Society of Toxicologic Pathology

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Print Full Issue

THE SCOPE

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Boston Marriott Copley Place Venue for 2012 Meeting

The STP headquarters hotel, Boston Marriott Copley Place, is the ideal venue for the 2012 STP meeting. Attendees will be able to enjoy cutting edge restaurants, renowned entertainment, and 200 years of history within steps of the hotel.

Boston Marriott Copley Place hotel is centrally located in the historic Back Bay district of the city and minutes away from historic Trinity Church and Boston Common. The hotel connects to shops at Copley Place and Shops at the Prudential. Whether looking to shop on ritzy Newbury Street or to cheer on your favorite sports team at Fenway Park or the TD Garden, Boston Marriott Copley Place hotel is in the ideal location for your visit to Boston.

The Boston Marriott Copley Place has several convenient restaurants and bars: Champions—a casual Boston sports bar with High Def TV's and 36 beers on tap. Open for Breakfast, Lunch, and dinner; Connexion Lounge—a casual yet stylish lounge with sofas and overstuffed chairs, a great spot for late afternoon snacks or a glass of wine in the evening. Open for lunch and dinner; Starbucks—for your early morning cup or your afternoon pick me up!

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The hotel's recreational facilities include a large health club with cardiovascular equipment, free weights, indoor pool, and whirlpool.

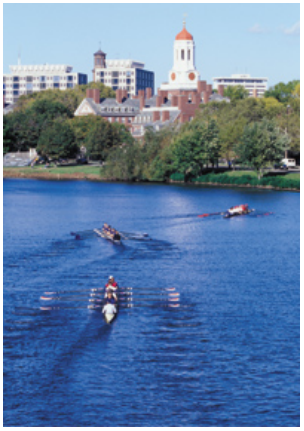
STP contracted for the 2012 room block several years ago in order to provide a discounted STP room rate and to ensure that there would be enough rooms for all attendees. Everyone is encouraged to stay at the Boston Marriott Copley Place. Wired Internet access (a $12.95 value) will be available in each room at no charge for STP meeting attendees. You will receive a login code when you check-in at the hotel.

Make Your Hotel Reservations.

Explore Boston!

Boston was incorporated as a town in 1630 and is one of America's oldest cities. Boston is known for its educational institutions and is a center for biotechnology and research. It is also known for its champion sports franchises, museums, and its unique place in American history. Boston is a city where the richness of American history is complemented by the vibrancy of a thriving, modern city. All meeting events will take place at the Boston Marriott Copley Place, which is located in the Back Bay neighborhood. This area is known for its picturesque streets lined with brownstones and its elegant architecture including the Boston Public Library and Trinity Church. The Back Bay got its name from the marshy tidal flat that drained from the Charles River until the 1850s when the

area was filled in to create a new neighborhood to accommodate the city's growth.



The Charles River

Boston Websites

- City of Boston—Comprehensive information and downloadable self-guided iPod tours
- Boston USA

Things to Do

Boston trolley tours and Duck tours are great ways to see Boston. Both make frequent regular stops at the Marriott and tickets can be purchased in the hotel lobby.

- Fenway Park tour
  - The stadium is an 8–10 minute walk from the Marriott hotel. Fenway does have tours as well hourly between 9:00 am–4:00 pm daily during the season. The tour is $12 for adults and is 50 minutes long.
  - Home game Tuesday (likely in the evening)—tickets in packages of 4 range from $60–$80 at current pricing.
- Duck Tours
  - You've never toured Boston in anything that comes close to Boston Duck Tours. The fun begins as soon as you board your "DUCK," a W.W.II style amphibious landing vehicle. First, you'll be greeted by one of our legendary tour ConDUCKtors, who'll be narrating your tour. Then you're off on a journey like you've never had before. You'll cruise by all the places that make Boston the birthplace of freedom and a city of firsts, from the golden-domed State House to Bunker Hill and the TD Banknorth Garden, Boston Common and Copley Square to the Big Dig, Government Center to fashionable Newbury Street, Quincy Market to the Prudential Tower, and more. And, as the best of Boston unfolds before your eyes, your ConDUCKtor will be giving you lots of little known facts and interesting insights about our unique and wonderful city. And just when you think you've seen it all, there's more. It's time for "Splashdown" as your ConDUCKtor splashes your DUCK right into the Charles River for a breathtaking view of the Boston and Cambridge skylines, the kind of view you just won't get anywhere else. ($26–$32; 60–80 minutes)
- Freedom Trail
  - The Freedom Trail is a 2.5 mile red-brick walking trail that leads you to 16 nationally significant historic sites, everyone an authentic American treasure. Preserved and dedicated by the citizens of Boston in 1958, when the wrecking ball threatened, the Freedom Trail today is a unique collection of museums, churches, meeting houses, burying grounds, parks, a ship, and historic markers that tell the story of the American Revolution and beyond. (9 daily tours; $11)
- Old Town Trolley tours
  - For over 30 years, Old Town Trolley Tours has provided sightseeing tours highlighting the best of Boston. Hop aboard one of our trolleys and you'll experience Transportainment, a delightful combination of transportation and entertainment. Our friendly conductors narrate the tour with a fascinating and fun mix of trivia and humorous stories. ($37–$42)
- Museums
  - Museum of Fine Arts
    - One of the largest museums in the United States, attracting over one million visitors a year. It contains over 450,000 works of art, making it one of the most comprehensive collections in the Americas. It is also the 54th most visited art museum in the world, as of 2010. ($22)
  - Museum of Science
    - A Boston landmark, located in Science Park, a plot of land spanning the Charles River. Along with over 500 interactive exhibits, the Museum features a number of live presentations throughout the building every day, along with shows at the Charles Hayden Planetarium and the Mugar Omni IMAX Theater, the only domed IMAX screen in New England. ($22)

President's Report

The STP Executive Committee (EC), consisting of Councilors **Diane Creasy, Susan Elmore, Kevin McDorman, Paul Snyder, Pierre Tellier,** Secretary-Treasurer **Ken Schafer,** President-elect **Dan Morton,** Past-President **Wanda Haschek-Hock,** and myself, met recently for a face-to-face meeting and a tour of the conference facilities at the Marriott Copley Place in Boston, Massachusetts, the site of next year's 31st Annual STP Meeting. Both Boston and the Marriott Copley look to be a great venue for our 2012 meeting. The Scientific Program Co-Chairs, **Richard Peterson, Carl Alden,** and **Dan Rudmann** have organized an exciting symposium with the theme 'Mechanisms of Toxicity.' Please see the 2012 Annual Meeting website for full details on the meeting.

Since our annual meeting, the EC has been active with STP operations including a response to a recent NIH funding opportunity to gain input on the future of the biomedical research workforce. STP, in addition to ACVP and the STP/ACVP Coalition, each responded directly to the NIH emphasizing the importance of NIH funding to train future veterinary pathologists. To date, The EC has approved four 'Specialty Interest Groups (SIGs); the policy and application form for new SIGs are now posted on our website (See related article). Those of you interested in forming a SIG should inquire through the STP website. There has been much success recently by the Education Committee, chaired by **Kevin Keene,** in organizing and promoting STP jointly sponsored regional day events including the STP-Boston Area Pharmaceutical Toxicology Group meeting on carcinogenicity testing, the Midwest Regional Chapter of the SOT joint meeting on reproductive toxicology, the Pacific Northwest meeting on current trends in comparative and toxicologic pathology and the joint meeting with CL Davis in Washington DC on

interacting with the regulatory community. Some of these lectures were recorded and will be added to our Web Education section of our website.

The EC, in working with **John Foster,** the Editor in Chief of *Toxicologic Pathology*, have approved an additional issue for publication for 2012 due to increased manuscript submissions and the continued release of INHAND reviews. Our participation continues in the Scientific Liaison Coalition (SLC), originating from SOT, with **Kevin McDorman** serving as our STP representative. The SLC now includes 15 scientific organizations with the goal of aligning the scientific community and fostering joint collaborations on scientific topics of mutual interest.

Finally, the EC continues to strategize and gain input from our membership on our globalization goal, especially in these difficult economic times where 'big pharma' is becoming more "lean" and continually downsizing. Analysts agree that this change is strategic, not temporary, and relates squarely to the higher long-term risk profile of this business. To survive, we must have the ability to innovate, analyze, and execute around a global approach that can accommodate diverse cultures and perspectives of doing business. To assist our members for the future in toxicologic pathology, please anticipate a STP survey for your input on how we can continue to best serve our members. The survey is being prepared by **Binod Jacob** of the Membership Committee with EC guidance by **Dan Morton**. I strongly encourage all to complete the survey.

The EC and I continue the work of the STP and as always, we welcome your comments which can be directed to **Sue Pitsch,** our Executive Director or me.
Sincerely,

Thomas Monticello
2011–2012 STP President

Annual Meeting News

STP 31st Annual Symposium: Mechanisms of Toxicity

The Boston Marriott Copley Place in Boston, Massachusetts will be the headquarters hotel for the STP 31st Annual Symposium, June 24–28, 2012. The award-winning Boston Marriott Copley Place hotel is centrally located in the historic Back Bay district of the city and is just minutes away from historic Trinity Church, and Boston Common. Boston, Massachusetts is a "hub" of biotechnology and basic research, not to mention of early American history. We hope you will join us for this exciting program.

Northwest corner of Copley Square in Boston, Massachusetts, USA, showing the Boston Public Library at left, and Trinity Church at right. Photo by: GearedBull Jim Hood

The Scientific Program Co-Chairs for the 2012 Annual Meeting, Mechanisms of Toxicity, are Richard Peterson, Carl Alden, and Dan Rudmann. The global regulatory agencies and the general public require outstanding scientific rigor and quality in the human risk assessment of xenobiotics. To meet these demands, the toxicology and pathology professions are positioned to take advantage of key learnings captured from major advances in the molecular understanding of host defense, disease and toxicity processes. The purpose of the 2012 Annual Symposium of the Society of Toxicologic Pathologists will be to examine mechanisms of toxicity in six general sessions covering tissue injury related to the following: 1) host factors, 2) chemical structure, 3) xenobiotic cellular targets (on- and off-target), 4) new technologies (e.g., nanotechnology, siRNA therapy and immunoconjugates), 5) cellular organelle specific effects, and 6) high profile environmental chemicals and consumer products.

The traditional NTP Satellite Symposium, entitled Pathology Potpourri, in advance of the symposium will focus on the customary presentations of challenging lesions.

Five continuing education sessions will be held on Sunday before the general sessions begin including: "Mechanism- Based Approaches to Cardiovascular Safety Assessment;" "Non-Traditional Applications of Clinical Pathology in Drug Discovery and Preclinical Toxicology;" the ACT-Sponsored "Drug Development 101" course, "The Placenta As an Immune Organ and Its Relevance in Toxicological Studies;" and A half-day Career Development Workshop: "Presentation Skills for the Toxicologic Pathologist."

A Career Development Lunchtime Series, held on Monday, will provide participants guidance on Careers in Environmental Toxicology.

On Wednesday IATP and STP will co-sponsor "Ethical Figure Adjustments for Publication," which is part two of "Responsible Authorship & Publication Practices" given at last year's meeting. There will be a nominal fee to cover lunches this year and participants may bring specific questions and problem images for one-on-one interaction with imaging experts after the presentations.

Call for Awards

STP Student Travel Awards

Student Travel Award recipients will be selected from the abstracts submitted to the STP. Award selection will be based on the scientific content and impact of the research, and composition and clarity of the abstract. Several trainees may also be asked to give an additional short oral presentation concurrent with the general scientific sessions. All award recipients will receive free registration and a ($1,000) stipend to be used for lodging and travel to the Annual Symposium of the STP, which will take place June 24–28, 2012, in Boston, as well as complimentary student membership in the STP for the following year. Applicants must submit a Travel Award application, letter of nomination, *Curriculum Vitae,* and Statement of Career Goals.

Submit Abstracts Online by March 1, 2012

Submit an abstract on-line (should be limited to 250 words) describing your original work involving clinical or experimental research that relates to experimental or toxicologic pathology.

Student Travel Award Flyer and Application can be found on the Awards Page.

Poster Guidelines

Student Events

There will be a student outing to the Tuesday afternoon, June 26. This will be a fun opportunity to meet fellow students and interact with mentors. This function has been the highlight of past meetings for many students. Details will be e-mailed to student registrants when available.

STP Young Investigator Awards

Three (3) Young Investigator Award (YIA) recipients will be selected by the judges from posters presented at the STP Symposium and will receive $500, $250, or $100 for 1st, 2nd, and 3rd place, respectively. Award recipients will be selected after evaluation of an oral poster presentation (based on a submitted abstract), and award selection will be based on the scientific content and impact of the research, the composition and clarity of the poster, and the ability to concisely and clearly present the information orally. Application for the YIA involves checking the YIA box on the abstract submission form.

The recipients of the STP Student Travel Awards and Young Investigator Awards will be recognized at an Awards Ceremony prior to the Annual Business Meeting on Wednesday, June 27, 2012, as well as subsequently in one or more press releases and publications distributed by the STP.

What our award recipients have to say...

"I had the opportunity to receive the student travel award and young investigator award and attend the STP symposium both as a pathology resident and a graduate research student. The most important aspect for me was that this symposium especially focused on reaching out to research students and future toxicologic pathologists via the mentoring program, student outing and career outreach activities. Attending these symposia gave me unique opportunities to interact with leaders in industry and academic toxicologic pathology, which was quite inspiring."

The Charles Capen Travel Award (IATP)

The Charles Capen Travel Award recognizes Dr. Charles Capen and his legacy as a researcher, teacher, and mentor to the pathology and toxicology communities spanning more than four decades. Dr. Capen was recognized worldwide as an exceptional leader in veterinary and biomedical research. He was a highly regarded mentor to graduate students and postdoctoral scientists. His students and trainees are now leaders throughout academia, government, and industry and have contributed significantly to his reputation as an outstanding teacher and research mentor. The International Academy of Toxicologic Pathology funds an award in the amount of $750 USD which can be used by the successful applicant for travel or registration costs to attend a conference of a Society of Toxicologic Pathology or related meeting.

The successful applicant will have demonstrated achievements in the field of toxicologic pathology including but not limited to:

1. Research contributing to public safety as it relates to the adverse health effects of xenobiotics;
2. Establishing test methods and standards that enhance the field of toxicologic pathology; and/or
3. Developing new or novel uses of toxicologic pathology in safety research.

IATP was established in 1999. Its purpose is to recognize and accredit toxicologic pathologists whose work affects the public welfare throughout the world. Fellows of IATP are scientists who have achieved expert status in the practice of toxicologic pathology through scientific leadership and innovation which benefits society and their profession. Accreditation in IATP is based on formal training in pathology, demonstrated achievement, proven ability, continuing practice and expertise. Agencies, universities and other organizations regularly seek out IATP Fellows to serve as guest lecturers, panel experts, and consultants.

Capen Award application details will be posted on the Awards Page soon.

STP 31st Annual Symposium Exhibit Hall Update

The Exhibit Hall at the STP 31st Annual Symposium in Boston will open the evening of Sunday, June 24 and close the afternoon of Wednesday, June 27. All of the exhibit booths will be spread out inside the Exhibit Hall. The scientific poster sessions, Internet Café, and Microscope room will all be available inside the hall and closely located to Exhibitors.

The hugely successful exhibitor-sponsored buffet luncheon held during the 2010 and 2011 Annual Meetings will return to the Exhibit Hall in Boston on Monday, June 25 and is offered to all attendees. High top tables will be available in the Exhibit Hall to accommodate the luncheon, as well as the welcome reception, continental breakfasts, and refreshment breaks throughout the week. These events can be sponsored by one company or can be partially sponsored by multiple companies.

Prime booth spots are still available in the Exhibit Hall! Please visit the STP 2012 Annual Meeting website or contact **Maureen Kettering** if your company would like more information about exhibit space or sponsorship opportunities in Boston.

STP News

New Members

Applicant	Company
Mehrdad Ameri	Amgen
Muriel Bellot	F. Hoffmann-La Roche
Helen Booler	Royal Veterinary College
TzuYu Chen	National Laboratory Animal Center (NLAC)
Crystal Johnson	Charles River Laboratories
Heeyoun Kim	Asan Institute for Life Science
Bruce LeRoy	Abbott Laboratories
Michael Logan	Covance
Carlos Lopez Mendez	Atlantic Veterinary College
Kimberly Maratea	Genzyme
Chandrassegar Saravanan	Tufts Cummings of Veterinary Medicine
Helmut Schmid	Harlan Laboratories Ltd
Lean Schutt	Genentech, Inc.
Qurban Ali Shah	Sindh Agriculture University
Leandro Teixeira	University of Wisconsin-Madison
Caroline Zeiss	Yale University, Comparative Medicine

STP Special Interest Groups Form Communities on ToxPathNet

Several informal interest groups that met before morning sessions during the Annual Meeting in June have requested and received formal recognition from STP. The Reproductive Pathology Special Interest Group, the Environmental Toxicologic Pathology Special Interest Group, the Clinical Pathology Special Interest Group (CPIG), and the Neuropathology Special Interest Group (SIGN) now have ToxPathNet communities for group communications. Any STP member can join one or more groups and receive its communications by visiting a Special Interest Group's ToxPathNet page and selecting the "Join" button. There is no fee to join.

Each of the groups submitted a mission statement and signatures of interested members based on guidelines created by the Special Interest Group Task Force (**Ken Schafer,** Chair). The STP supports special interest groups (SIGs) composed of STP members that specifically enhance networking and scientific exchanges relevant to the mission and strategic plan of the STP. It is anticipated that these groups will provide scientific contributions to STP and may serve as a resource for educational programming for the STP. These groups can serve to maintain discipline in the forefront of developments by providing a forum for the quick exchange of novel ideas and developments, which could lead to publications, Continuing Education (CE) courses, symposium sessions (e.g. Town Hall topics), or other programs. STP SIGs are specifically defined as member organized efforts that further the strategic objectives of the organization and should specifically be linked to those objectives, broadly understood. In general, supported groups would represent specific scientific disciplines or educational interests.

To access a Special Interest Group community:

Either

- Select "Special Interest Group" from the Members Menu on the STP homepage
- From the Special Interest Group page, select the ToxPathNet Community link of any group under its name

Or

- From the STP homepage select the ToxPathNet logo in upper right area of page, (you will be prompted for your login)
- Select Communities
- Select the Special Interest Group button
- Select the name of the Special Interest Group from the list

To join a Special Interest Group

- Select "Join Community" button in upper right area of the group's page

ACVP/STP Coalition Board News

On behalf of STP, thank you to outgoing Coalition Board of Governors member **Denzil Frost** (Covance). Dr. Frost began serving in January 2009 and will complete a three-year term on the Board at the end of this year.

Welcome to **Noel Dybdal** (Genentech), who has been appointed by the Executive Committee for a three-year term that begins in January. Four other STP members also represent STP on the Board: **Curtis Colleton** (Bristol-Myers Squibb), **Tom Rosol** (The Ohio State University), **William Iverson** (Medimmune), and **Bhanu Singh** (E.I. duPont de Nemours and Co., Inc). For more information about the Coalition and its activities, visit the website.

The ACVP/STP Coalition for Veterinary Pathology Fellows Extends Its Reach

Gary Cockerell, *Director of the Coalition*

The purpose of this article is to summarize the current status and future plans for the ACVP/STP Coalition for Veterinary Pathology Fellows. Since it began operating in 2005, 29 positions have been established at 16 different North American training institutions, supported by >$6.8M in financial contributions from sponsors. Fifteen fellows have completed their fellowships and either entered additional phases of training or accepted positions with biopharmaceutical companies, contract research organizations, private diagnostic laboratories, or academic institutions. Seventy-one percent of Fellows (12/17) who have taken the ACVP Certification Examination have passed, and 92% of those passed all parts on their first attempt. These measures of success reflect the quality of the fellows, the excellence of their training programs, the foresight of sponsors that have provided support and the need for this unique educational initiative. In an effort to extend its reach, a strategic plan was recently drafted with three primary objectives to define the Coalition's direction over the next 5 years.

The first objective remains the same as the original purpose of the Coalition – to increase the number of privately funded veterinary pathology training positions. Of particular note this year, the Coalition established two positions supported by donations to the ACVP. The "Charles and Sharron Capen Fellowship in Veterinary Pathology," and the "Linda Munson Fellowship for Research in Wildlife Pathology Research" were competitively awarded to **Lisa Berman-Booty** at The Ohio State University, and **Patricia Gaffney** at the University of California, Davis and San Diego, respectively. These two fellowships are unique for several reasons; they are the first to be supported with funds other than from industry, they require specific areas of PhD dissertation research, and they require cost-sharing by the training institution. It is hoped that other ACVP and STP members will consider making similar contributions while efforts continue to secure additional industrial support. The next Request for Applications for newly funded training positions will be issued in early June 2012.

Additionally, and with consideration to the STP Globalization Limited Duration Team Task Force and ACVP Global Impact Committee of the Complementary Resources Task Force, the Coalition plans to implement a program to assist foreign-trained DVMs to competitively apply for post-DVM veterinary pathology training. North American training institutions frequently receive applications from such candidates, often with funds supplied by their home country, government or other sources. The objective of the program is to make it easier for foreign students to apply for training and for North American institutions to have broad access to these students.

The second objective is to develop and implement novel industry-academia collaborations and specialized training opportunities to augment pathologists' career development. While sponsors have provided generous support for new positions and training institutions have submitted highly competitive applications, the Coalition has never attempted to identify unique types of positions that sponsors would be particularly interested to fund or that training institutions could offer. Therefore, as an initial step toward this objective, a Request for Concepts is being planned for early 2012, to assess sponsors' specific needs and to categorize training institutions' specific areas of expertise. The outcome should make it possible to better align specific needs of sponsors with capabilities of training institutions, resulting in veterinary pathologists with unique skill sets.

The third objective is to work in collaboration with academic partners to lead relevant initiatives identified by the ACVP Credentialing and Training Committees for North American-based veterinary pathology training programs. Implementation will be dependent on results of on-going work and final output of

these committees; however, many existing resources can be applied toward this objective, e.g., the process for evaluating applications for newly funded Coalition training positions, pathology clubs, training coordinators and the ACVP Examination Committee.

Further information on Coalition activities, including a listing of all sponsors, mentors and fellows is available on the Coalition website. On behalf of the members of the Board of Governors I would like to thank our participating sponsors and training institutions for their continued enthusiastic response to the Coalition. I look forward to working with you in the coming years to implement the new objectives listed in the strategic plan.

Enhancing Our Society

STP has become the standard for excellence in toxicologic pathology throughout the world. A great society is defined by its foundation, our generous donor firms. STP is vital to your career education and development because of the commitment of our many generous donors, including Abbott Laboratories, Charles River Laboratories, Experimental Pathology Laboratories, Harlan-AnaPath, and Pfizer (Diamond (≥$15K) Donors), Amgen, Boehringer Ingelheim and Hoffman-LaRoche, National Institute of Environmental Health Sciences and National Toxicology Program (Emerald ($10K–$14,999) donors), AstraZeneca and Genentech (Opal ($7K–9,999) donors), Biogen Idec Glaxo SmithKline, Huntingdon Life Sciences, Millennium and Novartis, (Ruby ($5K–6,999) Donors), Bristol Myers Squibb, Daiichi Sankyo, DuPont Haskell, GEMpath, Lilly USA, LLC, MPI Research, Sanofi, Seventh Wave, Takada Global R&D, and WIL Research (Sapphire ($2.5K–4,999) Donors), Ani Lytics, inc., Alizee Pathology, JCL Schuh, PLCC, CanBioPharma Consulting, David Fairchild, DVM, Inc., Pharmaron, Inc., and Pre-Clinical Safety, Inc. (Pearl ($1K–2,499) Donors). If your firm is not listed above, encourage them to join the foundation of firms sustaining our important Society.

Consider a personal commitment to STP, as well. There are many programs that are vital to our Society and to our profession that we also need individual members to support. The programs include supporting graduate students to travel to and present their research at our annual symposium or at regional meetings, funding best poster awards, helping fund the INHAND efforts, underwriting the costs of webinars and regional meetings sponsored by the STP, and many of the other passions that the membership has. Consider a pledge of $50 or more per annum for the next five years to your Society. Donate when renewing your annual membership or by visiting the membership renewal page at any time during the year. Together, we can build an even stronger and more relevant Society of Toxicologic Pathology.

Journal to Increase from Seven to Eight Yearly Issues

Toxicologic Pathology will increase to eight regular issues/volume in 2012 to accommodate the increasing number of manuscripts submitted to the journal. The extra issue will alleviate the need for STP to purchase additional pages over the number contracted with Sage Publications, as has been necessary over the last two years. The extra issue will also directly benefit authors, who will see a significant decrease in the time between acceptance and appearance in print of their articles. Member 2012 dues were not increased to cover the cost of the new issue. The publisher expects increased royalties from subscriptions to institutions, as well as increased advertising, to balance the extra cost to the Society and STP will reevaluate the situation in late 2012.

Committee News

Wanted: A Few Good Courses

Have you ever sat at your microscope and fervently wished for a good up-to-date summary of some topic with which you are struggling? Do you have an area of expertise of value to STP members? Almost assuredly you have and you do. The newly formed Continuing Education (CE) Subcommittee is looking for nominations for STP Annual Symposium CE courses for 2013 and beyond. If you have an idea for an interesting, relevant CE course suitable for the annual symposium, please don't keep it to yourself, but let us know! Kindly send your topic suggestions, along with as much of the following information as you can to **Sarah Hale** or **Stephane Thibault**.

1. Course title
2. Brief outline of course and potential speakers (CE courses are generally about 3–4 hours long and have 3–5 speakers.)
3. Whether or not you would be willing to chair the CE course you are recommending or a suggestion of someone who might

STP members are what make our organization unique and valuable. Thanks for your input.

Evaluation of Recovery or Reversibility in Preclinical Toxicology Studies

As many Toxicologic Pathologists are aware, the International Conference on Harmonisation (ICH) is a project that brings together regulatory authorities and experts from the pharmaceutical industry from Japan, Europe and United

States in an effort to reach consensus on the scientific and technical aspects of drug development. One of the key guidances produced by the ICH process is the M3 guidance titled "Guidance on Nonclinical Safety Studies for the Conduct of Human Clinical Trials and Marketing Authorization for Pharmaceuticals." The M3 guidance was revised in December of 2009. This revision provided more information regarding the timing of pre-clinical studies to support clinical trials and clear guidance regarding exploratory clinical trials. As commonly occurs, when more information and details are included in a guidance this leads to more questions. The ICH Expert Working group, which drafted the revision collected questions following implementation of the revision and in July 2011 posted the questions and answers to provide additional clarity on specific topics: 1) limit dose for toxicity studies, 2) metabolite safety assessments, and 3) reversibility in toxicity studies. The Q&A document can be found at the ICH website.

The last question and answer in this Q&A publication is in regards to the evaluation of recovery or reversibility in a preclinical toxicology study. This was the topic of the Town Hall meeting at the annual STP meeting in Denver this year. There is also an STP working group on this topic whose efforts are ongoing and their findings will eventually be published in *Toxicologic Pathology*. The answer given by ICH provides a clear perspective that follows the ICH guidelines and a clear guidance to both sponsors and regulatory authorities. The approach has a strong focus on the collection of preclinical data on reversibility in animals when there is severe toxicity in a nonclinical study with potential adverse clinical impact. This question and answer regarding reversibility within preclinical toxicity studies is shown below.

> Question: When is assessment of reversibility considered to be appropriate and is it important to demonstrate full reversibility or is it sufficient to demonstrate the potential for full reversibility?
>
> Answer: *ICH M3(R2) states the following in Section 1.4, General Principles:*
> *'The goals of the nonclinical safety evaluation generally include a characterization of toxic effects with respect to target organs, dose dependence, relationship to exposure, and, when appropriate, potential reversibility."*

Evaluation of the potential for reversibility of toxicity (i.e., return to the original or normal condition) should be provided when there is severe toxicity in a nonclinical study with potential adverse clinical impact. The evaluation can be based on a study of reversibility or on a scientific assessment.

The scientific assessment of reversibility can include the extent and severity of the pathologic lesion, the regenerative capacity of the organ system showing the effect and knowledge of other drugs causing the effect. Thus, recovery arms or studies are not always critical to conclude whether an adverse effect is reversible. The demonstration of full reversibility is not considered essential. A trend towards reversibility (decrease in incidence or severity), and scientific assessment that this would eventually progress to full reversibility, are generally sufficient. If full reversibility is not anticipated, this should be considered in the clinical risk assessment.

A toxicity study that includes a terminal non-dosing period is generally warranted if a scientific assessment cannot predict whether the toxicity will be reversible and if:

1. there is severe toxicity at clinically relevant exposures (e.g., ≤10-fold the clinical exposure); or
2. the toxicity is only detectable at an advanced stage of the pathophysiology in humans and where significant reduction in organ function is expected. (The assessment of reversibility in this case should be considered even at >10-fold exposure multiples.)
   A toxicity study that includes a terminal non-dosing period is generally not warranted when the toxicity:
3. can be readily monitored in humans at an early stage before the toxicity becomes severe; or
4. is known to be irrelevant to humans (e.g., rodent Harderian gland toxicity); or
5. is only observed at high exposures not considered clinically relevant (see 2 above for exception); or
6. is similar to that induced by related agents, and the toxicity based on prior clinical experience with these related agents is considered a manageable risk.

If a study of reversibility is called for, it should be available to support clinical studies of a duration similar to those at which the adverse effects were seen nonclinically. However, a reversibility study is generally not warranted to support clinical trials of a duration equivalent to that at which the adverse effect was not observed nonclinically.

If a particular lesion is demonstrated to be reversible in a short duration (e.g., 2 week or 1 month) study, and does not progress in severity in longer term studies, repeating the reversibility assessment in longer term toxicity studies is generally not warranted.

If a reversibility study is warranted it is efficient to conduct it as part of a chronic study so that all toxicities of concern can be assessed in a single study provided that it is not critical to conduct it earlier to support a specific clinical trial.

This article was submitted on behalf of the STP SRPC to update members on recent and/or important regulatory issues.

Regional Meetings A Success

> The STP Regional Meeting Program, coordinated by the Education Committee, recently wrapped a very successful fall 2011 calendar of events. There were five meetings that were sponsored or co-promoted

with a variety of host sites and affiliated science organizations that advance the STP's goal of providing regional educational and networking opportunities. Additionally, several of these meetings broadened the opportunity for remote participation by broadcasting the keynote address via webinars.

The success of these meetings is credited primarily to the local organizing committee that is formed for each event and administers the selection of a meeting topic, recruits speakers, and handles the venue logistics. "The STP is extremely grateful to our members who went above and beyond the call of duty to provide such high-caliber professional growth opportunities for our colleagues both within the STP and other affiliated science-based organizations and regulatory agencies" expressed **Kevin Keane,** Chairperson of the STP Education Committee.

The recent meetings venues and organizing committee include Washington, DC by **Marcia Pereira** and **Sarah Hale** at the Uniform Services Health Sciences Campus with host Major **Eric Lombardini** and co-promoted by the CL Davis Foundation; in Andover, MA by **Raju Mantena** and **Dan Morton** at Pfizer and co-promoted by the Boston Area Pharm-Tox Group with **Tim MacLachlan;** and in Seattle, WA by **Hajime Hiraragi** and **Charlie Dean** at Amgen. Other fall meetings were co-promoted by the STP in cooperation with affiliated organizations include the CL Davis Foundations Northeast Regional Tox Path meeting in Hopewell, NJ by **James Loy** and **Zadok Ruben** at Bristol-Myers Squibb and the Society of Toxicology Midwest Regional Meeting in Champaign, IL by **Wanda Haschek-Hock, Christina Wilson, Susan Henwood, Matthew Schroeder,** and **Michael Biehl**.

The STP Education Committee is also partnering with the Web-based Education Task Force to archive these outstanding webinars and slide presentations by our colleagues. ToxPath.org has a web education link that is available to members only for this purpose. The Education Committee's goal is to populate this link with high quality science and regulatory material delivered at these meeting delivered by both members and other invited speakers. It is further the Committee's goal that this material will become a reference archive for current and future STP members that complements our Journal.

With the conclusion of the fall meetings, the Education Committee now turns its attention to planning 2012 educational and networking opportunities. The keystone to organizing a regional meeting is the selection of a venue and date for the event. If you are affiliated with an organization that would like to host a regional meeting, than please contact any member of the Education Committee for consideration. These events are excellent opportunity to network with local colleagues on topics of mutual interest and to showcase your organization's scientific excellence in a friendly environment.

Other educational events that are currently being developed by the Education Committee include a modular mini-course in toxicologic pathology. These courses are currently in the planning stages to teach recent graduates the fundamental of toxicologic pathology that are not routinely covered in traditional veterinary pathology training programs. These courses will rotate through various organ systems at intervals throughout the year and will provide intensive, didactic, and interactive feedback on the interpretation and reporting of toxicologic pathology data in human-risk assessment. For more information, please contact any member of the Education Committee.

Allied Group News

SOT Toxicologic and Exploratory Pathology Specialty Section

Douglas Wolf, *President of TEPSS*

Toxicologic and Exploratory Pathology is a Specialty Section (TEPSS) embedded within the Society of Toxicology (SOT) and open to its membership. The TEPSS was established as an advocacy group to support scientific and educational programs dealing with the advances in experimental pathology and their application to regulatory policy and risk assessment practices. TEPSS sponsors scientific and educational programs including symposia, poster and platform sessions, workshops, and continuing education courses on contemporary scientific advances and scientific policy issues that promote the science of toxicology through the tools used by toxicologic and experimental pathologists. TEPSS fosters communication and interaction among toxicologic pathologists and toxicologists in government regulatory agencies, regulated industries, and academia pertaining to issues relevant for research and development of health care products and specialty chemicals vital to society. TEPSS supports the development of young scientists by providing funding opportunities for students and postdoctoral trainees that apply the techniques of toxicologic pathology in their work and opportunity for presentation at the SOT Annual Meeting. The next time you attend the SOT Annual Meeting, please join your colleagues at the TEPSS get together and consider becoming a member.

Member Spotlight

An Interview with Kevin B. Donnelly

By ***Anoop Murthy Kavirayani***

Where do you work and what are your main job responsibilities?

I work in Chandler, Arizona as a Senior Program Manager in the Molecule Development Group of Covance Laboratories. I am the only veterinary pathologist in this small group of experienced senior scientists who are divided between the UK and USA. We are the scientific advisors in drug development programs for Covance clients including big pharmaceutical companies and several small startup biotechnology firms.

When a client approaches Covance with a request for drug development studies in humans, animals or both, rather than doing the study and simply furnishing them with data which is a transactional business relationship, we provide them with program management services. As part of such services, a senior scientist such as myself is assigned to the program and we provide them with the big picture of where they are in the scheme of drug development. We advise them on regulatory issues, milestones, scientific issues, options for genetic toxicology or pharmacology studies, etc. We provide them with a lot of scientific advice on their molecule and its development program. We also assist them with clinical trials and related issues. Many companies find these services quite useful.

In summary my main job responsibility entails multifaceted scientific advisory interaction, which is the new model for contract research organizations, as opposed to the linear transactional business relationship that was typical of older models of drug development with contract research partners.

How did your career evolve to its current stage? Do you find it fulfilling?

I trained in veterinary anatomic pathology and subsequently earned a doctorate in immunology. Following this I started my career in industry as a staff pathologist for Eli Lilly where I worked for 11 years during which I gained most of my experience in drug development as a project pathologist. When our division of Eli Lilly was purchased by Covance, I automatically became a contract research laboratory employee. I have been affiliated with Covance for three years as a pathologist and laboratory animal veterinarian. This year I have been selected to join their program management group. In my career thus far, I have performed all of the traditional toxicologic pathology and drug development related roles. I have gained experience as a study director or project leader (a role usually performed by a toxicology scientist) and also as the attending laboratory animal veterinarian. It is along these trajectories that I arrived at my current stage.

Traditionally, a veterinary toxicologic pathologist might not arrive at this atypical career outcome. Generally pathologists being highly trained and specialized, focus their careers on toxicologic pathology. Some pathologists go into management roles and become scientific managers of departments or divisions. The outcome for me is not a predictable one for most pathologists going into industry. But I definitely find it very fulfilling. It allows me to engage in scientific oversight of the entire drug development process and not just in toxicologic pathology. However, my experience as a pathologist is one of the reasons I was selected to join this group because they wanted a team member who could bring a pathologist's knowledge and perspectives to the drug development process. It is an interesting and exciting career outcome that enables me to make strong contributions to Covance and its clients and I strive to represent pathology well in that arena.

What are your primary professional interests and subspecialties?

My primary professional interest is in the drug development process on a global scale. By that I mean innovation that benefits all of human and veterinary medical science. Through contract research, I enable the drug development process to put more tools into the hands of health care providers globally and thus participate in the process of realizing innovations and improving medicine. I want to emphasize the word global, because by far, the most important unmet medical needs globally include major infectious diseases and epidemics of obesity, diabetes, lung cancer and melanoma.

When it comes to subspecialties, my interests in pathology generally revolve around the cardiovascular and pulmonary systems. I also hold an adjunct faculty appointment in the Department of Pathobiology at Purdue University in Indiana. In that capacity, I guest lecture and sit on graduate student committees. I am also an invited speaker at scientific conferences and conventions both in the US and abroad, sometimes on cardiovascular pathobiology and at other times on drug development.

What aspects in your current position and in your career in general do you find most rewarding?

The most rewarding aspect of my current career is being able to provide the comparative and translational perspective in interpreting scientific research findings in animals and applying them to humans, because the primary goal of drug development is human health and medical progress. I see a general lack of understanding of comparative biomedicine in some sections of the scientific community. I believe veterinarians and veterinary pathologists can provide that perspective.

Where did you receive your veterinary and pathology training?

I received my training in veterinary medicine at Purdue University in Indiana.
I received my pathology training at Colorado State University as part of a combined six-year program that comprised three years of residency training followed by three years of PhD training.

What or who "sparked" your interest in pathology?

Biology was my favorite subject in school and as a high school student I went out and bought a student's microscope kit from a hobby store. Even at that time I was interested in veterinary medicine. When I started my veterinary training I had no specific ambitions toward pathology. During the second year of veterinary school, one of our professors announced a pathology field trip to a research facility where veterinary pathologists worked. We traveled to Eli Lilly in Indianapolis. During our daylong tour of the facility, I met the staff pathologist at Lilly. I went home that night and said to myself *"I know what I want to do in Veterinary Medicine."* Little did I think that I would start my career at that exact same site; but I knew I wanted to be a veterinary pathologist from that day. I pursued the rest of my veterinary training with the goal of making it as broad based and interesting as possible by taking rotations in a variety of clinical disciplines. Then I went straight into veterinary pathology training. I have never looked back since, and it has been a superb career.

Do any aspects of your pathology training seem uniquely suited to your current career?

The primary aspect is a thorough understanding of a variety of animal systems and their diverse responses to different processes. This appreciation for key differences in interspecies biology and pathology came about through broad based training in a wide variety of animal species. I do wish to point out that my early training in pathology had very little to do with drug development and toxicologic pathology. Obviously most pathology training programs are at veterinary schools and the work that one gets to do as a resident in a veterinary teaching institution revolves around traditional veterinary medicine based on companion, exotic and farm animals. Very few programs train veterinary pathologists specifically for toxicology practice. All of my specialization as a toxicologic pathologist came about once I entered industry through my first position at Lilly.

Where might you see the field of toxicologic pathology headed in the next five to ten years?

The primary role of toxicologic pathology in serving the drug development industry will not be changing significantly other than greater emphasis on increased visibility and broader participation in the whole process. While continuing to fulfill an important role in the discovery process, toxicologic pathology is going to be become exceedingly global and unified. There have already been a lot of initiatives focused on globalization of toxicologic pathology and some initiatives are examining the training and qualifications of multinational individuals. So there should be awareness that the practice of toxicologic pathology around the world is no longer done in isolation. As more and more drug development studies and basic medical research in toxicology are being done in Brazil, India, South Africa, China and so on, the American, British and European Societies of Toxicologic Pathology are reaching out, understanding, cooperating and benchmarking with the rest of the world. As an organization and as a profession toxicologic pathology is going to have greater multinational and global involvement in the next decade.

Do you feel such globalization will lead to various positive and negative consequences seen in other arenas such as manufacturing?

It certainly will. There is a well-established pattern of how the positives and negatives affect any profession once globalization happens. Personally I think the positives outweigh the negatives because of the progress made. While we will have some control over how it happens, I do not think we will be spared from some of its impacts.

Would the key then be to retain competitiveness and blend into the change in the best possible way?

Right. We need to be proactive about it. The STP, BSTP and ACVP have the opportunity to lead the way. There are people in these organizations that are trying to do that now so that we can have a reasonable say in benchmarking education standards, making decisions on qualifications, and validating veterinary and toxicologic pathology standards around the world. Rather than wait for broader organizations such as the international committee on harmonization (ICH) to adopt such benchmarks and validation criteria, it is better if organizations such as ours are proactive in stating their preferences before being acted upon by regulatory bodies.

Globalization aside, with increasing levels of digitization and computerization, do you feel the microscope might be replaced in the future?

If you ask a hundred pathologists you will get a hundred different answers. Broadly they fall into two groups: "*yes*" and "*no*." Technology streaks ahead in fascinating ways. We've come a long way from cell phones the size of shoeboxes to the amazing compact hand-held devices of today. I personally think digitization will become the standard practice, but not as soon as we expect. Digital imaging to the extent of regulatory driven practice of toxicologic pathology is still a long way. But I am very excited and interested about its progress; I personally endorse our investigation and utilization of this technology.

What are some of the hardships you've had to endure along the way and some of the obstacles you've had to overcome?

My training was at a good institution. But it is really difficult to perform well as a pathology resident and PhD candidate at the same time. Combined programs such as this are quite common; but it is hard to excel at both in a short time span. Looking back I wish I had learned more as a resident, which would have better prepared me for the board examinations. I also think I could have done better in my PhD and published more of my work. Challenges in my career have been few. Fortunately things have unfolded very well and I have been able to work at good institutions in the company of good colleagues.

What do you envision doing when you retire?

As a retiree I plan to pursue my strong interest in international aid in developing countries particularly in southern Africa. I am already a founding board member of a charity organization that works in Zambia, Africa. I also would like to continue to teach or lecture in the field of toxicologic pathology and drug development. I will also stay involved in professional organizations such as STP and attend or speak at various conferences.

What advice do you have for other pathologists and trainees?

The singular question I am most often asked by trainees is *"should they also do a PhD?"* Despite having just mentioned the difficult and challenging nature of a combined residency and PhD program, my answer is always yes. Doing a PhD is critical and will do a great deal to enhance one's whole career as a pathologist above and beyond residency training and board certification. Many important aspects of my career evolution are based upon the fact that I have a second doctorate. So for people seeking to train in the United States at this point, I would recommend finding an institution that can make a PhD happen and making the most of it. Combined programs are tough, but if one can qualify with board certification or eligibility in pathology and a second doctoral degree, one's career in scientific research would be greatly enhanced. For junior pathologists who have already started their career I would not recommend a second doctoral degree if they already do not have it. If they wish to, they could explore alternate avenues of professional advancement such as part time degree programs in management, for example.

What is your formula for work-life balance?

I have a performance management goal of trying to leave the office by 5 pm everyday. So I am sure to start early. Regarding the formula for success, I try and take care of business on my desk everyday. I strive against procrastination and task accumulation. I also make sure that there is time set aside for non-work activities, family commitments and personal life. I make that a relatively strict calendar process and try not to let things from work bleed over into other areas. That was easier to do when I was a project pathologist and my work schedule was simpler; I was attending post mortems, reading slides and generating data. It is harder now as I am dealing with a global clientele that uses email and telephones almost 24/7. Many of my interactions with them often fall outside of business hours. But I still have not allowed myself to give up on personal activities, hobbies and interests. I am not sure if there is a succinct formula for work life balance other than to say, *"don't stop having a personal life."*

What are your hobbies and other interests?

I am a certified semi-professional rugby and soccer referee. I continually enroll myself every season as an eligible and available referee and I periodically accept game assignments. I am also an angler. I fly fish and tie my own flies. I am also a motorcycle rider. Besides commuting to work on my motorcyle, I take periodic day or weekend motorcycle trips with my wife around Arizona and California where we have beautiful riding weather. The mountains of Arizona are superb and we also hike a lot, almost every weekend or at least as best as we can.

Would you like to tell us about your family?

My parents are British and I was born in Zimbabwe. So my original home is in Southern Africa. I have been in the United States since I was 20 years old, when I came here for university. The U.S. is home for me now. My wife Abigail is a medical dermatologist and works with dermatologic cancer patients. I have three children. Barry, my oldest son and Brenna my daughter are college students. My youngest son Gabriel is about to enter high school. None of them intend to choose careers in veterinary medicine or science. When they were young children, I would either be on call or often studying or working in the weekends as a trainee. At that time, they told me *"we don't want to be like you Dad, because we don't want to miss Saturday morning cartoons."*

Do you have any pets?

We have one dog and one cat. Our cat was a rescue animal that was about to be euthanized with serious ocular disease and needed tender care and expensive medications. I decided to adopt him and he has been with us ten years since. Our dog is an Italian Greyhound. She is one-sixth the size of a regular Greyhound and is one of the sweetest and smartest dogs I have known.

Is there something you would like to reveal to the member community that they would be surprised to know about you?

Nothing immediately comes to mind. I suppose they would be surprised to know that I have always been a fan of heavy metal and loud rock music. I have a large and very current collection of heavy metal music. I also regularly go to concerts; I can sometimes be seen in the third row of the audience at some Swedish death metal band concert!

The views expressed in this article are those of the interviewee and do not necessarily represent the views of the Society of Toxicologic Pathology.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