VOLUME 14 ISSUE 2

MDCPSS

SPRING NEWSLETTER

March 2024

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PRESIDENT'S MESSAGE

Dear MDCPSS Members,

Hope you are doing well! As we get ready for the SOT 2024 Annual Meeting, we would like to share a summary of MDCPSS events planned for SOT 2024 and a recap of our 2023-2024 accomplishments.

Overall, 2023-2024 has been a very productive and successful year for MDCPSS! We grew from 242 to 253 members, received generous donations from new sponsors, built new partnerships with other Specialty Sections, increased MDCPSS visibility at SOT, and hosted webinars to discuss newly published ISO standards.

Thanks to Dr. Hiromi Hosako for leading the fundraising committee, for her persistent outreach to potential sponsors, and for bringing those new sponsors for MDCPSS. For the first time, MDCPSS will be co-hosting a mentoring event with RASS and IVAM at SOT 2024. Thanks to Dr. Ju Young (Julie) Park for chairing the mentoring committee and leading the partnership with RASS and IVAM on behalf of MDCPSS. We encourage all undergrads, recent grads, postdocs, and early career scientists interested in learning about career paths in medical devices and combination products, risk assessment, and *in vitro* and alternative methods to attend this event. More details can be found later in this newsletter.

We are excited to share that 2 sessions endorsed by MDCPSS have been accepted for presentation at SOT 2024. More details can be found below. As we continue to work towards increasing MDCPSS visibility within SOT, we encourage all our members to start thinking about topics related to medical devices and combination products for session proposals for SOT 2025.

In January 2024, MDCPSS hosted a two-part webinar series to facilitate the understanding of recently published ISO 10993-17:2023. Thanks to Dr. Shelby Skoog for leading the development of these webinars where the speakers discussed different aspects of biological risk management including hazard identification, derivation of tolerable intake values, calculating estimated exposure and margin of safety values. Video recordings of these webinars can be found on our website.

Lastly, on behalf of the MDCPSS Executive Committee, I would like to invite you all to the MDCPSS reception and other MDCPSS events at SOT 2024. Please see the details below.

Wishing you all safe travels to Salt Lake City! See you at the SOT 2024 Annual Meeting shortly!

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

RECENT WEBINARS

MDCPSS was pleased to host the two-part webinar series:

Toxicological Risk Assessment of Medical Device Constituents: Consistent Application through Comprehensive Review

PART 1: "Biological Risk Management: Hazard Identification and Derivation of Tolerable Intake Values"

PART 2: "Biological Risk Management: Calculating Estimated Exposure Dose and Margin of Safety Values"

Thank you to all who attended and to our speakers listed below:

Sherry Parker, PhD, *President, SParker Toxicology Consulting LLC*
Todd Kennedy, PhD DABT, *Principal Toxicologist, WL Gore and Associates Inc.*
Alan Hood, PhD, *Research Toxicologist, US FDA*

Past webinar slides and recordings are available on the MDCPSS website

AWARD OPPORTUNITIES

The following MDCPSS awards will be presented at our Reception:

- ***Best Overall Abstract Award***
- ***Best Published Paper Award***
- ***Best Poster Award***
- ***Student Achievement Award***

To apply or nominate for SOT 2025, please use the links on our website.

ANNUAL MEETING 2024

SOT
SALT LAKE CITY • MARCH 10–14, 2024

MDCPSS will be hosting the following events at SOT 2024 in Salt Lake City!

Monday, March 11

Poster Session | Medical Devices

Posters will be presented in the Medical Device session, with presentations from industry, academia, consulting, and regulatory bodies.

Abstract Numbers: #3346-3378

LOCATION ToxExpo, Exhibit Hall C

TIME 9:15 - 11:15 AM

ANNUAL MEETING 2024
(CONTINUED)

Tuesday, March 12

MDCPSS Endorsed Session

Taking a Closer Look at Biological Evaluations for Ocular Medical Devices and Combination Products

Chairs

Andrea Rodrigues | AbbVie Inc.
William Cook | Merck & Co. Inc.

In this session, an overview of ISO 10993 will be presented, with an emphasis on Parts 17 and 18. Chemical characterization (presented in ISO 10993-18) and toxicological risk assessment practices (presented in ISO 10993-17) address how chemistry data should be evaluated by a toxicologist to identify and address risks to patients.

The US FDA Center for Devices and Radiological Health's expectations for biocompatibility testing of devices will be presented by a US FDA reviewer in the device sector. The biological evaluation plan, or testing strategy, are critical for successful review and US FDA clearance. Since March 2022, the US FDA intends to regulate container closure systems, such as eye dropper bottles, products as drug-led combination products composed of a drug constituent part that provides the primary mode of action and a device constituent part (an ophthalmic dispenser).

Finally, a case study for a newly approved medical device, a drug-eluting contact lens, will be presented as an example of a successfully carried out biocompatibility evaluation plan. This session will benefit scientists and engineers interested in biocompatibility evaluations for development of medical devices and anyone interested in learning medical device development expectations and how to address leachable issues.

1) ***An Eye on ISO 10993-17 and 10993-18 and the Establishment of Allowable Limits and Safety Threshold for Leachable Substances for Consumables, Medical Devices, and Combination Products***
Mercedes Salvador-Silva | Alcon

2) ***Biocompatibility Strategy for New Ocular Drug-Medical Device Combination Products***
Bailin Liang | Johnson & Johnson Innovation LLC

3) ***Biocompatibility Assessment of Ophthalmic Medical Devices***
Simona Bancos | CDRH, US FDA

LOCATION

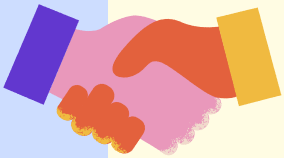
Grand Ballroom B

TIME

3:00 - 4:30 PM

ANNUAL MEETING 2024 (CONTINUED)

Tuesday, March 12



Joint Specialty Section Mentoring Event

This year, MDCPSS has partnered with the **In Vitro and Alternative Methods Specialty Section (IVAM)** and the **Risk Assessment Specialty Section (RASS)** to bring our members a joint mentoring event.

The session is designed to stimulate interest the Specialty Section areas and provide career insights in a social-friendly environment to undergraduate and graduate students, postdoctoral scholars, and early-career scientists. The event facilitates opportunities for mentees to network with expert mentors from diverse job backgrounds and to learn more about the variety of potential career paths and skills required to advance as toxicologists in this field.

LOCATION Salt Lake Ballroom E, Hyatt Regency

TIME 5:00 - 6:00 PM

MDCPSS Reception

At our annual MDCPSS reception, the MDCPSS Executive Committee will present 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 is also expected to present.

The reception provides a fun, social environment for MDCPSS members and colleagues to engage and connect. We hope to see you there!

LOCATION Salt Lake Ballroom E, Hyatt Regency

TIME 6:00 - 7:30 PM

ANNUAL MEETING 2024
(CONTINUED)

Thursday, March 14

MDCPSS Endorsed Session

Overcoming Unique Challenges Associated with Biological Evaluation of Absorbable/Degradable Medical Devices and Combination Products: Regulatory and Scientific Considerations from Successful Case Studies

Absorbable medical devices possess unique physicochemical material properties, such as solvent incompatibility during chemical characterization, complexity of degradation testing, limitation of preclinical models to predict long-term biological effects, and pitfalls when using *in silico* tools for toxicological risk assessment.

Feedback received from attendees at the 2023 workshop indicated the absence of successful case studies and suggested a continuation that describes solutions to tackle the existing challenges. This session will address this need by advancing the discussion of successful case studies that highlight strategies to overcome some of the existing challenges when evaluating the biocompatibility of absorbable medical devices.

LOCATION Grand Ballroom J

TIME 8:30 - 11:15 AM

ANNUAL MEETING 2024 (CONTINUED)

Chairs

Daysi M. Diaz-Diestra, PhD | North American Science Associates, LLC
Teresa Palacios-Hernandez, PhD | Center for Devices and Radiological Health, US FDA

Presentations

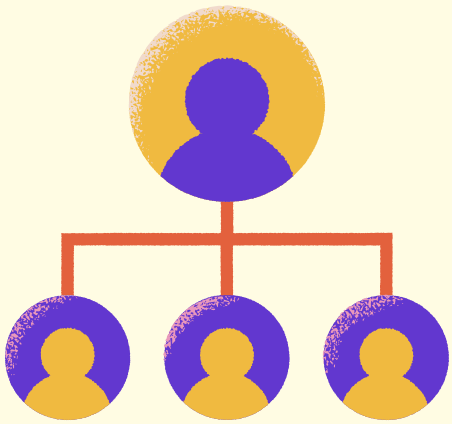
1) ***Harnessing Biodegradable Materials to Study and Direct Immune Function Studies***
Christopher Jewell | University of Maryland

2) ***Chemical Toxicological Risk Assessment: What to Consider in Accordance with ISO 10993-17, ISO 10993-1, and ISO 14971***
Alan Hood | CDRH, US FDA

3) ***Case Study 1: Chemical Characterization Methodology Challenges for Degradable Polymers***
Yijun Lu | Johnson & Johnson

4) ***Case Study 2: Biological Evaluation of an Absorbable Device That Polymerizes In Vivo***
Phillip Smiraldo | North American Science Associates LLC

5) ***Regulatory Considerations for Absorbable Metallic Bone Fixation Fasteners***
Ryan Trombetta | CDRH, US FDA



Please consider donating to MDCPSS

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!

Donations can be made via SOT's site (QR code and hyperlink below) or by contacting any of our board members for more info.

Scan/click for donation! Please consider company matching!