

Medical Device and Combination Product Specialty Section

ANNUAL REPORT: 2019-2020

May 1, 2019 to April 30, 2020

I. Officers/Committees

Officers

	<u>2019 – 2020</u>	<u>2020 – 2021</u>
President:	Sherry Parker	Whitney Christian
President-Elect:	Jan Oberdoerster	Shelby Skoog
Vice President:	Whitney Christian	Jan Oberdoerster
Secretary:	Shelby Skoog	Megan Hahn
Treasurer:	Shelby Skoog	Megan Hahn
Past President	Taylor Builee	Sherry Parker
Councilors:	Melissa Badding James J. Kleinedler	Xiaoling (Sharlene) Dai James J. Kleinedler

PDA Representative:	Dakshesh Patel	Ju (Julie) Young Park
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Grad Student Representative:	Kazi M. Tasneem	TBD
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Committees

Programs Committee:

Whitney Christian (chair), Shelby Skoog, Jim Kleinedler, Taylor Builee

Nominating Committee:

Sherry Parker (chair)

Awards Committee:

Whitney Christian (chair), Jan Oberdoerster, Melissa Badding, Shelby Skoog

Mentoring Committee:

Whitney Christian (chair), Kazi Tasneem, Melissa Badding, Sherry Parker

Membership Committee:

Jan Oberdoerster (chair), Sherry Parker, Taylor Builee

Postdoc Committee:

Dakshesh Patel (chair)

Graduate Student Committee:

Kazi Tasneem (chair)

Outreach Committees

Website and ToXchange:

Shelby Skoog (chair), Taylor Builee

Newsletter:

Melissa Badding (chair), Whitney Christian, Kazi Tasneem, Jan Oberdoerster

II. 2019 – 2020 Membership total: 191

III. Key Outcomes in 2019 – 2020:

Activities

A. 2020 SOT Annual Meeting Virtual Activities (e.g. courses, scientific sessions, or virtual receptions)

Unfortunately, due to the COVID-19 situation, MDCPSS was unable to meet in person during the 2020 SOT Annual Meeting. The MDCPSS leadership decided to honor the 2020 MDCPSS award recipients, thank our outgoing officers, and welcome our incoming officers by posting the MDCPSS 2020 annual meeting reception slides on the MDCPSS website. In addition, all available, digital versions of the posters that would have been presented at the 2020 MDCPSS poster session were posted on the MDCPSS website.

B. 2020 Awards Information

Best Abstract Award: Frances K. Hsia, Sherry P. Parker, Sarah L. Huebert, and Catherine D. Christensen. “A critical evaluation of the NAVI model for thrombogenicity evaluation of cardiovascular medical devices: Correlation between *in vitro* hemocompatibility test results and *in vivo* thrombus scores.”

Best Published Paper Award: David M. Saylor, Vaishnavi Chandrasekar, David D. Simon, Paul Turner, Laura C. Markley, and Alan M. Hood. 2019. “Strategies for Rapid Risk Assessment of Color Additives Used in Medical Devices.” *Toxicological Sciences*, Volume 172, Issue 1, November 2019, pp. 201 – 212.

Best Poster Award: Bradford D. Bagley, Dayna Dreher, Tim Dunbar, Tim Dunbar, and JoAnne Fitch. “Risk Assessment of Extractables from Warmed and Room Temperature Dental Composite Restoratives.”

Student Travel Award: Alexander Nguyen. “Cytotoxicity and Mutagenicity Assessment of Lithium Phenyl(2,4,6-trimethylbenzoyl) phosphinate (LAP) Photoinitiator with Exposure to 405 nm Light.”

Executive Committee Service Awards:

Postdoctoral Representative – Dakshesh Patel

Graduate Student Representative – Kazi Tasneem

Councilors – Melissa Badding

Past President – Taylor Builee

President – Sherry Parker

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

2020 SOT Annual Meeting Courses/Sessions

The MDCPSS-sponsored workshop “Known Unknowns: Challenges and Approaches for Handling Chemical, Hazard, and Regulatory Uncertainty in Medical Device Safety Assessments” was presented as a webinar on Thursday, April 16, 2020 at 1:00 – 2:45 pm (EDT).

MDCPSS 2019 – 2020 Webinars

“CDRH Scientific Perspective on Analytical Testing and Toxicological Risk Assessment for Medical Devices” Alan Hood, Berk Oktem, and Jennifer Goode, Center for Devices and Radiological Health, U.S. Food and Drug Administration on Wednesday, May 22, 2019 at 11:00 AM – 12:30 PM (EDT).

“Biological Risk Assessments for Ocular Medical Devices” Simona Bancos, Center for Devices and Radiological Health, U.S. Food and Drug Administration on Wednesday, August 28, 2019 at 12:30 – 1:30 pm (EDT).

“Impact of 2017/745 EU Medical Device Regulation (MDR) on Biological Evaluation of Medical Device” Jeremy Tinkler, Director of Regulatory Consultancy and Quality Assurance, MedPass International SAS; Rachel Hardy, Senior Strategy Consultant, MedPass International SAS on Thursday, January 16, 2020 at 11:00 am – 12:00 pm (EDT).

D. Communication Activities

Newsletter publication frequency:

Fall 2019 Newsletter

Key Announcements/blogs:

SOT Meeting - important dates and links

Information on MDCPSS webinars

MDCPSS member achievements

Updates on standards development - ISO 10993 Technical Committee 194

Cobalt Hazard Up-Classification

Website highlights:

Posting of webinar recordings and slides for all 2019 – 2020 MDCPSS webinars

New job postings

E. Mentoring activities

Due to the COVID-19 situation, the MDCPSS was unable to hold its annual networking mixer and its career panel mentoring event at the 2020 SOT Annual Meeting. The MDCPSS worked with members of the Ocular Toxicology Specialty Section (OTSS) to plan the mentoring event. Fortunately, the MDCPSS/OTSS plan to hold this mentoring event as a virtual career panel in the summer/fall of 2020.

IV. Feedback and Ideas

- A. 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?):

Communication

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

Access to session content

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, perhaps limiting session access to 3 events. Members feel they are paying to attend the conference but cannot get access to all the information, education, and training they are paying for.