

Medical Device and Combination Product Specialty Section

ANNUAL REPORT: 2021–2022

May 1, 2021 to April 30, 2022

I. Officers/Committees

Officer

President:

Vice President:

Vice President-Elect:

Secretary/Treasurer:

Past President:

Councilors:

2021–2022

Jan Oberdoerster

Shelby Skoog

Mansi Krishan

Megan Hahn

Whitney V. Christian

Xiaoling (Sharlene) Dai

Mercedes Salvador-Silva

2022–2023

Shelby Skoog

Mansi Krishan

Xiaoling (Sharlene) Dai

Hiromi Hosako

Jan Oberdoerster

Mercedes Salvador-Silva

Bhaves K. Ahir

Postdoctoral Representative:

Kevin Trout

TBD

Graduate Student Representative:

Christopher Michael Pohl

Deniz Jade Emul

Committees:

Nominating Committee:

Jan Oberdoerster (chair)

Programs Committee:

Shelby Skoog (chair), Mercedes Salvador-Silva, Jan Oberdoerster, Mansi Krishan, Whitney Christian

Awards Committee:

Shelby Skoog (chair), Jan Oberdoerster, Sharlene Dai, Christopher Pohl

Mentoring Committee:

Mansi Krishan (chair), Whitney Christian, Megan Hahn, Kevin Trout

Membership Committee:

Jan Oberdoerster (chair), Whitney Christian, Sharlene Dai, Christopher Pohl, Mercedes Salvador-Silva

Postdoc Committee:

Kevin Trout (chair)

Graduate Student Committee:

Christopher Pohl (chair)

Outreach Committee - Website and ToXchange:

Shelby Skoog (chair), Megan Hahn

Outreach Committee - Newsletter:

Sharlene Dai (chair), Whitney Christian, Megan Hahn, Kevin Trout

II. 2021 Membership total: 239

III. Key Outcomes in 2021–2022:

- A. Hosted several webinars, including multi-speaker webinars across a variety of topics with significant membership attendance.
- B. Published 2 newsletters reviewing MDCPSS activities and current events related to ISO 10993 standards updates and international regulatory updates.
- C. Held successful MDCPSS reception and mentoring event at the 2022 SOT meeting

IV. Activities

- A. SOT Annual Meeting Activities (e.g., courses, scientific sessions, receptions):

Medical Device and Combination Product Specialty Section Poster Session

Date and Time: March 28, 2022, from 9:00 am – 10:45 am PST

Summary: Authors presented a variety of poster topics related to the safety and evaluation of medical devices.

Medical Device and Combination Product Specialty Section Mentoring Event

Date and Time: March 28, 2022, from 5:00 pm – 6:00 pm PST

Summary: In-person event intended to provide students, postdocs, and early-career scientists the opportunity to learn about toxicology career paths from mentors in diverse job sectors (government, academia, industry, contract research organizations, non-profit organizations).

Medical Device and Combination Product Specialty Section Meeting/Reception

Date and Time: March 28, 2022, from 6:00 pm – 7:30 pm PST

Summary: The MDCPSS Executive Committee provided an annual activity update and announced award recipients.

Medical Device and Combination Products Specialty Section Roundtable Session: “Harmonization of Approaches for the Biological Safety Assessment of Medical Devices and Pharmaceutical Packaging: Implications for Drug-Device Combination Products”

Date and Time: March 29, 2022, from 11:00 am – 12:20 pm PST

Chair: Ronald Brown, Risk Science Consortium LLC

Co-Chair: Cheryl Stults, C&M Technical Consulting LLC

Primary Endorser: Medical Device and Combination Product Specialty Section

Summary: The session discussed similarities and differences in methods to conduct safety assessments of medical devices and pharmaceutical packaging/delivery systems and will propose harmonized approaches that may be useful for the safety assessment of drug-device or biologic-device combination products

B. 2022 Awards Information:

Best Overall Abstract Award:

Ju Young Park and Alan Hood for “A Step Forward in the Preclinical Safety Assessment of Medical Devices: Evaluation Methods of Reproductive and Developmental Toxicity Endpoints”

Best Published Paper Award:

Bradford D. Bagley, Jordan N. Smith, and Justin G. Teeguarden for “Risk Assessment of Predicted Serum Concentrations of Bisphenol A in Children and Adults Following Treatment with Dental Composite Restoratives, Dental Sealants, or Orthodontic Adhesives using Physiologically Based Pharmacokinetic Modeling” (Regulatory Toxicology and Pharmacology)

Best Poster Award:

YuChi (Rachel) Chang, Alexander K. Alverson, and Joel M. Cohen for “A Rubric for Identifying Potentially Genotoxic Polycyclic Amines and Derivation of a Chemical Class-Specific TTC”

Malek Toxicology Delaware LLC Student Excellence Award:

Yizhong Liu for “Dynamic Evaluation of Vascular Endothelial Cell Toxicity of Silver Nanoparticles: Flow Rate, Concentration, and Size-Dependent Cellular Uptake, Inflammation, and Cytotoxicity”

Executive Committee Service Awards:

Past President: Whitney Christian

Secretary/Treasurer: Megan Hahn

Councilor: Xiaoling (Sharlene) Dai

Postdoctoral Representative: Kevin Trout

Graduate Student Representative: Christopher Pohl

C. Other Educational Activities Conducted (e.g., webinars, in-person meetings):

MDCPSS Webinar: Evolving Use of In Vitro Hemocompatibility for the Biological Evaluation of Blood Contacting Medical Devices (March 2021)

- **Date:** March 30, 2021 from 12:00 PM to 1:30 PM EST
- **Presentation 1: *Overview of In Vitro Thrombogenicity Testing—US FDA/CDRH Research Update and Regulatory Considerations***, Qijin Lu, PhD, US FDA
- **Presentation 2: *Evaluation of the NAVI Model for Thrombogenicity Assessments: Correlation between In Vitro Hemocompatibility Test Results and In Vivo Thrombus Scores***, Frances Hsia, MS, MPH, DABT, Boston Scientific Corporation
- **Presentation 3: *In Vitro Hemocompatibility Testing: Continuing Development of an Ovine Blood-Loop Assay***, Yan Chen, PhD, American Preclinical Services, LLC
- **Presentation 4: *Design Considerations for Mechanical Hemolysis Testing***, Christopher Pohl, BS, and Miki Giffin, MS, Nelson Laboratories, LLC

MDCPSS Webinar: Biostability and Product Life-Cycle Evaluation of Medical Devices (May 2021)

- **Date:** May 7, 2021 from 12:00 PM to 1:30 PM EST
- **Presentation 1: *In Vivo Long-Term Durability of Materials That Comprise Implanted Medical Devices***, Dr. Kim Chaffin, Medtronic
- **Presentation 2: *Evaluation of Biological Safety over the Whole Life-Cycle of a Medical Device—Aspects to Be Considered***, Dr. Katharina Weidmann, Tüv Süd Product Service GmbH

MDCPSS Webinar: Practical Application of Computational Models to Predict Release Kinetics and Toxicity of Compounds Released from Medical Devices

- **Date:** June 2, 2021 from 12 PM to 1:30 PM EST
- **Presentation #1: *Use of Computational Models to Predict the Toxicity of Compounds Released from Medical Device Materials***, Ron Brown, Risk Science Consortium, LLC
- **Presentation #2: *Physics-based models to predict patient exposure to medical device leachables***, David Saylor, US Food and Drug Administration

MDCPSS Webinar: Nitrosamines: Evolving Regulatory Landscape and Its Potential Impact on Medical Devices and Combination Products (January 2022)

- **Date:** January 25, 2022 from 12:00 PM to 1:00 PM EST
- **Presentation #1: *Overview of US FDA guidance on “Control of Nitrosamine Impurities in Human Drugs”***, Owen McMaster, US FDA
- **Presentation #2: *Opportunities and Challenges: Perspective from Medical Devices and Combination Product Industry on Recent Regulatory Guidance for Nitrosamines***, Daniel Nazarenko, PhD, Becton, Dickinson, and Company (BD)

D. Communication Activities:

1. Newsletter publication frequency:
 1. Fall 2021 Newsletter
 2. Spring 2022 Newsletter
2. New or significant announcements/blogs:
 1. Information on MDCPSS webinars
 2. SOT Annual Meeting updates and reminders, including MDCPSS Awards
 3. Call for MDCPSS officers and election reminders
 4. May 2021 Announcement for New and Recently Updated Medical Device Standards and Guidance Documents.
3. Highlights of website enhancements:
 1. Posting of webinar recordings and slides for all 2021-2022 MDCPSS webinars
 2. New job postings

E. Mentoring Activities:

SOT Annual Meeting - Medical Device and Combination Product Specialty Section Mentoring Event

Date and Time: March 28, 2022, from 5:00 pm – 6:00 pm PST

Summary: In-person event intended to provide students, postdocs, and early-career scientists the opportunity to learn about toxicology career paths from mentors in diverse job sectors.

V. **Feedback and Ideas:**

- A. In what ways is your group fostering and maintaining an inclusive environment? Please give examples of any current practices used to support inclusion in processes such as 1) leadership selection and promotion, 2) award descriptions and selection, and 3) endorsement of proposals for the annual meetings.

The MDCPSS EC reaches out to MDCPSS members regarding volunteer opportunities on committees, proposal of topics of interest related to webinars and newsletter articles, presenters for webinars, contributors of newsletter articles, member highlights and achievements, and additional member feedback.

- B. How might SOT better support your group's activities (perhaps something the Society should be doing that we currently do not do, or do not do effectively, that would be of importance/benefit to the members of your component group?):

Note: If funding is listed, please provide detail on the membership need that the funding would support.

Communication

Assistance with informing SOT members about upcoming MDCPSS webinars, events, and mentoring activities as well as membership benefits, especially international members.

Annual Meeting Access

Due to the COVID-19 pandemic, numerous MDCPSS members were unable to attend this year's annual meeting in person. The majority of SOT Annual Meeting events, including the MDCPSS reception and poster session, were only available to those in attendance in-person.

Additionally, as with each Annual Meeting, scheduling of events during Annual Meetings often results in conflicts, where members cannot attend sessions that are of interest but occurring simultaneously. There is a request for SOT to record or offer session content for these scenarios. Members feel they are paying to attend the conference but cannot get access to all the information, education, and training they are paying for.

- C. What is one thing that the Society is currently doing that impacts your component group that should be changed (e.g., stopped, modified, etc.)?

None at this time.

- D. What changes do your component group anticipate making in the way in which it operates in the coming year?

None at this time.