

MDCPSS WINTER NEWSLETTER

President's Message

Dear Medical Device and Combination Products (MDCPSS) Colleagues,

Greetings. I am honored to serve you in the role of President this term, and have been working with an outstanding team to deliver relevant programs and information. I extend my welcome to new officers of the executive committee, **Dr. Shelby Skoog** as Treasurer and Secretary, **Dr. Melissa Badding** as Councilor and **Kazi Tasneem** as Graduate Student Representative. Postdoctoral Representatives, **Dr. Banu Saritas-Yildirim** served from June to October 2018 and **Dr. Elissa Wong** is serving the remaining term from November 2018 to May 2019. **Dr. Saritas-Yildirim** stepped down from the position to accept a new role as Senior Staff Fellow at US FDA. Congratulations, **Dr. Banu Saritas-Yildirim**. Of course, it is not without noting, how lucky we are have continuous support from **Dr. Whitney Christian** who was formerly a Councilor and is now Vice President Elect, **Dr. Barbara Henry** who transitions to Past President, as does **Dr. Sherry Parker** to Vice President and **Dr. Megan Hahn** who remains in the role of Councilor. I want to personally thank the current roster of officers for their dedication to our mission and acknowledge past officers for a strong history of leadership. As of 2019, the specialty section is only nine years old and has an impressive membership headcount of approximately 170 which has been sustained since 2017. It goes without saying, the contribution of members is the foundation for our success. So, please continue to encourage colleagues, especially graduate students and postdocs, who are interested in the field to join the specialty section. Furthermore, the student membership remains free of charge since 2014, due to generous donations from **NAMSA** and **Dr. Kelly Coleman**.



One of my goals this year is to increase collaborative activities by developing programs with cross-disciplinary focus. Medical devices and combination products naturally lend to this potential because of the industry's diverse products used in a wide range of indications. As such, there are many great programs to build upon with other specialty sections and interest groups. To name a few, the group maintains a collaborative relationship with the Regulatory and Safety Evaluation SS and more recently with the In Vitro and Alternative Methods SS where in the past two years we co-sponsored one 2018 Continuing Education course, two webinars and a survey on the topic of US FDA Medical Device Development Tools (MDDT).

We sponsored a webinar on ISO 18562 Biocompatibility evaluation of breathing gas pathways in healthcare applications with guest speaker, **James Morrison**, Senior Consultant at Brandwood Biomedical, and we are co-planning another webinar with officers of the Ocular Toxicity SS. We are also organizing several other webinars, one of which will include US FDA guest speakers.

The second aim of this post is to celebrate success of the 2018 SOT Annual Meeting. A description of activities is [below](#).

Lastly, this [newsletter](#), made available due to the diligent effort of our editors, **Dr. Megan Hahn** (*cont. on next page*)

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and **Dr. Melissa Badding** and contributing authors, contains valuable articles/information on current regulatory updates and pathology considerations in medical device safety testing. Carefully peruse the content to keep abreast of MDCPSS activities whose focus is to serve membership interest. Should you have comments, volunteer interests and/or suggestions, please reach out to any officer for discussion.

Best regards,

Taylor Builee, MS

MDCPSS President 2018-2019

Visit us on:



2018 SOT Annual Meeting Recap

by **Taylor Builee**

I'd like to personally thank the officers and members of MDCPSS who put a tremendous amount of effort into making sure the annual meeting activities were successful. This was the second year the group convened in San Antonio, TX and keeping up with tradition, the agenda and activities were plentiful and engaging.

Considering the competitiveness of gaining a continuing education (CE) course due to a limited schedule, this past meeting had not one, but two CE sessions co-sponsored by MDCPSS. The morning session was an IVAMSS collaboration co-chaired by Dr. Kelly Coleman and Dr. Amy Clippinger titled, *In Vitro Testing: Tales from the Real World*. The afternoon session, titled, *Evaluation of Leachable Substances from Materials with Applications in Foods and Pharmaceuticals: Science- and Risk-Based Approaches* was organized by Dr. Kim Li and Dr. Greg Erexson, both of whom are Extractables and Leachables Safety Information Exchange (ELSIE) Consortium Board of Director members and MDCPSS members.

The executive officers meeting was held on Monday, March 12, 2018 at Hilton River's Edge Café over a modest breakfast and discussion of the remaining week of activities.

The poster session and poster tour, and mentoring event were held on Tuesday, March 13, 2018 at the convention center. Twenty-two poster abstracts were accepted and on display covering a range of topics.

The annual reception was held the evening of March 13, 2018 at the Grand Hyatt Texas with approximately 80 in attendance and was called to order by then presiding President, Dr. Barbara Henry. Each officer in attendance presented on topics where they had the greatest impact. Dr. Barbara Henry, Dr. Sherry Parker, Dr. Kelly Coleman, Dr. Whitney Christian, Dr. Megan Hanh, and Dr. Daniel Luo, prepared an excellent reception.

Regretfully, Dr. Monica Pombo, Dr. Shawn Deng, and myself were not able to attend, but were assured the meeting was in good hands.

OFFICERS (2018-2019)

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Elissa Wong

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Newsletter Editors

Melissa Badding
Megan Hahn
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2018 SOT Annual Meeting Recap (cont.)

The highlight of the evening was met recognizing award winners, who included:

Best Overall Abstract: Timo Wille, John Mikler, Andreas Wosar, Madlen Baumann, Horst Thiermann and Franz Wore for ***“Development of a Robust but Sensitive, Easy-To-Use, and Generic Organophosphate Skin Disclosure Kit”***

Best Published Paper: Yusuke Nomura, Michelle Lee, Chie Fukui, Kayo Watanabe, Daniel Olsen, Audrey Turley, Yuki Morishita, Tsuyoshi Kawakami, Toshiyasu Yuba, Hideo Fujimaki, Kaoru Inoue, Midori Yoshida, Kumiko Ogawa, and Yuji Haishima for ***“Proof of concept testing of a positive reference material for in vivo and in vitro skin irritation testing”*** J Biomed Mater Res Part B 2017:00B:000–000

Best Overall Poster Award: Françoise Cottrez, Christian Pellevoisin, Kelly P. Coleman and Hervé Groux for ***“In vitro assessment of medical device extracts potential to produce skin sensitization”***

Two Student Travel Award Winners: David Pitts Jr., Washington College for work completed at Office of Science and Engineering Laboratories CDRH FDA for ***“Extrapolation of nickel toxicity to tissues adjacent to metallic implant”*** and Dharmin Rokad, Iowa State University for ***“Manganese Exposure Enhances the Release of Misfolded α -Synuclein via Exosomes by Impairing Endosomal Trafficking Machinery”***

Following the reception, a social mixer, co-sponsored by donation from W.L. Gore and Associates, was held at the Guadalajara Grill and Restaurant and was attended by 60 professional and student members (nearly 75% of the reception audience).

The energy of Tuesday's activities was carried through to Wednesday, March 14, 2018 at the workshop titled, **“Matching Methods to Markets”** co-chaired by **Dr. Barbara Henry** and **Dr. Sherry Parker**, where it was received by a full house (~ 90-100 attendees), marking the finale of MDCPSS official business at the annual meeting.

Meeting Memories...



Best Poster Award winners:
Christian Pellevoisin and Hervé Groux



AM06 CE Course presenters:
Sean Gehen, David Allen, Anna Lowit, Wim De Jong, and Nicole Kleinstreuer

MDCPSS Webinars

MDCPSS hosted a webinar entitled "Assessing the Hazards of Fluoropolymers, a Class of Per- and Polyfluoroalkyl Substances (PFAS)", held February 27, 2018.

Webinar speaker was Dr. Barbara Henry, Toxicologist, W.L. Gore and Associates

Abstract: This webinar will be of interest to all toxicologists who perform toxicological risk assessments. The regulation of per- and poly-fluoroalkyl substances (PFAS) is a growing topic of interest, due in part to the widespread detection of perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS). Some believe the most appropriate approach to PFAS regulation or consideration of their potential risks is to lump together both polymeric and non-polymeric categories, treating them as if they were a single class of substances. Fluoropolymers become aggregated into the highly broad PFAS classification without regard to distinct characteristics that qualify them as meeting the globally accepted criteria for Polymers of Low Concern (OECD, 2009; BIO by Deloitte, 2015).

A new paper, in review for publication in Integrated Environmental Assessment and Management (IEAM), is intended to drive further clarity on the broad group of chemistry known as PFAS. The authors conducted a thorough review of the regulatory history of the hazard assessment of polymers and non-polymers, as well as the scientific foundation for the resulting paradigm ("polymers of low concern"), and they articulate a clear and compelling scientific basis for segregating fluoropolymers from other PFAS. Separation of fluoropolymers from the larger list of thousands of substances grouped into five different classes of PFAS is based upon the authors' demonstration that fluoropolymers constitute a distinct class within the PFAS group and, therefore, should be considered separately for hazard assessment or regulatory purposes. The paper further establishes that grouping fluoropolymers with all classes of PFASs for "read-across" or structure-activity relationship assessment is not scientifically appropriate, when a complete, good quality data set exists, as it does for fluoropolymers.

This webinar is available on the MDCPSS website:

<http://www.toxicology.org/groups/ss/MDCPSS/pastevents.asp>



MDCPSS hosted a webinar entitled "The Application of Reconstructed Human Epidermis (RhE) Models as an In Vitro Skin Irritation Test for Detection of Irritant Activity in Medical Device Extracts", held May 9, 2018.

Webinar speaker was Dr. Wim De Jong, RIVM

Abstract: Assessment of dermal irritation is an essential component of the safety evaluation of medical devices. Testing the irritant capacity of medical device extracts is currently performed by either topical or intradermal injection in rabbits. Attendees will learn about an international validation study that evaluated living human tissues as potential replacements for the rabbit irritation test. In the chemical industry, the RhE model as described in OECD Test Guideline 439 is used to identify irritant chemicals. Although the basic principles remain the same, for application in other domains, adaptation of the assay may be necessary. Therefore, the OECD 439 protocol was modified for testing of medical device extracts. This modified protocol was first evaluated to demonstrate the

MDCPSS Webinars (cont.)

presence of spiked irritant chemicals added to medical device extracts to show the capability of the modified RhE test protocol to detect irritants in a complex extract mixture. The real proof of the test would be to detect irritants in extracts of medical devices or materials used in the production of medical devices. Therefore, specific polymer materials were prepared containing irritant chemicals within the polymer matrix. With these materials two RhE models, EpiDerm™ (MatTek, Inc.) and SkinEthic™ RHE (EpiSkin, SA), were evaluated in an international round robin study. The read-out endpoint was the same as in OECD 439, that being tissue viability by the MTT method; in addition, Interleukin 1a release was also considered. In order to enhance the impact and future implementation of the RhE assay for medical device safety testing, a broad range of stakeholders were encouraged to join the round robin. Participants included medical device companies, contract research organizations, university and governmental laboratories. The results of the round robin study showed that RhE tissue models could detect the presence of strong skin irritants at low levels in dilute medical device polymer extracts. Consequently, the protocol will now be adapted and proposed as a new ISO 10993 standard for medical device irritation testing.

This webinar is available on the MDCPSS website:

<http://www.toxicology.org/groups/ss/MDCPSS/pastevents.asp>



MDCPSS hosted a webinar entitled "ISO 18562 biocompatibility evaluation of breathing gas pathways in healthcare applications, what does it cover and how to put it to use", held May 9, 2018.

Webinar speaker was James Morrison, Senior Consultant at Brandwood Biomedical

Abstract: The ISO 18562 series of standards Biocompatibility evaluation of breathing gas pathways in healthcare application was published by ISO in 2017. The series includes four parts, which cover the current thinking on gas pathway requirements. On June 7th 2018, US FDA added the ISO 18562 standards to their list of Recognized Consensus Standards, with partial recognition. ISO 18562 standards are now referenced in the newly released ISO 10993–1:2018, as international acceptance of these standards increases.

Unlike the ISO 10993 series of biocompatibility standards, which is a set of biological test methods, ISO 18562 evaluates biocompatibility using a set of toxicological risk analyses. These toxicological methods are not novel, but their application in this way will greatly expand the knowledge and use of these concepts.

In this webinar, we discuss the four published standards, their applications, and add commentary about putting them into practice in real word situations.

This webinar is available on the MDCPSS website:

<http://www.toxicology.org/groups/ss/MDCPSS/pastevents.asp>



2019 SOT Annual Meeting



Monday, March 11, 2019

- 1:45 - 4:30 pm: Workshop, A Tale of an In Vitro Method: From Inception to International and Regulatory Acceptance, CC Ballroom IV

Tuesday, March 12, 2019

- 8:00 - 9:00 am: MDCPSS Executive Committee Officers Meeting, Bistro 3000 Restaurant

Wednesday, March 13, 2019

- 9:15 am - 4:30 pm: Poster Session, Medical Devices #371 - 392, CC Exhibit Hall
- 10:30 - 11:30 am: Exhibitor-Hosted Session, Case Studies and Challenges of Risk Assessments using Physical and/or Chemical Information Per ISO 10993 Part 1 (Presented by WuXi AppTec), CC Room 339
- 1:30 - 3:00 pm: MDCPSS Poster Tour, Medical Devices #371 - 392, CC Exhibit Hall, Poster #371
- 5:00 - 6:00 pm: MDCPSS Mentoring Q&A Event & Mock Interview/CV Review Session, Hilton Baltimore Key 6
- 6:00 - 7:30 pm: MDCPSS Evening Reception, Hilton Baltimore Key 6
- 8:00 - 10:00 pm: MDCPSS Mentoring & Membership Mixer, Sullivan's Steakhouse (1 E. Pratt St., Ste. 102)



Workshop, A Tale of an In Vitro Method: From Inception to International and Regulatory Acceptance

Chairperson: Kelly Coleman, Medtronic PRL, Minneapolis, MN

Primary Endorser: Medical Device and Combination Product Specialty Section

Other Endorser(s): In Vitro and Alternative Methods Specialty Section

In vitro alternative test methods sound promising but can often be difficult to implement on a global scale in a way that will be truly impactful. This is a tale of success for one such method. Medical devices are evaluated for biological safety in accordance with the ISO 10993 biocompatibility standards. Every medical device, irrespective of its nature or body contact, must be assessed for its potential to cause cytotoxicity, irritation, and sensitization. Historically, cytotoxicity was the only approved in vitro method. However, over the past decade an in vitro irritation method using reconstructed human epidermis (RhE) was validated for pure chemicals as described in OECD 439. It

2018 SOT Annual Meeting (cont.)

seemed logical that this method, with a few adjustments, could also be used to assess medical device extracts. Introducing this test as the preferred method to address the irritation potential of medical devices will greatly reduce the number of animals used for the biological safety assessment of medical devices and combination products prior to market release. This session will present the monumental collaboration that took place to bring the in vitro irritation method for medical devices to the industry, including manufacturing an extractable positive control, designing and performing an international interlaboratory round-robin study, and presenting of tools to fast-track the method into regulatory acceptance.

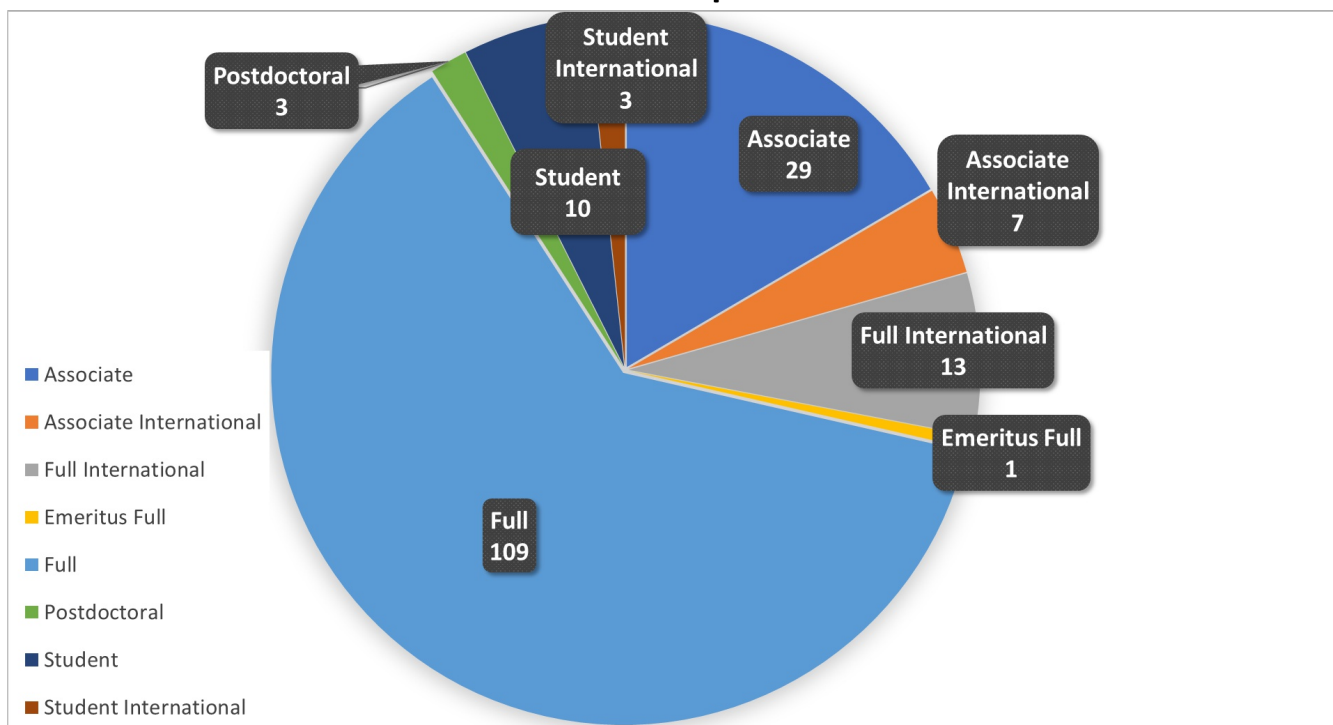
Membership Update

by **Sherry Parker, PhD**

The MDCPSS was formed in 2009 with 51 founding members. Since then we've grown steadily and now have 175 members.

Our members come from industry, government, consulting, and academia. The majority of our membership includes Full SOT Members, followed by Associate Members, Student Members, and Full International Members. Educational backgrounds range from BS degrees to those with MBAs, MPHs, PhDs, DVMs, and MDs.

MDCPSS Membership = 175 Total



Treasury Update

by **Shelby Skoog, PhD**

2018 Net Assets

Dec	2018	\$20,509
June-Nov	2018	\$19,009
May	2018	\$14,793
April	2018	\$12,793

2018 MDCPSS Sponsors

Edwards Lifesciences
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The MDCPSS Executive Committee would like to thank our sponsors for helping to make MDCPSS 2018 activities possible. MDCPSS had a successful year in member registrations and net assets, with modest expenses.

To support MDCPSS activities, please consider making a tax deductible donation. If you would like to dedicate a contribution to supporting one or more activities, the EC will gladly facilitate your tax free donation and recognize your support at the annual event and in our communication. MDCPSS accepts donations by check or credit card. For additional information regarding donations to MDCPSS, please contact the MDCPSS Secretary/Treasurer, **Shelby Skoog** (Shelby.Skoog@fda.hhs.gov), or **Mina Klier** (mina@toxicology.org) at SOT Headquarters.

ISO 10993 TC 194 Meeting Update

by **Sherry Parker, PhD**

International WG 1, 11, and 15 Member of ISO/TC 194

International technical committee for ISO 10993 (ISO/TC 194) "Biological and clinical evaluation of medical devices" met December 3-7 in Berlin, Germany. Many of our MDCPSS members participate in this technical committee. There are many standards under significant revision. Here is a summary of the working groups (WG) that met:



International
Organization for
Standardization

- WG 2: Degradation aspects related to biological testing
- WG 3: Animal protection aspects
- WG 4: Clinical investigations of medical devices in humans
- WG 6: Mutagenicity, carcinogenicity and reproductive toxicity
- WG 8: Irritation, sensitization
- WG 10: Implantation

ISO 10993 TC 194 Meeting Update (cont.)

- WG 11: Allowable limits for leachable substances
- WG 12: Sample preparation and reference materials
- WG 14: Material characterization
- WG 15: Strategic approach to biological assessment
- WG 16: Pyrogenicity

WG 14 will discuss the latest draft international standard (DIS) for ISO 10993-18. This represents a significant revision to the current (2005) version and will provide guidance on conducting extractable/leachable studies to support chemical characterization of medical devices and materials. WG 11 discussed the new draft technical specification ISO DTS/21726: Application of the threshold of toxicological concern (TTC) for assessing the biocompatibility of extractable substances from medical devices; and the draft amendment to ISO 10993-7: 2008 Ethylene Oxide Sterilization Residuals. Amendment 1 to ISO 10993-7 will address the need for lower EO limits for sensitive patient populations (i.e. children, infants, neonates). A completely revised working draft of ISO 10993-17, with a proposed title to be changed to Toxicological Risk Assessment of Medical Device Constituents, was circulated for comment and discussed at the meeting. WG 8 is working on the new ISO 10993-23 CD: 2018 "Tests for irritation" and will include an in vitro irritation test method. ISO 10993-10 is now Tests for Skin Sensitization. The other groups above are also very active in standards revisions; expect changes to come.

Preclinical Evaluation of Medical Devices - The Pathologist's Perspective

by **Elizabeth Neyens, DVM, DABT**
Pathologist at Flanders ToxPath Consulting

Preclinical evaluation of medical devices has multiple similarities with the drug approval process of pharmaceuticals. Although safety and efficacy are the main objectives, many manufacturers of medical devices are dealing with specific challenges related to the class of medical device and the country in which they are looking to receive regulatory approval.

A typical medical device preclinical program includes information on the scope of available biomaterials, the appropriate selection of animal model, followed by GLP/non-GLP necropsy procedures, with specific histopathological evaluations. Overall, only an analytical approach will support the R&D process. Necropsy assessment should include at least the presence or absence of the medical device as it represents a gross bio resorption evaluation, including the associated host responses such as inflammation, adhesions, hemorrhage, and exudation. The objective of the microscopic evaluations is to perform semi-quantitative analysis that is consistent with regulatory guidelines (e.g., ISO-10993-6). If appropriate, more in-depth quantifications (e.g., image analysis) can be requested by regulatory authorities.

Before evaluating the microscopic changes of the medical device, it is important to focus on its detailed composition and engineering properties. Consequently, the histology department has a critical role in order to sample, fixate, and trim the tissues/organs without damaging the host-device interface. Also,

The Pathologist's Perspective (cont.)

some medical devices include one or more biological compounds resulting in sophisticated pathophysiological responses corresponding to the classical wound healing processes, but which are also prone to chronic uncontrolled inflammatory responses. Overall it is important to determine the specific study objectives and anticipated host responses in order to perform the post-mortem evaluations with success.

From a pathologist's review, it is important to report all findings and analyze them in a consistent manner, in order to classify them as adverse or not and categorize them to a short, medium or long post-implantation period. An experienced comprehensive team composed of surgeons, pathologists, toxicologists, and experienced study directors is critical.

The short review below^{1,2} lists only a few of the GLP challenges when evaluating Class III/IV hemostatic devices, but also similar surgically implanted mesh devices. Both of these devices are commonly implanted during peritoneal surgery.

- Choosing the appropriate animal model remains an important challenge as various options are available, but only one animal model should include the requested end points for your program. Benefits from the use of large animals (swine and sheep) versus small animals (rabbit, rat) should be considered.
- At necropsy, in situ and ex vivo documentations are vital as implantation-related adhesions should be separated from post-surgical-related adhesions. Adhesions may vary from fibrinous (loose) to fibrous (tight) and they may even migrate to abdominal organs (spleen, liver, kidneys, etc.).
- Sampling of tissues, organs and/or adhesions should be performed carefully, and separate sets can be selected for different purposes such as: histology, mechanical properties, electronic microscopy, and molecular analysis. Trimming notes are useful in documenting the study procedure. The goal is to obtain the representative sections in order to write the safety conclusion.
- In microscopic evaluations, scoring systems support pathological evaluations. However, it is important to note that each scoring system will be specific to each study and will vary for each different medical device. Special histology procedures are available including special stains, but are recommended only for non-pathologist reviewers; they can be added at request for nonpathologists in order to easily visualize the chronic inflammatory changes. In the case of chronic implantation, fibrosis will produce different types of collagen fibers (Collagen type I and type III).
- The following endpoints should be included: fibrosis, inflammation, degree of tissue ingrowth, degenerative changes and implant-specific findings such as debris or migration of material. In addition to these local changes, additional expertise is required for interpretation of findings from the local lymph nodes or surrounding lymphoid tissues.
- Often, pathologists are asked to score the amount of 'scar tissue'. Given the loose and colloquial definition of scar tissue, such evaluations should take place with caution and should include consideration of macroscopic and microscopic features discussed above.
- The examination of draining lymph nodes in medical device studies presents additional challenges, due to the wide variety of tissues and organs that devices are implanted into. The draining regional lymph nodes exhibit potential wear or degradation products, and the likely disruption of normal lymphatic drainage by surgical procedures makes it even more challenging. References describing regional draining lymph nodes for common implantation sites are very useful when writing study protocols. However, special care should remain the gold standard when selecting the appropriate draining lymph nodes in medical device studies.

The Pathologist's Perspective (cont.)

With their clinical prevalence and increasing frequency, medical devices represent a common subject of preclinical evaluation which is important for pathologists and toxicologists to understand. The complexity of the medical device safety and efficacy studies is high, and their rapidly evolving designs calls for consistent and detailed pathologic evaluation (semi-quantitative and morphometry) to determine host responses and to assess safety. Overall, knowledge of anticipated responses for medical devices Class III/IV in a preclinical setting at specific times will help determine the appropriate tissue processing, staining, evaluation and interpretation of safety profiles.

REFERENCES:

1. Preclinical Evaluation of Mesh Implants: The Pathologist's Perspective. Journal of Toxicological Pathology 1-11, 2018. John H. Keating, Raffaele Melidone, and Fernando Garcia-Polite.
2. Regional Draining Lymph Nodes: Considerations for Medical Device Studies Lyn M. Wancket.

Upcoming Events

IMPORTANT DATES FOR MDCPSS

April 4, 2019: Brussels, Belgium

- Public hearing on preliminary guidelines on the presence of phthalates in certain medical devices.
- The preliminary guidelines on the benefit-risk assessment of the presence of phthalates in certain medical devices covering phthalates, which are carcinogenic, mutagenic, toxic to reproduction (CMR) or have endocrine-disrupting (ED) properties are produced by the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) at the request of the European Commission.

[Read the mandate.](#)

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:

<https://www.toxicology.org/groups/ss/MDCPSS/index.asp>