

MDCPSS

Summer Newsletter

August 2023

MDCPSS OFFICERS

President

Mansi Krishan

Vice President Xiaoling
(Sharlene) Dai

Past President Shelby
Skoog

Vice President-Elect Ju
Young (Julie) Park

Secretary/Treasurer
Hiromi Hosako

Councilors

Bhavesh Ahir
William Wustenberg

Student Representative
Deniz Emul

*Postdoctoral
Representative* Vacant
Position

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**MDCPSS Executive Committee Members
SOT Annual Meeting 2023**

PRESIDENT'S MESSAGE

Dear SOT MDCPSS Members,

Hope you are enjoying summer! SOT 2023 was my first in-person SOT since 2019 and it was so nice seeing several of you in-person. Even though MDCPSS poster session and reception were scheduled on the last day, both events were packed and it was a great turn out! Thanks to everyone who attended and participated in MDCPSS events at SOT. This newsletter will provide a summary of the MDCPSS events at SOT and what we have planned for the remainder of the year.



On behalf of the MDCPSS Executive Committee, I would like to welcome our new incoming officers, Ju Young (Julie) Park, VP Elect, and William (Bill) Wustenberg, Councilor. Also, I would like to thank our outgoing officers, Jan Oberdoerster, Immediate Past President, and Mercedes Salvador-Silva, Councilor for their leadership and contributions. Congratulations to all the 2023 MDCPSS award winners! Please see the details below to learn more about the award winners and their research. MDCPSS also held a mentoring event at SOT with over 10 mentors from industry, government, and consulting. This year we also had a mentor from recruiting to share his unique perspective with the mentees. For more details on the mentoring event, please see below.

As we kicked off a new term in May, we received session proposals for pre-review, and endorsement. Out of the three proposals endorsed by MDCPSS, two have been selected by the SOT Program Committee for presentation at SOT 2024 Annual Meeting. Thanks to Dr. Sharlene Dai, Chair MDCPSS Program Committee for chairing and starting the work on pre-review even before her term started. The Program Committee has also been busy reviewing proposals to co-host webinars and planning webinars. If you have an idea for a webinar or would like to co-host a webinar, please reach out to [Dr. Sharlene Dai](#) and [Deniz Emul](#). Thanks to Deniz Emul and all the members of the newsletter committee including member volunteers 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. [Hiromi Hosaka](#) and [Julie Park](#).

We are thrilled to share that we recently launched the [MDCPSS LinkedIn page](#) to share updates related to MDCPSS and stay connected with our current members and new potential members through LinkedIn. Thanks to Dr. Bhavesh Ahir for leading this effort and launching the page in such a short duration of time. We encourage you all to follow [MDCPSS LinkedIn page](#) to stay up to date on our events. Towards the end of the year, we will be requesting nominations for different officer positions. If you are interested in running for an officer position or would like to nominate someone, please reach out to [Dr. Shelby Skoog](#), Chair of MDCPSS Nominations Committee. Also, we encourage you to submit your nominations for [MDCPSS awards](#) to [Dr. Bhavesh Ahir](#), Chair of MDCPSS Awards Committee.

A big THANK YOU to MDCPSS Executive Committee members for your leadership, hard work, and commitment. I am thrilled to be a part of this Executive Committee, full of energy, and willing to explore new opportunities. Also, thanks to all the existing and new members and sponsors for continued support. If you have any thoughts and suggestions to help improve our specialty section or would like to share your scientific and career achievements, please feel free to contact any of the officers or me.

Sincerely,

Mansi Krishan, PhD, DABT, ERT
President, MDCPSS (2023-2024)

NEW COMMITTEE MEMBERS

INTRODUCING...

VP-ELECT

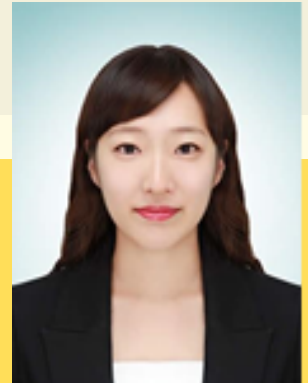
Ju Young (Julie) Park, PhD, DABT

Food and Drug Administration

Dr. Ju Young (Julie) Park is a toxicologist at the Food and Drug Administration, where she reviews and provides recommendations to the Sponsor's research protocols, toxicological and chemical risk assessment data, and biocompatibility data to support the safety and efficacy of medical devices and drugs.

She received her doctorate in Toxicology in conjunction with risk assessment emphasis courses from the University of Washington in 2017. From 2017 – 2019, she was a postdoctoral fellow at the same University, identifying and characterizing new alternative *in vitro* methods for reproductive and developmental toxicity (DART) evaluations as well as assessing DART effects after exposures to chemical agents such as heavy metals and nanoparticles. She then joined the US FDA as an ORISE fellow in 2019, where she evaluated *in silico* quantitative risk assessment methodologies that could be applied to assess the potential reproductive and developmental toxicity of chemicals present in, or released from, a medical device. Dr. Park is the author/co-author of multiple peer-reviewed publications, with many more to come.

She is a board-certified toxicologist since 2021 and has been an active member of SOT since 2014. In 2020 – 2021, she served as a postdoctoral representative for SOT MDCPSS.



COUNCILOR

William Wustenberg, DVM

Mycroft Medical LLC



William (Bill) Wustenberg, DVM (OSU & WSU, 83; BS Chemistry Willamette U, 79) has been an independent biomaterials toxicology consultant for medical device clients for over 25 years. Consulting for over 1000 companies to date, he has overseen more than a thousand devices through biological safety plan design, implementation and regulatory approval processes for the US FDA, EU CE Mark, and other international venues.

In 1991, Bill moved to Minnesota from Oregon and started his medical device career working through a diverse set of jobs that provided a deep understanding of GLP toxicology study design, pathology, toxicology, biocompatibility testing, animal models, viral and TSE safety of animal sourced materials, polymer science, analytical chemistry, managing regulatory processes and clarifying complex issues of biological safety for most types of medical devices. Bill has been a member of SOT since 2011 and is looking forward to working as a Counselor for the MDCPSS.

2023 ANNUAL MEETING NEWS

Monday, March 20



NASHVILLE
March 19–23

Medical Device and Combination Product Mentoring Event

MDCPSS Mentoring event was held at The Omni Nashville Hotel Convention Center. It was 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 facilitated 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.

This event was well attended, and approximately 15 mentees who participated had an opportunity to meet with more than 10 mentors as well as other professionals in the field. Thank you for those who participated!

I was new to this specialty section but attended because I was keen on expanding my knowledge and network to this area. Both events were well-attended, dynamic, and full of friendly and fun attendees. I met dozens of people doing very exciting work – both junior and senior – and was able to have many meaningful conversations with them. I was able to get one-on-one advice and coaching from several senior toxicologists. It felt like 8 hours of career counseling and advice bundled into 1 hour with some of the best minds. If I can give one piece of advice to other students and postdocs who are planning on attending next year's SOT, it would be to make sure to attend these mentoring events. If you are looking for a place to start, I highly recommend MDCPSS!

Dushani Palliyaguru
MDCPSS Mentoring Event Mentee

Thank you mentors...

Joseph Carraway, DVM, MS
Kelly Coleman, PhD, DABT, ERT, ATS, RAC
Xiaoling (Sharlene) Dai, PhD
Molly Ghosh, PhD
Hiromi Hosako, PhD, DABT
Frances Hsia, MS, MPH, DABT
Mansi Krishan, PhD, DABT, ERT
Terry Leyden
Mercedes Salvador-Silva, PhD, DABT
Shelby Skoog, PhD

...and all additional mentors!

2023 ANNUAL MEETING NEWS (CONTINUED)

Monday, March 20

MDCPSS Endorsed Session

Biocompatibility Assessment of Absorbable/Degradable Materials Employed in Medical Devices: Challenges, Pitfalls, and Emerging Testing Methods

Workshop Highlights

- Speakers from academia, industry, and government with expertise on the development and evaluation of absorbable medical devices.
- Discussed challenges of assessing absorbable medical device degradation and biological evaluation, existing standards/methods and their limitations, as well as emerging methods to improve safety assessments of absorbable medical devices.
- Included case studies of safety assessments of absorbable medical devices with different physico-chemical properties and degradation mechanisms, highlighting various considerations and approaches.
- Well-attended (~150) and interactive, with a 40-minute Q&A with enthusiastic dialogue between attendees and panelists, including insights into the future for safety assessment of absorbable medical devices.

Chairs

Daysi M. Diaz-Diestra, PhD | North American Science Associates, LLC (NAMSA)

Teresa Palacios-Hernandez, PhD | Center for Devices and Radiological Health, US FDA

Presentations

1) A Users Guide to Degradation Testing of Resorbable Polymers: from In Vitro to In Vivo Studies

Elizabeth Cosgriff-Hernández | Department of Biomedical Engineering, The University of Texas at Austin

2) Regulatory Process and Industry Challenges Regarding Bioabsorbable/Biodegradable Materials

Mehdi Kazemzadeh-Narbat, PhD, PMP, CQA | MCRA LLC

3) Challenges with Biological Evaluation of Absorbable Medical Devices

Shelby Skoog, PhD | Center for Devices and Radiological Health, US FDA

4) Challenges with ISO 10993 Biological Studies of Biomaterials and Bioabsorbables

Chad Reiter, PhD, DABT | North American Science Associates, LLC (NAMSA)

5) Chemical Characterization and Non-Targeted Analysis of Medical Device Extracts from Novel Materials

Berk Oktem, PhD, DABT | Center for Devices and Radiological Health, US FDA

6) New Approach Methods for Toxicological Risk Assessment of Extractable Compounds from Biodegradable/Bioresorbable Medical Devices

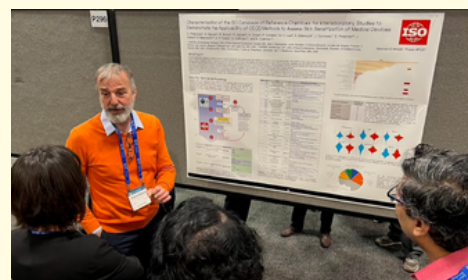
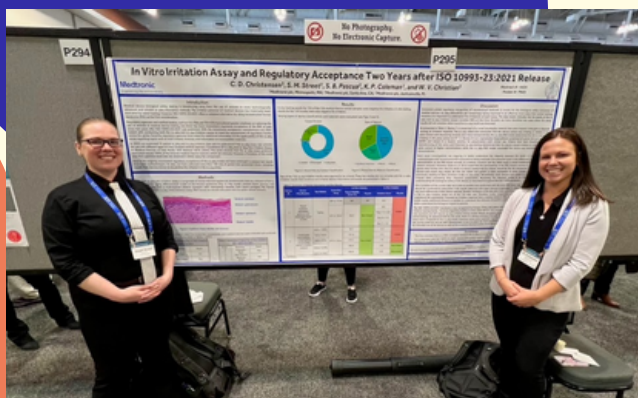
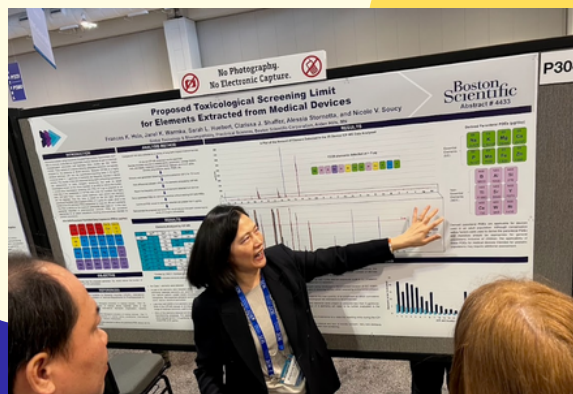
Joel Cohen, ScD, DABT | Gradient

2023 ANNUAL MEETING NEWS (CONTINUED)

Wednesday, March 22

Poster Session | Medical Devices

21 Posters were presented in the Medical Device session, with submissions from industry, academia, consulting, and regulatory bodies.



2023 ANNUAL MEETING NEWS (CONTINUED)

Medical Device and Combination Product Specialty Section Reception

At the MDCPSS reception, the MDCPSS Executive Committee presented an overview of MDCPSS including the current and upcoming MDCPSS officers, subcommittees, treasury update, membership report, annual meeting activities, webinars and newsletter, and the MDCPSS awards. The Student Achievement Award winner, Deniz Emul, contributed an excellent presentation on her abstract "Design of Clinically-Relevant Leachables Studies for Medical Device Replacement Schedules". The reception was well-attended and provided a fun, social environment for MDCPSS members and colleagues to engage and connect.





Best Abstract Award

Best Overall Abstract Award

"Development of an In Vitro Test Method for Irritation of Medical Devices Used in the Oral Cavity"

Marek Puskar (1), Jennifer Mollignano (2), Christian Pellevoisin (2), Silvia Letasiova (1), and Mitch Klausner (2)

(1) MatTek *In Vitro* Life Science Laboratories, Bratislava, Slovakia
(2) MatTek Corporation, Ashland, MA, USA

Best Published Paper Award

"A case study: Re-evaluating the biological risk following a processing aid change on a marketed cardiovascular implant device" (Frontiers in Medical Technology)

Frances K. Hsia, Alessia Stornetta, and Nicole V. Soucy

Global Toxicology and Biocompatibility, Preclinical Sciences, Boston Scientific Corporation, Arden Hills, MN, US



Best Published Paper Award

Best Poster Award

"Characterization of the ISO database of reference chemicals for interlaboratory studies to demonstrate the applicability of OECD methods to assess skin sensitization of medical devices"

Christian Pellevoisin (1), Andrew Nguyen (2), Ron Brown (2), Rose-Marie Jenvert (3), Hervé Groux (4), Peter Cornelis (5), Michelle H. Lee (6), Austin Zdawczyk (7), Joseph Carraway (2), Emma Pedersen (8), Joel M. Cohen (9), David Waeckerlin (10), Audrey P. Turley (5), Sebastian Hoffmann (11), and Kelly P. Coleman (12)

(1) MatTek Life Sciences, Ashland, USA; (2) Risk Science Consortium, Arnold, MD, USA; (3) SenzaGen, Lund, Sweden; (4) ImmunoSearch, Le plan de Grasse, France; (5) Nelson Lab, Leuven, Belgium; (6) Nelson Lab, Salt Lake City, MD, USA; (7) NAMS, Northwood, OH, USA; (8) Key2Compliance, Stockholm, Sweden; (9) Gradient Corp, Boston, MA, USA; (10) SonovaAG, Stäfa, Switzerland; (11) seh-cs, Paderborn, Germany; and (12) Medtronic, Saint Paul, MN, USA.

Student Achievement Award

"Design of Clinically-Relevant Leachable Studies for Medical Devices with Replacement Schedules"

Deniz Emul

ResMed Pty Ltd, Australia

Executive Committee Service Awards

Past President: Jan Oberdoerster

Councilor: Mercedes Salvador-Silva



Best Poster Award



In the post-pandemic era, the MDCPSS community is experiencing significant growth, reflecting the increasing recognition of toxicological evaluation in medical devices and combination product development. This expansion was evident in this year's SOT meeting with the active engagement of the participants throughout the session talks, Q&A sections, and the overflowing audiences at the MDCPSS reception meeting. The networking event was filled with many buzzwords on the topics of 10993-17 revisions, E.O. Sterilization, and Bioabsorbable Challenges.

Medical Device and Combination Product Specialty Section Reception



Once again, this year MDCPSS reception provided a memorable and impactful experience leaving attendees with a sense of satisfaction and fueling the enthusiasm of the toxicology community.



Sainath Babu
MDCPSS Reception Attendee

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.

***Please consider
donating to MDCPSS***

2022-2023 NET ASSETS

October	\$24,645	January	\$24,645
November	\$24,645	February	\$24,295
December	\$24,645	March	\$15,131

2023 MDCPSS SPONSORS

We would like to thank our 2023-2024 sponsor **WL Gore & Associates** for their support. 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 event and in our communication. MDCPSS accepts donations through the [SOT Component Group Donation Form site](#). For additional information regarding donations to MDCPSS, please contact the MDCPSS Secretary/Treasurer, [Hiromi Hosako](#) or [Julia Melone](#) at SOT Headquarters.



JOIN US ON LINKEDIN!

<https://www.linkedin.com/company/sot-medical-device-and-combination-product-specialty-section/>

PAST WEBINARS

Past webinar slides and recordings are available on the [MDCPSS website](#)

ANNUAL MEETING 2024

More on this in our next newsletter!

