

## Medical Device and Combination Product Specialty Section

### ANNUAL REPORT: 2020-2021

May 1, 2020 to April 30, 2021

#### **I. Officers/Committees:**

| <u>Officers</u>              | <u>2020-2021</u>                                       | <u>2021-2022</u>                                   |
|------------------------------|--------------------------------------------------------|----------------------------------------------------|
| President:                   | Whitney V. Christian                                   | Jan Oberdoerster                                   |
| Vice President:              | Jan Oberdoerster                                       | Shelby Skoog                                       |
| Vice President-Elect:        | Shelby Skoog                                           | Mansi Krishan                                      |
| Secretary:                   | Megan Hahn                                             | Megan Hahn                                         |
| Treasurer:                   | Megan Hahn                                             | Megan Hahn                                         |
| Past President:              | Sherry P. Parker                                       | Whitney V. Christian                               |
| Councilors:                  | James (Jim) John Kleinedler<br>Xiaoling (Sharlene) Dai | Xiaoling (Sharlene) Dai<br>Mercedes Salvador-Silva |
| PDA Representative:          | Ju Young (Julie) Park                                  | Kevin Trout                                        |
| Grad Student Representative: | Christopher Michael Pohl                               | Christopher Michael Pohl                           |

#### **Committees**

##### **Programs Committee:**

Jan Oberdoerster (chair), Whitney Christian, Shelby Skoog, Sherry Parker, Jim Kleinedler

##### **Nominating Committee:**

Whitney Christian (chair)

##### **Awards Committee:**

Jan Oberdoerster (chair), Sharlene Dai, Shelby Skoog, Julie Park

##### **Mentoring Committee:**

Whitney Christian (chair), Sherry Parker, Megan Hahn, Julie Park

##### **Membership Committee:**

Whitney Christian (chair), Jan Oberdoerster, Julie Park

##### **Postdoc Committee:**

Julie Park (chair)

##### **Graduate Student Committee:**

Chris Pohl (chair)

#### **Outreach Committees**

##### **Website and ToXchange:**

Shelby Skoog (chair), Megan Hahn

##### **Newsletter:**

Megan Hahn (chair), Sharlene Dai, Whitney Christian

II. **2020 Membership total:** 218

III. **Key Outcomes in 2020-2021:**

A. Maintained consistent membership during COVID pandemic

B. Held successful virtual MDCPSS meeting at the 2021 SOT meeting, including multiple guest speakers and a virtual tour of Orlando.

IV. **Activities**

A. **2021 SOT Virtual Annual Meeting Activities** (e.g., courses, scientific sessions, or virtual receptions)

**Medical Device and Combination Product Specialty Section Virtual Meeting/Reception**

**Date and Time:** March 16, 2021, from 6:30 pm – 8:30 pm ET

**Summary:** The MDCPSS Executive Committee provided an annual activity update, announced award recipients, and reflected on the 10-year anniversary of the Specialty Section. In addition, there were presentations from a keynote speaker as well as from award recipients.

**Medical Device and Combination Products Specialty Section Informational Session**

**Safety Assessment of Devices Used in Assisted Reproduction Technology: Mouse Embryo Assay**

**Date and Time:** March 23, 2021, from 2:45 pm – 4:05 pm ET

**Summary:** Chris Hung (US FDA, CDRH), Brett Glazar (Vitrolife), and Niranjana Goud (Greenwood Toxicology Associates) discussed the test methodology and case study examples of the mouse embryo assay when evaluating the biocompatibility of devices used during *in vitro* fertilization procedures.

**Medical Device and Combination Product Specialty Section Poster Session**

**Date and Time:** March 24, 2021, from 11:15 am – 1:00 pm ET

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

B. **2021 Awards Information**

**Best Overall Abstract Award:** Joshua Schmidt, Rose-Marie Jenvert, and Ron Brown for “Applicability domain of the GARDskin Medical Device test for *in vitro* skin sensitization testing of medical devices”

**Best Published Paper Award:** Wim H. De Jong, Joseph W. Carraway, Chenghu Liu, Chunguang Fan, Jia Liu, Audrey P. Turley, Thor S. Rollins, and Kelly P. Coleman for “The suitability of reconstructed human epidermis models for medical device irritation assessment: A comparison of *In Vitro* and *In Vivo* testing results”

**Best Poster Award:** Caroline Pinto, Hainsworth Shin, and Alan Hilton for “Evaluation of a Toxicological Screening Limit (TSL) Approach to Reduce the Burden of Toxicological Risk Assessments of Medical Device Analytical Screening Data”

**Student Achievement Award:** Zi Yae (Grace) Kang for “Effects of carbon nanodots on cytotoxicity and tumor necrosis factor alpha-induced pro-inflammatory cytokine expression in vitro (endothelial cells) and in vivo (C57BL/6)”

**Executive Committee Service Awards:**

Past President: Sherry Parker

Councilor: James Kleinedler

Postdoc Representative: Dakshesh Patel

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

**MDCPSS Webinar: Industry, CRO, and FDA Perspectives on Medical Device Chemical Characterization per ISO 10993-18:2020**

**Date:** September 25, 2020

**Duration:** 2 hours

**Speaker 1:** Dr. Jianwei Li, Medtronic

**Speaker 2:** Dr. Mark Jordi, Jordi Labs

**Speaker 3:** Dr. Berk Oktem, US FDA

**Attendees:** 295

**MDCPSS Webinar: Evolving Use of In Vitro Hemocompatibility for the Biological Evaluation of Blood Contacting Medical Devices**

**Date:** March 30, 2021

**Duration:** 1.5 hours

**Speaker 1:** Qijin Lu, US FDA

**Speaker 2:** Frances Hsia, Boston Scientific Corporation

**Speaker 3:** Yan Chen, American Preclinical Services, LLC

**Speaker 4:** Christopher Pohl and Miki Giffin, Nelson Laboratories, LLC

**Attendees:** 153

**D. Mentoring Activities**

**MDCPSS and OTSS Co-sponsored Virtual Career Panel – SOT Mentoring Event**

**Date:** September 21, 2020

**Duration:** 1 hour

**Panelists**

**Academia:**

Mindy Reynolds, Washington College

Neera Tewari-Singh, Michigan State University

**Government:**

Rob Brown, Risk Science Consortium

Alan Hood, US FDA

Elissa Wong, US FDA

**Industry:**

Hiromi Hosako, Alcon

James Kleinedler, Boston Scientific

Bob Przygoda, Johnson & Johnson (Retired)

Ed Reverdy, Johnson & Johnson

**Consulting:**

Joel Cohen, Gradient Corporation

Andrea Rodrigues, Tox Strategies

William Wustenberg, Mycroft Medical LLC

**Attendees: 54**

**E. Communication Activities:**

**Newsletter publication frequency:**

Fall 2020 Newsletter

**Key Announcements/blogs:**

Information on MDCPSS webinars

SOT Virtual Meeting updates and reminders, including MDCPSS Awards

Call for MDCPSS officers and election reminders

March 2021 Member Survey

May 2021 Announcement for New and Recently Updated Medical Device Standards and Guidance Documents.

**Website highlights:**

Posting of webinar recordings and slides for all 2020-2021 MDCPSS webinars

New job postings

**V. Feedback and Ideas:**

- A. **In what ways is your group fostering and maintaining an inclusive environment?**  
*We reach out to our members for volunteer opportunities on committees, for topics of interest related to webinars and newsletter articles, for presenters for webinars, for contributors of newsletter articles, to obtain member highlights and achievements, and to gather our members' 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.*  
**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.*
- 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.*