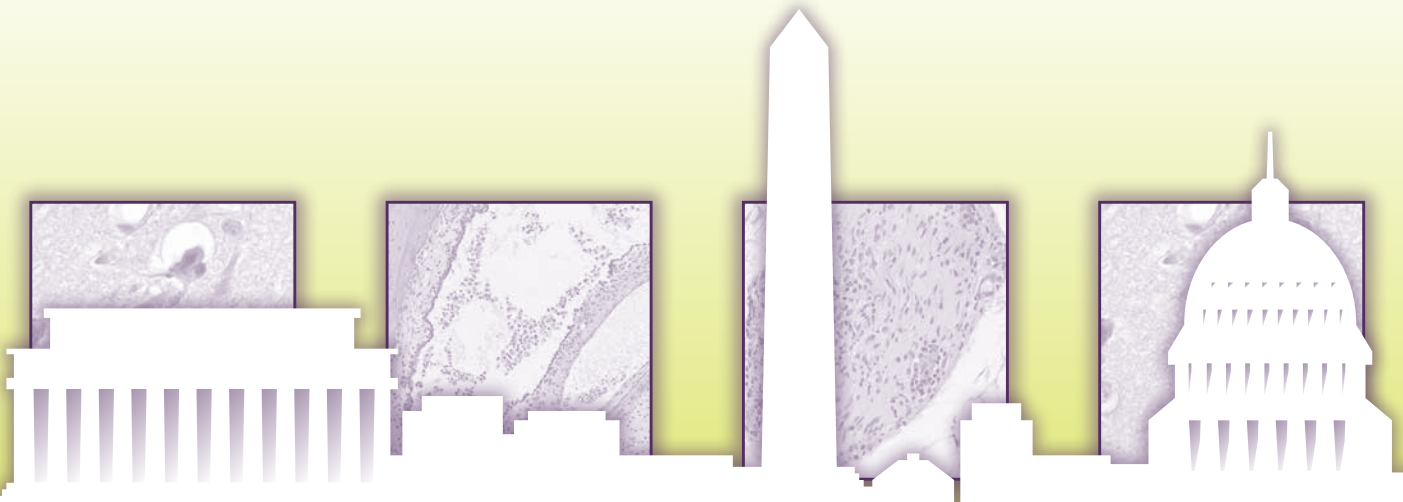




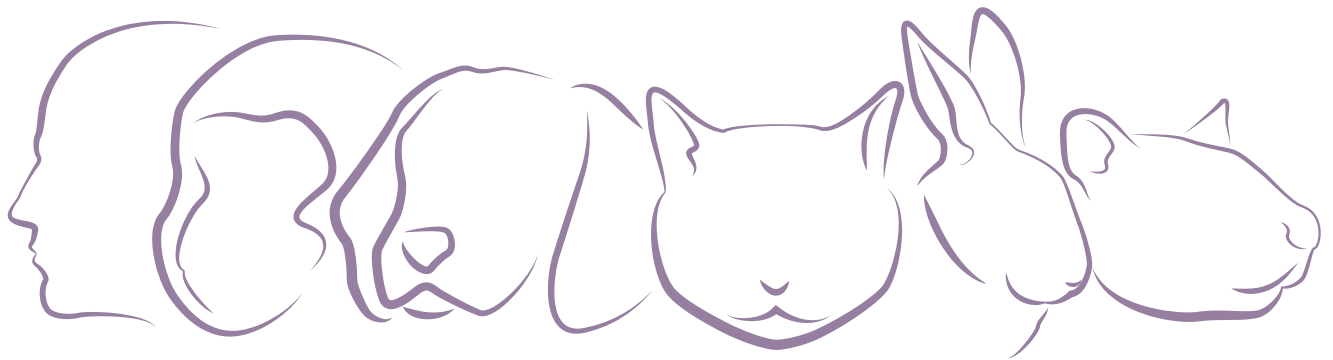
Society of Toxicologic Pathology

33rd Annual Symposium



TRANSLATIONAL PATHOLOGY:

*Relevance of Toxicologic Pathology
to Human Health*



Washington, DC

Marriott Wardman Park Hotel

June 22–26, 2014

www.toxpath.org

Annual Symposium Overview

Registration Desk Hours

Atrium, Exhibit Level

Friday, June 20	4:00 PM–6:00 PM
Saturday, June 21	8:00 AM–6:00 PM
Sunday, June 22	7:00 AM–6:00 PM
Monday, June 23	7:00 AM–5:30 PM
Tuesday, June 24	7:00 AM–5:30 PM
Wednesday, June 25	7:30 AM–5:30 PM

Registration B, Mezzanine Level

Thursday, June 26	7:30 AM–12:00 Noon
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All events are in the Marriott Wardman Park Hotel unless otherwise indicated.

Saturday, June 21

9:00 AM–4:30 PM	NTP Satellite Symposium: Pathology Potpourri Thurgood Marshall Ballroom
7:00 PM–10:00 PM	Sponsored Reception Virginia Suite

Sunday, June 22

8:00 AM–12:00 Noon	CE1: Biomarkers of Endocrine Effects and Reproductive Toxicity Thurgood Marshall Ballroom South/West
8:00 AM–12:00 Noon	Career Development Workshop: Effective Communication of Pathology Results in Regulatory Studies Thurgood Marshall Ballroom North/East
1:30 PM–5:25 PM	CE 2: Scientific and Regulatory Considerations in the Safety Evaluation of Stem Cell-Derived Therapies in Preclinical Studies Wilson Room
1:30 PM–5:25 PM	CE 3: Fundamentals of Translational Neuroscience in Toxicologic Pathology: Optimizing the Value of Animal Data for Human Risk Assessment Thurgood Marshall Ballroom North/East
1:30 PM–5:15 PM	CE 4: The Art of Study Monitoring and Pathology Peer Review: How to Maintain a Relationship of Mutual Respect with CROs Thurgood Marshall Ballroom South/West
5:30 PM–7:00 PM	STP Welcome Reception/Exhibits Opening Exhibit Hall C

Monday, June 23

7:00 AM–8:00 AM	Continental Breakfast Thurgood Marshall Ballroom Foyer
8:00 AM–8:05 AM	Symposium Welcome Thurgood Marshall Ballroom
8:05 AM–8:10 AM	Introduction Thurgood Marshall Ballroom
8:10 AM–9:00 AM	Keynote Address: Translational Research and Development (TR&D) in the Context of Toxicologic Pathology Thurgood Marshall Ballroom
9:00 AM–12:00 Noon	Session 1: Toxicity Concordance from Animals to Humans: How Predictive Are Traditional Preclinical Studies of Adverse Effects or Toxicities in Clinical Studies? Thurgood Marshall Ballroom
9:45 AM–4:00 PM	Exhibits and Posters Open Exhibit Hall C
10:30 AM–11:00 AM	Break/Posters/Exhibits Exhibit Hall C
12:15 PM–1:15 PM	Exhibitor/Sponsor Hosted Session Madison Room
12:30 PM–1:30 PM	Career Development Lunchtime Series: Draft OECD Guidance on the GLP Requirements for Peer Review of Histopathology: A Panel Discussion Wilson Room

1:30 PM–5:00 PM

Session 2: Progress in Preclinical Testing for Translational Science

Thurgood Marshall Ballroom

3:00 PM–3:35 PM

Break/Poster/Exhibits

Exhibit Hall C

5:30 PM–6:30 PM

Town Hall Meeting

Thurgood Marshall Ballroom

7:00 PM–10:00 PM

Sponsored Reception

Washington Room

Tuesday, June 24

7:00 AM–8:00 AM

Continental Breakfast

Exhibit Hall C

7:00 AM–8:00 AM

Exhibitor/Sponsor Hosted Session

Madison Room

7:00 AM–4:00 PM

Exhibits and Posters Open

Exhibit Hall C

8:00 AM–12:00 Noon

Session 3: Emerging Technologies

Thurgood Marshall Ballroom

9:45 AM–10:20 AM

Break/Posters/Exhibits

Exhibit Hall C

12:00 Noon–1:30 PM

Exhibitor Sponsored Lunch for Registered Scientific Attendees

Exhibit Hall C

1:30 PM–5:00 PM

Session 4: The Role of the Toxicologic Pathologist in Informing Regulatory Decisions and Guiding the Interpretation and Application of Data from New Technologies and Tools

Thurgood Marshall Ballroom

3:00 PM–3:35 PM

Break/Poster/Exhibits

Exhibit Hall C

Wednesday, June 25

7:00 AM–8:00 AM

Continental Breakfast

Exhibit Hall C

7:00 AM–11:30 AM

Exhibits and Posters Open

Exhibit Hall C

8:00 AM–12:00 Noon

Session 5: Epigenetic Endpoints in Toxicologic Pathology and Relevance to Human Health

Thurgood Marshall Ballroom

10:05 AM–10:40 AM

Break

Exhibit Hall C

12:00 Noon–1:30 PM

Excel Tips and Tricks: Easy Ways to Quickly Visualize Your Pathology Data—Sponsored by IATP and STP

Wilson Room

1:30 PM–5:00 PM

Session 6: Environmental Toxicologic Pathology and Prediction of Human Health Risks

Thurgood Marshall Ballroom

2:40 PM–3:15 PM

Break

Thurgood Marshall Ballroom Foyer

5:30 PM–5:50 PM

Awards Ceremony

Thurgood Marshall Ballroom

5:50 PM–6:30 PM

Annual Business Meeting

Thurgood Marshall Ballroom

7:00 PM–9:00 PM

President's Reception

Exhibit Hall C

Thursday, June 26

7:00 AM–8:00 AM

Continental Breakfast

Thurgood Marshall Ballroom Foyer

8:00 AM–12:00 Noon

Session 7: The Challenges of Safety Evaluation in Populations with Concurrent Disease

Thurgood Marshall Ballroom

10:05 AM–10:40 AM

Break

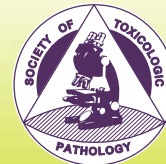
Thurgood Marshall Ballroom Foyer

12:00 Noon

Meeting Adjourned



TRANSLATIONAL PATHOLOGY:
Relevance of Toxicologic Pathology to Human Health



Society of Toxicologic Pathology

Welcome!

Dear Colleagues and Guests,

On behalf of the Society of Toxicologic Pathology, it is my pleasure to welcome you to the STP 33rd Annual Symposium and to Washington, DC. The 2014 Scientific Program Planning Committee has organized an exceptional week of sessions on "Translational Pathology: Relevance of Toxicologic Pathology to Human Health." I encourage you to take a few minutes to review the schedule of scientific and poster sessions and the many special events in this *Program* to get the most benefit from the week ahead.

The interactive NTP Satellite Symposium, "Pathology Potpourri," will be held all day on Saturday, June 21 and will focus on presentation of challenging lesions. It is free to all annual symposium attendees.

You may still register for one or more of the Sunday Continuing Education courses by stopping by the STP Registration Desk just outside the exhibit hall. CE 1 (AM)—Biomarkers of Endocrine Effects and Reproductive Toxicity, CE 2 (PM)—Scientific and Regulatory Considerations in the Safety Evaluation of Stem Cell-Derived Therapies in Preclinical Studies, CE 3 (PM)—Fundamentals of Translational Neuroscience in Toxicologic Pathology: Optimizing the Value of Animal Data for Human Risk Assessment, CE 4 (PM)—The Art of Study Monitoring and Pathology Peer Review: How to Maintain a Relationship of Mutual Respect with CROs.

The topic of the Sunday half-day Career Development Workshop is "Effective Communication of Pathology Results in Regulatory Studies." The Monday Career Development Lunchtime Series will present a panel discussion on "Draft OECD Guidance on the GLP Requirements for Peer Review of Histopathology." There is no extra fee to attend either career session; however, please stop by the Registration Desk if you are not registered and would like to attend.

You won't want to miss the Town Hall meeting on Monday evening when "The NOAEL in Nonclinical Regulatory Reports—Definition, Application, and Communication" will be the topic of lively discussion.

The exhibit hall is always an important part of our meeting and I am pleased that the exhibitors will sponsor a Tuesday buffet lunch in the hall for all symposium attendees. Be sure to visit our exhibitors' booths throughout the week. STP programs throughout the year, including this meeting, would not be possible without the support of our corporate sponsors, many of whom are also exhibitors. They are listed on the back cover and I wish to extend a thank you to all of them.

June is a wonderful time to enjoy Washington, DC and I encourage you to visit some of Washington, DC's wonderful museums and monuments. Most are only a few Metro stops from the hotel. Be sure to plan time to visit the National Zoo, which is located less than half of a mile from the Marriott Wardman Park Hotel.

I look forward to meeting you during the week and at the President's Reception on Wednesday evening following the Awards Ceremony and Business Meeting. Enjoy the meeting and thank you for your participation!!

Sincerely,

Robert C. Sills, DVM, PhD, DACVP, FIATP
STP President

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Global Vet Pathology

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(EC Liaison) Huntingdon Life Sciences

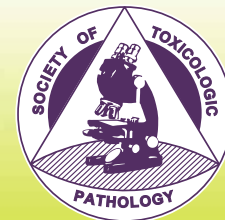


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You will be prompted for a login. Members can access with normal STP login. Other attendees can access with login provided via email.

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Awards



33rd Annual Symposium

Washington, DC

Marriott Wardman Park Hotel

June 22–26, 2014

STP 2014 Lifetime Achievement Award Recipient



**Daniel Morton, DVM, MS,
PhD, DACVP, DACLAM**

The STP is proud to honor Daniel Morton, DVM, MS, PhD, Diplomate, ACVP, Diplomate, ACLAM as the recipient of the 2014 STP Lifetime Achievement Award. Dr. Morton has distinguished himself as a thought leader in toxicologic pathology, a committed lifelong contributor and leader in the STP, and a mentor to many other pathologists.

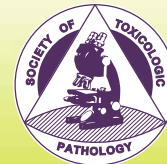
Dr. Morton earned a BS in Agricultural Science from Montana State University in 1978 and his DVM degree from Colorado State University in 1983. He went on to complete an MS degree from The Ohio State University in 1985 and a PhD in Veterinary Medical Science from the University of Illinois in 1990. Dr. Morton successfully passed the ACVP board certification examination in Anatomic Pathology in 1987 and the ACLAM board certification examination in 1992. He served as a Clinical Assistant Professor and Assistant Director in the Office of Laboratory Animal Care at the University of Illinois from 1989 to 1993, as Senior Research Scientist at Baxter Healthcare Corporation from 1993 to 1994, Veterinary Pathologist for Abbott Laboratories from 1994 to 1998, Assistant Director, Associate Director, and Director of Pathology Sciences at Pharmacia Corporation from 1993 to 2003, and as Associate Research Fellow and Research Fellow at Pfizer from 2003 to the present.

Dr. Morton has been an indefatigable advocate of the STP. He has served as President of the STP for 2012–2013, as Secretary-Treasurer from 2008 to 2011, and has served on multiple committees, including the Fundraising Committee, the Peer Review Working Group, Continuing Education Committee, Organ Weights Working Group, Reporting Pathology Interpretations Working Group, Standardized Tissue List Committee, Ovary Evaluation Working Group, and has served as chair or co-chair for the Scientific and Regulatory Policy Committee, Peto Analysis Working Group, and the Hyperplasia Working Group. Dr. Morton also served as a Section Editor for Toxicologic Pathology. Dr. Morton was the person largely responsible for initiating the effort that became an international collaboration now known as INHAND.

Dr. Morton's support of professional organizations has extended well beyond the STP. For ACLAM, Dr. Morton has served on the ACLAM examination committee, including as chair, as well as the Training Program Recognition Committee, the Forum Program Committee, and the Ad hoc Committee on Exam Consultant's Report. For the ACVP, He has also served on the Examination Committee, also as chair, the Strategic Planning Committee, and the Role Delineation Task Force. He has been an active force in the ongoing Boston-area Pharmaceutical Toxicology Group as well as playing roles related to PhARMA, and involvement in ACT.

Dr. Morton has served as a mentor for many pathologists on and off the job. He actively leads by example and has had a positive influence on many colleagues and members of the STP. He has been described as a quiet leader—one who leads not through the force of their ego but by their thoughts and actions. Unique among their colleagues, quiet leaders elevate those around them, giving credit for successes rather than taking it, and accepting personal responsibility for mistakes instead of directing blame at others. Their effective leadership is in their intelligence, integrity and ability to persuade others through rational arguments.

The list of Dr. Morton's accomplishments in his CV is self-evident, only a few of which have been mentioned above. Dr. Morton's commitment to promoting consistency and exceptionalism in the practice and interpretation of toxicologic pathology for drug safety has been extraordinary. His positive impact on toxicologic pathology has been felt globally. The STP guidance and best practice documents have given confidence to many toxicologic pathologists, particularly those new to the field, on how to "do the right thing." But it is also in his quiet accomplishments that so much of his value derives. He encourages but never pushes. He mentors gently without undue criticism. He promotes others before he promotes himself. He is a thinker. He is exceptional. He undoubtedly deserves to receive the STP Lifetime Achievement Award.



STP 2014 Outstanding Mentor Award Recipient



**David E. Malarkey, DVM,
PhD, DACVP, FIATP**

The Society of Toxicologic Pathology is proud to honor David E. Malarkey, DVM, PhD, DACVP, FIATP, as recipient of the 2014 STP Outstanding Mentor Award. Dr. Malarkey has over 20 years of experience in diagnostic pathology and teaching and has mentored over 60 pathology trainees, veterinary students, and graduate students. He has also published over 100 peer-reviewed journal articles as well as several book chapters that highlight his vast knowledge and expertise in hepatic carcinogenesis, molecular carcinogenesis, and toxicologic pathology. Dr. Malarkey has worked at the National Institute of Environmental Health Sciences (NIEHS) as the Head of the National Toxicology Program (NTP) Pathology Group and has led the NTP/NIEHS Toxicological Pathology Training Program since 2005.

Dr. Malarkey received BS and MS degrees in biology from the University of Bridgeport in 1981 and 1986, respectively. He also studied pathology at Boston University School of Medicine in 1984–1985. He earned his DVM degree in veterinary medicine from Tufts University in 1989 and worked as a resident in anatomic pathology at Angell Memorial Animal Hospital in Boston, Massachusetts before joining the College of Veterinary Medicine at North Carolina State University (NCSU-CVM) as an instructor in anatomic pathology in 1991. In 1993, he became a IRTA fellow in the Environmental Toxicology Program at the NIEHS and entered the PhD program at NCSU. Upon receiving his PhD in pathology and biotechnology in 1997, he became an assistant professor of pathology in the Department of Population Health and Pathobiology at the NCSU-CVM where he worked until accepting a position at the NIEHS in 2002.

Despite his heavy workload as the Head of the NTP Pathology Group, Dr. Malarkey has always found the time to teach and mentor; a quality that often makes him stand out among his peers. He has maintained an adjunct assistant professorship at the NCSU-CVM since 2003 so that he may continue to teach classes and serve on graduate student examination committees for his NTP trainees. He has counseled and guided many veterinary students to future careers in toxicologic pathology. He has shared his knowledge, skills, information, and perspective to foster the personal and professional growth of many through either the NIEHS postdoctoral fellowship program, the NIEHS summer program for students and residents, or by simply encouraging veterinary students to spend one or two weeks of their elective rotations at the NTP. He teaches the trainees about pathology (macroscopic and histologic), coaches them on diagnostic and writing skills, facilitates their growth by sharing resources and networks, challenges them to move beyond their comfort zones, and focuses on the mentee's total development as a future toxicologic pathologist. His excellent work and dedication to trainees was previously recognized in 2011 with the NIH Merit Award for his contributions to the NTP Training Program.

Dr. Malarkey has been an STP member since 2002. He has served on the Editorial Board of *Toxicologic Pathology*, the official journal of STP, since 2006, having also served as an Associate Editor from 2008–2010. He also serves as a Councilor for the American College of Veterinary Pathologists (ACVP), a position he has held since 2010. He is a member of the US FDA advisory panel, endocrine section, and fellow of the International Academy of Toxicologic Pathology. For his significant role and remarkable dedication to advancing toxicologic pathology education, Dr. David E. Malarkey is the 2014 recipient of the STP Outstanding Mentor Award.



Awards

33rd Annual Symposium

Washington, DC

Marriott Wardman Park Hotel

June 22–26, 2014

Awards

STP 2014 Distinguished Early Career Award Recipient



Arun R. Pandiri, BVSc&AH, MS, PhD, DACVP, DABT

system pathology, and avian pathology.

Dr. Pandiri's professional education began at the College of Veterinary Science, Acharya N. G. Ranga Agricultural University in India where he graduated in 1998. He received a Master of Science degree in Poultry Science at the University of Arkansas, Fayetteville in 2000 and a PhD in Veterinary Pathology from the Michigan State University in 2005, where he worked at the USDA-ARS Avian Disease and Oncology Laboratory. He was a resident instructor at Michigan State University in 2006 and a resident in anatomic pathology at North Carolina State University from 2007–2008. He became board-certified by the American College of Veterinary Pathologists in anatomic pathology in 2008 and in 2013 he passed the American Board of Toxicology examination. Dr. Pandiri was a postdoctoral fellow within the National Toxicology Program (NTP) of the National Institute of Environmental Health Sciences from May 2009–February 2010. He joined Experimental Pathology Laboratories, Inc. (EPL ®) in Research Triangle Park, North Carolina in 2010 and works as a research pathologist in the Cellular and Molecular Pathology Branch at the National Toxicology Program (NTP) at the National Institute of Environmental Health Sciences (NIEHS) working under the direction of Dr. Mark Hoenerhoff and Dr. Robert Sills.

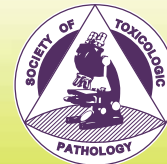
Dr. Pandiri has distinguished himself in public health by making significant advances in molecular pathology by evaluating both single genetic changes and global genomic alterations in tumors from NTP studies. In the assessment of spontaneous tumors, Dr. Pandiri analyzed global gene expression of spontaneous pulmonary carcinomas in B6C3F1 mice and compared the findings to non-small cell lung cancer (NSCLC) in humans. This research provided important genomic information on the mechanisms of pulmonary carcinogenesis in B6C3F1 mice, which included pathways associated with cancer, metabolism, and immune responses that are relevant to human NSCLC.

Another important achievement was the molecular profiling of aloe vera whole leaf extract in colon tumors in F344 rats. Dysregulation of pathways important for human colorectal cancer (e.g., MAPK, WNT, and TGF- β signaling) were identified in colonic tumors in F344 rats exposed to aloe vera whole leaf extract in drinking water, providing important molecular information for hazard characterization and potential relevance to humans. As a result of the significance of this research that aloe vera whole leaf extract induced colon tumors shared several similarities to human colon cancer at the morphological and molecular levels, Dr. Pandiri was awarded an NTP Best Paper of the Year Award for 2011.

He has become an accomplished toxicologic pathologist with broad interests and an impressive record of publications in peer-reviewed literature. He has led or contributed to several important programs including *in vivo* subchronic and chronic studies to assess carcinogenicity and the molecular analysis of the effects of the related chemicals. He is moving the forefront of our understanding of the molecular signatures of different types of chemical injury, particularly those that lead to neoplasia. In addition to his role at the NTP, Dr. Pandiri continues to actively pursue avian pathology research publication and presentation with investigators on Marek's disease research at North Carolina State University.

Dr. Pandiri participates in professional activities nationally and internationally as evidenced by his participation in the GI INHAND project and his work on the NTP non-neoplastic atlas of exocrine pancreas and salivary gland. He serves on the STP Annual Symposium Committee and participates in the STP Environmental Toxicologic Pathology Special Interest Group as well as the Gastrointestinal INHAND Committee. He serves as an associate editor for the *Avian Diseases* journal, the official journal of the American Association of Avian Pathologists.

Dr. Pandiri was the first place winner of the American College of Veterinary Pathologists (ACVP) Young Investigator Award in 2006 in the natural disease category. He received the 2009 Merit Award for significant pathology contributions to NTP and DIR testing and research programs and he also received a 2013 NIH Merit Award for significant impact on the investigation of molecular mechanisms of carcinogenesis in the NTP bioassay. For his significant early career accomplishments in toxicologic pathology, Dr. Arun R. Pandiri is awarded the 2014 STP Distinguished Early Career Award.



Toxicologic Pathology 2013 Best Paper Award

Unexpected Thrombocytopenia and Anemia in Cynomolgus Monkeys Induced by a Therapeutic Human Monoclonal Antibody

Toxicol Pathol, 2013; 41(7): pp. 951-969, originally published online 7 March 2013.

Nancy Everds¹, Nianyu Li¹, Keith Bailey², Madeline Fort¹, Riki Stevenson³, Remi Jawando¹, Kevin Salyers³, Vibha Jawa³, Padma Narayanan¹, Erin Stevens¹, Ching He¹, Mai Phuong Nguyen¹, Sam Tran¹, Nancy Doyle⁴, Florence Poitout-Belissent⁴, Jacquelin Jolette⁴, Cen Xu³, and Katherine Sprugel¹

¹Amgen Inc., Seattle, Washington, USA, ²Oklahoma State University, Stillwater, Oklahoma, USA, ³Amgen Inc., Thousand Oaks, California, USA, ⁴Charles River Preclinical Services Montreal, Senneville, Quebec, Canada

Society of Toxicologic Pathology Student Travel Awards

Mitscheli Sanches da Rocha

São Paulo State University

Murilo Del Grande

University of São Paulo

Lauren Himmel

The Ohio State University

Charlotte Hollinger

Michigan State University

Viviane Pascotto

São Paulo State University

Diane Peters

Tufts University

Artem Shkumatov

University of Illinois at Urbana-Champaign

Jessica Simmons

The Ohio State University

Surendra Singh

University of Colorado

Kristin Wilson

The Ohio State University

Society of Toxicologic Pathology Student Poster Award

Charles Halsey, DVM, MS, DACVP

Colorado State University—Animal Cancer Center/NIH National Cancer Institute

We would like to congratulate Charles Halsey, DVM, MS, DACVP, for winning the 2014 ACVP/STP Student Poster Award for his poster entitled, "Development of an *In Vitro* Model of Acquired Resistance to Toceranib Phosphate (Palladia®) in Canine Mast Cell Tumor."

The Eighth Annual STP Student Poster Award competition occurred at the concurrent meetings of the ACVP and ASVCP held in Montreal, QC, Canada on November 16–20, 2013, at LeWestin Hotel Montreal and Palais des Congrès de Montréal. The poster presentations were evaluated by a panel of judges composed of members of the Society of Toxicology Pathology and the American College of Veterinary Pathology.

IATP Charles Capen Trainee Award

Mitscheli Sanches da Rocha

São Paulo State University

Society of Toxicologic Pathology Young Investigator Awards

(See pages 10 or 27 for judging times.)

Winners will be announced at the Awards Ceremony at 5:30 pm on Wednesday, June 25, in the Thurgood Marshall Ballroom.



General Information



33rd Annual Symposium

Washington, DC

Marriott Wardman Park Hotel

June 22–26, 2014

Meeting Events

Saturday Evening Sponsored Reception

Saturday, June 21, 7:00 PM–10:00 PM

Virginia Suite

All attendees and their guest/spouse are invited. See page 37 for details.

Welcome Reception

Sunday, June 22, 5:30 PM–7:00 PM

Exhibit Hall C

The STP Welcome Reception will kick off the week in the Exhibit Hall for all registered meeting attendees. Please wear your badge and bring your Welcome Reception ticket that was provided with your badge. Drink tickets (one alcoholic and one soda) will be distributed at the door. Tickets for guests 18 years of age or older* accompanying a registered attendee may be purchased for \$30 at the registration desk.

**To ensure their safety, children under the age of 18 are not permitted in the Exhibit Hall.*

Guest/Spouse Tour

Monday, June 23, 12:15 PM

If you registered for a STP guest/spouse tour, please meet at 12:15 pm in main lobby of the Marriott Wardman Park.

Town Hall Meeting

Adversity and the NOAEL in Nonclinical Regulatory Reports—Definition, Application, and Communication

Monday, June 23, 5:30 PM–6:30 PM

Thurgood Marshall Ballroom

The Town Hall Meeting this year is one not to miss! The SRPC Working Group that is developing a best practice manuscript on “Adversity in Preclinical Reports” will be discussing the nature of “adversity” and the NOAEL in general, as well as the best means of communicating the concept of adversity and the ramifications of using the term “adverse” within study reports and other regulatory documents. Be there and have your voice heard!

The audience is asked to actively participate in these discussions, and present their perspectives and concerns with the use, or lack of use, of thresholds, and recommendations for how best consistency in thresholding can be achieved. The objective of this meeting is to openly discuss and debate the topic of thresholding but not to come to a “best practice” conclusion on how and when thresholds should be applied.

Monday Sponsored Reception

Monday, June 23, 7:00 PM–10:00 PM

Washington Room

All attendees and their guest/spouse are invited. See page 37 for details.

Lunch in the Exhibit Hall

Tuesday, June 24, 12:00 Noon–1:30 PM

Exhibit Hall C

Lunch sponsored by the exhibitors for all scientific attendees.

Student Outing

Tuesday, June 18, 12:30 PM

The STP student outing will be a National Zoo Scavenger Hunt led by Watson Adventures. 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 were emailed to student registrants.

Awards Ceremony

Wednesday, June 25, 5:30 PM–5:50 PM

Thurgood Marshall Ballroom

STP Award recipients will be recognized at this time.

Annual Business Meeting

Wednesday, June 25, 5:50 PM–6:30 PM

Thurgood Marshall Ballroom

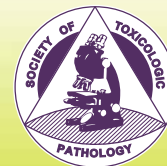
The STP Annual Business Meeting will be held immediately following the Awards Ceremony.

President’s Reception

Wednesday, June 25, 7:00 PM–9:00 PM

Exhibit Hall C

One ticket to this event is provided to all meeting registrants. Please wear your badge and bring your President’s Reception ticket that was provided with your badge. Drink tickets (two alcoholic and one soda) will be distributed at the door. Additional tickets can be purchased on-site for \$65 (Children of attendees 11–17 yrs \$35). Children under 11 years of age are permitted to attend the President’s Reception at no charge as long as the child is under the supervision of the parent at all times.



Registration

Atrium, Exhibit Level

Friday, June 20	4:00 PM–6:00 PM
Saturday, June 21	8:00 AM–6:00 PM
Sunday, June 22.....	7:00 AM–6:00 PM
Monday, June 23	7:00 AM–5:30 PM
Tuesday, June 24	7:00 AM–5:30 PM
Wednesday, June 25	7:30 AM–5:30 PM

Registration B, Mezzanine Level

Thursday, June 26	7:30 AM–12:00 Noon
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Registration Materials

Badges, Program, event tickets, and ribbons (if appropriate), will be available for pick up at the Registration Desk. Attendees are encouraged to bring a bag or backpack as meeting bags will not be provided.

Meeting Materials

Meeting publications, handouts, attendee list, committee and ancillary meetings schedule, and evaluation forms will be posted on the Annual Meeting “Meeting Materials” page when available.



STP members will use their regular login to access this page. Nonmember attendees will receive a login and password to access the site.

Scan this code for quick and easy access to up-to-date Annual Meeting information.

Symposium Registration

Member, Nonmember, and Student full meeting registration fee include the symposium proceedings, access to scientific sessions, Exhibit Hall, daily continental breakfast, morning and afternoon breaks during the scientific sessions, Tuesday lunch in the Exhibit Hall, and admission for one to the Welcome Reception and President’s Reception.

Exhibitor Registration

Complimentary: Two full meeting registrations are provided to exhibiting companies with the purchase of each booth. The Exhibitor registration fee includes admission to the scientific sessions, Exhibit Hall access, daily continental breakfast, morning and afternoon breaks, Tuesday lunch held in the Exhibit Hall, and admission for one to the Welcome Reception and President’s Reception.

Reduced Registration: The Exhibitor registration fee (\$380) is for companies with more than two exhibitors. This reduced registration does not include admission to the scientific sessions, but does include continental breakfasts, breaks in the Exhibit Hall, and one admission to the Welcome Reception and President’s Reception.

Guest/Spouse Registration

The Guest/Spouse registration fee includes daily continental breakfast in the STP Guest/Spouse Hospitality Suite (Room 8228, Lobby Level) at the Marriott Wardman Park, afternoon breaks, one admission to the Welcome Reception, the President’s Reception, and a Monday afternoon half-day tour.

US Government Employee Tuesday-Only Sessions Registration

The scientific sessions on Tuesday, June 24, have been designed in response to requests from the Federal regulatory community. Interested US Government employees may register to attend Tuesday sessions listed below at no charge (Full meeting attendees also may attend at no charge). Registration is required.

- Tuesday AM Scientific Session: *Emerging Technologies*
- Tuesday PM Scientific Session: *The Role of the Toxicologic Pathologist in Informing Regulatory Decisions and Guiding the Interpretation and Application of Data from New Technologies and Tools*

One-Day Registration

One-Day Registration is offered Monday through Thursday and includes Scientific Session(s), continental breakfast and break(s), Exhibit Hall access (Monday–Wednesday). The Tuesday fee includes lunch in the Exhibit Hall; Wednesday includes one ticket for the President’s Reception.

SPECIAL MEMBERSHIP OFFER: Nonmembers who apply for membership prior to July 1 and who are accepted will receive complimentary membership for the remainder of 2014 and the online journal issues for the remainder of the year. Please visit www.toxpath.org to apply for membership.

Speaker Ready Room

Taft Room

Friday, June 20	4:00 PM–6:00 PM
Saturday, June 21	8:00 AM–5:00 PM
Sunday, June 22.....	7:00 AM–5:00 PM
Monday, June 23	7:00 AM–5:00 PM
Tuesday, June 24	7:00 AM–5:00 PM
Wednesday, June 25	7:00 AM–5:00 PM
Thursday, June 26	7:00 AM–11:00 AM



General Information



33rd Annual Symposium

Washington, DC

Marriott Wardman Park Hotel

June 22–26, 2014

Headquarters Hotel

Marriott Wardman Park Hotel

2660 Woodley Road, NW
Washington, DC 20008
Tel: 202-328-2000

Registered Guest/Spouse Hospitality Suite

Room 8228, Lobby Level

The Guest/Spouse registration fee includes continental breakfast (Monday through Thursday) in the STP Guest/Spouse Hospitality Suite at the Marriott Wardman Park.

Monday, June 23 8:00 AM–5:00 PM
Tuesday, June 24 8:00 AM–5:00 PM
Wednesday, June 25 8:00 AM–5:00 PM
Thursday, June 26 8:00 AM–12:00 Noon

Poster Information

Exhibit Hall C

The poster board size is 4 x 8 Feet (horizontal) and requires the use of pushpins to hold the poster in place.

Poster Setup

Sunday, June 22 8:00 AM–3:00 PM

Your poster must be set up by 3:00 pm on Sunday, June 22.

Poster Teardown

Wednesday, June 25 11:30 AM–1:00 PM

If your poster is not removed before 1:00 pm on Wednesday, June 25, it will be removed and placed near the Registration Desk for pick up.

Poster Presentation Times

Please plan to attend your posters during the following times:

Sunday, June 22 (Optional) 6:00 PM–6:30 PM
Monday, June 23 10:30 AM–11:00 AM
..... and 3:00 PM–3:35 PM
Tuesday, June 24 9:45 AM–10:20 AM
..... and 3:00 PM–3:35 PM
Wednesday, June 25 10:05 AM–10:40 AM

Young Investigator Judging Times

Monday, June 23 7:15 AM–8:00 AM
..... 10:30 AM–11:00 AM
..... and 3:00 PM–3:35 PM
Tuesday, June 24 9:45 AM–10:20 AM

Exhibit Hall

Exhibit Hall C

The Exhibit Hall will be a center of activity during this year's Symposium, kicking off with a Welcome Reception in the Exhibit Hall on Sunday evening, June 22.

An exhibitor sponsored buffet luncheon in the Exhibit Hall will be offered for all registered attendees on Tuesday, June 24 and continental breakfasts and refreshment breaks will be held in the hall throughout the week unless otherwise noted. The Internet Café, where attendees can check email during exhibit hours, will be provided again this year. Scientific poster sessions will also be held Sunday evening through Wednesday in the Exhibit Hall.

The Microscope and Digital Slide Viewing Room will also return to the Exhibit Hall this year. This is a great opportunity for attendees to meet and discuss slides.

The Society values the support of exhibitors and believes the relationship between exhibiting companies and the STP membership is a mutually beneficial one. Don't forget to visit Exhibit Hall C.

Exhibit Hall Policies

Out of courtesy for the scientific presenters and exhibitors, we appreciate your compliance with the following policies:

Photography Policy

- Photography of poster presentations is prohibited without the specific consent of the presenter(s)/author(s).
- Photography of exhibitor booths and/or equipment is prohibited without the specific consent of the exhibitor.

Children Under 18 Years of Age

- To ensure their safety, children under the age of 18 are not permitted in the Exhibit Hall at any time including during the Exhibits Opening, regular hours, Welcome Reception, and Poster Sessions.

Exhibitor Setup

Saturday, June 21 1:00 PM–4:00 PM
Sunday, June 22 8:00 AM–3:00 PM
..... All exhibits must be set up by 3:00 PM

Exhibit Hall Hours

Sunday, June 22 (Welcome Reception) 5:30 PM–7:00 PM
Monday, June 23 9:45 AM–4:00 PM
Tuesday, June 24 7:00 AM–4:00 PM
Wednesday, June 25 7:00 AM–11:30 AM

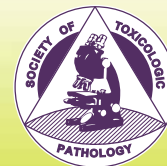
Exhibitor Teardown

Wednesday, June 25 11:30 AM–3:00 PM



TRANSLATIONAL PATHOLOGY:
Relevance of Toxicologic Pathology to Human Health

General Information



Society of Toxicologic Pathology

Internet Café

Be sure to take advantage of the computers in STP's Exhibit Hall! The Internet Café will be available during Exhibit Hall hours so that you can check email.

WiFi Options of Marriott Wardman Park Hotel

Complimentary WiFi

The Marriott Wardman Park offers complimentary internet access in their lobby lounge located on the lobby level.

Guest Rooms: Wireless, Wired

There are two WiFi/wired Internet access plans for individual purchase.

High Speed \$12.95 USD/day	Check email and browse the Web
Enhanced High Speed \$16.95 USD/day	Video chat, download large files, and stream video

Microscope and Digital Slide Viewing Area

Exhibit Hall C

Please bring any slides you would like to discuss with colleagues during exhibit hours.

Thank you to Leica Biosystems Imaging, Inc. for providing the equipment.

Safety and Security Tips

1. When inside the conference venue, nametags should be worn and visibly displayed at all times. For security reasons, we recommend that you **DO NOT** wear your badge outside of the conference venue. If you lose your badge, please notify registration immediately.
2. Walk in well-lighted areas at night and never alone.
3. Please do not leave any bags or articles unsecured in any display area, meeting room, or public area. Laptops and other small computers are easy targets for thieves. If you note any suspicious articles, packages, persons, or activity please contact the event staff or security immediately.
4. Due to the nature of our meeting, there is a risk that we may be the target of protest activity. STP has a response plan to address this possibility. Here are some guidelines to deal with protest activity:
 - a. If you see a protest forming or in progress, you should notify STP or venue staff immediately. We will implement our response plan to ensure our meeting is safe and secure.
 - b. Do not attempt to engage or argue with protestors. These groups seek confrontation as a tool for publicity.
 - c. Do not give interviews to press personnel. STP representatives will respond to the press.
 - d. If you notice any suspicious individuals in the meeting areas or hotel, especially handing out literature, please notify STP security or venue security personnel. You should not attempt to engage these persons or stop them yourself
 - e. If there is a disruption in a meeting room, you should remain calm. Notify security and allow them to deal with the disruption.
5. Do not give your lodging information to any person outside of known STP staff.
6. Photography is not permitted in the Exhibit Hall. This includes digital pictures taken using cell phone cameras.
7. Large packages and bags are not permitted in the Exhibit Hall area.



General Information



33rd Annual Symposium

Washington, DC

Marriott Wardman Park Hotel

June 22–26, 2014

Marriott Wardman Park Hotel Maps

Lobby Level

Information

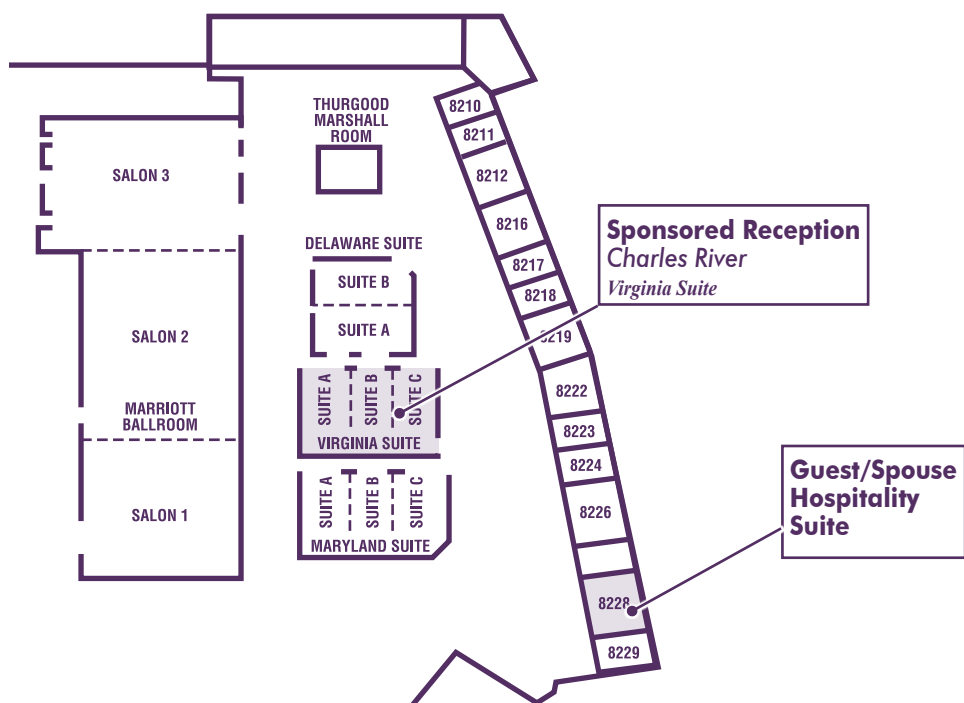
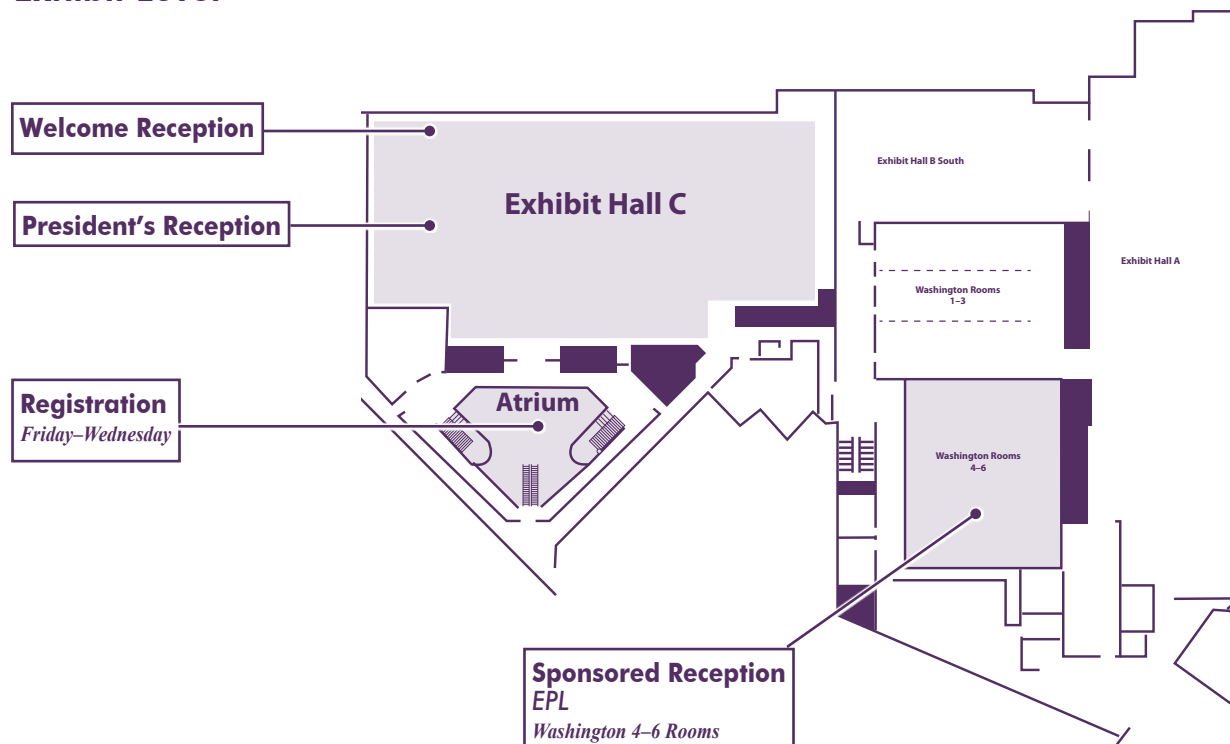


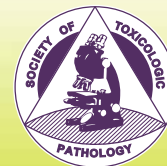
Exhibit Level





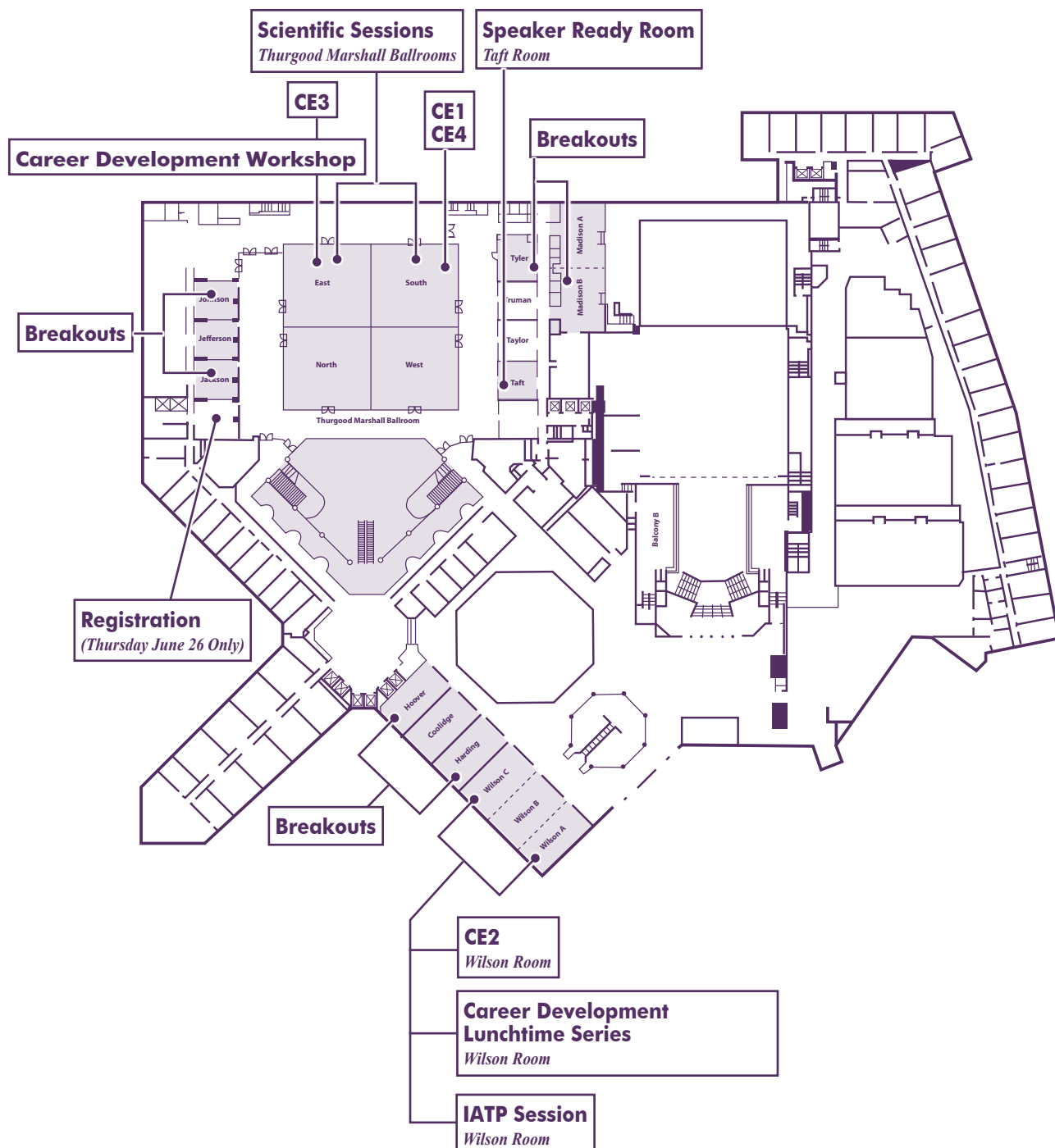
TRANSLATIONAL PATHOLOGY:
Relevance of Toxicologic Pathology to Human Health

General Information



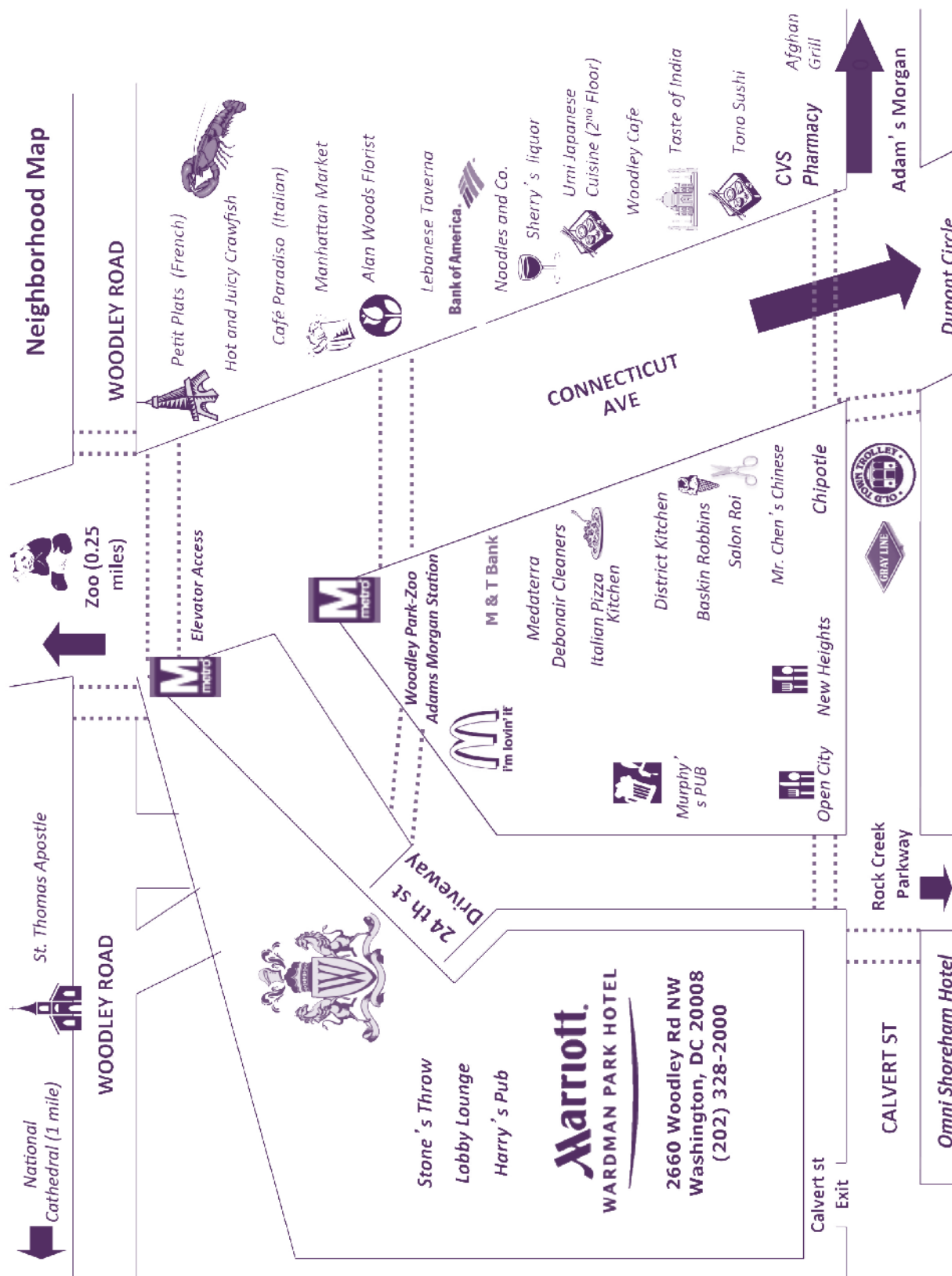
Society of Toxicologic Pathology

Marriott Wardman Park Hotel Maps Mezzanine Level



Information

Information





Society of Toxicologic Pathology

SPECIAL MEMBERSHIP OFFER: Nonmember registrants who apply for membership prior to **July 1** and who are accepted, will receive complimentary Membership for the rest of 2014 and the online journal issues for the remainder of the year.

What Are the Benefits of STP Membership?

STP Journal

STP Full and Associate Members receive regular and supplemental issues of *Toxicologic Pathology*, the premier, peer-reviewed journal in the field of toxicologic pathology. The journal focuses on the multidisciplinary elements that constitute toxicologic pathology, including spontaneous and experimentally induced morphological and functional changes, environmental exposures, case reports, and risk assessment and investigative techniques. *Toxicologic Pathology* publishes original articles, symposia papers, brief communications, current topic reviews, current issues, and fast-track articles.

Scientific Collaboration

The Society provides opportunities for formal and informal exchange of information among colleagues in toxicologic pathology and related fields through its annual symposium, committees, working groups and other activities. The Scientific and Regulatory Policy Committee identifies common and emerging toxicologic pathology issues within the drug, chemical, and device industry world-wide and takes a leadership role in addressing those issues to help better promote appropriate industry practices and regulatory policy.

Member Website and ToxPathNet

ToxPathNet, a professional network that features an enhanced member directory and online collaboration tools, was recently launched along with a redesigned STP website for members. Access to the member website at www.toxpath.org allows members to view webinars, draft position papers, the latest *Scope* Newsletter, and information on current issues. Members can vote for office, volunteer to serve on a committee, update their membership information, and handle most Society business online.

Continuing Education, Modular Education Course, Regional Meetings, and Webinars

One of the main goals of STP is to provide opportunities for members to keep current in a rapidly changing world. The annual meeting offers three full days of scientific sessions as well as optional premeeting continuing education courses on current topics and free career development sessions. The STP Modular Education Series focuses on individual organ systems. Each three-day course includes both didactic and practical sessions. STP regional meetings, sometimes held in collaboration with allied nonprofit educational organizations, are low-cost opportunities to gain high-quality continuing education on topics that emphasize local interests and expertise. STP members have access to live webinars and also past presentations that are posted on the member website.

Scope Newsletter

Scope is a quarterly online newsletter that gives details of upcoming meetings and events, news of committee and working group activities, and member interviews.

Special Interest Groups (SIGs)

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 Society. SIGs provide a forum for the quick exchange of novel ideas and developments, which could lead to publications, continuing education (CE) courses, symposium sessions, or regional meetings. The Cardiovascular Toxicologic Pathology Special Interest Group (CVIG), Clinical Pathology Special Interest Group (CPIG), Environmental Toxicologic Pathology Special Interest Group, Special Interest Group in Neuropathology (SIGN), and Reproductive Pathology Special Interest Group meet each year at the annual symposium and communicate throughout the year using ToxPathNet and teleconferences. Information about each group is available under the Members menu on the STP website. There is no fee to join.

Student Resources

Student Members receive online access to *Toxicologic Pathology*. They also have access to the member section of the STP website and ToxPathNet. Students may participate in STP webinars and receive free registration for the annual symposium. They have access to career resources and student travel award information. Students also receive access to *PATHWAYS*, a joint newsletter of STP and ACVP for students of veterinary pathology. Students are encouraged to volunteer to participate on STP committees.

Fast and Easy Online Membership Application

To learn more about STP activities visit www.toxpath.org. To apply online, select Membership Application from the navigation bar. Students are invited to apply for Student Membership.

www.toxpath.org





Program

33rd Annual Symposium

Washington, DC

Marriott Wardman Park Hotel

June 22–26, 2014

Saturday, June 21

NTP Satellite Symposium: Pathology Potpourri

9:00 AM–4:30 PM

Thurgood Marshall Ballroom

(Free Event, Registration Required)

Chair: Susan A. Elmore, MS, DVM, DACVP, DABT, FIATP, NTP and NIEHS, Research Triangle Park, NC

The object of this interactive symposium is to provide continuing education on interpreting pathology slides, to generate lively and productive conversation, and to have a good time. During each talk, the speakers will project a series of images of lesions on one screen with a choice of diagnoses/answers on a separate screen. The members of the audience with wireless keypads will then vote and the voting results will be displayed on the screen. After each voting session, time is allowed for discussion.

9:00 AM–9:10 AM

Welcome and Introductory Remarks

Susan A. Elmore, MS, DVM, DACVP, DABT, FIATP, NTP and NIEHS, Research Triangle Park, NC

9:10 AM–9:30 AM

NTP Non-Neoplastic Lesion Atlas

Mark Cesta, DVM, PhD, DACVP, NTP and NIEHS, Research Triangle Park, NC

9:30 AM–9:50 AM

An Unusual Lung Lesion in a Mouse

Margarita M. Gruebbel, DVM, PhD, EPL Inc., Research Triangle Park, NC

9:50 AM–10:30 AM

Perplexing Vascular Lesions in Wistar Han Rats

Jessica S. Hoane, DVM, DACVP, Charles River Pathology Associates, Research Triangle Park, NC

10:30 AM–11:00 AM

Break

11:00 AM–11:30 AM

The ABCs of PEMD—Vaginal Cytology of the Rat and Mouse

Michelle C. Cora, DVM, DACVP, NTP and NIEHS, Research Triangle Park, NC

11:30 AM–12:00 Noon

A Puzzling Pancreatic Problem

Rachel Peters, DVM, DACVP, Takeda Pharmaceuticals International Co., Cambridge, MA

12:00 Noon–1:30 PM

1:30 PM–1:50 PM

1:50 PM–2:10 PM

2:10 PM–2:30 PM

2:30 PM–3:00 PM

3:00 PM–3:30 PM

3:30 PM–3:50 PM

3:50 PM–4:30 PM

7:00 PM–10:00 PM

Lunch Break

Eye-Catching Findings in the Rodent Retina

Kathleen A. Szabo, DVM, MS, DACVP, Charles River Pathology Associates, Research Triangle Park, NC

Looking Beyond Lymphoma

Bhanu P. Singh, BVSc, MS, DACVP, DABT, FIATP, Janssen Research and Development, LLC, Spring House, PA

Thrown Off Track by the Thymus

Jessica S. Hoane, DVM, DACVP, Charles River Pathology Associates, Research Triangle Park, NC

Angiomatous Lesions in Mesenteric Lymph Nodes

Schantel A. Hayes, DVM, PhD, DACVP, Charles River Pathology Associates, Research Triangle Park, NC

Break

An Unusual Retinal Lesion of the Fovea

Susan Elmore MS, DVM, DACVP, DABT, FIATP (for Dr. Kolji Tanaka), NTP and NIEHS, Research Triangle Park, NC

Nomenclature Challenges from the Endocrine INHAND Organ Working Group

Thomas Rosol, DVM, PhD, DACVP, Ohio State University, Columbus, OH

Sponsored Reception

Virginia Suite

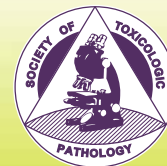
NTP Symposium Continuing Education Credits AAVSB RACE Provider #56

The NTP Satellite Symposium was reviewed and approved by the AAVSB RACE program for five hours of continuing education credits in jurisdictions which recognize AAVSB RACE approval; however participants should be aware that some boards have limitations on the number of hours accepted in certain categories and/or restrictions on certain methods of delivery of Continuing Education. Certificates of attendance will be provided at the conclusion of the NTP Satellite Symposium. Please contact the AAVSB RACE program if you have any comments/concerns regarding this program's validity or relevancy to the veterinary profession.



TRANSLATIONAL PATHOLOGY:
Relevance of Toxicologic Pathology to Human Health

Program



Society of Toxicologic Pathology

Sunday, June 22

Continuing Education Courses

CE 1 (Sunday AM) 8:00 AM–12:00 Noon

Thurgood Marshall Ballroom South/West

Biomarkers of Endocrine Effects and Reproductive Toxicity

Co-Chairs: Adam Aulbach, DVM, DACVP, MPI Research, Mattawan, MI; and David Honor, DVM, PhD, DACVP, AbbVie, Inc., Worcester, MA

The evaluation of endocrine and reproductive clinical pathology endpoints in nonclinical safety studies presents a unique set of preanalytical, analytical, and interpretative challenges to the regulatory scientist. Regulatory guidance does not require the inclusion of these endpoints in traditional safety studies; however, they are sometimes incorporated without appropriate consideration for their use. These sessions will provide an overview of the current principles and approaches to assessing toxicity of the endocrine and reproductive systems with an emphasis on the appropriate selection and utility of endocrine biomarkers. Discussions will focus on regulatory requirements for the inclusion of these markers as well as strategies used in the pharmaceutical industry and drug development. These sessions will be of interest to both industry and regulatory pathologists and scientists.

8:00 AM–8:50 AM

Overview of Reproductive and Developmental Toxicology Studies

Alan Hoberman, PhD, DABT, ATS, Charles River Laboratories, Horsham, PA

8:50 AM–9:40 AM

The Use of Hormone Measurements in Preclinical Safety Studies: Study Design, Analysis, and Interpretation

John C. O'Connor, PhD, DuPont Haskell Global Centers for Health and Environmental Sciences, Newark, DE

9:40 AM–10:15 AM

Break

10:15 AM–11:05 AM

Male Reproductive Toxicology, Evaluation of Inhibin B, and Future Directions

Robert E. Chapin, PhD, Pfizer, Inc., Groton, CT

11:05 AM–12:00 Noon

Reproductive Endocrinology and Toxicology in Female Nonhuman Primates

Mark Cline, DVM, PhD, DACVP, Wake Forest School of Medicine, Winston-Salem, NC

Career Development Workshop

Sunday, June 22

8:00 AM–12:00 Noon

Thurgood Marshall Ballroom North/East

Effective Communication of Pathology Results in Regulatory Studies

(Free Event, Registration Required)

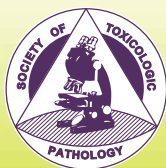
Co-Chairs: Sabine Francke, DVM, PhD, FIATP, US FDA/CFSAN, College Park, MD; Emily Meseck, DVM, DACVP, DABT, Covance Laboratories, Inc., Madison, WI; Steven R. Mog, DVM, DACVP, US FDA/CFSAN, College Park, MD; Annette Romeike, Dr Med Vet, DACVP, FTAPath, Covance Laboratories SAS, Porcheville, France; and Charles E. Wood, DVM, PhD, DACVP, US EPA, Research Triangle Park, NC

Anatomic pathology endpoints in nonclinical safety studies have a central role in the safety/risk assessment for chemicals, food ingredients, devices, and drugs. The goal of this course is to present issues and recommendations for communicating pathology results of toxicologic safety studies more effectively with regulatory agencies. Topics of discussion are based on recent issues experienced by pathologists and toxicologists/pharmacologists at regulatory, industry, and contract pathology organizations and will provide a general overview of tools and strategies to effectively communicate pathology information for regulatory purposes. Several case study-based presentations will be given, followed by a panel discussion at the end of the session. Perspectives will be provided by a diverse group of speakers and panelists including non-pathologist regulatory reviewers, regulatory pathologists (EPA/FDA), as well as a US and European perspective of regulated industry pathologists (CRO and corporate pharma). Specific topics include pathology report issues addressed by regulatory (FDA) reviewers, peer review guidelines, terminology harmonization efforts such as INHAND and SEND, use of historical control data and web-based pathology resources. This information should provide a stimulating exchange for toxicologic pathologists and regulatory reviewers involved in safety evaluation.

8:00 AM–8:10 AM

Introduction/Overview: Communicating More Effectively in Pathology Reports

Charles E. Wood, DVM, PhD, DACVP, US EPA, Research Triangle Park, NC



Program

33rd Annual Symposium

Washington, DC

Marriott Wardman Park Hotel

June 22–26, 2014

Program

8:10 AM–9:10 AM

Common Pathology Report Issues from a Nonpathologist Regulatory Reviewer's Perspective

Christopher Toscano, PhD, DABT, FDA/CDER/OND/DNP, Silver Spring, MD; and Lois Freed, PhD, FDA/CDER, Silver Spring, MD

9:10 AM–9:40 AM

Communicating with Regulators: OECD Peer Review Guidelines as a Case Example

Annette Romeike, Dr Med Vet, DACVP, FTAPath, Covance Laboratories SAS, Porcheville, France

9:40 AM–10:10 AM

Current Web-Based Pathology Resources for Regulatory Study Reports

Steven R. Mog, DVM, DACVP, US FDA/CFRAN, College Park, MD

10:10 AM–10:30 AM

Break

10:30 AM–11:00 AM

The Role of Historical Control Data in the Interpretation of Nonneoplastic Pathology Findings in Preclinical Toxicology Studies

Emily Meseck, DVM, DACVP, DABT, Covance Laboratories, Inc., Madison, WI

11:00 AM–11:30 AM

Updates and Issues Related to INHAND and SEND Terminology Harmonization Efforts

Charlotte Keenan, VMD, DACVP, FIATP, CM Keenan ToxPath Consulting, Doylestown, PA

11:30 AM–12:00 Noon

Open Discussion

CE 2 (Sunday PM) 1:30 PM–5:25 PM

Wilson Room

Scientific and Regulatory Considerations in the Safety Evaluation of Stem Cell-Derived Therapies in Preclinical Studies

Co-Chairs: Basel Assaf, BVSc, PhD, DACVP, Oregon National Primate Research Center, Beaverton, OR; and Timothy Bertram, DVM, PhD, DACVP, Tengion, Inc., Winston-Salem, NC

Stem cell-derived products have the potential to treat a diversity of medical conditions, many with unmet medical needs. The properties of stem cells, such as their differentiation and proliferative potential, pose safety concerns unique from those of small molecule drugs and other macromolecule biologics. These cellular products carry risks associated with localized host tissue response, long term persistence, ectopic tissue formation, differentiation to undesired cell and tissue types, off-target distribution, tumorigenicity, and immunogenicity. These risks are generally evaluated in preclinical studies as part of a comprehensive preclinical safety program prior to administration in humans. However, safety assessment for these products can be challenging due to inadequately defined host tissue responses to these products and due to the lack of standardized approaches in evaluating in vivo host responses. A primary goal of this session is to introduce this product class to the toxicologic pathology community and provide a forum for discussion of the scientific and the regulatory considerations in the evaluation of host responses to stem cell-derived therapies.

1:30 PM–2:05 PM

Stem Cell-Derived Cellular Therapy Products: Discovery to Translational Research

Mahendra Rao, MD, PhD, NIH Center for Regenerative Medicine, Bethesda, MD

2:05 PM–2:40 PM

Toxicologic Pathology Approaches in Evaluation of Stem Cell-Derived Cellular Therapy Products

Julia F. M. Baker, BVMS, Dip RC Path, MRCVS, Charles River Pathology Associates, Frederick, MD

2:40 PM–3:15 PM

FDA/CBER Regulatory Considerations in the Preclinical Evaluation of Cellular Therapy Products

Mercedes A. Serabian, MS, DABT, US FDA/CBER, Rockville, MD

3:15 PM–3:50 PM

Break

3:50 PM–4:25 PM

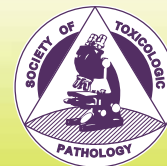
Challenges in Evaluating the Tumorigenic Potential of Cell-Based Products

Alex Bailey, PhD, US FDA/CBER, Rockville, MD



TRANSLATIONAL PATHOLOGY:
Relevance of Toxicologic Pathology to Human Health

Program



Society of Toxicologic Pathology

4:25 PM–5:00 PM

Industry Experience on the Preclinical Development, Challenges, and Tumorigenicity/Toxicology Testing of Stem Cell-Based Products

Jane Lebkowski, PhD, Asterias Biotherapeutics, Menlo Park, CA

5:00 PM–5:25 PM

Panel Discussion

CE 3 (Sunday PM) 1:30 PM–5:25 PM

Thurgood Marshall Ballroom North/East

Fundamentals of Translational Neuroscience in Toxicologic Pathology: Optimizing the Value of Animal Data for Human Risk Assessment

Co-Chairs: Alok Sharma, BVSc, MVSc, MS, PhD, DACVP, DABT, Covance Laboratories, Inc., Madison, WI; and James Morrison, DVM, DACVP, Charles River Pathology Associates, Durham, NC

Extrapolation of animal data to predict possible human outcomes is an elemental conundrum in drug discovery and development. This problem often is of particular significance when investigating therapeutic candidates with neuroactive properties or that induce structural alterations in the central nervous system (CNS), especially when the portfolio management process and/or regulatory review are given to individuals with limited or no formal training in neurobiology. This session is designed to impart fundamental information on basic neurobiological principles necessary for pathologists, toxicologists, and regulators to gain confidence in their abilities to translate CNS structural changes in test animals for risk assessment in humans. The last talk is included as a practical example regarding the application of such principles to address a current issue facing many pharmaceutical companies and regulatory agencies.

1:30 PM–2:10 PM

Structural-Functional Correlations in Neuropathology Evaluations: Rodents

Deepa Rao, BVSc, MS, PhD, DABT, DACVP, ILS/NTP, Research Triangle Park, NC

2:10 PM–2:50 PM

Structural-Functional Correlations in Neuropathology Evaluations: Non-Rodents

Ingrid Pardo, DVM, MS, DACVP, Pfizer, Inc., Groton, CT

2:50 PM–3:25 PM

Break

3:25 PM–4:05 PM

Pathology Considerations in Developmental Neurotoxicity Testing

Robert H. Garman, DVM, DACVP, Consultants in Veterinary Pathology, Inc., Murrysville, PA

4:05 PM–4:45 PM

Neglected Factors That May Confound Translational Neuroscience

Brad Bolon, DVM, MS, PhD, DACVP, DABT, ATS, FIATP, The Ohio State University, Columbus, OH

4:45 PM–5:25 PM

Polyethylene Glycol (PEG)-Associated Vacuolation in Epithelial Cells of the Choroid Plexus and Its Impact on Development of PEG-Conjugated Therapies

Wolfgang Kaufmann, Dr Med Vet, FTAPath, DECVP, FIATP, Merck KGaA, Darmstadt, Germany

CE 4 (Sunday PM) 1:30 PM–5:15 PM

Thurgood Marshall Ballroom South/West

The Art of Study Monitoring and Pathology Peer Review: How to Maintain a Relationship of Mutual Respect with CROs

Co-Chairs: Daniel Kemp, PhD, DABT, GlaxoSmithKline, Research Triangle Park, NC; and John Wilson, MS, GlaxoSmithKline, King of Prussia, PA

One of the most important decisions a company can make is to outsource the responsibility of conducting regulatory required studies. Therefore, oversight of this activity can be imperative to assure that adequate protection and safety are involved to maintain the quality and integrity of the resulting data. While the study director is ultimately responsible for the study, with proper oversight and communication the sponsor standards can still be met. Effective study monitoring and peer review through preparation, transparency, continuing education, and effective communication can help remediate unexpected findings, clarify discrepancies, and decrease the time for issue resolution within expedited timelines if a solid working relationship has been established with the contract research organization (CRO). Establishing a working relationship with CROs may require visits to the facilities, an in-depth review of data, QA, AALAC, and laboratory procedures, and reviewing interim updates. It also requires an in-depth knowledge of individual CRO capabilities and study management skills. This CE course will focus on expectations of study monitors, peer review pathologists, CRO study directors, and CRO pathologists; and will offer skills to reduce program drift, late reporting, conflicting deadlines,



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and corrective actions. This would appeal to pharmaceutical, chemical, contract, and medical device industries.

1:30 PM–1:50 PM

The Art of Study Monitoring and Pathology Peer Review

Daniel Kemp, PhD, DABT, GlaxoSmithKline, Research Triangle Park, NC

1:50 PM–2:30 PM

The Peer Review Process and Issue Resolution

Kevin McDorman, DVM, PhD, DACVP, Charles River Pathology Associates, Frederick, MD

2:30 PM–3:10 PM

The CRO Perspective on Study Monitoring and Pathology Peer Review

Fotini (Fay) Vlasseros, BSc, Charles River, Senneville, Quebec, Canada; and Luc Chouinard, DVM, DACVP, Charles River, Senneville, Quebec, Canada

3:10 PM–3:45 PM

Break

3:45 PM–4:25 PM

Study Monitoring—The Sponsor Perspective

John Wilson, MS, GlaxoSmithKline, King of Prussia, PA

4:25 PM–5:15 PM

Peer Review—A Regulatory Pathologist's Perspective

Sabine Francke, DVM, PhD, FIATP, US FDA/CFSAN, College Park, MD; and Steven R. Mog, DVM, DACVP, US FDA/CFSAN, College Park, MD

5:30 PM–7:00 PM

STP Welcome Reception

Exhibit Hall C

Continuing Education Course and Scientific Session Credits

AAVSB RACE Provider #56

The CE Courses have been reviewed and approved for three to three and a half hours of Continuing Education credits (per course) in jurisdictions which recognize AAVSB RACE approval and the Scientific Sessions have been reviewed and approved for 19 hours; however participants should be aware that some boards have limitations on the number of hours accepted in certain categories and/or restrictions on certain methods of delivery of Continuing Education. Certificates of attendance will be provided at the conclusion each CE Course and also at the end of the final Scientific Session. Please contact the AAVSB RACE program if you have any comments/concerns regarding this program's validity or relevancy to the veterinary profession.

TRANSLATIONAL PATHOLOGY: Relevance of Toxicologic Pathology to Human Health

Scientific Co-Chairs: *Sabine Francke, DVM, PhD, FIATP, US FDA/CFSAN, College Park, MD; Mark Hoenerhoff, DVM, PhD, DACVP, University of Michigan, Ann Arbor, MI; and Lee Silverman, DVM, PhD, DACVP, Agios Pharmaceuticals, Cambridge, MA*

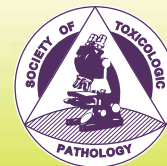
Toxicologic pathologists work in diverse settings studying changes elicited by pharmacological, chemical, and environmental agents and factors that modify these responses. This work involves the integration of pathology data into hazard identification, risk assessment, and risk communication frameworks that guide safety for potentially toxic substances. A central part of this process is the translation of pathologic effects in animal models to address specific issues in public health.

This symposium will focus on translational science and the relevance of toxicologic pathology to human health. Topics will include the predictive value of nonclinical models and how animal model and human endpoints inform each other. Progress in the development of new nonclinical animal models and other types of models will be discussed, highlighting areas where models are highly predictive of human endpoints and areas where alternative models are needed. Emerging technologies which have the potential to improve translational capabilities will also be presented, with an emphasis on advancements that will impact regulatory decision making in coming years. As the field of epigenetics is rapidly advancing, the role and utility of epigenetic endpoints in toxicologic pathology and their relevance to human health will be addressed. Environmental toxicologic pathology plays a critical role in understanding health impacts of environmental exposures; therefore, how pathology outcomes inform human health assessments and regulatory decisions will be discussed. Finally, as the incidence of comorbidities in the human population increases, there is a greater need to develop translational models that provide useful information on human populations with comorbidities; the challenges of developing such relevant animal models will be addressed. By the end of this symposium, the audience will have a better understanding of current trends and data needs in translational pathology and how the field of toxicologic pathology can leverage expertise and tools to meet these needs.



TRANSLATIONAL PATHOLOGY:
Relevance of Toxicologic Pathology to Human Health

Program



Society of Toxicologic Pathology

Monday, June 23

Scientific Sessions

Monday Morning

- 7:00 AM–8:00 AM **Continental Breakfast**
Thurgood Marshall Ballroom Foyer
- 8:00 AM–8:05 AM **Symposium Welcome**
Robert C. Sills, DVM, PhD, DACVP, FIATP, National Toxicology Program, National Institute of Environmental Health Sciences, Research Triangle Park, NC, STP President
Thurgood Marshall Ballroom
- 8:05 AM–8:10 AM **Introduction**
- 8:10 AM–9:00 AM **Keynote Address:**
Translational Research and Development (TR&D) in the Context of Toxicologic Pathology
Bruce D. Car, BVSc, PhD, DACVP, DABT, Bristol-Myers Squibb Company, Princeton, NJ
Thurgood Marshall Ballroom
- 9:45 AM–4:00 PM **Exhibits and Posters Open**
Exhibit Hall C

Session 1

9:00 AM–12:00 Noon

Thurgood Marshall Ballroom

Toxicity Concordance from Animals to Humans: How Predictive Are Traditional Preclinical Studies of Adverse Effects or Toxicities in Clinical Studies?

Co-Chairs: Jeff Engelhardt, DVM, PhD, DACVP, FIATP, Isis Pharmaceuticals, Inc., Carlsbad, CA; Daniela Enmulat, DVM, PhD, DACVP, GlaxoSmithKline, King of Prussia, PA; and Sabine Francke, DVM, PhD, FIATP, US FDA/CFSAN, College Park, MD

Testing of xenobiotics in animals prior to human use has been a regulatory requirement since 1939. Since that time, safety testing has been an integral part of the development of regulated compounds such as pharmaceuticals, food additives, and environmental chemicals. As new chemicals or biologics and their targets have become more sophisticated or specialized, so have the questions regarding the reliability of the animal models. As translational toxicologic pathology relies on the predictive value of target organ toxicities identified in animal studies for responses in humans, robustness of the concordance

between target organ toxicities identified as morphologic or biochemical changes in preclinical species and humans will be highlighted in this session. Limitations and advantages of animal models and traditional or nontraditional biomarkers for successful translation of preclinical study findings for clinical use will also be explored. For example, questions to be addressed are: do routine safety studies identify the safety information needed by clinical investigators or are specific, hypothesis-driven studies needed? Are there better ways to interrogate toxicity data through the use of shared databases? What have we learned of early biomarkers and their concordance with tissue morphologic changes and their translational utility?

- 9:00 AM–9:10 AM **Overview: Setting the Stage for Translational Pathology**
Jeff Engelhardt, DVM, PhD, DACVP, FIATP, Isis Pharmaceuticals, Inc., Carlsbad, CA
- 9:10 AM–9:50 AM **Nonclinical Safety Testing: Considerations of Current and Future Performance Characteristics**
Thomas W. Jones, PhD, DABT, Eli Lilly and Company, Indianapolis, IN
- 9:50 AM–10:30 AM **Successful Integration of Nonclinical and Clinical Findings in Interpreting the Clinical Relevance of Rodent Neoplasia with a New Chemical Entity**
Kirk Ways, MD, PhD, Janssen Research and Development, LLC, Raritan, NJ
- 10:30 AM–11:00 AM **Break**
Exhibit Hall C
- 11:00 AM–11:20 AM **IQ-PSLG Nonclinical to Clinical Translational Safety Database Initiative**
Thomas M. Monticello, DVM, PhD, DACVP, Amgen, Inc., Thousand Oaks, CA
- 11:20 AM–11:40 AM **Biomarker Development: "Burning Down the Haystack" to Find, Develop, and Qualify Translational Biomarkers**
Daniela Enmulat, DVM, PhD, DACVP, GlaxoSmithKline, King of Prussia, PA



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11:40 AM–12:00 Noon

Clinical Perspective on Novel Renal Safety Biomarker Utilization in Drug Development

Scott Adler, MD, AstraZeneca, Wilmington, DE

Career Development Lunchtime Series

12:30 PM–1:30 PM

Wilson Room

Draft OECD Guidance on the GLP Requirements for Peer Review of Histopathology: A Panel Discussion

Presented by the STP Career Development and Outreach Committee

(Free Event, Registration Required)

Chair: Bevin Zimmerman, DVM, PhD, DACVP, Janssen Pharmaceuticals Research and Development, Spring House, PA

Panelists and audience members will discuss the Draft OECD Guidance Document on the GLP Requirements for Peer Review. This session will allow attendees to become more familiar with the guidance document and the potential impact it may have on the Peer Review Process.

Panelists: Erio Barale, DVM, Janssen Research and Development, Beerse, Belgium; Greg Furrow, WIL Research, Ashland, OH; David Jacobson-Kram, PhD, DABT, ToxRox Consultancy, McLean, VA; Peter C. Mann, DVM, DACVP, FIATP, EPL, Inc., Seattle, WA; James F. Reindel, DVM, PhD, DACVP, Amgen, Inc., Seattle, WA

Monday Afternoon

Session 2

1:30 PM–5:00 PM

Thurgood Marshall Ballroom

Progress in Preclinical Testing for Translational Science

Co-Chairs: Glenn H. Cantor, DVM, PhD, DACVP, Bristol-Myers Squibb Company, Princeton, NJ; Jerrold M. Ward, DVM, PhD, DACVP, FIATP, Veterinary Pathologist, Montgomery Village, MD; and Cory Brayton, DVM, DACLAM, DACVP, Johns Hopkins University School of Medicine, Baltimore, MD

Nonhuman animals used as human surrogates in preclinical testing and hypothesis-driven translational science have led to important medical and scientific breakthroughs. Preclinical (aka nonclinical) research in animals also has received scrutiny and criticism for insufficient relevance to human conditions. Current issues in the development of pharmaceuticals and biopharmaceuticals, and some new approaches in mouse models, will be presented. This session will focus on new

findings and strategies to optimize preclinical translational research.

1:30 PM–2:15 PM

The Future of Preclinical Animal Models in Pharmaceutical Discovery and Development: A Need to Bring In Cerebro to the In Vivo Discussions

Jeffrey Everitt, DVM, GlaxoSmithKline, Research Triangle Park, NC

2:15 PM–3:00 PM

Translational Approaches to Using Genetically Diverse Mouse Population Models to Understand and Predict Drug Toxicity in Humans

Alison Harrill, PhD, University of Arkansas for Medical Sciences, Little Rock, AR

3:00 PM–3:35 PM

Break

Exhibit Hall C

3:35 PM–4:15 PM

Extensive Double Humanization of Both Liver and Hematopoiesis in FRGN Mice

Markus Grompe, MD, Oregon Health and Science University, Portland, OR

4:15 PM–5:00 PM

Opportunities for Pathology in the Changing World of Translational Sciences and Biologic Modalities

Emanuel Schenck, DVM, PhD, MedImmune, LLC, Gaithersburg, MD

Town Hall Meeting

Adversity and the NOAEL in Nonclinical Regulatory Reports—Definition, Application, and Communication

Monday, June 23, 5:30 PM–6:30 PM

Thurgood Marshall Ballroom

The Town Hall Meeting this year is one not to miss! The SRPC Working Group that is developing a best practice manuscript on “Adversity in Preclinical Reports” will be discussing the nature of “adversity” and the NOAEL in general, as well as the best means of communicating the concept of adversity and the ramifications of using the term “adverse” within study reports and other regulatory documents. Be there and have your voice heard!

7:00 PM–10:00 PM

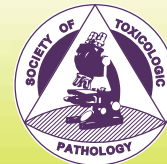
Sponsored Reception

Washington Room



TRANSLATIONAL PATHOLOGY:
Relevance of Toxicologic Pathology to Human Health

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Society of Toxicologic Pathology

Tuesday, June 24

Tuesday Morning

7:00 AM–8:00 AM **Continental Breakfast**
Exhibit Hall C

7:00 AM–4:00 PM **Exhibits and Posters Open**
Exhibit Hall C

Session 3

8:00 AM–12:00 Noon

Thurgood Marshall Ballroom

Emerging Technologies

Co-Chairs: Eric Blomme, DVM, PhD, DACVP, AbbVie, Inc., North Chicago, IL; and Gary Boorman, DVM, PhD, DACVP, FIATP, Covance Laboratories, Inc., Chantilly, VA

Emerging technologies offer exciting promise to address many diseases that have been refractory to traditional therapies, but also to improve toxicological assessment and human risk assessment. An increasing number of novel therapeutic approaches, such as oligonucleotide-based agents, antibody-drug conjugates, or new delivery systems, are in preclinical and clinical studies with some already approved by regulatory agencies. Likewise, a multitude of analytical technologies based on recent advances in molecular biology or engineering are available to evaluate exploratory compounds in vitro or in vivo. Discovery pathologists need to become familiar enough with these potentially useful technologies to offer salient advice on utility, data interpretation, or experimental designs. Pathologists involved in preclinical safety assessment also face new challenges associated with the interpretation of frequently complex toxic changes of poorly characterized mechanisms and of unknown relevance to humans. This session will discuss the role that pathologists in the pharmaceutical industry can play in the identification, application, and development of emerging technologies to improve toxicity prediction and characterization, but also in the assessment of the safety of novel treatment modalities. This session is designed to provide a framework for pathologists to expand their contribution to this exciting but increasingly complex area of therapeutic development and safety assessment.

8:00 AM–8:45 AM **Evaluation of the Potential and Utility of New Technologies for Early Compound Characterization**
Yvonne Will, PhD, Pfizer, Inc., Groton, CT

8:45 AM–9:30 AM

How Discovery Technologies Have Impacted Toxicology-Related Attrition and Influenced Regulatory Preclinical Assessment

Eric Blomme, DVM, PhD, DACVP, AbbVie, Inc., North Chicago, IL

9:30 AM–9:45 AM

Student Presentation: Perfusion Recovery in a Mouse Model of Hind Limb Ischemia Is Enhanced by Mesenchymal Stem Cell-Laden Alginate Implants

Artem Shkumatov, University of Illinois at Urbana-Champaign, Champaign, IL

9:45 AM–10:20 AM

Break

Exhibit Hall C

10:20 AM–11:10 AM

Antisense Oligonucleotides: The Promise and the Problems

Kendall Frazier, DVM, PhD, DACVP, DABT, FIATP GlaxoSmithKline, King of Prussia, PA

11:10 AM–12:00 Noon

Recent Efforts in Prediction and Characterization of Adverse Effects on the Immune System

Ellen Evans, DVM, PhD, DACVP, Pfizer, Inc., Groton, CT

12:00 Noon–1:30 PM

Exhibitor Sponsored Lunch

*Exhibit Hall C
For Registered Scientific Attendees*

Tuesday Afternoon

Session 4

1:30 PM–5:00 PM

Thurgood Marshall Ballroom

The Role of the Toxicologic Pathologist in Informing Regulatory Decisions and Guiding the Interpretation and Application of Data from New Technologies and Tools

Co-Chairs: Shashi Amur, PhD, US FDA/CDER, Silver Spring, MD; and Douglas C. Wolf, DVM, PhD, FIATP, ATS, Syngenta, Greensboro, NC

The use and application of data generated through the use of emerging technologies and novel tools holds great promise in aiding drug, food, and environmental safety assessments. After scientific and analytic validation of these new methods, integration of the validated methods within safety assessments



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is necessary for appropriate application in regulatory decision making. The first presentation will describe a new method which recapitulates the basic functions of an organ *in vitro*, organ-on-a-chip. The science behind this approach as well as some of the issues that would need to be addressed for its application in safety assessment will be described in this talk. The issue of verification and applicability of new technologies is very important to the regulatory community. The application of genomics, which is now widely used as a basic tool in science, is still in the early stages for safety assessment. Its application will be addressed in the second presentation. While new tools hold a lot of promise in aiding safety assessments, issues surrounding the application and interpretation of the classic indicators of adversity continue to be important. Evaluation of clinical chemistry, its interpretation, and translation relative to tissue responses will thus be addressed in the third talk. The second half of the session will address the development, qualification, and use of biomarkers and bioindicators for exposure, effects, clinical trial design and clinical response in drug development, clinical management, and risk management decisions from a regulatory perspective, followed by a panel discussion on issues relative to identifying and establishing biomarkers and bioindicators.

1:30 PM–2:00 PM

Organs-on-Chips

Anthony Bahinski, PhD, MBA, FAHA, Wyss Institute for Biologically Inspired Engineering at Harvard University, Boston, MA

2:00 PM–2:30 PM

Toxicogenomics for Safety Assessment

Weida Tong, PhD, US FDA/NCTR, Jefferson, AR

2:30 PM–3:00 PM

Evaluation, Correlation, and Interpretation of Clinical Pathology with Histopathology in Toxicity Studies

Nancy Everds, DVM, DACVP, Amgen, Inc., Seattle, WA

3:00 PM–3:35 PM

Break

Exhibit Hall C

3:35 PM–4:05 PM

FDA Perspective—Biomarkers as Drug Development Tools

Shashi Amur, PhD, US FDA/CDER, Silver Spring, MD

4:05 PM–4:35 PM

EPA Perspective—Exposure and Effects Prediction and Monitoring

Jon Sobus, PhD, US EPA, Research Triangle Park, NC

4:35 PM–5:00 PM

Panel Discussion on Issues around Biomarker Needs

Wednesday, June 25

Wednesday Morning

7:00 AM–8:00 AM

Continental Breakfast

Exhibit Hall C

7:00 AM–11:30 PM

Exhibits and Posters Open

Exhibit Hall C

Session 5

8:00 AM–12:00 Noon

Thurgood Marshall Ballroom

Epigenetic Endpoints in Toxicologic Pathology and Relevance to Human Health

Co-Chairs: Jim Hartke, DVM, PhD, DACVP, Celgene Corporation, Summit, NJ; and Mark Hoenerhoff, DVM, PhD, DACVP, University of Michigan, Ann Arbor, MI

Epigenetics is the study of heritable changes in gene expression caused by mechanisms that do not alter the underlying DNA sequence. Epigenetic alterations include histone modification, DNA methylation and acetylation, small interfering RNA (siRNA) mechanisms, and epithelial-stromal interactions, to name a few. While epigenetic mechanisms of carcinogenesis have been studied for decades, their application to drug development and discovery, risk assessment, hazard identification, and toxicologic pathology in general is relatively recent. It is becoming increasingly clear that epigenetic alterations not only play a role in cancer development, but also reproductive, developmental, and degenerative diseases in humans. How epigenetic mechanisms alter the biologic system to contribute to disease and toxicity is an area of ongoing and intense interest and research. This session will discuss the utilization of epigenetic endpoints in toxicity testing, and how they relate to human disease due to exposures in the process of reproductive, developmental, degenerative, and neoplastic disease, and the assessment of these endpoints within the safety assessment and hazard characterization paradigms in toxicologic pathology for the study of human health.

8:00 AM–8:45 AM

An Integrated View of Epigenetics: Implications for Toxicologic Pathology

Jay I. Goodman, PhD, Michigan State University, East Lansing, MI

8:45 AM–9:25 AM

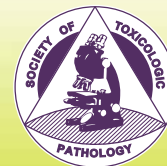
Investigating the Role of Epigenetics in Product Safety Assessment

Reza J. Rasoulpour, PhD, The Dow Chemical Company, Midland, MI



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Society of Toxicologic Pathology

9:25 AM–10:05 AM

Epigenetic Changes in Cancers, Methodologies to Detect Them, and Potential Therapies

Stephen Baylin, MD, The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins, Baltimore, MD

10:05 AM–10:40 AM

Break

Exhibit Hall C

10:40 AM–11:10 AM

Chromatin Remodeling in Development and Disease

Michael C. Boyle, DVM, PhD, DACVP, DABT, Amgen Inc., Thousand Oaks, CA

11:10 AM–11:40 AM

Epigenetics and the Microbiome

Theresa Alenghat, VMD, PhD, DACVP, University of Pennsylvania, Philadelphia, PA

11:40 AM–12:00 Noon

Student Presentation: Wnt Signaling in Prostate Cancer Bone Metastasis

Jessica Simmons, The Ohio State University, Dublin, OH

Excel Tips and Tricks: Easy Ways to Quickly Visualize Your Pathology Data

Wednesday, June 25
12:00 Noon–1:30 PM

Wilson Room

Sponsored by IATP and STP

*Nancy Everds, DVM, DACVP
Amgen, Inc., Seattle, WA*

(Free Event, Registration Required)

This interactive presentation will demonstrate ways to quickly visualize numeric pathology data primarily using Microsoft Excel. Although Excel's built-in graphing capabilities are limited compared to dedicated graphing programs, some of its functions are ideally suited to evaluating pathology data from toxicity studies. Registrants are encouraged to bring their computers along with the example Excel spreadsheet that will be emailed to registrants prior to the session. The session will begin by demonstrating methods to get data into Excel from Word and PDF documents and how to best format different types of data. Next, several methods of graphing will be demonstrated, including scatterplots and pivot charts. For scatterplots, the demonstration will include on-the-fly review, optimizing visualization, and annotating graphs. For pivot tables and charts, the demonstration will include

pros and cons of pivot charts, flipping data to be pivot-ready, creating and modifying a chart, customizing a data table or chart for export to PowerPoint or Word, and annotating graphs and data. For data sets not easily graphed in Excel, alternative graphing programs will be mentioned. At the end of this session, attendees will have new tools to evaluate data for interpretation and presentations

Wednesday Afternoon

Session 6

1:30 PM–5:00 PM

Thurgood Marshall Ballroom

Environmental Toxicologic Pathology and Prediction of Human Health Risks

Co-Chairs: Charles E. Wood, DVM, PhD, DACVP, US EPA, Research Triangle Park, NC; Wanda Haschek-Hock, BVSc, PhD, DACVP, DABT, FIATP, University of Illinois, Urbana, IL; and David Malarkey, DVM, PhD, DACVP, FIATP NIEHS, Research Triangle Park, NC

Evaluating the impact of environmental factors on human health and disease is an integral part of translational science. For toxicologic pathologists, the study of environmental health effects and their mechanisms, and the use of this information in risk assessment and policy decisions, involves a range of different animal models and bioassays. Recently, there has also been increased interest in the use of higher-throughput alternative models, including *in vitro* and computational approaches, for assessing human health hazards due to environmental agents. This session will focus on translational applications of data derived from different model systems used in hazard identification and risk assessment of environmental compounds.

Specific areas of focus will include current regulatory issues in chemical safety, evaluation of environmental obesogens and metabolic disruptors, emerging approaches for testing of reproductive toxicants, comparative pathology of rodent lung tumors, and health effects of phycotoxins from harmful algal blooms.

1:30 PM–2:05 PM

Current and Emerging Issues in Chemical Safety

Jeffrey Morris, PhD, US EPA Office of Chemical Safety and Pollution Prevention, Washington, DC

2:05 PM–2:40 PM

Interface of Air Pollution, Diabetes, and the Metabolic Syndrome: Translational Studies on Health Effects

Jack Harkema, DVM, PhD, DACVP, Michigan State University, East Lansing, MI



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2:40 PM–3:15 PM

Break

Thurgood Marshall Ballroom Foyer

3:15 PM–3:50 PM

Rodent vs. Human Lung Cancer: The Good, the Bad, and the Ugly!

Arun Pandiri, BVSc&AH, MS, PhD, DACVP, DABT, EPL, Inc./NTP, Research Triangle Park, NC; and Samuel M. Cohen, MD, PhD, University of Nebraska Medical Center, Omaha, NE

3:50 PM–4:25 PM

Deriving Points of Departure and Performance Baselines for Predictive Modeling of Systemic Toxicity using ToxRefDB

Matthew Martin, PhD, US EPA National Center for Computational Toxicology, Research Triangle Park, NC

4:25 PM–5:00 PM

Health Effects of Phycotoxins from Harmful Algal Blooms

Olga M. Pulido, MD, MSc, ABPath, FIATP, University of Ottawa, Ottawa, Ontario, Canada

5:30 PM–5:50 PM

Awards Ceremony

Thurgood Marshall Ballroom

5:50 PM–6:30 PM

Annual Business Meeting

Thurgood Marshall Ballroom

7:00 PM–9:00 PM

President's Reception

Exhibit Hall C

Thursday, June 26

Thursday Morning

7:00 AM–8:00 AM

Continental Breakfast

Thurgood Marshall Ballroom Foyer

Session 7

8:00 AM–12:00 Noon

Thurgood Marshall Ballroom

The Challenges of Safety Evaluation in Populations with Concurrent Disease

Co-Chairs: LuAnn McKinney, DVM, DACVP, US FDA/CDER/OND/DNP, Silver Spring, MD; and John E. Sagartz, DVM, PhD, DACVP, Seventh Wave Laboratories, Chesterfield, MO

Comorbidities in patient populations include overt cardiovascular disease, obesity, or diabetes, singly or in combination with other, less prominent conditions. When xenobiotics are administered, drug-related adverse events in

patients with concurrent disease may be detected during clinical trials. Often adverse responses are detected by post-marketing surveillance, by meta-analysis of clinical case reports, or through data mining by regulatory agencies. The challenge is to detect, predict, or ameliorate these adverse events in nonclinical studies before patients are adversely affected. This session will explore the current methodologies applied through the translational arc: the pharmacovigilance methodologies applied to clinical and post-marketing studies followed by discussion of the safety decisions in translation from normal animals to normal humans to patient populations to patients with concurrent disease. The session will also focus on the utility of studies in normal animals to predict adverse events in patient populations and review the efficacy of animal models of human disease to detect adverse safety signals. A panel discussion of these current challenges and how nonclinical studies may meet those challenges will follow.

8:00 AM–8:45 AM

The Evidentiary Basis of Safety Decisions from Normal Animal to Comorbid Patient

Ellis Unger, MD, US FDA/CDER (Office of Drug Evaluation, I), Silver Spring, MD

8:45 AM–9:25 AM

Overview of Pharmacovigilance Methodologies to Detect Adverse Clinical Events in Comorbidities

Ajay Singh, MD, GlaxoSmithKline, Collegeville, PA

9:25 AM–10:05 AM

How the Early Preclinical Safety Assessment Can Identify Safety Issues and Minimize or Circumvent Adverse Safety Events

John E. Sagartz, DVM, PhD, DACVP, Seventh Wave Laboratories, Chesterfield, MO

10:05 AM–10:40 AM

Break

Thurgood Marshall Ballroom Foyer

10:40 AM–11:20 AM

Animal Models of Human Disease for Nonclinical Safety Assessment of Novel Pharmaceuticals

Sherry J. Morgan, DVM, PhD, DACVP, AbbVie, Inc., North Chicago, IL

11:20 AM–12:00 Noon

Roundtable: What Can Preclinical Sciences Do to Meet This Clinical Challenge?

12:00 Noon

Meeting Adjourned



Poster Times and Poster Setup

Poster Setup

Sunday, June 22.....8:00 AM–3:00 PM
Your poster must be set up by 3:00 PM on Sunday, June 22.

Poster Presentation Times

(Please plan to attend your posters during the following times)

Sunday, June 22 (Welcome Reception)..... 6:00 PM–6:30 PM (Optional)
Monday, June 23..... 10:30 AM–11:00 AM and 3:00 PM–3:35 PM
Tuesday, June 24..... 9:45 AM–10:20 AM and 3:00 PM–3:35 PM
Wednesday, June 25..... 10:05 AM–10:40 AM

Poster Teardown

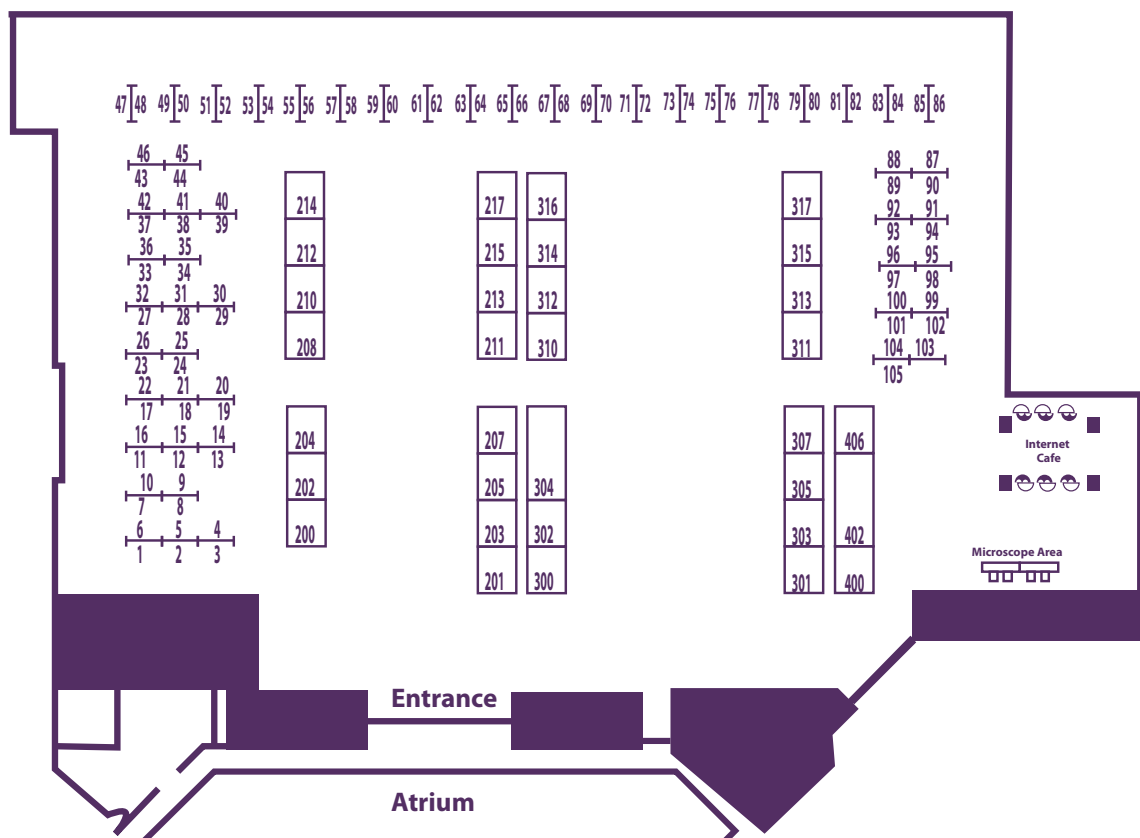
Wednesday, June 25..... 11:30 AM–1:00 PM
If your poster is not removed before 1:00 pm on Wednesday, June 25, it will be removed and placed near the Registration Desk for pickup.

Young Investigator Judging Times

Monday, June 23..... 7:15 AM–8:00 AM, 10:30 AM–11:00 AM, and 3:00 PM–3:35 PM
Tuesday, June 24..... 9:45 AM–10:20 AM

Marriott Wardman Park Hotel—Exhibit Hall C

Booths, Posters, Internet Café, Microscope and Digital Slide Viewing Area





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Poster Categories:

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Biomarkers 21–26

General Pathology/Toxicologic Pathology 27–52

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Oncology/Carcinogenesis 67–81

Systemic/Organ-Specific Toxicologic Pathology 82–104

§ Student Travel Award Winners

1 Protective Role of Sildenafil Against Carbon Tetrachloride-Induced Nephrotoxicity by Augmenting the Availability of Nitric Oxide and Antioxidant Enzymes

Shubham Goyal¹, Vaneeta Rani², Sawati Sharma¹, Nitin Verma¹, ¹School of Pharmacy and Emerging Sciences, Baddi University of Emerging Sciences and Technology, Vill-Makhnumajra, Baddi, Distt. Solan, HP, India, ²Himalyan Institute of Pharmacy, Kala-Amb, Distt. Sirmour, HP, India

2 Effects of Rosiglitazone on β -Cell Function in Metabolic Syndrome Patients with Impaired Glucose Tolerance

Ravinesh Mishra¹, Anees A Siddiqui², Asif Husain², Mohd Rashid¹, Viny Srinivasan³, ¹School of Pharmacy and Emerging Sciences, Baddi University of Emerging Sciences and Technology, Makhnumajra, Baddi, Distt. Solan, HP, India, ²Department of Pharmaceutical Chemistry, Faculty of Pharmacy, Jamia Hamdard (Hamdard University), Hamdard Nagar, New Delhi, India, ³Department of US Safety Evaluation, L'Oréal, Clark, NJ, USA

§3 Comparative Toxicity and Efficacy of Engineered Anthrax Lethal Toxin Variants with Broad Anti-Tumor Activities

Diane Peters^{1,2}, Benjamin Hoover³, Loretta Grey Cloud¹, Shihui Liu³, Alfredo Molinolo¹, Stephen Leppla³, Thomas Bugge¹, ¹National Institute of Dental and Craniofacial Research, Bethesda, MD, USA, ²Tufts University Sackler School of Graduate Biomedical Sciences, Boston, MA, USA, ³National Institute of Allergy and Infectious Disease, Bethesda, MD, USA

4 Reproductive Staging in the Göttingen Miniature Pig

Rebecca Terry¹, Jan Klapwijk², Franck Chanut², ¹Royal Veterinary College, London, UK, ²GlaxoSmithKline, Ware, UK

5 Histologic Changes Following Acid Reflux Challenge in Porcine Vocal Folds

Abigail Durkes¹, Paul Snyder¹, Preeti Sivasankar¹, ¹Purdue University, West Lafayette, IN, USA

6 Subchronic Toxicological Study of Two Artemisinin Derivatives in Dogs

Ji-ye Yin¹, He-mei Wang¹, Quan-jun Wang¹, Ri-gao Ding¹, ¹Beijing Institute of Pharmacology and Toxicology, Beijing, China

7 A Maximum Tolerated and Therapeutic Dose of Cholic Acid Rescues the Lethal Effects of Ethanol in the Zebrafish (*Danio rerio*) Fetal Alcohol Model: A Toxicity, Tolerability, and Macroscopic Morphological Study

Shemikah Colleton¹, Curtis Colleton², James Marrs⁴, Christian Lawrence³, Courtney Curtis⁴, Kara Maloney³, Mariah Gardner¹, Madeleine Walsh¹, Philip Marx², Lora Becker¹, ¹University of Evansville, Evansville, IN, USA, ²Bristol-Myers Squibb Company, Mt. Vernon, IN, USA, ³Boston Children's Hospital Aquatic Resources, Boston, MA, USA, ⁴Indiana University-Purdue University Indianapolis, Indianapolis, IN, USA

8 Chronic Comparative Embryonic Tolerability, Toxicity, and Macroscopic Morphological Study of Sub-Lethal Rectified and Medical Grade Ethanol Exposure in Zebrafish (*Danio rerio*)

Shemikah Colleton¹, Curtis Colleton², James Marrs⁴, Christian Lawrence³, Courtney Curtis⁴, Kara Maloney³, Madeleine Walsh¹, Mariah Gardner¹, Philip Marx², Lora Becker¹, ¹University of Evansville, Evansville, IN, USA, ²Bristol-Myers Squibb Company, Mt. Vernon, IN, USA, ³Boston Children's Hospital Aquatic Resources Program, Boston, MA, USA, ⁴Indiana University-Purdue University Indianapolis, Indianapolis, IN, USA

§9 Perfusion Recovery in a Mouse Model of Hind Limb Ischemia Is Enhanced by Mesenchymal Stem Cell-Laden Alginate Implants

Artem Shkumatov¹, Min Kyung Lee¹, Hyun Joon Kong¹, ¹University of Illinois, Urbana-Champaign, IL, USA



10 Development of a Tissue Image Analysis Algorithm for Celiac Drug Development

Erik Hagendorn¹, Christa Whitney-Miller², G. David Young¹, Steve Potts¹, ¹Flagship Biosciences, Boulder, CO, USA, ²University of Rochester School of Medicine and Dentistry, Rochester, NY, USA

§11 Wnt Signaling in Prostate Cancer Bone Metastasis

Jessica Simmons¹, Wessel Dirksen¹, Thomas Rosol¹, ¹The Ohio State University, Columbus, OH, USA

§12 Elucidating the Carcinogenic Mode of Action of Diuron on Rat Urothelium

Mitscheli Da Rocha^{1,2}, Lora Arnold², Puttappa Dodmane², Maria Luiza de Oliveira¹, Ana Paula Cardoso¹, Merielen Pontes¹, Karen Pennington², David Muirhead², Fang Qiu², Samuel Cohen², João Lauro de Camargo², ¹São Paulo State University, Botucatu, Brazil, ²University of Nebraska Medical Center, Omaha, NE, USA

§13 ALDH1B1 Is Crucial for Colon Tumorigenesis by Modulating Wnt/ β -catenin, Notch and PI3K/Akt Signaling Pathways

Surendra Singh¹, John Arcaroli², Ying Chen¹, David Orlicky⁴, David Thompson³, Wells Messersmith², Vasilis Vasilou¹, ¹Department of Pharmaceutical Sciences, University of Colorado Anschutz Medical Campus, Aurora, CO, USA, ²Division of Medical Oncology, University of Colorado School of Medicine, Aurora, CO, USA, ³Department of Clinical Pharmacy, University of Colorado Anschutz Medical Campus, Aurora, CO, USA, ⁴Department of Pathology, University of Colorado School of Medicine, Aurora, CO, USA

14 Cigarette Smoke Condensate Induces Early Epithelial-Mesenchymal Transition (EMT) in Cultured Human Ectocervical Cells

Xiaohua Gao¹, Linda Yu¹, Lysandra Castro¹, Deloris Sutton¹, Connie Cummings¹, Daniel Morgan¹, Grace Kissling², Darlene Dixon¹, ¹NIEHS, NTP, Research Triangle Park, NC, USA, ²NIEHS, Research Triangle Park, NC, USA

15 Identification of Differentially Expressed Genes Defining Heterogeneity of Cancer Cells by RNA-Seq using Next Generation Sequencing

Yongbaek Kim^{1,2}, Myung-Chul Kim¹, Na-Yon Kim¹, Hang-A Kim¹, Cui-Feng Ji¹, ¹Laboratory of Clinical Pathology, College of Veterinary Medicine, Seoul National University, Seoul, Republic of Korea, ²Research Institution of Veterinary Science, College of Veterinary Medicine, Seoul National University, Seoul, Republic of Korea

16 An Allelic Variant of the Mechanistic Target of Rapamycin (mTOR) Leads to Altered DNA Damage Repair

Joy Gary^{1,2}, Shuling Zhang¹, Ke Zhang¹, Wendy Dubois¹, Aleksandra Michalowski¹, Beverly Mock¹, ¹CCR, NCI, NIH, Bethesda, MD, USA, ²Michigan State University, East Lansing, MI, USA

17 Possible Mechanisms Underlying Exacerbation of Osmotic Nephrosis Caused by Pre-Existing Kidney Injury

Kohei Matsushita¹, Shinji Takasu¹, Yuji Ishii¹, Ken Kuroda¹, Aki Kijima¹, Keisuke Kitaura², Makoto Sato², Satoshi Matsumoto², Kumiko Ogawa¹, Takashi Umemura¹, ¹Division of Pathology, National Institute of Health Sciences, Tokyo, Japan, ²Safety Research Center, Otsuka Pharmaceutical Co., Ltd., Tokushima, Japan

18 Role of Cysteine-Rich Secretory Protein LCCL Domain Containing 2 [CRISPLD2] in Bile Duct Epithelial Branching Morphogenesis during Hepatic Fibrosis and Cholangiocarcinoma Progression

Chandrasagar Saravanan¹, Cheryl Spence¹, James Trevaskis¹, Xiaosong Wang¹, Jean-Rene Galarneau¹, William Chutkow¹, Keith Mansfield¹, ¹Novartis Institutes for Biomedical Research, Cambridge, MA, USA

19 Macrophage-Derived Galectin-3 Is the Key Regulator of Acute Hepatic Fibrogenesis in Rats

Hossain M. Golbar¹, Takeshi Izawa¹, Bondoc Alexandra¹, Kavindra K. Wijesundera¹, Anusha H. Tennakoon¹, Chisa Katou-Ichikawa¹, Miyuu Tanaka¹, Mitsuru Kuwamura¹, Jyoji Yamate¹, ¹Osaka Prefecture University, Izumisano City, Osaka, Japan

§20 Improved LV Function in Levosimendan-Treated Rats with Reversed Volume Overload Heart Failure Correlates with Normalized Alpha-to-Beta Myosin Heavy Chain Expression

Kristin Wilson^{1,2}, Mary Cismowski^{1,2}, Pamela Lucchesi^{1,2}, ¹The Ohio State University, Columbus, OH, USA, ²Nationwide Children's Hospital, Columbus, OH, USA

21 The Combined Use of Structural and Functional Cardiac Biomarkers Enhances the Ability to Understand the Pathogenesis of Cardiotoxicity

William Reagan¹, Vincent Bernardo¹, Raju Mantena³, Bernie Buetow², Jianying Wang², Allison Vitsky², Hugh Barton⁴, Jon Heyen², Karen Leach⁵, Dingzhou Li¹, Carrie Northcott¹, David Potter¹, Deb Burt¹, Rick Goldstein¹, Wendy Hu², Nick Edmunds¹, ¹Pfizer Drug Safety Research and Development, Groton, CT, USA, ²Pfizer Drug Safety Research and Development, La Jolla, CA, USA, ³Pfizer Drug Safety Research and Development, Cambridge, MA, USA, ⁴Pfizer Pharmacokinetics Dynamics and Metabolism, Groton, CT, USA, ⁵Pfizer Compound Safety Prediction Group, Groton, CT, USA



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22 Determination of Atrial Natriuretic Peptide in Sprague-Dawley Rat and C57BL/6 Mouse Serum: Comparison Between Two Immunoassays

Ahmad Farhad¹, Mehrdad Ameri¹, Jim Turk¹, ¹Comparative Biology and Safety Sciences, Amgen, Inc., Thousand Oaks, CA, USA

23 Altered Ubiquitin Expression in the Airways of Diacetyl-Exposed Mice

Ann Hubbs¹, Kara Fluharty¹, Rebekah Edwards¹, John Grantham^{1,2}, Linda Sargent¹, Steven Reynolds¹, Robert Mercer¹, Michael Kashon¹, Lori Battelli¹, Mark Jackson¹, Amy Cumpston¹, Travis Goldsmith¹, David Frazer¹, Tiffani Munro¹, Winnie Moyers¹, Kimberly McKinstry¹, Sherri Friend¹, Krishnan Sriram¹, ¹National Institute for Occupational Safety and Health, Morgantown, WV, USA, ²West Virginia University, Morgantown, WV, USA

24 Biomarkers of Hypercoagulability in a Rat Sepsis-Induced Model of Non-Overt Disseminated Intravascular Coagulation (DIC)

MB Brooks¹, JR Turk², CE Fishman³, DW Wilson⁴, AE Schultze⁵, JB Pierson⁶, members of the Cardiac Biomarkers Working Group of the HESI Cardiac Safety Technical Committee, ¹Cornell University, Ithaca, NY, USA, ²Amgen, Inc., Thousand Oaks, CA, USA, ³GlaxoSmithKline, King of Prussia, PA, USA, ⁴University of California, Davis, Davis, CA, USA, ⁵Eli Lilly and Company, Indianapolis, IN, USA, ⁶HESI, Washington, DC, USA

25 Application of Predictive Biomarkers for Renal Toxicity in Drug Development

Kaoru Toyosawa¹, Takayuki Iwaisako¹, Akiko Kusayanagi¹, Izumi Matsumoto¹, Mami Kouchi¹, Tomoaki Tochitani¹, Toru Yamada¹, Hitoshi Funabashi¹, ¹Dainippon Sumitomo Pharma Co., Ltd., Osaka, Osaka, Japan

26 Investigation of Urine Biomarker Performance in Rat Glomerular Injury Models

Bruce Homer¹, Steven Bailey², Eva Nagiec¹, Deborah Burt³, Mira Ko⁴, Karen Percival², Rounak Nassirpour², Radi Zaher², James Warneke², Thomas Brown³, ¹Pfizer, Inc., Cambridge, MA, USA, ²Pfizer, Inc., Andover, MA, USA, ³Pfizer, Inc., Groton, CT, USA, ⁴Pfizer, Inc., La Jolla, CA, USA

27 Unexpected Pituitary Pathology after Chronic Administration of MEDI412, a High Potency Anti-IgE Antibody

Mary McFarlane², William Iverson¹, Juerg Bluemel¹, ¹MedImmune, LLC, Gaithersburg, MD, USA, ²MedImmune, LLC, Cambridge, UK

28 Toxicological Findings in Beagle Dogs after 13 Weeks Oral Gavage of a DPP-4 Inhibitor

Jingjun Sun¹, Henglei Lu¹, Jianhong Pan¹, Junwen Qiao¹, Rongrong Tan¹, Hua Sheng¹, Jin Ren¹, ¹Center for Drug Safety Evaluation and Research, Shanghai Institute of Materia Medica, Shanghai, China

29 Dysregulation of Iron Homeostasis during Progression of Thioacetamide-Induced Liver Cirrhosis in Rats

Takeshi Izawa¹, Hiroshi Murakami¹, Rena Miyagi¹, Kavindra Wijesundera¹, Anusha Tennakoon¹, Golbar Hossain¹, Mitsuru Kuwamura¹, Jyoji Yamate¹, ¹Osaka Prefecture University, Osaka, Japan

30 Congenital Intrathoracic Left Kidney in a Cynomolgus Monkey

Henglei Lu¹, Jingjun Sun¹, Rongrong Tan¹, Jin Ren¹, ¹Center for Drug Safety Evaluation and Research, Shanghai Institute of Materia Medica, Shanghai, China

31 Repeated Subcutaneous Dose Toxicity Studies of Iron Oxide-Zinc Oxide Core-Shell Nanoparticles in C57BL/6 Mice

Jeong-Hwan Che¹, Jung-Hee Yoon¹, Byeong-Cheol Kang¹, Nam-Hyuk Cho², Seung Hyeok Seok², Young Keun Kim³, ¹Biomedical Research Institute, Seoul National University Hospital, Seoul, Republic of Korea, ²Department of Microbiology and Immunology, Seoul National University College of Medicine, Seoul, Republic of Korea, ³Department of Materials Science and Engineering and Pioneer Research Center for Biomedical Nanocrystals, Korea University, Seoul, Republic of Korea

32 Anti-Apoptotic Potential of Herbal Plant Extract in Rats with Cardiomyopathy

Harbir Kaur^{1,2}, Gurpreet Singh², Maninder Singh², Ankur Bansal², ¹School of Pharmacy and Emerging Sciences, Baddi University of Emerging Sciences and Technology, Makhnumajra, Baddi, Distt. Solan, HP, India, ²Department of Pharmaceutics, Rayat Institute of Pharmacy, Railmajra, Distt. SBS Nagar, Punjab, India, ³Ranbaxy Laboratories, Ltd., Mohali, India

33 Artfactual Positive Urine Reagent Test Strip Reactions Caused by Common Contaminants in Laboratory-Housed Nonhuman Primates and Beagle Dogs

William Siska¹, Dennis Meyer¹, A. Eric Schultze², Catherine Brandoff¹, Jamie West¹, Steven Wirth¹, ¹Charles River Laboratories, Reno, NV, USA, ²Department of Pathology, Lilly Research Laboratories, Indianapolis, IN, USA



34 Short-Term Carcinogenic Screening Study Using a Limited Number of Tg-rasH2 Mice

Yutaka Nakanishi¹, Satoshi Tsuji¹, Masaki Wakamatsu¹, Hironori Takagi¹, Minoru Sasaki¹, Shunsuke Tsutsumi¹, Yasushi Sato¹,
¹Drug Safety and Pharmacokinetics Laboratories, Taisho Pharmaceutical Co., Ltd., Saitama, Japan

35 Comparison of Historical Control Parameters Derived from Subchronic Studies Conducted in CD® IGS Rats Fed 5002 or 5CR4 Certified Diets

Mark Morse¹, Binod Jacob¹, Aaron Sargeant¹, ¹Charles River Laboratories, Spencerville, OH, USA

§36 Minocycline, a Putative Neuroprotectant, Co-Administered with Doxorubicin-Cyclophosphamide Chemotherapy in a Xenograft Model of Triple-Negative Breast Cancer

Lauren Himmel¹, Maryam Lustberg¹, A. Courtney DeVries¹, Charles Shapiro¹, Ching-Shih Chen¹, Samuel Kulp¹, ¹The Ohio State University, Columbus, OH, USA

37 Conditioning Agents for Gene Therapy: Busulfan vs. Irradiation—Common Histopathology Findings in Mice Used in Preclinical Studies.

Franck Chanut¹, Francesca Sanvito³, Giuliana Ferrari², Patrizia Cristofori¹, ¹GlaxoSmithKline David Jack Centre for R&D, Ware, UK, ²HSR-TIGET Ospedale San Raffaele, Milan, Italy, ³Pathology Unit, San Raffaele Scientific Institute, Milan, Italy

38 Sex Differences and Litter-Based Effects on Hematologic Parameters from 28-Day Old Harlan Sprague Dawley (Hsd:Sprague Dawley SD) Rats

Michelle Cora¹, Greg Travlos¹, Grace Kissling¹, Matt Stout¹, Angela King-Herbert¹, Molly Vallant¹, Chad Blystone¹, ¹National Institute of Environmental Health Sciences, Research Triangle Park, NC, USA

39 Common Bile Duct Injury in Wistar Rats Induced by Sorafenib Tosylate

Ke Chen^{1,2}, Yuanyuan Deng^{1,2}, Fen Wang^{1,2}, Hongxia Li^{1,2}, Xiaobo Cen^{1,2}, Chunyan Hu^{1,2}, Peter Mann³, ¹National Chengdu Center for Safety Evaluation, West China Hospital, Chengdu, Sichuan, China, ²West China Frontier Pharma Tech Co., Ltd., Chengdu, Sichuan, China, ³EPL Northwest, Seattle, WA, USA

40 Clinical Pathology Reference Intervals for Healthy Göttingen Minipigs Based on Tolerance Intervals

Hala Willis¹, Jodi Boysza¹, Alex Rodriguez¹, Vicky Satterfield¹, Carie Kimbrough¹, Holly Jordan¹, ¹GlaxoSmithKline, Research Triangle Park, NC, USA

41 Subchronic Inhalation Exposure of Rats to Libby Amphibole and Amosite Asbestos: Effects at 18 Months Post Exposure

Gabrielle A. Willson¹, Darol E. Dodd², Kay Roberts², Henry G. Wall¹, Stephen H. Gavett³, ¹Experimental Pathology Laboratories, Inc., Research Triangle Park, NC, USA, ²The Hamner Institutes for Health Sciences, Research Triangle Park, NC, USA, ³US EPA, Research Triangle Park, NC, USA

42 A 21st Century Roadmap for Human Health Risk Assessment

Douglas Wolf¹, Ammie Bachmann², Alan Boobis³, Samuel Cohen⁴, Michael Dellarco⁵, Ian Dewhurst⁶, John Doe⁷, Nancy Doerrer⁸, Angelo Moretto⁹, Timothy Pastoor¹, Richard Phillips², J. Craig Rowlands¹⁰, Jennifer Tanir⁸, Michelle Embry⁸, ¹Syngenta, Ltd., Greensboro, NC, USA, ²ExxonMobil Biomedical Sciences, Inc., Annandale, NJ, USA, ³Imperial College London, London, UK, ⁴University of Nebraska Medical Center, Omaha, NE, USA, ⁵National Institute of Child Health and Human Development, Bethesda, MD, USA, ⁶UK Chemicals Regulation Directorate, York, UK, ⁷Parker Doe Partnership LLP, Chesire, UK, ⁸ILSI Health and Environmental Sciences Institute, Washington, DC, USA, ⁹University of Milan, Milan, Italy, ¹⁰The Dow Chemical Company, Midland, MI, USA

43 Lack of In Vivo Genotoxicity and Rat Toxicity of Myricitrin Administered at Dietary Levels up to 5%

Shim-mo Hayashi¹, Jeffrey Davis², Cheryl Hobbs², Carol Swartz², Leslie Recio², Robert Maronpot³, ¹San-Ei Gen FFI, Inc., Osaka, Japan, ²Integrated Laboratory Systems, Inc., Research Triangle Park, NC, USA, ³Maronpot Consulting, LLC., Raleigh, NC, USA

44 Development of Photoaging Model Using UVB and Heat

Il-Hong Bae¹, Ji-Hae Lee¹, Dae-Yong Kim¹, ¹College of Veterinary Medicine, Seoul National University, Seoul, Republic of Korea

45 A Decade of Non-Neoplastic Histologic Background Lesions in Göttingen Minipigs at MPI Research

Charlotte Hollinger¹, Keith Nelson^{2,1}, ¹Department of Pathobiology and Diagnostic Investigation, Michigan State University, East Lansing, MI, USA, ²MPI Research, Mattawan, MI, USA



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46 Isoproterenol Induced Skeletal Troponin Elevation in Sprague Dawley Rats

Malar Pannirselvam¹, Quincey Simmons¹, Jessica Wan¹, Suzanne Botts¹, David Brewster¹, ¹Vertex Pharmaceuticals, Boston, MA, USA

§47 Effects of Perinatal Exposure to Single or Mixed Fungicides on the Female Rat Reproductive System

Viviane Pascotto¹, Carla Franchi¹, Janete Franchi², Ruither Carolino¹, João Lauro Camargo¹, ¹São Paulo State University UNESP Medical School, Botucatu, Brazil, ²School of Dentistry of Ribeirão Preto, University of São Paulo, USP, Ribeirão Preto, Brazil

48 Lysosomal Drug Accumulation and Precipitation in Rats Seen with an Amphoteric Compound

Barbara Lenz¹, Urs Niederhauser¹, Holger Fischer¹, Rodolfo Gasser¹, Claus Riemer¹, Alexander Flohr¹, Thomas Weiser¹, Thomas Singer¹, Nicole Wytenbach¹, Mudher Albassam¹, Monira Siam¹, ¹Hoffmann-La Roche, Basel, Switzerland

49 Mitochondrial Alteration in CD1 Mice Associated with Prenatal Exposures to Low Doses of Perfluorooctanoic Acid (PFOA): A PPAR α -Independent Mode of Action?

Erin Quist^{1,2}, Adam Filgo^{1,3}, Connie Cummings⁵, Grace Kissling⁴, Mark Hoenerhoff⁶, Suzanne Fenton¹, ¹NTP Laboratory Branch, NTP, NIEHS, NIH, DHHS, Research Triangle Park, NC, USA, ²Comparative Biomedical Sciences, College of Veterinary Medicine, North Carolina State University, Raleigh, NC, USA, ³Curriculum in Toxicology, University of North Carolina, Chapel Hill, NC, USA, ⁴Biostatistics Branch, DIR, NIEHS, NIH, DHHS, Research Triangle Park, NC, USA, ⁵UltraPath Imaging, Durham, NC, USA, ⁶Unit for Laboratory Animal Medicine, University of Michigan, Ann Arbor, MI, USA

50 Histologic Findings Associated with Chronic Femoral Artery Implantation of a Miniature Telemetry Blood Pressure Transmitter in Cynomolgus Monkeys

William Meier¹, Laura Kreckler¹, John Kremer¹, Mike Foley¹, Mark Holbrook², Niraj Tripathi¹, Alok Sharma¹, Emily Meseck¹, ¹Covance Laboratories, Madison, WI, USA, ²Covance Laboratories, Harrogate, UK

51 Non-Lesions, Misdiagnoses, Missed Diagnoses, and Other Interpretive Challenges in Fish Histopathology Studies: A Guide for Investigators, Authors, Reviewers, and Readers

Jeffrey Wolf¹, Wes Baumgartner², Vicki Blazer³, Alvin Camus⁴, Jeffery Engelhardt⁵, John Fournie⁶, Salvatore Frasca⁷, David Groman⁸, Michael Kent⁹, Lester Khoo¹⁰, Jerry Law¹¹, Eric Lombardini¹², Christine Ruehl-Fehlert¹³, Helmut Segner¹⁴, Stephen Smith¹⁵, Jan Spitsbergen¹⁶, Klaus Weber¹⁷, Marilyn Wolfe¹⁸, ¹Experimental Pathology Laboratories, Inc., Sterling, VA, USA, ²Department of Pathobiology/Population Medicine, College of Veterinary Medicine, Mississippi State, Mississippi State, MS, USA, ³US Geological Survey, Kearneysville, WV, USA, ⁴Department of Pathology, College of Veterinary Medicine, University of Georgia, Athens, GA, USA, ⁵Experimental Pathology Laboratories, Inc., Camarillo, CA, USA, ⁶US Environmental Protection Agency, National Health and Environmental Effects Research Laboratory, Gulf Ecology Division, Gulf Breeze, FL, USA, ⁷Connecticut Veterinary Medical Diagnostic Laboratory, Department of Pathobiology and Veterinary Science, University of Connecticut, Storrs, CT, USA, ⁸Aquatic Diagnostic Services, Atlantic Veterinary College, University of Prince Edward Island, Charlottetown, Prince Edward Island, Canada, ⁹Departments of Microbiology and Biomedical Sciences, Oregon State University, Corvallis, OR, USA, ¹⁰Mississippi State University, College of Veterinary Medicine, Stoneville, MS, USA, ¹¹Aquatic Ecotoxicology, North Carolina State University College of Veterinary Medicine, Raleigh, NC, USA, ¹²Divisions of Comparative Pathology and Veterinary Medical Research, Department of Veterinary Medicine, Armed Forces Research Institute of Medical Sciences, Bangkok, Thailand, ¹³Bayer HealthCare AG, Wuppertal, Germany, ¹⁴Centre for Fish and Wildlife Health, University of Bern, Bern, Switzerland, ¹⁵Virginia-Maryland College of Veterinary Medicine, Virginia Tech, Blacksburg, VA, USA, ¹⁶Fish Disease Research Group, Department of Microbiology, Oregon State University, Corvallis, OR, USA, ¹⁷AnaPath GmbH, Oberbuchsitzen, Switzerland, ¹⁸EPL, Inc., Sterling, VA, USA

52 Location Matters—the Behavior of Human Retinoblastoma Cells is Dependent on the Site of Implantation

Julia Baker¹, Shawna Jackman², ¹Charles River Pathology Associates, Frederick, MD, USA, ²Charles River Preclinical Services, Horsham, PA, USA

53 Quantitative Evaluation of Drug-Induced Microvascular Constriction in Mice Kidney Using a Novel Tool for 3D Geometrical Analysis of Ex Vivo Organ Vasculature

Raul Brauner², Yuval Ramot¹, Kongbin Kang^{2,4}, John V. Heymach³, Stacia Furtado^{2,4}, Abraham Nyska⁵, ¹Hadassah – Hebrew University Medical Center, Jerusalem, Israel, ²Bio-Tree Systems Inc., Framingham, MA, USA, ³MD Anderson Cancer Center, Houston, TX, USA, ⁴Brown University, Providence, RI, USA, ⁵Toxicologic Pathologist, Timrat, Israel

54 Significant Lessening of Local Reactions Following Continuous SC Administration of ND0701, a New Apomorphine Formulation for Parkinson's Disease—MRI and Histopathology Studies

Ronit Shaltiel-Karyo¹, Hanita Ovadia¹, Yonit Tzarfaty¹, Yael Schifffenbauer², Abraham Nyska³, Oron Yacoby-Zeevi¹, ¹NeuroDerm company, Ness-Ziona, Israel, ²Aspect Imaging, Shoham, Israel, ³Consultant in Toxicologic Pathology, and Tel Aviv University, Timrat, Israel



55 The Development of Image Analysis Algorithms to Objectively Characterize the Host Tissue Response to an Encapsulated Stem Cell Product

John J. O'Neil¹, Allison Rubin², Irina Batushansky², David Young³, ¹Janssen Research and Development, LLC., Raritan, NJ, USA, ²Janssen Research and Development, LLC., Springhouse, PA, USA, ³Flagship Biosciences, LLC., Boulder, CO, USA

56 The Use of Immunohistochemistry and Image Analysis to Objectively Characterize the Composition of a Stem Cell-Derived Therapy in Preclinical Studies

Jing Ying Ma¹, Allison Rubin², Irina Batushansky², John J O'Neil³, ¹Janssen Research and Development, LLC., La Jolla, CA, USA, ²Janssen Research and Development, LLC., Springhouse, PA, USA, ³Janssen Research and Development, LLC., Raritan, NJ, USA

57 First Time in Man Enabling Study Using Gene Therapy to Treat Beta-Thalassemia: Focus on the Histopathology

Franck Chanut¹, Francesca Sanvito^{3,2}, Francesca Tiboni², Giacomo Mandelli², Maria-Rosa Lidonnici², Paola Albertini², Luigi Naldini², Giuliana Ferrari², Patrizia Cristofori¹, ¹GlaxoSmithKline David Jack Centre for R&D, Ware, UK, ²San Raffaele-Telethon Institute for Gene Therapy (TIGET), Milan, Italy, ³Pathology Unit, San Raffaele Scientific Institute, Milan, Italy

58 Development of Tissue Image Analysis Tools to Identify Murine Pancreatic Intraepithelial Neoplasia

Famke Aeffner¹, Mirza Peljto¹, Michael O. Ports², Thorsten Hagemann³, G. David Young¹, ¹Flagship Biosciences, LLC., Boulder, CO, USA, ²Gilead Sciences, Seattle, WA, USA, ³Barts Cancer Institute, Queen Mary University of London, London, UK

§59 Photodynamic Therapy (PDT) Applied to the Primary Ehrlich Tumor Induces Inhibitory Effects on a Second Implant of the Same Tumor

Murilo Del-Grande¹, Maria Lucia Zaidan Dagli¹, ¹School of Veterinary Medicine and Animal Science, University of São Paulo, São Paulo, Brazil

60 Mass Spectrometry Imaging of Therapeutic Antibodies: Distribution of Unlabeled Trastuzumab in CB.17 SCID Mice Implanted with the Human Breast BT474 Xenograft

David BONNEL¹, Chassidy HALL², Robert J MULLIN² Kathryn Simon² and Jonathan STAUBER¹, ¹ImaBiotech, Lille, France ²Charles River Discovery Research Services-, North Carolina –Morrisville, USA

61 Mass Spectrometry Imaging in a Toxicology Study: Application in Induced Interstitial Pulmonary Fibrosis (IPF) Model

David Bonnel¹, Mary McElroy², Emeline Falaux¹, Gael Picard De Muller¹, Fabien Pamelard¹, Stephen Madden², Jonathan Stauber¹, ¹ImaBiotech, Lille, France, ²Charles River Discovery Research Services, Edinburgh, UK

62 Use of Legacy Data to Assess Species Concordance for Liver Injury

Stephanie Berry¹, Paul Bradley¹, ¹Instem Scientific, Cambridge, UK

63 Pathology of IL-33 Knock-In Mouse Model of Non-Resolving Inflammation

Maria Cristina De Vera Mudry¹, Juliana Bessa¹, Claas Aiko Meyer¹, Sonja Schlicht¹, Susan H. Smith², Thomas Weiser¹, Thomas Singer¹, Antonio Iglesias¹, Javier Cote-Sierra², ¹F. Hoffmann-La Roche Ltd., Basel, Switzerland, ²Stiefel, Research Triangle Park, NC, USA

64 Integration of MALDI Imaging and Optical Microscopy Allows New Insights into Molecular Distribution in Tissue

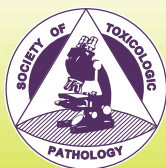
Katherine Kellersberger¹, M. Reid Groseclose², Stephen Castellino², ¹Bruker Daltonics, Billerica, MA, USA, ²GlaxoSmithKline, Research Triangle Park, NC, USA

65 A SEND Solution for Microscopic Pathology, In-Life, and Other Preclinical Toxicology Data Collected Using Multiple LIMS (Laboratory Information Management Systems)

Frederic Mura², Maro Schuster¹, Reto Aerni², Michael Wasko¹, Christina Wuermlin², Rich Buchanan¹, Amelia Bedoan², Laura Kaufman¹, ¹Preclinical Data Systems, Mt. Arlington, NJ, USA, ²Preclinical Data Systems, Basel, Switzerland

66 Characterizing and Diminishing Autofluorescence in Formalin-Fixed Paraffin-Embedded Human Respiratory Tissue

A. Sally Davis^{1,2}, Anke Richter³, Steven Becker¹, Jenna Moyer¹, Aline Sandouk¹, Jeff Skinner¹, Jeffery Taubenberger¹, ¹National Institute of Allergy and Infectious Diseases, Bethesda, MD, USA, ²North Carolina State University College of Veterinary Medicine, Raleigh, NC, USA, ³Defense Resources Management Institute, School of International Studies, Naval Postgraduate School, Monterey, CA, USA



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68 Evaluation of Key Events in the Mode of Action for a Carry-Over Carcinogen in Mice

Charles Wood¹, April Lake^{1,2}, Greg Olson³, Michael George¹, Susan Hester¹, Anthony DeAngelo¹, ¹US Environmental Protection Agency, Research Triangle Park, NC, USA, ²University of North Carolina-Chapel Hill, Chapel Hill, NC, USA, ³Toxicologic Pathology Associates, Jefferson, AK, USA

69 Immunohistochemical Characterization of Carbon Nanotube-Induced Malignant Mesotheliomas in Rats

Susanne Rittinghausen¹, Anja Hackbarth¹, Heinrich Ernst¹, Uwe Heinrich¹, Albrecht Leonhardt², Dirk Schaudien¹, ¹Fraunhofer Institute for Toxicology and Experimental Medicine, Hannover, Germany, ²Leibniz Institute for Solid State and Materials Research, Dresden, Germany

70 Proliferative Lesions in the Rete Ovarii of Aged Han Wistar Rats

Richard Haworth¹, Jaimini Kumar¹, David Lewis¹, ¹GlaxoSmithKline, Ware, UK

71 Early Detection of Carcinogenic Potential of CNT via Cell Proliferation Measurement

Dirk Schaudien¹, Anja Hackbarth¹, Heinrich Ernst¹, Albrecht Leonhardt², Uwe Heinrich¹, Susanne Rittinghausen¹, ¹Fraunhofer Institute for Toxicology and Experimental Medicine, Hannover, Germany, ²Leibniz Institute for Solid State and Materials Research, Dresden, Germany

72 The RITA Database—The Value of Incidences of Tumors in Young Animals

Dirk Schaudien^{1,3}, Rupert Kellner^{1,3}, Matthias Rinke^{2,3}, ¹Fraunhofer Institute for Toxicology and Experimental Medicine, Hannover, Germany, ²Bayer Pharma AG, Wuppertal, Germany, ³RITA-Registry of Industrial Toxicology Animal-Data, Hannover, Germany

73 Effect of Oral (Gavage) Administration of *Euphorbia tirucalli* (Aveloz) on the Ascitic Ehrlich Tumor Growth

Diego Pinha Alvez da Cruz¹, Gregory Mennecier¹, Andréia Latorre², Gokithi Akisue³, Mitsue Haraguchi⁴, Rueda Abu-Said⁵, Maria Lucia Zaidan Dagli¹, ¹University of São Paulo, São Paulo, Brazil, ²Adolpho Lutz Institute, São Paulo, Brazil, ³University of São Francisco, Bragança Paulista, Brazil, ⁴Biological Institute, São Paulo, Brazil, ⁵University of Santa Cruz, Ilhéus, Brazil

74 Immunohistochemical Characterization of ENU-Induced Brain Tumors in F344 Rats

Rebecca Moore¹, Holly Kolenda-Roberts², Nancy Harris¹, Young-Man Cho³, Kumiko Ogawa³, Jerry Hardisty¹, Rodney Miller¹, ¹Experimental Pathology Laboratories, Inc., Research Triangle Park, NC, USA, ²SNBL USA, Ltd., Everett, WA, USA, ³National Institute of Health Sciences, Tokyo, Japan

75 Influence of Processing Methods for Scanning Electron Microscopy in the Detection of Diuron-Induced Ultrastructural Alterations in the Rat Urinary Bladder

Rafaela Fava¹, Ana Paula Cardoso¹, Mitscheli da Rocha¹, Merielen Nascimento e Pontes¹, João Lauro de Camargo¹, Maria Luiza de Oliveira¹, ¹UNESP-São Paulo State University, Botucatu, Brazil

76 Role of Histone Citrullination in Macrophage Extracellular Trap (MET) Release and Characterization of METs in Human Tongue Squamous Cell Carcinoma

Sunish Mohanan^{1,2}, Angela Yan², Lynne Anguish², Dalton McLean², Sachi Horibata², Paul Thompson⁴, Neil A. Iyengar³, Andrew J. Dannenberg³, Scott A. Coonrod², ¹Eli Lilly and Company, Indianapolis, IN, USA, ²Baker Institute, Cornell University, Ithaca, NY, USA, ³Weill School of Medicine, Cornell University, New York, NY, USA, ⁴The Scripps Research Institute, Jupiter, FL, USA

77 NNK and Enantiomers of Its Metabolite, NNAL, Constituents of Tobacco Products, Induce Lung Tumors That Metastasize to Pancreas in F-344 Rats

Ramesh C. Kovi^{1,2}, Charles S. Johnson^{1,2}, Silvia Balbo², Stephen S. Hecht², M. Gerard O'Sullivan^{1,2}, ¹Comparative Pathology Shared Resource, St. Paul, MN, USA, ²Masoni Cancer Center, University of Minnesota, Twin Cities Campus, MN, USA

78 Hitherto Unknown Type of Adenocarcinoma in the Rat Mammary Gland

Heike Marxfeld¹, Silke Treumann¹, Karin Küttler¹, Sibylle Gröters¹, Bennard van Ravenzwaay¹, ¹BASF SE, Ludwigshafen, Germany

79 Epigenetic Regulation of Transcription Factor Promoter Regions by Low-Dose Genistein through MAPK and MSK1 Nongenomic Signaling

Linda Yu¹, Kyle Ham¹, Xiaohua Gao¹, Lysandra Castro¹, Norris Flagler¹, Ray Dong¹, Grace E. Kissling², Trevor K. Archer², Darlene Dixon¹, ¹NIEHS, NTP, Research Triangle Park, NC, USA, ²NIEHS, Research Triangle Park, NC, USA



80 Inhibitory Effects of Pequi (*Cariocar brasiliense* Camb) Oil on Preneoplastic Lesions in a Mouse Hepatocarcinogenesis Model

Simone Morais Palmeira¹, Paula Regina Pereira Silva¹, Cesar Kopi Grisoli², Paulo Hilário Nascimento Saldiva¹, Juliana Shimara Pires Ferrão¹, Maria Lucia Zaidan Dagli¹, Francisco Javier Hernandez-Blazquez¹, ¹University of São Paulo, São Paulo, Brazil, ²Federal University of Brasilia, Brasilia, Brazil

81 Multifunctional Photo-Theranostic Cancer Targeting Nanoporphyrin

Tzu-yin Lin¹, Yuanpei Li¹, Luo Yan¹, Qiangqiang Liu¹, Sebastian Wachsmann-Hogiu¹, Chongxian Pan¹, Kit Lam¹, ¹University of California-Davis, Sacramento, CA, USA

82 Post-Natal Development of the Ovary in the Rat

Catherine Picut¹, Amera Remick¹, Lydia Parker¹, Cynthia Swanson¹, Darlene Dixon², ¹WIL Research, LLC, Hillsborough, NC, USA, ²NIEHS, Research Triangle Park, NC, USA

83 Post-Natal Development of the Testes in the Rat

Catherine Picut¹, Cynthia Swanson¹, Lydia Parker¹, Amera Remick¹, ¹WIL Research, LLC, Hillsborough, NC, USA

84 The Estrous Cycle in Young Sexual Mature Göttingen Minipigs: A Morphologic Approach

Eveline de Rijk¹, Birgit Peter¹, Joost Lensen¹, Helle Lorentsen², Hetty van den Brink¹, ¹WIL Research Europe B.V., 's-Hertogenbosch, The Netherlands, ²Ellegaard Göttingen Minipig A/S, Dalmoose, Denmark

85 Diurnal Variation in Clinical Chemistry Indicators of Liver Injury in Rats and Dogs

Mehrdad Ameri¹, Ryan Morgan¹, Kim Stocking¹, Marnie Higgins-Garn¹, ¹Comparative Biology and Safety Sciences, Amgen Inc., Thousand Oaks, CA, USA

86 Wnt Inhibition Effects on Bone Formation in Preclinical Models Predicts Effects in Patients

Rene Meisner¹, Jie Wei¹, Jalpa Shah¹, Jennifer Cain¹, Tim Hoey¹, ¹OncoMed Pharmaceuticals, Redwood City, CA, USA

87 Ultrastructural Changes in Renal Papillary Duct Epithelium of Rats Treated with Trimethyltin Chloride

Kenichiro Kasahara¹, Hiroshi Edamoto¹, Mizuho Takagi¹, Ryo Ando¹, Kayoko Kudo¹, Rie Andoh¹, Kazutoshi Tamura¹, ¹BoZo Research Center, Inc., Shizuoka, Japan

88 Investigation of CNS Findings Following Raxibacumab Treatment against Inhalation Anthrax in the New Zealand White Rabbit Model

Maggie Dempster¹, Thi-Sau Migone², Sally Bolmer³, John Zhong⁴, Linda Hendey⁵, Dan Sanford⁵, Daphne Vasconcelos⁵, ¹GlaxoSmithKline, King of Prussia, PA, USA, ²Igenica, Burlingame, CA, USA, ³Consultant, San Francisco, CA, USA, ⁴Biogen Idec, Cambridge, MA, USA, ⁵Battelle, Columbus, OH, USA

89 The Histomorphometric Feature of the Femoral Growth Plate in Young Rats under Two-Week Administration of 5-Fluorouracil and Dietary Restriction

Chihiro Noguchi¹, Kenta Matsue¹, Yutaka Nakanishi¹, Fumiko Asanuma², Hiroto Miyata³, Minoru Sasaki¹, Syunsuke Tsutsumi¹, Yasushi Sato¹, ¹Drug Safety and Pharmacokinetics Laboratories, Taisho Pharmaceutical Co., Ltd., Saitama, Japan, ²Regulatory Affairs Division, Taisho Pharmaceutical Co., Ltd., Tokyo, Japan, ³Prescription Drug Pharmacovigilance Division, Taisho Pharmaceutical Co., Ltd., Tokyo, Japan

90 Immunohistochemistry on KIM-1 and BrdU Labeling of Cell Injury and Proliferation from 6-Month Repeated Dose Oral Toxicity Study of Canagliflozin in the Male Rat

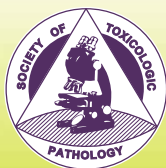
Jing Ying Ma¹, Sandra De Jonghe², Jim Proctor³, Mark D. Johnson³, Rao N. V. S. Mamidi³, Calvert Loudon⁴, Sandra Snook¹, ¹Janssen R&D, LLC, La Jolla, CA, USA, ²Janssen R&D, LLC, Beerse, Belgium, ³Janssen R&D, LLC, Raritan, NJ, USA, ⁴Janssen R&D, LLC, Spring House, PA, USA

91 Interpretation of Rodent Respiratory Histopathology Following Repeat Inhalation Exposures to Agrochemical Aerosols with Irritant Properties

Ronnie Chamanza¹, Jayne A Wright¹, Pramila Singh², Paul Hinderliter², Douglas Wolf², Richard Lewis¹, ¹Syngenta, Jealott's Hill, Bracknell, Berkshire, UK, ²Syngenta, Greensboro, NC, USA

92 Female SDT Fatty Rat Shows Non-Alcoholic Steatohepatitis (NASH)-Like Hepatic Lesions

Katsuhiro Miyajima¹, Takeshi Ota², Yoshiaki Katsuda², Yukihito Ishii², Kochi Kakimoto¹, Yuzo Yasui¹, Yusuke Kemmochi¹, Akiko Anagawa-Nakamura¹, Kaoru Toyoda¹, Eriko Tanigai¹, Akemi Takahashi¹, Yoshifumi Miyakawa², Toshiyuki Shoda¹, ¹Japan Tobacco Inc. Central Pharmaceutical Research Institute, Hadano, Kanagawa, Japan, ²Japan Tobacco Inc. Central Pharmaceutical Research Institute, Takatsuki, Osaka, Japan



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93 Histopathological Effects of Enrofloxacin in the Chicken Gastrocnemius Tendon

Uriel Blas-Machado¹, Sarah Quattlebaum¹, Deborah Keys¹, Jian Zhang¹, Jaroslava Halper¹, ¹University of Georgia, Athens, GA, USA

94 Conduritol β -Epoxide-Induced Neuroinflammation in C57Bl/6J Mice: A Translational Drug Discovery Tool for Neuropathic Gaucher Disease

Dinesh Bangari¹, John Marshall¹, Errin Roberts¹, Amy Allaire¹, Eva Budman¹, John Leonard¹, Beth Thurberg¹, ¹Genzyme, Framingham, MA, USA

95 Normal Anatomy, Histology and Spontaneous Pathology of the Nasal Cavity of the Cynomolgus Monkey

Ronnie Chamanza^{1,2}, Ian Taylor³, Colin Hill³, Mark Swann³, Joel Goodchild³, Kane Goodchild³, Jane Schofield³, Mark Aldous³, Michela Gregori², Vasanthi Mowat², ¹Syngenta Limited, Jealott's Hill, Bracknell, Berkshire, UK, ²Huntingdon Life Sciences, Huntingdon, Cambridgeshire, UK, ³Huntingdon Life Sciences, Eye, Suffolk, UK

96 Background Incidence of Spontaneous Adrenal Gland Lesions of Control Charles River CD-1 Mice (CrI: CD-1(ICR) BR) Used in 104-Week Toxicity Studies

Claudio Petterino¹, Stuart Naylor¹, Sydney Mukaratirwa¹, Alys Bradley¹, ¹Charles River, Ltd., Trarant, UK

97 Mesenchymal Tissue Formation in Renal Tubule Lumen of Cyclosporine-Induced Acute Kidney Injury in a Cynomolgus Monkey

Kiyonori Kai¹, Satoko Sato¹, Kayoko Ishikawa¹, Takashi Yamaguchi¹, Munehiro Teranishi¹, Wataru Takasaki¹, ¹Daiichi Sankyo Co., Ltd., Tokyo, Japan

98 Exogenous Human Thioredoxin-1 Ameliorates Acetaminophen-Induced Acute Liver Toxicity and Liver Failure through Reducing Peroxynitrite and Inhibiting Degradation of Endogenous Thioredoxin-1

Byungwoo Lee¹, Jonghyeok Ko¹, Seonyong Kim¹, Byungil Yoon¹, ¹Kangwon National University, Chuncheon, Gangwon-do, Republic of Korea

99 Comparative Histology of Mouth Mucosae (Sublingual Region)

Catherine Thirion-Delalande¹, Cécile Fisch², Roy Forster¹, Bernard Palate¹, ¹CiToxLAB, Evreux, France, ²Stallergenes S.A., Antony, France

§100 Non-Neoplastic Histologic Cutaneous Background Lesions in Göttingen Minipigs and Findings at Treatment Control Sites

Charlotte Hollinger¹, Keith Nelson^{2,1}, ¹Department of Pathobiology and Diagnostic Investigation, Michigan State University, East Lansing, MI, USA, ²MPI Research, Mattawan, MI, USA

101 Temporal Patterns of Candidate Biomarkers of Vascular Injury in the IL2 Rat Model

Cristina Bertinetti-Lapatki¹, Natalie Keirstead², Denise Knapp¹, Igor Mikaelian³, James R. Turk⁴, Bradley E. Enerson⁵, Holly W. Smith⁶, ¹Hoffmann-La Roche, Inc., Basel, Switzerland, ²AstraZeneca, Waltham, MA, USA, ³Abbvie, Inc., Worcester, MA, USA, ⁴Amgen, Inc., Thousand Oaks, CA, USA, ⁵Pfizer, Inc., Groton, CT, USA, ⁶Eli Lilly, Indianapolis, IN, USA

102 Renal Epithelial Hyperplasia Caused by Urinary Crystals of a Novel GKA and Its Metabolites after Acute Dosing in Sprague Dawley Rats

ES Tien³, NE Everds², JR Turk¹, MP Nguyen², Q Ye⁴, P Cao⁴, L Jim⁴, KA Samoya⁴, PD Schnier⁴, RC Kelly⁴, JF Schroeder¹, CA Afshari¹, ¹Amgen, Inc., Thousand Oaks, CA, USA, ²Amgen, Inc., Seattle, WA, USA, ³Amgen, Inc., Cambridge, MA, USA, ⁴Amgen, Inc., South San Francisco, CA, USA

103 Drug Candidate-Induced Changes in the Thyroid Gland: Contrasting Case Studies

Joan Lane¹, Doriana Froim¹, Daniel Aleksandrowicz¹, Jeffrey Horrigan¹, Katie Zokowski¹, Ken Loveday¹, David Peters¹, Evelyn Polack¹, ¹Biogen Idec, Inc., Cambridge, MA, USA

104 Characterization of a Minipig Model of Gastrointestinal Acute Radiation Syndrome Using Total Body Irradiation and Partial Body Irradiation: A Focus on Intestinal Pathology

Julius Haruna¹, Wieslaw Wierzbicki², Mylene Pouliot¹, Leanne Bossett¹, Alexis Ascah¹, Simon Authier¹, ¹CiToxLAB North America, Laval, QC, Canada, ²Centre Vétérinaire DMV, Lachine, QC, Canada

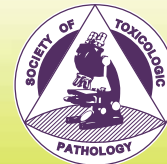
105 Mechanisms of Acquired Resistance to Toleranib Phosphate (Palladia®) in Canine Mast Cell Tumor

Charles Halsey¹, Daniel Gustafson¹, Barbara Rose¹, Robert Burnett¹, Dawn Duval¹, Anne Avery¹, Donald Backos², Philip Reagan², Douglas Thamm¹, ¹Colorado State University College of Veterinary Medicine and Biomedical Sciences, Fort Collins, CO, USA, ²University of Colorado Health Science Center, Aurora, CO, USA



TRANSLATIONAL PATHOLOGY:
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7:00 PM–10:00 PM

**Cocktail Reception Sponsored by
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All STP attendees and guests are invited.

Monday, June 23

7:00 AM–8:00 AM

**Continental Breakfast Sponsored by
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Monday, June 23

7:00 PM–10:00 PM

Reception Sponsored by EPL

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Tuesday, June 24

12:00 Noon–1:30 PM

Exhibitor Sponsored Lunch

Exhibit Hall C

All registered scientific attendees are invited.

EXHIBITOR/SPONSOR HOSTED SESSIONS

Monday, June 23

12:15 PM–1:15 PM

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Advance registration is requested.

***From Bit to Bedside—Digital Pathology Lessons from
Pharma***

As regulatory hurdles surround the use of whole slide images for making primary diagnoses in human medicine, and GLP inhibits its use by toxicopathologists, the transformative potential of this technology is largely overlooked. The value of whole slide imaging is not because pathologists will eventually make diagnoses while looking at a monitor, rather its value is that it will change anatomic pathology from a primarily descriptive to a primarily quantitative discipline.

Tuesday, June 24

7:00 AM–8:00 AM

**Marshall BioResources and
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Madison Room

Histopathology of the Göttingen Minipig

The session provides an over view of the minipig in safety assessment studies, highlighting their advantages and disadvantages. The focus will be on unusual histological features and background pathology. Special attention will be given to the male and female reproductive tracts and sexual maturity.

Exhibitors

Microscope and Digital Slide Viewing Area

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Please bring any slides you would like to discuss with colleagues.

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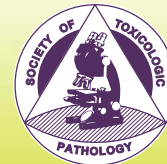
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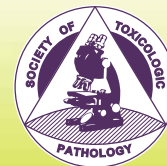
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Fraunhofer ITEM is part of the Fraunhofer society, Europe's largest application-oriented research organization. Among other services Fraunhofer ITEM provides high quality inhalation studies including nanoparticles and carbon nanotubes. At the institute the RITA (Registry of Industrial Toxicology Animal-data) database is located which contains historical control data of peer-reviewed histopathological diagnoses of incidences of tumors and other proliferative lesions from more than 26,000 rodents. ITEM also developed the goRENI information system, which is used for the INHAND nomenclature.

Categories: Cancer Biology/Carcinogenicity, Environmental Health, Inhalation Research/Testing, Pathology



Exhibitor Directory



Washington, DC

Marriott Wardman Park Hotel

33rd Annual Symposium

June 22–26, 2014

HistoTox Labs, Inc.

310

5541 Central Avenue, Suite 160
Boulder, CO 80301
Tel: 303-633-5401
Fax: 303-565-3764
Email: jbishop@histotoxlabs.com
Website: www.histotoxlabs.com

HistoTox Labs is a GLP compliant contract laboratory performing routine and specialized Histology, Immunohistochemistry and Pathology services for toxicity, arthritis, cancer, and inflammation related studies. Additional services include decalcified bone techniques, antibody optimization, full slide scanning, image analysis, special stains and frozen techniques. Our commitment to outstanding customer service, high quality sections, competitive pricing and quick turnaround times, have made HistoTox Labs the ideal source for reliable histopathology services for over 10 years.

Categories: GLP–Good Laboratory Practice Services, Histology, Histopathology, Immunohistochemistry Research/Supplies

HSRL, Inc. (Histo-Scientific Research Labs)

302

5930 Main Street
Mt. Jackson, VA 22842
Tel: 540-47-4440
Fax: 540-477-4448
Email: pschwartz@hsrl.org
Website: www.hsrl.org

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Categories: Archiving/GLP Compliant Archiving, Histology, Immunohistochemistry Research/Supplies, Pathology

IDEXX Bioresearch

217

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Tel: 207-556-8620
Email: melissa-terrano@idexx.com
Website: www.idexxbioresearch.com

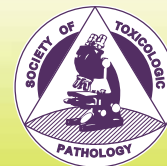
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Categories: Hematology, Immunology Research/Testing, Instruments, Pathology



TRANSLATIONAL PATHOLOGY:
Relevance of Toxicologic Pathology to Human Health

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Society of Toxicologic Pathology

Indica Labs

314

2469 Corrales Road, Building D, Suite D
Corrales, NM 87048
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Categories: Data Acquisition, Immunohistochemistry Research/Supplies, Software

Instem

300

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Categories: Data Acquisition, Data Management, Data Reporting Systems, Software

International Academy of Toxicologic Pathology (IATP)

315

116 White Owl Trail
Mullica Hill, NJ 08062
Tel: 856-233-5174
Email: iatpfellows@verizon.net
Website: www.iatpfellow.org

The International Academy of Toxicologic Pathology (IATP) objectives are to establish standards of excellence in education, training, and practice in toxicologic pathology; to advise government policy leaders on issues relevant to toxicology and pathology; and to develop expert opinions on issues relevant to toxicologic pathology. Academy fellows are scientists globally recognized by their peers based on highest professional accomplishments in toxicologic pathology and scientific contributions.

We will have a double-headed microscope available and invite you to bring along histologic slides and/or data to share and get a "second opinion." IATP Fellows will be at the booth during all coffee breaks.

Categories: Accreditation, Consulting Services, Education, International Organizations



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June 22–26, 2014

Leica Biosystems Imaging, Inc.

304

1360 Park Center Drive
Vista, CA 92081
Tel: 760-539-1100
Fax: 760-539-1164
Email: aperio@leicabiosystems.com
Website: www.leicabiosystems.com/aperio

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Categories: Archiving/GLP Compliant Archiving, Image Capture Devices, Pathology

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Categories: Animal Husbandry, Animal Models, Animal Use & Welfare, Cells/Tissues

microDimensions

213

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Email: sales@micro-dimensions.com
Website: micro-dimensions.com

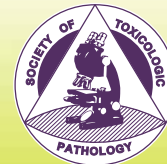
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Categories: Histopathology, Pathology, Research, Software



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Society of Toxicologic Pathology

NeuroScience Associates

311

10915 Lake Ridge Drive
Knoxville, TN 37934
Tel: 865-675-2245
Fax: 865-675-2787
Email: chris@nsalabs.com
Website: www.nsalabs.com

NeuroScience Associates (NSA) provides mass production neurohistology services for safety and R&D studies utilizing proprietary MultiBrain® technology. NSA specializes in the design and execution of safety studies including GLP safety certifications, low-cost R&D safety screens and evaluations. NSA also provides neurohistology services for R&D including traditional histology staining, immunohistochemistry, specialty stains for Alzheimer's pathology and silver stains for disintegrative degeneration.

Categories: CRO—Contract Research Organization, High-Throughput Test Systems, Pharmaceutical Product Safety/Toxicology, Preclinical Research/Testing

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Categories: Computing Systems, Data Acquisition, Pathology, Software

Premier Laboratory, LLC

301

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Categories: CRO—Contract Research Organization, GLP—Good Laboratory Practice Services, Histology, Immunohistochemistry Research/Supplies



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Washington, DC

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QPS, LLC

400

Three Innovation Way, Suite 240
Newark, DE 19711
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Fax: 302-369-5602
Email: bhavna.malhotra@qps.com
Website: www.qps.com

QPS is a GLP/GCP-compliant contract research organization. We provide quality services to pharmaceutical and biotechnology clients worldwide. Our core competencies include DMPK, Toxicology, Bioanalysis, Translational Medicine, Early Stage Clinical Research, Phase 2–4 Clinical Research and Program Management. At QPS-CTPS Taiwan, our commitment is to provide our valued customers with a fast and reliable route to clinical phase 1–2 studies. We offer a wide range of toxicology and DMPK studies as well as other preclinical safety tests that are essential for drug development programs.

Categories: Bioanalytical Services, GLP—Good Laboratory Practice Services, Histopathology, Preclinical Research/Testing

Society of Toxicologic Pathology (STP)

402

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Reston, VA 20190
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Fax: 703-438-3113
Email: stphq@toxpath.org
Website: www.toxpath.org

The Society of Toxicologic Pathology (STP) is a nonprofit association of pathologists and other scientists whose principal aim is the advancement of pathology as it pertains to changes elicited by pharmacological, chemical and environmental agents, and factors that modify these responses. The Society's Vision: Be an international leader for improvement of human, animal, and environmental health using an interdisciplinary scientific approach based in pathology and toxicology. This vision will be accomplished through four primary goals: advocacy, education, globalization, and recruitment.

Categories: Education, Organizations, Pathology

Visiopharm

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Broomfield, CO 80038
Tel: 877-843-5268 x705
Fax: 877-843-5268
Email: sales@visiopharm.com
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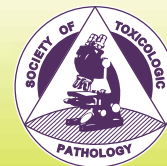
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Categories: Microarrays, Pathology, Research, Software



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Society of Toxicologic Pathology

WIL Research

307

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Ashland, OH 44805
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Email: info@wilresearch.com
Website: www.wilresearch.com

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Categories: Clinical Pathology, CRO—Contract Research Organization, Histopathology, Pathology

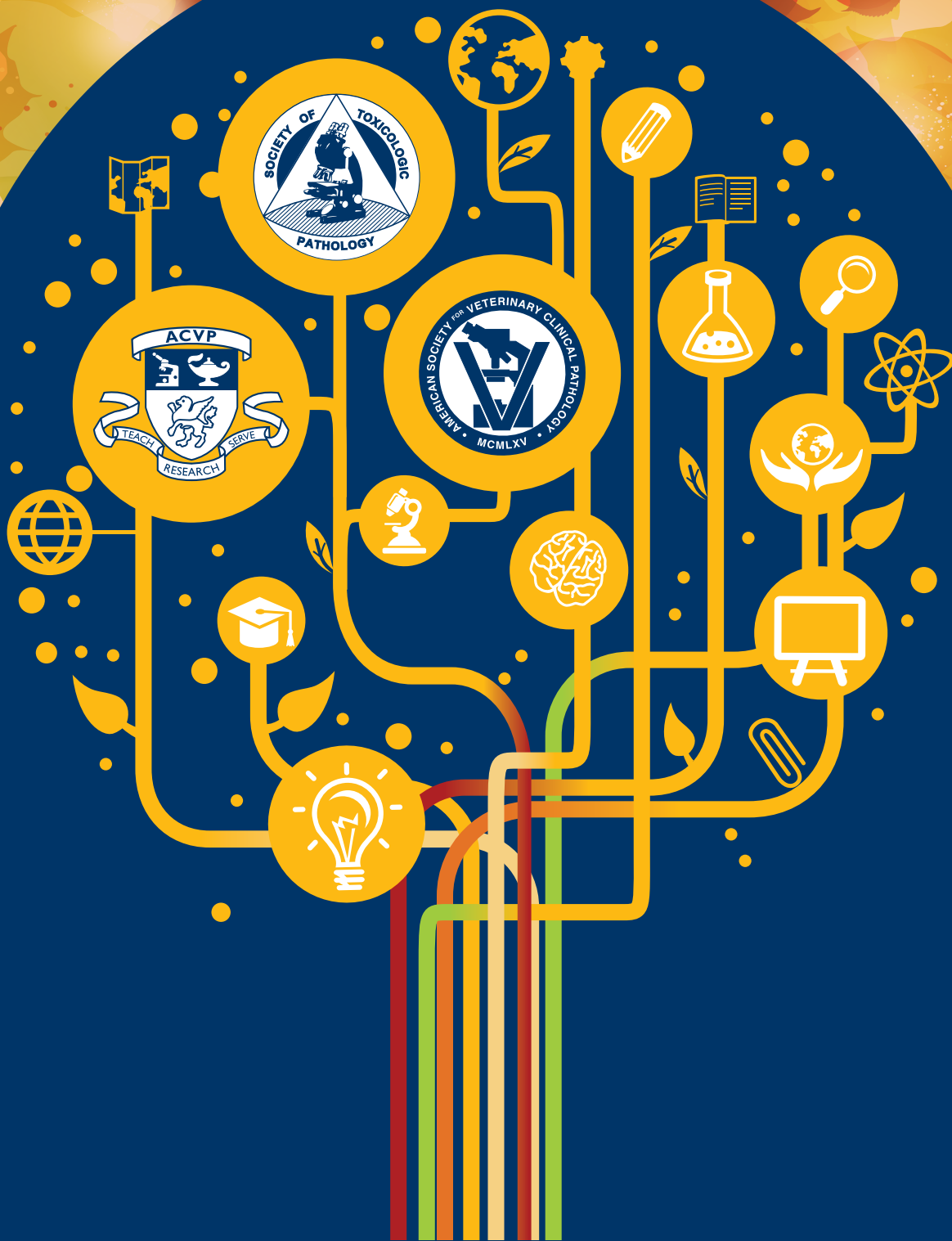
Xybion Medical Systems

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Categories: Computing Systems, Data Management, Data Reporting Systems



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Combined Annual Meeting | October 17-21, 2015
Minneapolis Convention Center and Hyatt Regency Minneapolis Hotel

33rd Annual Symposium

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