESIDENT'S MESSAGE

Dear MDCPSS Members,

Greetings and I hope that everyone is enjoying a wonderful September!

It's an honor to serve as your 2024-2025 MDCPSS President alongside our new Executive Committee: Mansi Krishan (Past President), Ju Young (Julie) Park (Vice 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).

I also sincerely appreciate the following previous MDCPSS Executive Committee members who provided significant contributions to MDCPSS-organized and -sponsored activities in the past year: Shelby Skoog (Past President), Hiromi Hosako (Secretary/Treasurer), Bhavesh Ahir (Councilor), and Deniz Emul (Graduate Student Representative). Thank you very much for your service on the MDCPSS Executive Committee!

The MDCPSS Executive Committee is dedicated to continuing to improve MDCPSS through a focus on promoting scientific contribution via webinars, membership communications, SOT Annual Meeting scientific sessions and posters, 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 2024 SOT Annual Meeting and were very excited to greet MDCPSS members at the poster session and annual reception! Congratulations to all the 2024 MDCPSS award winners. Please see the details below to learn more about the award winners and their state-of-the-art research. MDCPSS, together with the *In Vitro* and Alternative Methods Specialty Section and Risk Assessment Specialty Section, hosted a successful mentoring event at SOT with 16 mentors from industry, government, and consulting. For more details on the mentoring event, please see below.

As we kicked off a new term in May to develop Scientific Session and Continuing Education course proposals for the 2025 SOT Annual Meeting, our EC received seven scientific proposals for pre-review and endorsement, and three have been selected by the SOT Program Committee for presentation at the 2025 SOT Annual Meeting. These are awesome efforts contributed by our exceptional MDCPSS members! We thank Dr. Ju Young (Julie) Park, Chair of the MDCPSS Program Committee, for leading the work on pre-review, detailed feedback, and formal review and recommendation process.

Updates have been made to the award criteria for the MDCPSS Awards at the 2025 SOT Annual Meeting to better recognize and promote individuals and young scientists in the medical devices/combination product world. Two major changes include the Best Overall Abstract Award and Early Career Achievement Award. Thank you, our Award Committee Chair/Co-Chair and members Drs. Ju Young (Julie) Park, Bill Wustenberg, Mansi Krishan, and Bhavesh Ahir, for your thoughtful consideration! We strongly encourage you to submit your nominations for MDCPSS awards to Drs. Ju Young (Julie) Park and Bill Wustenberg to be considered in the 2025 SOT Annual Meeting.

Toward the end of the year, we will be inviting nominations to serve in different officer positions in 2025-2026. If you are interested in running for an officer position or would like to nominate someone, please reach out to Dr. Mansi Krishan, Chair of the MDCPSS Nominations Committee.

In addition to the webinar presented in May on the *Biological Evaluations for European Union Medical Device Regulation: Challenges, Experiences, and Tips*, we continue to develop and organize several device safety related webinars throughout this year. Please stay tuned!

Thanks to all the existing and new members and sponsors for your continued support! MDCPSS is now inviting sponsors in 2024-2025. Our members play vital roles in their respective areas and make significant contributions

to toxicology research and application, ensuring the safety of medical devices and combination products. We greatly appreciate your financial support for MDCPSS to continuously host and organize various SOT Annual Meeting events, awards, and activities for our members. Please contact Dr. Bhavesh Ahir and me for sponsorship opportunities.

Thanks to Rachel Chang, Qiran Chen, Julie Park, and all the members of the newsletter committee for putting together this newsletter. If you would like to be more involved with MDCPSS activities or would like to volunteer for a committee, please reach out to MDCPSS Membership Committee Chairs Drs. Rachel Chang and Qiran Chen.

Please continue to check the MDCPSS website for updates and feel free to contact me or any other Executive Committee member with ideas for programs, outreach, webinars, or suggestions for improvement.

A big THANK YOU to MDCPSS Executive Committee members for your leadership, hard work, and commitment. I have been very lucky to be a part of this awesome team to serve our members together.

I am looking forward to planning the MDCPSS activities for the SOT 64th Annual Meeting in Orlando, Florida, and hope to see you in person!

Sincerely,

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

President, MDCPSS (2024-2025)

WATCH MDCPSS WEBINARS

Biological Evaluations for European Union Medical Device Regulation: Challenges, Experiences, and Tips

Date and Time: May 16, 2024

Speakers:

Lina Burman, PhD, Sr. Scientific Affairs Manager, Biocompatibility and Toxicology, Veranex

Monica Grekula, ERT, MSc, MSc, Sr. Director Scientific Affairs, Biocompatibility and Toxicology, Veranex

Abstract: Adapting the biological evaluation to the market you want to put your product in is sometimes called regulatory toxicology. While there are usually underlying reasons for the approval requirements, they are sometimes difficult to interpret. The ultimate goal is to have safe products while also gaining quick market access. This webinar offers perspectives from speakers based in Europe who have extensive experience in working with different Notified Bodies (NB) and products of different risk classes. They also highlight how the requirements differ from the US FDA. They share challenges and experiences gathered during their time as consultants in the field.

This webinar slides and recording are available on the MDCPSS website:
http://www.toxicology.org/groups/ss/MDCPSS/pastevents.asp

PAST SOT ANNUAL MEETING

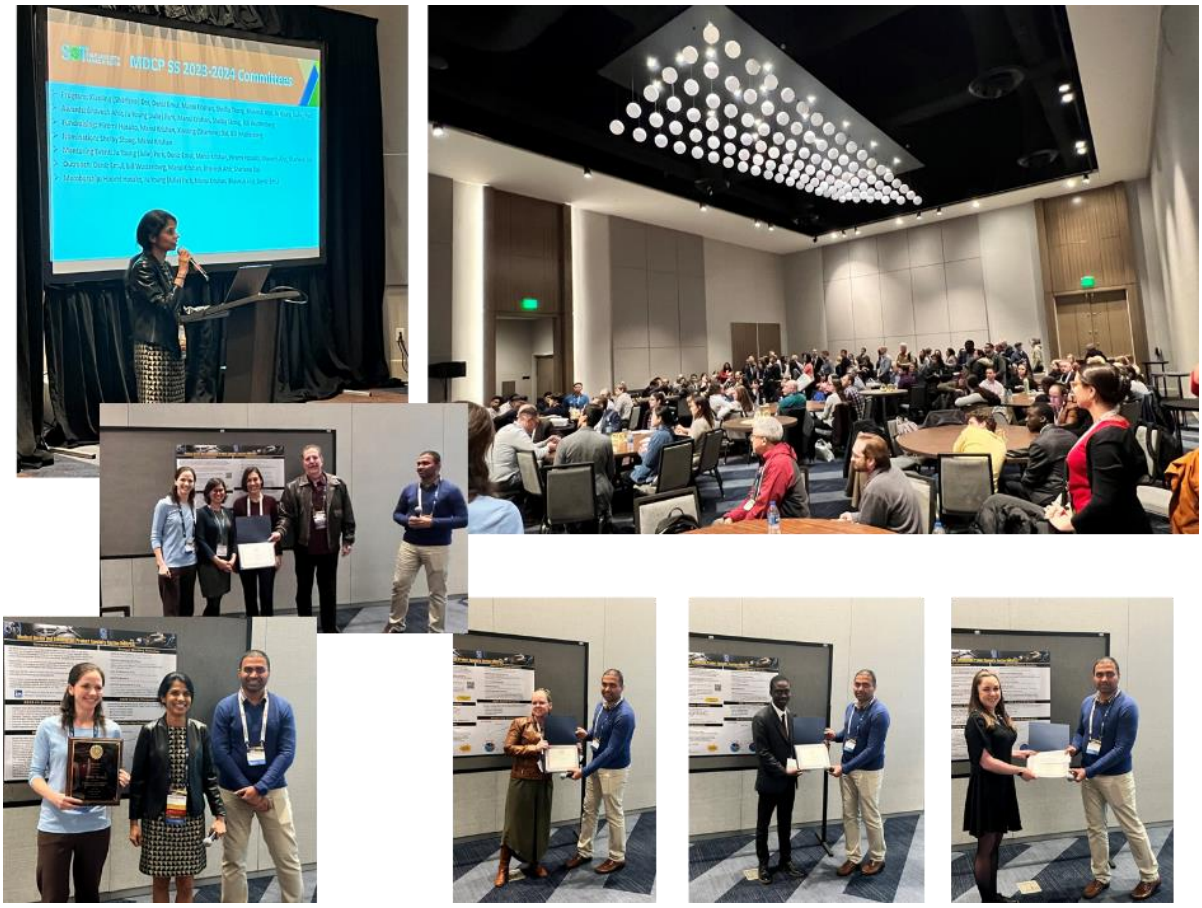
2024 SOT Annual Meeting Highlights

Medical Device and Combination Product Specialty Section Events held at the 2024 SOT Annual Meeting & ToxExpo:

- **Medical Device and Combination Product Specialty Section Reception: Tuesday, March 12, 6:00 to 7:30 PM**

  200+ Attendees

  Summary: The reception included a presentation overview of the 2023-2024 MDCPSS activities, 2024 SOT Annual Meeting MDCPSS activities, MDCPSS officers, subcommittees, treasurer's report, membership report, 2023-2024 webinars, MDCPSS award winners, and upcoming opportunities.

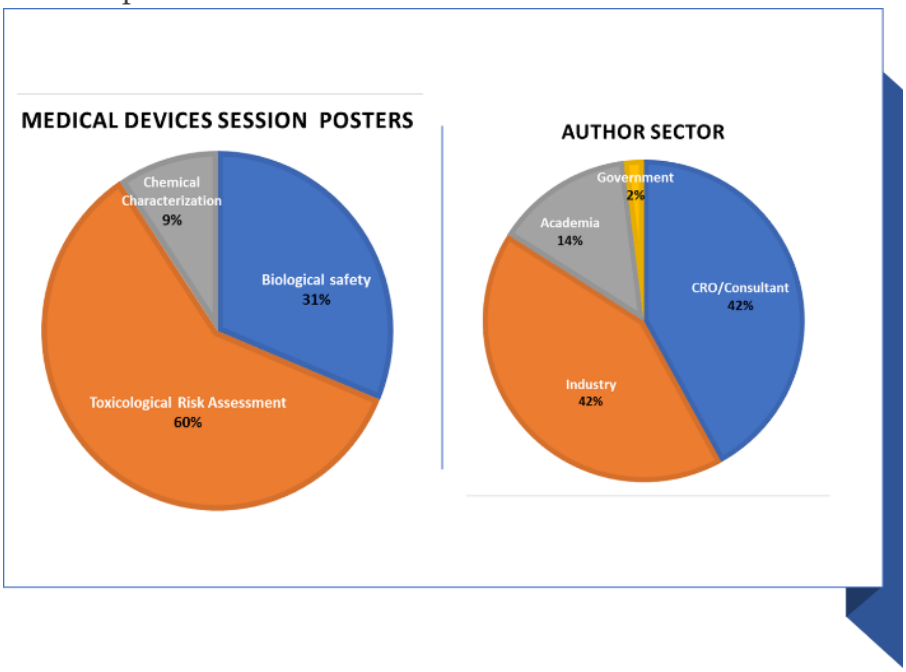


- **2024 MDCPSS Joint Mentoring Event Recap**

For the first time, MDCPSS co-hosted a joint mentoring event with the *In Vitro* and Alternative Methods Specialty Section and Risk Assessment Specialty Section during the 2024 SOT Annual Meeting. The event was held at Hyatt Regency Salt Lake City on Tuesday, March 12, 2024. It provided opportunities for undergraduate students, graduate students, postdoctoral scholars, and early-career scientists to meet with mentors with different expertise from diverse sectors and learn more about the variety of potential career paths and skills required to advance as toxicologists. This event was well attended with over 16 mentors and 29 mentees.

Thank you to those who participated!

- **Medical Device Posters: 48 posters**
  - Medical Devices Session: 32 posters
  - Other Sessions: 16 posters



- **MDCPSS Session Proposals**
  - **Symposium**
    Taking a Closer Look at Biological Evaluations for Ocular Medical Devices and Combination Products
    Chair(s): Andrea Rodrigues, AbbVie Inc.; and William Cook, Merck & Co. Inc.
  - **Workshop**
    Overcoming Unique Challenges Associated with Biological Evaluation of Absorbable/Degradable Medical Devices and Combination Products: Regulatory and Scientific Considerations from Successful Case Studies
    Chair(s): Daysi Diaz-Diestra, North American Science Associates LLC; and Teresa Palacios-Hernandez, US FDA/CDRH
  - **Informational Session:**
    From My Cosmetics to Smart Watch, Toxicology Touches It All!
    Chair(s): Mansi Krishan, Meta Platforms Inc.; and Tom Lewandowski, Gradient

Congratulations to our 2024 SOT Annual Meeting Award Winners!!!

Best Abstract Award
Are ICH Q3D Permissible Daily Exposure (PDE) Limits for Elements Adequately Protective for Medical Device Exposures
Sarah Colleen Campbell, Matthew Jorgensen, Trevor Fish, Ravi Sajja

Best Published Paper Award
Harmonisation of read-across methodology for drug substance extractables and leachables (E&Ls) (Regul Toxicol Pharmacol 2023 Dec)
Melisa Masuda-Herrera, Hannah T Rosen, Anders Burild, Thomas Broschard, Tyler Bell, Jessica Graham, Troy Griffin, Jedd Hillegass, Penny Leavitt, Brian Huta, Patricia Parris, Uma Bruen, Maureen Cruz, Joel Bercu

Best Poster Award
Evaluation of the Ability of the *In Vitro* Reconstructed Human Epidermis (RhE) Irritation Assay to Predict the Irritation Potential of Medical Devices Compared with the *In Vivo* Intracutaneous Reactivity Assay per ISO 10993-23
S. Skoog, C. Silva, T. Kudlyk, N. Twaddle, C. Ghosh, L. Camacho, and P. Goering

Postdoc Achievement Award
Novel point-of-care assay for acetaminophen overdose associated drug-induced liver injury
K. M. Scullion, S. Sloan-Dennison, B. Clark, P. Fineran, J. Mair1, D. Creasey, C. Rathmell, C. Weir1, K. Faulds, D. Graham, and J. W. Dear

Student Achievement Award
Comparison between Inductively Coupled Plasma-Mass Spectrometer (ICP-MS) and X-ray fluorescence (XRF) Performance for Trace Elemental Analysis in Rat Tissue Samples
K. E. Adesina, S. A. Parducci, and A. J. Specht

Executive Committee Service Awards
Past President – Shelby Skoog
Secretary/Treasurer – Hiromi Hosako
Councilor – Bhavesh Ahir
Graduate Student Representative – Deniz Emul

The **SOT 64th Annual Meeting and ToxExpo** will feature more than 70 Featured Scientific Sessions, 2,000 presentations, 250 exhibitors, and 5,000 attendees.

More details on these sessions, as well as the official schedule, will be available in the coming months. https://www.toxicology.org/events/am/AM2025/index.asp

Abstract submission due:

- **Abstract submissions are due at 11:59 pm (US EST) on Wednesday, November 13.**

  Abstracts must be submitted through the online Abstract Submission System for consideration for the 2025 SOT Annual Meeting and ToxExpo. Please note that some SOT Awards (Award Opportunities—2025 SOT Annual Meeting (toxicology.org)) are contingent upon having an abstract submitted to and accepted for the SOT Annual Meeting. Some of these award deadlines precede the abstract submission deadline, so plan accordingly.

Information on registration fees and other registration-related details for the meeting will be available soon. Stay tuned!

2025 SOT MDCPSS Awards

- Best Overall Abstract Award
- Best Poster Award – **Review at SOT Annual Meeting during Medical Device and Combination Product Poster Session**
- Best Published Paper Award
- Early Career Achievement Award

For more information on awards, see our website.

2025 SOT MDCPSS Award Criteria

Changes in the Award Criteria for 2025 MDCPSS Awards

Attention, members! Updates have been made to the award criteria for MDCPSS Awards to better recognize individuals and young scientists in the medical devices/combination product world. Major changes include the following:

1. **MDCPSS Best Overall Abstract Award** has been opened up to any abstract accepted for presentation at the SOT Annual Meeting that indicates medical devices/combination product focus or impact. To ensure consideration for this award, please make sure to include 'medical device' and/or 'combination product' as a keyword and send a copy of the accepted abstract to us. Top three winners will be provided with a ribbon to put on during the MDCPSS poster session, and the lead author of the best abstract will receive a plaque.

2. **The title of 'MDCPSS Student Achievement Award has been changed to 'MDCPSS Early Career Achievement Award'** to recognize the research accomplishments of young scientists in their early career. The leadership will now select up to two award recipients—one for undergraduate/graduate students and one for postdoctoral fellows/individuals with less than 5 years post-graduation experience.

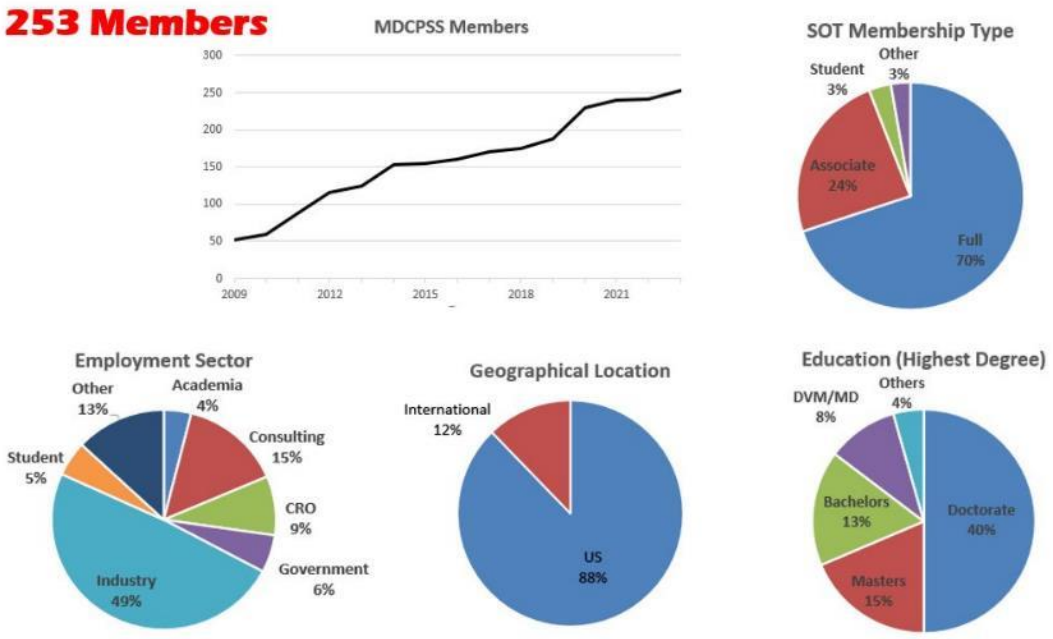
To nominate for this award, please submit the SOT notice of abstract acceptance, the accepted abstract, a letter of support from a supervisor/mentor, and a brief justification statement. The winners will receive a plaque and monetary award.

In addition to these awards, we will continue to recognize SOT accepted posters and papers related to medical devices and combination products with the MDCPSS Best Poster Award and Best Published Paper Award. We encourage our members to submit their work for 2025 MDCPSS awards! If you have any questions, contact William Wustenberg and Ju Young (Julie) Park.

MEMBERSHIP UPDATES

The MDCPSS was formed in 2009 with 51 founding members. Since then we've grown steadily and now have 253 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 (see Figure below). Educational backgrounds range from BS degrees to those with MBAs, MPHs, PhDs, DVMs, and MDs.



MDCPSS Recommendations for SOT Speaker Directory 2024-2025.

1. Mansi Krishan, PhD, DABT, ERT (Meta)
2. Richard Hutchinson, PhD, DVM, DABT (J&J)
3. Joseph Carraway, MS, DVM (NAMSA)
4. Xiaoling (Sharlene) Dai,MD, PhD, DABT, RAC (Abbott)
5. Kim Ehman, PhD, DABT (Wuxi AppTec)

Recommended speakers from previous years are available on SOT ToXchange.
https://toxchange.toxicology.org/speakerdirectory?executeSearch=1&Topics=device

MEMBER HIGHLIGHT

Congratulations to MDCPSS Member and Former President, Kelly Coleman, Inducted into the American Institute for Medical and Biological Engineering (AIMBE) College of Fellows

Founding member and former president Kelly Coleman was recently inducted into the prestigious American Institute for Medical and Biological Engineering (AIMBE) College of Fellows (https://aimbe.org/college-of-fellows/COF-9027/). As noted on their website, "Election to the AIMBE College of Fellows is among the highest professional distinctions accorded to medical and biological engineers, comprised of the top two percent of engineers in these fields." Kelly was selected for admission to the College of Fellows "for scientific and engineering contributions to biocompatibility and toxicology that have supported advancements in both medical technology and testing standards." Congratulations, Kelly!

NEW COMMITTEE MEMBERS

Bhavesh Ahir, PhD, DABT

Bhavesh Ahir is currently working as a toxicologist/biologist at the US FDA. Previously, Dr. Ahir worked as a senior toxicologist at the Eurofins Medical Device Testing with specialties in toxicological risk assessment and evaluating biocompatibility of medical devices. At Eurofins Medical Device Testing, his primary responsibilities were biocompatibility assessment, biological evaluation plan, writing gap analyses, toxicological risk assessment of medical devices (Class-I, II and III), and toxicological risk assessment of biopharmaceutical drug products including container-closure system. Additionally, Dr. Ahir has a working knowledge of US FDA, EU MDR, and other global medical device regulations and preclinical safety evaluation of pharmaceutical drug products based on US FDA and EMA regulatory guidance. Previously, Dr. Ahir also involved as a US Expert on ISO Technical Committee 194's Working Group 11, which is responsible for the medical device toxicology risk assessment standard (ISO 10993-17). Before joining Eurofins Medical Device Testing, Dr. Ahir worked at the University of Illinois at Chicago as a research scientist in cancer biology and computational genomics field. Dr. Ahir also worked as an ORISE postdoctoral research fellow at the National Center for Computational Toxicology (now it is known as Center for Computational Toxicology and Exposure). Dr. Ahir received his PhD in Developmental and Reproductive Toxicology from the University of Nottingham, UK. Dr. Ahir is author/co-author of more than 19 peer-reviewed publications, two white papers and one book chapter.

Dr. Ahir has been an active member of the SOT since 2012 and has served in several elected positions for the Medical Devices and Combination Products Specialty Section (MDCPSS) and Molecular Systems Biology Specialty Section (MSBSS). Dr Ahir is also a full member of the Society of

Birth Defects Research & Prevention (BDRP) and the American College of Toxicology (ACT). Dr. Ahir previously served as a Postdoctoral ad hoc member in BDRP (Previously known as The Teratology Society) Communication Coordination Working Group, Website Committee, and Public Affairs Committee.

Sharlee More, PhD, DABT

Sharlee More is the new Vice President-Elect of MDCPSS. She is a board-certified toxicologist who works at MCRA, an IQVIA business. She has extensive knowledge and experience in toxicology and human health risk assessment related to medical devices. She is excited to serve on the MDCPSS Executive Committee and work with the members dedicated to ensuring safe devices make it to market.

Rachel Chang, PhD, DABT

Rachel Chang is the new Jr. Councilor of MDCPSS. She is a board-certified toxicologist since 2022 and has been an active member of SOT since 2013. Dr. Chang is a senior toxicologist at Gradient where she supported medical device biological safety and risk assessment in accordance with ISO 10993 and ISO 18562. During her time at Gradient, Dr. Chang has shepherd a wide variety of medical device products including long term implant, combinational products, dermal patches, and breathing gas pathway devices intended for patients as young as neonates through regulatory approval for the US FDA, and EU. Dr. Chang received her doctorate in Toxicology from the University of Washington in 2018, where she investigated autism related neurodevelopmental outcome following prenatal exposure to diesel exhaust in rodent model.

Qiran Chen, PhD

Qiran Chen is a Postdoctoral Associate in the Department of Environmental and Global Health at the University of Florida. She received her PhD in Environmental Health from Indiana University. Her doctoral research focused on the improvement of dose-response analysis in chemical risk assessment. Before joining the University of Florida, Dr. Chen was a Postdoctoral Associate at the Institute of Computational Comparative Medicine at Kansas State University. She is also the author/co-author of 11 peer-reviewed articles. She became a member of SOT in 2020. Her relevant work was recognized by the Society of Toxicology and awarded Andersen-Clewell Trainee Award (2020), Perry J. Gehring Award (2022), the Best Postdoctoral Publication Award (2023), and AACT and InnoStar Best Abstract Award (2024). Besides, she was elected as the Treasurer of the Postdoctoral Assembly Executive Board in 2023-2024 and the Postdoctoral Representative of the Biological Modeling Specialty Section in 2023-2025.

Ishita Virmani
Ishita Virmani is currently pursuing a PhD in Environmental Health Sciences at Masaryk University, Czech Republic. She is a member of the Cell and Tissue Toxicology group. During her PhD, she has assessed the biocompatibility of the hydrogels and is interested to explore New Approach Methodologies (NAMs) for risk assessment. Prior to her PhD, Ishita earned an MRes degree from Newcastle University in the UK.

MEDICAL DEVICE STANDARD AND REGULATION UPDATES

ISO 18562:2024 *Biocompatibility evaluation of breathing gas pathways in healthcare applications – Parts 1 through 4* : Evaluation and testing within a risk management process

- Alex Gauthier, PhD, Sr. Toxicologist, Gradient
- Corey Campbell, CHMM, Industrial Hygienist, Legend Technical Services, Inc.
- Rachel Chang, PhD, DABT, Sr. Toxicologist, Gradient

In March 2024, ISO released the latest version of this Standard, recognized by the US FDA in May 2024. ISO 18562:2024 is a major update and provides a reinvigorated and state-of-the-art framework to evaluate the biocompatibility of gas pathway devices. Highlights from the updated Standard include:

- Emphasis on conducting risk evaluation over the entire lifespan of the device, from raw materials to the final, finished device (including packaging, sterilization, shelf-life assessment, expected service life, and reprocessing).
- Emphasis on evaluation of devices up to the end of their expected service life.
- New terms and definitions for infrequent or intermittent use and emphasis on using clinically relevant conditions to inform how biological evaluation is performed.
- Biological evaluation plans (BEPs) should assess the following endpoints: ISO 10993-1 biocompatibility, leachable substances, material and physical characterizations, degradation, volatile organic substances, and particulate matter generation. These endpoints should be evaluated at all of a device's lifespan/lifecycle stages, as described above, within an ISO 14971 risk management process.
- Recommendation to use a weight-of-evidence approach that allows for the use of relevant nonclinical safety studies, clinical trials, and post-market surveillance data.

Key updates to the Standard that will affect analytical chemistry testing of breathing gas pathway devices include the following:

- ISO 18562-3:2024 – Test for emissions of volatile organic substances:
- Testing for volatile substances now separates the substances into three classes:
  1. Very volatile organic compounds (VVOCs, boiling point 0-50°C)
  2. Volatile organic compounds (VOCs, boiling point 50-250°C)
  3. Semivolatile organic compounds (SVOCs, boiling point range >250-400°C)
- Targeted compounds at <1 µg/m^3 and non-targeted tentatively identified compounds <2 µg/m^3 need not be reported.

- Additional testing for aldehydes (specifically formaldehyde and other carbonyl compounds) should be included in the gas pathway testing of medical devices. Monitoring for carbon dioxide, carbon monoxide, ozone, and nitric oxide (NO_x) is also included for specific devices.
- In addition, in ISO 18562-2:2024 (Test for emissions for particulate matter), testing for particulate matter ($PM_{2.5}$/PM_{10}) includes the same testing criteria as the 2017 version of the standard.

There are also several major updates to the Standard that will influence risk assessment considerations:

- ISO 18562-1:2024 introduced the concept of infrequent use and a total exposure period for devices: "If the medical device or accessory is intended to be used for a recurring condition, then the determination as to whether this is treated as infrequent use is based on the likelihood that the patient recovers from any toxicological effects of the between episodes. If there is likely to be a cumulative effect then the total exposure period across all treatment episodes shall be considered …. If use of the medical device or accessory is deemed to be infrequent use, then the total exposure period is determined for a single treatment episode."
- Evaluating a device as an infrequently used device can be justified with toxicokinetic data on the elimination rate of each identified extractable compound from the device or with an *in vivo* systemic toxicity study of the device.
- ISO 18562-1:2024 includes expanded patient categories and updated associated parameters, such as body weight and breathing volume.
- This part of the Standard also introduced maximum exercise ventilation for children (3-10 years old), adolescents (10-18 years old), and adults (>18 years old) of 1.8, 2.6, and 4.6 m^3/hour, respectively. Assessors will need to know if patients will be active while using the device, and the duration of patients' active time per day, to estimate patient exposure to the device. In general, exercise ventilation rates are higher than resting ventilation rates, which will lead to increased patient exposure while active.
- ISO 18562-4:2024 noted the following scenarios in which risk assessment on leachable compounds should not be conducted:
- If the worst-case condensate volume is <0.1 mL/24 hours, no further testing/assessment is required.
- If the volume of patient-contacting condensate from a use error is "so large that it presents an unacceptable risk" (*i.e.*, aspiration pneumonia or drowning), regardless of the amount of leached substances from the device, that use error should be addressed and not be considered in the toxicological risk assessment.
- ISO 18562-1:2024 updated the thresholds of toxicological concern (TTCs) based on a device's use duration.
- For VOCs, the accepted TTC for limited use (≤24 hours) is now the same as the TTC for prolonged use (>24 hours but <30 days) (120 µg/day, from the current version of the ICH M7 guidance [dated 9/2023]), and the accepted TTC for long-term exposure (≥30 days) is 2 µg/m^3 (from the indoor air standard for organic compounds [ISO 16000-6:2021]).
- For leachable substances, the accepted TTCs for ≤1 month, >1 month to ≤1 year, >1 year to ≤10 years, and >10 years are 120, 20, 10, and 1.5 µg/day, respectively (from the current version of the ICH M7 guidance).
- ISO 18562-1:2024 notes that the ICH M7 mutagenic TTCs are considered sufficiently protective of general patient populations and "shall not be scaled according to body mass."

TREASURY UPDATE

The MDCPSS Executive Committee would like to thank our sponsors for helping to make MDCPSS 2023-2024 activities possible.

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

2023-2024 Net Assets

January	$22,554
February	$23,454
March	$14,106
April	$14,606
May	$14,203
June	$20,177

SPONSOR 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 thank you for your support at the Annual Meeting event and in our MDCPSS commincations. MDCPSS accepts donations through the SOT Component Group Donation Form. 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 SOT Headquarters (SOTHQ@toxicology.org).

Our MDCPSS members sincerely appreciate the generous sponsorship of our 2023-2024 sponsors. Invaluable financial support from our sponsors has been instrumental in making our Specialty Section a resounding success. Thanks to your contributions, we were able to provide not only financial support but also awards to our members. Your sponsorship not only helped us achieve our goals but also inspired many participants and attendees. Thank you for your invaluable support.

- **Boston Scientific**
- **Gore Medical**
- **Myocraft Medical LLC – Dr. William Wustenberg**
- **Medtronic plc – Dr. Kelly Coleman**
- **Johnson & Johnson MedTech – Dr. Betina Lew**

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