

MDCPSS WINTER NEWSLETTER

President's Message



MDCPSS Executive Committee (EC) wishes everyone a wonderful 2015-2016 Winter holiday season. In this edition of the MDCPSS newsletter, there is a lot of content for MDCPSS members. The EC thanks Brenda Sideman, Doug Ball, and Ron Brown for presenting a webinar to the membership during

the past six months. This newsletter would not exist without the contributions of the medical device community. We thank all of our contributors.

In this newsletter, Dr. Lori Moilanen provides an update to ISO/NP Technical Report 10993-22: Guidance on Nanomaterials (p4), a currently scientific hot topic and increasingly important area for medical device toxicologists. Dr. Kelly Coleman provides an update on the application of *in vitro* irritancy testing for medical devices (p6). Application of an *in vitro* irritancy screen reduces animal use and may improve the safety evaluation process. Dr. Robert Pryzgoda writes about the application of genotoxicity testing to medical devices (p7). Dr. Pryzgoda's findings could have impact on new approaches for medical device toxicologists when conducting genotoxicity evaluations. Don't forget about the two job opportunities (p8).

Over the last six months, SOT HQ has improved ToXchange. Now is the time to take advantage of this communication tool. Should MDCPSS expand its use of ToXchange (p9)? Be sure to check out the useful tips on making ToXchange quicker, easier, and improved email notifications (p10).

In October and November, I was reminded of the importance of networking, the old fashioned way, by meeting and greeting in person. I attended the Northeast Society of Toxicology (NESOT) Regional Chapter annual meeting. NESOT President (Ebru Caba Downs) afforded me short amount of time at the podium to announce the MDCPSS 2016 student travel awards. I met new industry representatives, spreading the word to students about the availability of MDCPSS travel funds. Talking to students at the event reminded me of the importance of networking. I wondered whether participation in regional chapter meetings could be a great way for MDCPSS identify students who could benefit from a travel award. Thanks to the efforts of Sandra Chang, Rich Hutchinson, Greg Erexson, Kelly Coleman, and other MDCPSS members, spreading the word about MDCPSS travel award at the regional level has begun. MDCPSS representation at additional annual regional chapter meetings might also boost our student number.

The MDCPSS EC continues to work towards a great 2015-2016 year. Our goal is to foster dissemination of important toxicology issues throughout the MDCPSS community. MDCPSS will continue to leverage SOT HQ webinar technology in 2016, so expect some announcements soon. We must not forget that an important goal is communication of emerging toxicological science into future updates of medical device regulations and standards. The MDCPSS EC looks forward to serving you as we say good bye to 2015 and hello to the new year.

Alan Hood,
MDCPSS President

Table of Contents (click to move directly to page)

Events	2	In Vitro Sensitization Pilot Project Results	6
Medical Device News	3	Research in Progress: Evaluation Genotox Testing	7
Combination Product News	4	Job Opportunities	8
ISO/TR 10993-22 Draft Guidance on Nanomaterials	4	Expand ToXchange for MDCPSS?	9
Announcements	5	ToXchange Tips	10
Membership Update	5	SOT 2016 Annual Meeting	11
Treasury Update	6	MDCPSS Mission	11

Events

MDCPSS Webinar:

MDCPSS hosted a webinar entitled "The Threshold of Toxicological Concern: Application to Medical Devices and Pharmaceuticals" held on November 16, 2015. Webinar speakers were Ron Brown, FDA/CDRH, and Douglas Ball, Pfizer.

Abstract: Over the past 50 years, this question of assessing human health risk of unstudied or incompletely characterized chemicals has been the subject of many publications. The most widely accepted scientific approach to assess the risk of exposure to incompletely characterized chemicals is to consider a level of exposure for all chemicals below which there is no appreciable risk to human health; a threshold of toxicological concern (TTC). The concept of a TTC holds true across a wide spectrum of toxicity endpoints, such as genotoxicity, carcinogenicity, neurotoxicity, reproductive and developmental toxicity and acute and repeated dose systemic toxicity (Munro and Kroes [JECFA], 1998; Muller, 2006; Delaney et al., 2007; Bernauer et al., 2008; van Ravenzway, 2011). The literature provides evidence of the scientific community's acceptance of the TTC concept, which many regulatory authorities around the world have also endorsed. The TTC concept has been applied to many applications including food packaging, food flavorings, pesticide metabolites in groundwater, pharmaceuticals, herbal substances and preparations and genotoxic drug impurities.

Upcoming MDCPSS Webinar:

Title: "SCENIHR Opinion on the Determination of Potential Health Effects of Nanomaterials Used in Medical Devices"

Date: Tentatively scheduled for January 21, 2016 11:00 AM -12:00 Noon ET.

Webinar Speaker: Wim De Jong DVM PhD, Centre for Health Protection at the National Institute for Public Health and the Environment (RIVM), Bilthoven, the Netherlands

Abstract: The use of nanomaterials in medical devices poses a challenge for the safety evaluation and risk assessment of these medical devices as the specific character of the nanomaterial used should be taken into consideration. The various aspects of safety evaluation and risk assessment of medical devices containing nanomaterials are addressed in this Guidance. The use of nanomaterials in medical devices can vary considerably.

Examples are the use of free nanomaterials being a medical device and administered to the patient as such (e.g. iron oxide or gold nanomaterials for heat therapy against cancer), free nanomaterials in a paste-like formulation (e.g. dental filling composites), free nanomaterials added to a medical device (e.g. nanosilver as antibacterial agent in wound dressings), fixed nanomaterials forming a coating on implants to increase biocompatibility (e.g. nano-hydroxyapatite) or to prevent infection (e.g. nano-silver), or

OFFICERS

(2015-2016)

Click on names

President

Alan Hood

Vice President

Kelly Coleman

Past President

Gregory L. Erexson

Vice President-Elect

Barbara Henry

Treasurer/Secretary

Jim Kleinedler

Councilors

Shawn Deng

Sherry Parker

Student Representative

Kevin Trout

Postdoctoral Rep

Sandra Chang

MDCPSS Website

MDCPSS EC

Newsletter Editors

Sherry Parker

Shawn Deng

Alan Hood

MDCPSS EC



Events (continued)

embedded nanomaterials to strengthen biomaterials (e.g. carbon nanotubes in a catheter wall). In all these cases the potential exposure to the nanomaterials should be considered. It is additionally recognised that wear-and-tear of medical devices may result in the generation of nanosized particles even when the medical device itself does not contain nanomaterials.

Guidance is provided on physico-chemical characterisation of nanomaterials, the determination of hazards associated with the use of nanomaterials, and risk assessment for the use of nanomaterials in medical devices. The safety evaluation of the nanomaterials used in medical devices is discussed in the context of the general framework for biological evaluation of medical devices as described in the ISO 10993-1:2009 standard. Therefore, the risk assessment should be performed taking into consideration the type of device, the type of tissue contact, and the contact duration, thus identifying the specific exposure scenario.

A phased approach is recommended for evaluating the risk of the use of nanomaterials in medical devices based on potential release and characteristics of the nanomaterials to avoid unnecessary testing. In phase 1 an evaluation of the potential for the device to release nanoparticles either directly or due to wear of the device during use should be carried out. In phase 2 the aim is to determine the distribution of the particles released and also their persistence potential. In phase 3 the hazard is assessed using appropriate toxicity tests taking account of the exposure characteristics and potential for persistence in specific organs. This will provide input for the final risk characterisation (phase 4). The estimated risk needs to be compared to the risk from the use of comparable devices not incorporating nanomaterials in judging the acceptability of the risk. In conclusion, the potential risk from the use of nanomaterials in medical devices is mainly associated with the possibility for release of free nanoparticles from the device and the duration of exposure.

Medical Device News

New FDA Draft Guidance: General Considerations for Animal Studies for Medical Devices (October 14, 2015).

This guidance provides recommendations for conduct of acute and chronic GLP animal studies to support medical device submissions. The draft document is available at the link below:

<http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev/gen/documents/document/ucm466358.pdf>

CDRH Announces 2016 Priorities (October 20, 2015).

Sixteen (16) priorities for 2016 are announced, which includes modernizing biocompatibility / biological risk evaluation of device materials. All 2016 priorities is available at the link below:

<http://www.fda.gov/MedicalDevices/ScienceandResearch/ucm467550.htm>

CFDA and AdvaMed Meet to Discuss Color Additive Use in Medical Devices

On October 9th 2015, CFDA key policy makers hosted a meeting at FDA's White Oak facility with AdvaMed SubGroup on Color Additive representatives and a representative from a test laboratory to discuss a draft FDA proposal on 1) use, 2) testing, and 3) submission requirements for medical device color additives. The draft proposal was highly supported by industry, although areas of refinement were acknowledged. The meeting concluded with agreement to continue refining submission requirements of medical device color additives.

Combination Product News

New Draft Guideline: Addendum to the ICH M7: Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk. Calculation of Compound-Specific Acceptable Intakes M7(R1). In this draft guidance, Acceptable Intakes (AIs) or Permissible Daily Exposures (PDEs) were derived for a set of mutagens and carcinogens that are common pharmaceutical impurities. Compounds are included in which the primary method used to derive acceptable intakes for carcinogens with a likely mutagenic mode of action is the “default approach” from ICH M7 of linear extrapolation from the calculated cancer potency estimate, the TD50. The draft document is available at the link below:

http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Multidisciplinary/M7/M7_Addendum_Step_2.pdf

ISO/TR 10993-22 Draft Guidance on Nanomaterials Nears Completion

Contributed by Dr. Lori Moilanen: After almost four years of work, a final voting draft of ISO/TR 10993-22 Biological evaluation of medical devices – Part 22: Guidance on nanomaterials is nearing completion. Document development began at the 2012 ISO Technical Committee (TC) 194 meeting in San Diego with formation of an international writing committee within the recently formed Working Group (WG) 17 - Nanomaterials. Progress on the document has been sustained by a series of two-day WG 17 sessions at subsequent ISO TC 194 meetings, as well as interim meetings in Delft, St. Paul, and Ottawa. MDCPSS members including Lori Moilanen, Ed Reverdy, and Kelly Coleman have been involved throughout the document development process.

ISO/TR 10993-22 is intended as guidance for the biological evaluation of medical devices that contain, generate, or are composed of nanomaterials. Nanomaterials present in medical devices while incorporated in a matrix, as nanostructured material, or as surface structures on materials and/or medical devices are also considered within scope. Recognizing that multiple definitions exist, ISO/TR 10993-22 adopts the definition of a nanomaterial given in ISO/TS 80004-1:2010. By this definition, a material is considered a nanomaterial when it has a size at the nanoscale including external and internal dimensions, i.e. when it has a size or is composed of structures with a size of approximately between 1 nm and 100 nm.

Significant challenges in the development of ISO/TR 10993-22 have included the broad scope of the document, the evolving state of nanomaterial science, and limited availability of consensus methodology for nanomaterial characterization, dosimetry, and risk assessment. ISO 10993-22 was initially conceived as a normative Technical Specification. At the 2014 TC194 meeting held in Mishima Japan, a majority of WG 17 members voted to change the status of the document to an informative Technical Report based on concerns that appropriate tools and methods for characterization and evaluation of nanomaterials are still under development. This decision was reaffirmed at the 2015 ISO TC 194 WG 17 meeting in Lund, Sweden. As currently written, ISO/TR 10993-22 provides a general approach to biological evaluation of nanomaterials (with discussion of potential pitfalls) and addresses how the other parts of the ISO 10993 series may be used in the process.

The current timeline for ISO/TR 10993-22 includes completion of the voting draft in April 2016, followed by a three-month voting and comment period. Comments and voting results will be discussed at the 2016 ISO TC 194 meeting tentatively scheduled for September in the Washington DC area. For additional information on the ongoing development of ISO/TR 10993-22, please contact Lori Moilanen (lhmoilanen@mmm.com).

Announcements

Annual Meeting and Reception

The MDCPSS annual meeting and reception at SOT 2016 in New Orleans will take place 6:00-7:30 pm on Wednesday, March 16. Location TBD.

SOT Communique Blog

Sandra Chang, PhD, Postdoctoral Representative for MDCPSS authored an article titled *National Postdoctoral Appreciation Week-I've Got a PhD! Now What?* see web link: <http://toxchange.toxicology.org/p/bl/et/blogid=9&blogaid=1667>

Award Deadline

This year the Medical Device and Combination Product Specialty Section (MDCPSS) is offering a Best Abstract Award, Best Published Paper Award, and two \$1,000 Student Travel Awards to the 2016 SOT annual meeting in New Orleans. Information about these awards is available at the following link: <http://www.toxicology.org/groups/ss/MDCPSS/awards.asp>. Applications should be sent to Dr. Kelly Coleman (see contact information below) before January 4th, 2016.

MDCPSS Officer Nominations

Please nominate an 2016-2017 MDCPSS Officer candidate for the following positions that will become open May 1, 2016. Nominate by sending via email a biography sketch to any current MDCPSS officer ([Alan Hood](#), [Kelly Coleman](#), [Barbara Henry](#), [Jim Kleinedler](#), [Sherry Parker](#), [Shawn Deng](#), [Kevin Trout](#), [Sandra Chang](#), or [Greg Erexxson](#)) by December 31, 2015.

- MDCPSS Vice President Elect
- Secretary/Treasurer
- Councilor
- Post-Doctoral Representative
- Graduate Student Representative

Include the following:[Full Name, including degrees and affiliations]. Dr. [Last Name] is a/the [Current position] at [Place of employment], where he/she [Summary of work]. He/She received his/her doctorate in [Field] from [School/University] in [Year] and was a postdoctoral fellow at [Institution] from [Years, i.e. 1995-1998]. Dr. [Last Name] has served on the [Study sections, Panels, etc.] at the [Organization, i.e. NIH, EPA, etc.]. He/She is author/co-author of [Number] [Publications including peer-reviewed articles and/or book chapters, etc.]. He/She has been a member of the SOT since [Year] and has served the SOT in the following capacities: [Offices/positions held].

Membership Update

Contributed by Dr. Kelly Coleman: The MDCPSS was formed in 2009 with 51 founding members. Since then we've grown steadily and now have 161 members.

- Our members come from industry, government, consulting and academia
- Educational backgrounds range from BS degrees to MBAs, MPHs, PhDs, DVMs, and MDs.
- Student memberships are free. So if you're in school, please consider joining.

Treasury Update

MDCPSS Financial Information 2015

General Fund

June	2015	\$ \$20,481
July	2015	\$ \$21,231
August	2015	\$ \$21,531
September	2015	\$ \$22,231

2015 MDCPSS Sponsors

NAMSA	John Cammack
APS	Kelly Coleman
Abbvie	Medtronic
Ron Brown	Ethicon

Contributed by Dr. James Kleinedler: MDCPSS had a successful year in member registrations and net assets, with modest expenses. Thanks to a strong year of support from sponsors, MDCPSS net assets increased throughout the year. The MDCPSS Executive Committee thanks all this year's sponsors for helping to make MDCPSS 2015 activities possible. Please consider making a tax-deductible donation of any amount to support MDCPSS.

MDCPSS accepts donations by check or credit card. Checks can be sent to SOTHQ, and other forms of payment may be completed by email or by phone directed to Raul A. Suarez (raul@toxicology.org) at SOT Headquarters (703) 438-3115 x1461. All donations should have the minimal information, donor's name, contact information, amount of donation and payment information directed to the Medical Device and Combination Product Specialty Section, Society of Toxicology, 1821 Michael Faraday Drive, Suite 300, Reston, VA 20190. When the donation is completed a receipt will be sent to the donor and SOT will notify the MDCPSS President and Treasurer.

In Vitro Sensitization Pilot Project Results

Contributed by Dr. Kelly Coleman: In June Medtronic and Cyprotex published a paper in *Applied In Vitro Toxicology* entitled "**Evaluation of an In Vitro Human Dermal Sensitization Test for Use with Medical Device Extracts**," which presented the results of a recent pilot project. The goal of this study was to determine if the *in vitro* SenCeeTox® assay could be an acceptable alternative to existing *in vivo* methods. The authors evaluated ten known sensitizers and non-sensitizers, six of which were incorporated into medical grade silicone, while the others were added to extracts of plain silicone. EpiDerm™ tissues were dosed with solvent extracts after which cell viability, LDH release, and reactivity were measured along with the expression of 11 sensitization marker genes. Eight of the 10 test samples (80%) were correctly identified as positive or negative sensitizers. These results indicate that the SenCeeTox® assay combined with EpiDerm™ tissues can detect the presence of sensitizers in medical device extracts. If these findings are confirmed, then this model may be a suitable replacement for the animal methods currently used to evaluate medical device biocompatibility.

Kelly P. Coleman, Lori R. McNamara, Thomas P. Grailer, Jamin A. Willoughby, Sr., Donald J. Keller, Prakash Patel, Simon Thomas, and Clive Dilworth. 2015. Evaluation of an In Vitro Human Dermal Sensitization Test for Use with Medical Device Extracts. *Applied In Vitro Toxicology* 1(2): 118-130.

<http://online.liebertpub.com/doi/abs/10.1089/aivt.2015.0007>

Research in Progress: Evaluation of Genotoxicity Testing for Medical Devices: Are the Current Methods Sufficient for Hazard Identification?

Contributed by Dr. Robert Przygoda: For biological evaluations of medical devices, extracts prepared according to ISO 10993-12 are used in several genetic toxicity test systems to identify potential hazards. The adequacy of the various extraction procedures allowed in ISO 10993-12, for genotoxicity testing described in ISO 10993-3 is still being debated. The concern is that some extraction procedures may not be adequate for hazard identification. The literature was searched for the lowest positive dose (LPD) induced by various mutagenic chemicals in each of the following tests: bacterial reverse mutation (Ames), *in vitro* chromosomal aberration (CA), and the *in vivo* micronucleus (MI). For the Ames bacterial reverse mutation test and the *in vivo* micronucleus test, results from 161 IARC carcinogens were evaluated. For the *in vitro* chromosomal aberration test, results from 474 clastogenic chemicals were extracted from a report by M. Ishidate, *et. al.* (1988). The cumulative frequency of LPDs at selected extract concentrations was determined and used to assess the percentage of mutagens detected at each these concentrations. This comparison was used to determine if the extract concentrations were sufficient to induce the LPD. In addition, results from 104 Non-Volatile-Residue (NVR) analyses were used to determine the frequency that each of 6 targeted dose-concentrations (0.001% to 10%) was achieved. When device extract concentrations were $\leq 0.1\%$, which occurred 83% of the time in this analysis, the percentage of mutagenic chemicals that could be detected is less than 50% with the exception of the CA test using media (see Table 1). The CA test using media could detect 76% of the mutagens at 0.1%. Therefore, for extract concentrations of 0.1% or less, the ISO 10993-12 method was considered inadequate for genetic toxicity hazard identification. When device extract concentrations were $> 0.1\%$, which occurred 17% of the time in this analysis, the percentage of mutagenic chemicals that could be detected varied between 36% and 100% (see Table 1). At 1% extract concentrations, 36% to 76% of the mutagens could be detected. At 10% extract concentration between 76% and 97% on the mutagens could be detected. Therefore, the ISO 10993-12 extraction method, which 83% of the time only achieves concentrations $\leq 0.1\%$, was only considered adequate at 10% (occurring $< 17\%$ of the time in this analysis). These data suggest that extraction conditions for the majority of tests evaluated in this analysis do not produce extracts that are concentrated enough to detect genotoxic chemicals, and are insufficient for hazard identification. *This work has been submitted for publication.*

Table 1: Comparison of the extract concentration to final test concentration in test system per ISO 10993-12

Test	Dose Volume	Percent extracted from device					
		10%	1%	0.1%	0.01%	0.001%	0.0001%
Theoretical Maximum	N/A	20mg/mL	2mg/mL	0.2mg/mL	0.02mg/mL	0.002mg/mL	0.0002mg/mL
Ames	0.1 mL	2mg/plate	0.2mg/plate	0.02mg/plate	0.002mg/plate	0.0002mg/plate	0.00002mg/plate
<i>In vivo</i> Micronucleus	0.5 mL	400mg/kg	40mg/kg	4mg/kg	0.4mg/kg	0.04mg/kg	0.004mg/kg
<i>In vitro</i> genetic toxicity tests	0.1 mL	0.2mg/mL	0.02mg/mL	0.002mg/mL	0.0002mg/mL	0.00002mg/mL	0.000002mg/mL
	1.0 mL	2.0mg/mL	0.2mg/mL	0.02mg/mL	0.002mg/mL	0.0002mg/mL	0.00002mg/mL
	8.5 mL	17mg/mL	1.7mg/mL	0.17mg/mL	0.017mg/mL	0.0017mg/mL	0.00017mg/mL
		17% of the Extractions are greater than 0.1%		83% of the Extractions are equal to or less than 0.1%			
Color code % Mutagens Detected		91-100%	81-90%	61-80%	31-60%	11-30%	$\leq 10\%$

Job Opportunities

Toxicologist Vacancy at the FDA

The Obstetrics and Gynecology Devices Branch in the Division of Reproductive, Gastro-Renal, and Urological Devices [FDA/Center for Devices & Radiological Health (CDRH); Silver Spring, Maryland] is recruiting outstanding toxicologists with training and/or experience in development and review of toxicological risk assessments, ISO 10993 biocompatibility tests, and/or in vivo animal testing to join our team of scientific reviewers.

The Obstetrics and Gynecology Devices Branch is responsible for premarket review of a wide variety of devices used for reproductive health, including male and female barrier contraceptives and sexually transmitted infection prophylactics, electronic fetal monitors, endometrial ablation devices, fibroid treatment devices, adhesion barriers, devices used for assisted reproduction, urogynecological surgical mesh and instrumentation, endoscopes for gynecologic and fetal surgery, instrumentation used during gynecologic and fetal surgery, and many more novel and state-of-the-art technologies.

The incumbent will be a member of a multidisciplinary (e.g., clinical, engineering, statistical, and microbiological) team that reviews protocols and analyzes data on bench, animal, and human studies to assess the safety and effectiveness of medical devices.

Review duties require written analyses and recommendations, as well as public presentations. Other duties include meeting with regulated industry to provide guidance on study design and regulatory process and engineering assessment of post-market device recalls and adverse events.

If you are interested, please email a copy of your resume/CV with a cover letter to Sharon Andrews at sharon.andrews@fda.hhs.gov.

Two Postdoctoral Positions at J&J

Ethicon Surgical Care, part of the Global Surgery Group (GSG) and a member of Johnson & Johnson Family of Companies, is recruiting for a 2-year Postdoctoral fellowship position, Toxicologist, located in Somerville, NJ. Opportunities may include designing & implementing testing systems & procedures for biocompatibility testing, as well as careful review of existing data in order to conduct Toxicology Risk Assessments for all Ethicon devices, drugs and combination products.

Principal Duties and responsibilities include but are not limited to ensuring that testing meets all international & domestic test requirements according to ISO (International Standards Organization), FDA (Food & Drug Administration)-CDRH (Center for Devices & Radiological Health), ICH (International Conference on Harmonisation) & GLP (Good Laboratory Practice) guidelines, overseeing, designing, implementing, & analyzing testing systems, procedures & test results for biocompatibility / toxicology evaluation for all Ethicon materials & products. Act as study director to support & coordinate pre-clinical activities related to initiation & generation of study proposals for biocompatibility testing for in-house and CRO based studies. Review & approve or modify protocols & study proposals. Review & approve final reports. Effectively communicating with CRO in oral & written form regarding test requirements, issues, deviations & special requests. Summarizing & interpreting raw data from reports & supporting coordination of central documentation procedures required for reports. Ensuring appropriate documentation is established & maintained. Collaborating with associates of diverse technical backgrounds (chemistry, physiology, materials science, engineering, and veterinary) to achieve desired project outcomes. Interacting closely & providing consultative direction to R&D, Clinical Affairs, Regulatory Affairs, Surgical R&D & Supplier Management within Ethicon, reviewing regulatory submissions and providing input.

Job Opportunities continued

Writing biocompatibility/toxicology sections of regulatory submissions and responses to questions. Maintain current knowledge in existing regulations, requirements and standards, including but not limited to global regulatory requirements (ISO, ICH, FDA, etc.) and compliance requirements (GLP, USDA, AAALAC, departmental SOP's, company policies, etc.). Actively interact with the internal and external scientific community to maintain state of the art knowledge. Perform literature searches as appropriate for hazard and toxicology assessments. Support R&D development teams for determination of test requirements, sample preparation & submission procedures for materials & products and assist in maintenance of corporate biocompatibility database.

This position requires a PhD in Toxicology, Biology, Bioengineering, Biomedical Engineering or related field, with knowledge of basic toxicology principles. Candidates need to possess the ability to work independently and efficiently in order to meet timelines. Candidates must be detail oriented and have the ability to prioritize tasks and projects. Candidates must have the ability to work on multiple projects simultaneously and able to communicate complex issues & concepts in a clear, concise manner to different disciplines i.e., (Engineers, Physicians, etc.)

Knowledge of ISO, GLP & FDA-CDRH guidelines is preferred. Knowledge of Toxicology principles is essential.

Primary Location: North America-United States-New Jersey-Somerville.

Apply online now <http://jobs.nnj.com/s/CS04pA>.

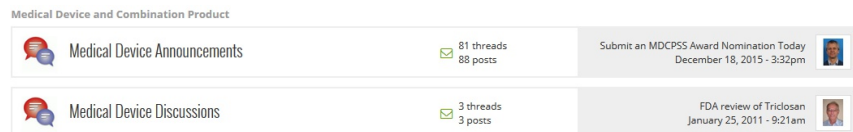
Expand ToXchange for MDCPSS?

Contributed by Dr. Alan Hood: There is a general perception that ToXchange is under utilized by SOT membership. ToXchange is a communication tool for individual members, SOT HQ newsletter, SOT Job Bank, Leadership Groups, Open Groups, Regional Chapters, and Specialty Sections. This past year (2015), the ToXchange website was completely overhauled requiring users to re-learn how to navigate the new system. To understand whether MDCPSS is utilizing ToXchange to its fullest potential, it is important to know what it has to offer the community.

For MDCPSS community, ToXchange has two functional areas: Files and Forums. The Files area contains MDCPSS officer candidate bios and newsletters.



The Forums area contains a history of announcements and discussions sent via email to each MDCPSS member. The Announcement section is actively used



by MDCPSS leadership as the principal communication tool to members. SOT HQ also offers a Discussion Forum where individual MDCPSS members can communicate to the wider community.

The last Discussion Forum post was 2011 and has not been used since. Is it time to utilize the MDCPSS Specialty Section Discussion section? If yes, what should be posted? If you have an idea of what you would like to post to the Discussion Forum, send the idea to a MDCPSS officer (click on officer name on [Page 2](#)). In Q1 of 2016, the ideas will be communicated to MDCPSS community.

ToXchange Tips

Contributed by Dr. Alan Hood: Using ToXchange can be made easier with the following tips:

Quick Login

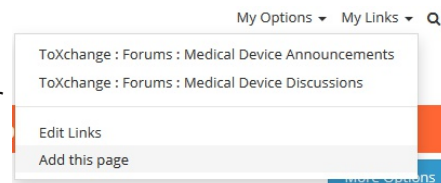
Users don't have to log into toxicology.org first to access ToXchange. It is quicker to directly log into ToXchange by using the URL <http://toxchange.toxicology.org>.

Easier Login

Everybody has accumulated many website usernames and passwords, remembering them all is problematic. Make login easier by allowing the web browser you use to remember your login username and password. To improve security, use [LastPass](#) or [KeePass](#) password managers.

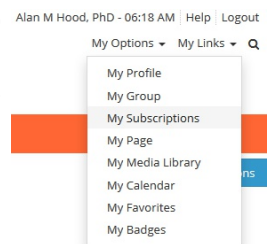
Quicker Access to ToXchange Groups

Use the My Links feature to store a favorite ToXchange webpage for quicker access to job postings, groups, forums, and any other ToXchange site.



Reduce Email Clutter

Membership to multiple Specialty Sections, Regional Chapters, and more can result in numerous emails per day. The emails you receive can be more manageable by changing your forum subscription from Immediate to once-a-day Summary Digest or once-a-day Full Digest. To access your subscription settings, log into ToXchange and click on My Options and then My Subscriptions. In your personal subscriptions page, click on the edit link next to each subscription to change how emails are sent.



Immediate:

Sends any forum posts directly to your email account as soon as they are received.

Immediate Digest with Links:

Send directly to your email account the first 100 characters of any forums posts as soon as they are received. A link to the full post and any attachments will be provided.

Summary Digest

Sends a digest directly to your email account once per day listing the titles from any forum posts received during that day. Links will be provided to view the full forum post within the system.

Full Digest with Attachments

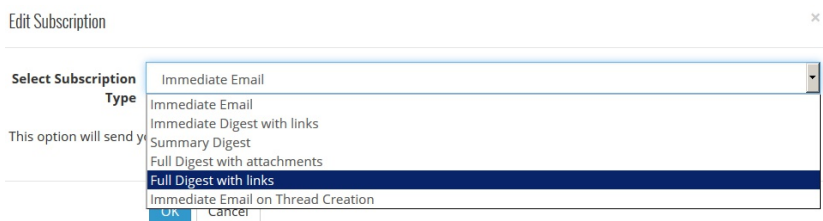
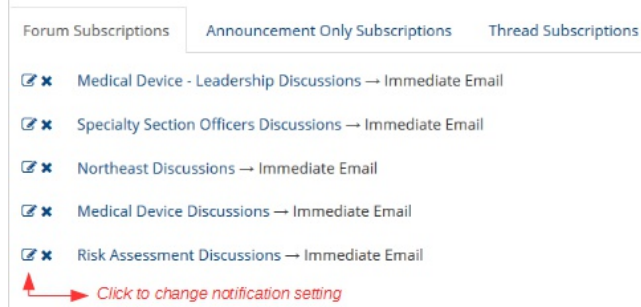
Sends a digest directly to your email account once per day with the full text from any forum posts received during that day, and all of the attachments from those posts.

Full Digest with Links

Sends a digest directly to your email account once per day with the full text from any forum posts received during that day, and links to download any of the attachments from those posts.

Immediate Email on Thread Creation

Sends an email when a new thread is created in the topic selected.



SOT 2016 Annual Meeting

Early Bird Registration for the SOT 2016 Annual Meeting is now open!



Some New Orleans photos are courtesy of New Orleans Convention & Visitors Bureau. Some photos by Pat Garin.

As mentioned earlier, the MDCPSS annual meeting and reception at SOT 2016 in New Orleans will take place 6:00-7:30 pm on Wednesday, March 16. Location TBD.

Don't forget to renew your annual SOT membership....Deadline December 2015

MDCPSS Mission

The objectives of the Medical Device and Combination Products Specialty Section of the SOT are 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.