

NAME OF SPECIALTY SECTION____Medical Device & Combination Product_____

ANNUAL REPORT: 2016-2017

May 1, 2016 to April 30, 2017

I. Officers/Committees:

Officers	2016-2017	2017-2018
President:	Kelly P Coleman	Barbara J Henry
Vice President:	Barbara J Henry	Taylor L Builee
Vice President-Elect:	Taylor L Builee	Sherry P Parker
Secretary/Treasurer:	Xiaomin Deng	Xiaomin Deng
Past President	Alan M Hood	Kelly P Coleman
Councilors:	Sherry P Parker	Megan Hahn
	Whitney V Christian	Whitney V Christian
PDA Representative:	Monica Pombo	Monica Pombo
GSLC Representative:	Jie Luo	Jie Luo

Committees:

- 1) **Nominating Committee**
Kelly Coleman, Chair
- 2) **Program and Awards Committee**
Taylor L Builee, Chair
- 3) **Mentoring Committee**
Whitney Christian, Chair
- 4) **Membership Committee**
Kelly Coleman, Chair
- 5) **Outreach Committee**
Kelly Coleman, Chair
- 6) **Graduate Student and Postdoc Committee**
Monica Pombo, Chair
- 7) **Newsletter**
Sherry Parker, Whitney Christian, Alan Hood
- 8) **Website and ToXchange**
Daniel Luo, Chair
- 9) **Budget**
Xiaomin Deng, Chair

II. Activities:

2016 SOT Annual Meeting Medical Device and Combination Product Specialty Section Reception was held in Baltimore, MD at the Hilton Key Ballroom 5 on March 13, 2017 from 6 -7:30 pm. A student mentoring event (~13 students) was held in that room from 5:00 – 6:00 pm before the reception.

- Approximately 90+ people were in attendance.
- Dr. Kelly Coleman called the meeting to order at 6PM and presided over the business meeting, including budget and membership updates. Barbara Henry presented MDCPSS award winners along with Taylor Builee. Student award winner presentations were followed by social networking.

Medical Device and Combination Product Specialty Section Awards for 2016-2017:

Best Overall Abstract in 2016: Wim H De Jong, Sebastian Hoffmann, Michelle Lee, Helena Kandarova, Silvia Letasiova, Liset JJ De La Fonteyne, Christian Pellevoisin, Carine Tornier, Cristelle Bremond, Yuji Haishima, Austin M Zdawczyk, Audrey Turley, Jamin A Willoughby,

Michael Bachelor, Beau Rollins, Kelly P Coleman. *Round Robin Study to Evaluate the Reconstructed Human Epidermis (RhE) Model as an In Vitro Skin Irritation Test for Detection of Irritant Activity in Medical Device Extracts*

Best Published Paper in 2016: Brooke E Tvermoes, Kenneth M Unice, Bethany Winans, Michael Kovochich, Whitney V Christian, Ellen Donovan, Ernest S Fung, Brent L Finley, Ian Kimber, Dennis J Paustenbach. (2016) *A preliminary evaluation of immune stimulation following exposure to metal particles and ions using the mouse popliteal lymph node assay*. *Toxicol. Appl. Pharmacol*; 308:77-90.

Best Overall Poster Award in 2016: Whitney V. Christian and Jason Brown. *Food Allergy in Medical Devices: Risk Assessment of Tropomyosin in Chitosan-Containing Products*

Student Travel Awards in 2016: Brian Palmer, University of Rochester, and, Daniel Luo, Iowa State University.

2016-2017 SOT Annual Meeting Courses/Sessions: (at the Baltimore Convention Center)

Monday, March 13, 2017, 2:00-4:45 pm. Workshop, Modernizing Toxicological Risk Assessment for Compounds Released from Pharmaceutical, Consumer, Medical Device and Combination Products: Alternative Tools and Methods (CC Room 321)

Monday, March 13, 2017, 5:00-6:00 pm. Hilton Baltimore Key Ballroom 5. Coffee Q&A mentoring event (same room as the MDCPSS reception)

Monday, March 13, 2017, 6:00-7:30 pm. Hilton Baltimore Key Ballroom 5. Medical Device and Combination Product Specialty Section Meeting/Reception

Tuesday, March 14, 2017, 1:15-4:30 pm. Poster Session, Medical Devices (P401-P425)

Tuesday, March 14, 2017, 1:00-2:00 pm. Poster session tour mentoring event (P401-P425)

Endowment Fund Details: None.

Newsletters: Two newsletters - Summer 2016 & Spring, 2017

Webinar 1: Kim Li, PhD, DABT, MPH, Amgen Inc., shared a 1-hour webinar on April 10, 2017 at 11am EST on *ISO 10993-1 Biological Evaluation – the Risk Management of Unstudied Extractables and Leachables (E&L) Impurities in Medical Devices and Combination Products*, and, *Animal-Specific Modelling for the 3R in Preclinical Assessment: A Bone Drugs Example* by Marco Viceconti, Executive Director, Insigneo Institute for *in silico* Medicine, The University of Sheffield and Sheffield Teaching Hospital NHS Foundation Trust

Webinar 2: Alison Elder, PhD, Associate Professor of Toxicology in the Department of Environmental Medicine at the University of Rochester Medical Center gave a 1-hour webinar on *Effects of Nanoscale Particles in the Brain* on January 23, 2017, 1:30 PM–2:30 PM Eastern Time

Webinar 3: Michael Wolf, BS, MS, Medtronic Inc. gave a 1.25 hour webinar on *ISO 10993-4 Biological Evaluation of Medical Devices: Selection of Tests for Interaction with Blood* on December 14, 2016, 11:00 AM–12:15 PM EST

Webinar 4: Robert Przygoda, PhD, Johnson & Johnson, Co-chair of AAMI Genotoxicity, Carcinogenicity and Reproductive Toxicity Working Group (U.S. Sub-TAG for ISO/TC 194/WG 6) gave a 1-hour webinar on *Evaluation of Medical Devices for Genetic Toxicity: A Global Perspective* on October 19, 2016, 1:00 PM–2:00 PM Eastern Time.

Contributions to SOT website: The MDCPSS website was maintained and updated.

Committees: If applicable.