

# General Information

## Symposium: Cancer

Washington, D.C.  
June 21–25, 2009

## Symposium: Cancer

*Symposium Co-Chairs: Jerrold M. Ward, DVM, PhD, DACVP, Global VetPathology, Montgomery Village, MD, and Kathleen A. Funk, DVM, PhD, DACVP, EPL, Inc., Sterling, VA*

The 2009 STP Symposium will cover the broad topic of Cancer in animals and humans. Cancer is a major cause of death in humans throughout the world. Cancer involves all organ systems and has many etiologies including chemicals, viruses, and irradiation but also has many important modifying factors such as genetics and diet. Cancer is the endpoint of a multistage process which begins as focal hyperplastic lesions and progresses, often through benign neoplasia, to malignant neoplasia. Toxicologic pathologists are often involved in studies involving tumors as an endpoint, including basic cancer research, studies with genetically engineered mice, and toxicology and carcinogenicity assays for safety assessment of chemicals. This symposium will cover various aspects of cancer: human cancer, cancer biology, mechanisms of carcinogenesis, regulation of carcinogens, use of genetically engineered mice for carcinogenesis bioassays, and tumor pathology. Continuing education courses on cancer drug development and other subjects with the Saturday NTP session, emphasizing tumor pathology, rounds out the Symposium on Cancer.

### U.S. Government Employees Invited to Attend Tuesday Sessions (Free Session, Advance Registration Required by June 1)

The scientific sessions on Tuesday, June 23, have been designed in response to requests from the Federal regulatory community. "Alternative Mouse Models for Carcinogenicity Assessment" (Tuesday morning) and "Background Disease in Animal Models of Toxicity: Relevance and Interpretation in Risk Assessment" (Tuesday afternoon) will be open at no cost to U.S. government employees as well as those registered as a full meeting attendee.

### Continuing Education

#### NTP Satellite Symposium Saturday, June 20

(9:00 AM–4:30 PM) Free Event; registration required

#### Tumor Pathology and INHAND Nomenclature

*Chair: Susan A. Elmore, MS, DVM, DACVP, National Institute of Environmental Health Sciences, Research Triangle Park, NC*

The objectives of this symposium are to provide continuing education on interpreting pathology slides, to generate lively and productive conversation, and to have a good time! The theme for the symposium this year is tumor pathology, corresponding with the STP meeting theme of cancer. The American Association of Veterinary State Boards (AAVSB) has approved the NTP Symposium for five and one-half (5.5) hours of RACE continuing education credits.

#### Continuing Education Courses Sunday, June 21

*Continuing Education Course Chair: Brian R. Berridge, DVM, PhD, DACVP, GlaxoSmithKline, Research Triangle Park, NC*

There will be four half-day CE sessions in 2009, two concurrent morning courses and two concurrent afternoon courses.

Additional fees required

#### Sunday, June 21 AM Concurrent Sessions

CE 1—Cancer Therapeutics, Development Strategies in the Era of Targeted Therapies

CE 2D Drug-Induced Hematotoxicity What's New?

#### Sunday, June 21 PM Concurrent Sessions

CE 3—Unintended Mechanism-Based Adverse Events Associated with Cancer Chemotherapy

CE 4—Drug Development for Pediatric Populations

#### Continuing Education Credits AAVSB RACE Provider #56

STP is an approved provider for the American Association of Veterinary State Board (AAVSB) RACE continuing education credits as in past years. The continuing education courses during the Annual Meeting have been approved for continuing education credit in the medical/surgical category in jurisdictions that recognize AAVSB RACE approval. **Four credits** will be given for CE 1, CE 2, CE 3, and CE 4. Participants should be aware that some boards have limitations on the number of hours accepted in certain categories and/or restriction on certain methods of delivery. **Twenty hours** of classroom delivery credit is expected to be given for attendance at the scientific sessions. Certificates of attendance will be provided at the conclusion of each course and on Thursday for the scientific sessions.



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### Exhibit Installation Dates

Saturday, June 20 ..... 1:00 PM–4:00 PM  
 Sunday, June 21 ..... 8:00 AM–3:00 PM  
**All exhibits must be set up by 3:00 PM.**

### Exhibit Hall Hours

Sunday, June 21 ..... 5:15 PM–6:45 PM  
 Monday, June 22 ..... 7:00 AM–11:00 AM  
 12:00 PM–4:30 PM  
 Tuesday, June 23 ..... 7:00 AM–4:00 PM  
 Wednesday, June 24 ..... 7:00 AM–1:00 PM  
**Exhibitor tear down is 1:00 PM–5:00 PM.**

### Meeting Events

#### Exhibits Opening

##### Exhibit Hall C (lower level)

The Exhibit Hall will be open on Sunday evening, June 21 from 5:15 PM–6:45 PM.

#### Internet Caf 

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

#### Student Outing

All students are cordially invited to the Society of Toxicologic Pathology Student/Trainee Outing at the National Zoo on Tuesday afternoon, June 23, 2009. All Students Registrants will receive an invitation via e-mail.

This is a chance to meet fellow students and interact with scientists representing all facets of the Society as you discuss your future and the various career paths available to you. The STP will be designating members to act as mentors for each student who attends, so this will be a great opportunity for one-on-one discussions, as well as for networking with your STP colleagues. Lunch will be provided. This function has been the highlight of past meeting for many students.

Details will be e-mailed to student registrants as they are finalized. Registration by June 3 will help to ensure early contact with your mentor(s), however we will try to accommodate all students/trainees interested in attending.

#### President's Gala Reception

##### Salon 1

The President's Gala Reception will be held on Wednesday evening, June 24, from 7:00 PM–9:00 PM. One ticket to this event is provided to Member, Non-Member, Exhibitor, and Student registrants as well as registered Spouse/Guests. Additional tickets can be purchased on-site. Attire is casual.

#### Town Hall Meeting

##### Thurgood Marshall Ballroom

#### International Recognition of Qualified Toxicologic Pathologists

Plan to attend the Town Hall Meeting Monday, June 22, at 5:30 PM–6:30 PM to hear presenters express differing viewpoints on the proposed recognition process followed by a spirited debate and audience participation. (See page 22 for additional details.)

The International Federation of Societies of Toxicologic Pathology, of which the STP is a member, has been deliberating the implementation of a global process for recognizing qualified toxicologic pathologists. The initial proposal is to develop a mechanism to recognize those individuals engaged in regulatory-type (GLP) nonclinical toxicology studies. The rationale for instituting such a scheme, and for limiting recognition at first to anatomic pathologists performing safety assessment functions, has been described in a document recently published in *Toxicologic Pathology* (37:553-561) slated for simultaneous publication in the other leading journals of toxicologic pathology ([www.toxpath.org/membersonly/pos](http://www.toxpath.org/membersonly/pos) or [www.toxpath.org/AM2009/agenda.asp](http://www.toxpath.org/AM2009/agenda.asp)).

The STP Executive Committee (EC) seeks to understand the opinions of the Society's membership before making a decision regarding whether or not to endorse such a global recognition mechanism. STP members will be requested to participate in a formal survey which will be e-mailed in late June 2009.

#### Awards Ceremony/Annual Business Meeting

##### Thurgood Marshall Ballroom

The Awards Ceremony will take place on Wednesday evening, June 24, at 5:30 PM. Student award winners and outgoing Committee chairs will be recognized at this time. The Annual Business Meeting will be held immediately following the Awards Ceremony.

#### Registration Desk Hours

Friday, June 19 ..... 4:00 PM–6:00 PM  
 Saturday, June 20 ..... 8:00 AM–6:00 PM  
 Sunday, June 21 ..... 7:00 AM–6:00 PM  
 Monday, June 22 ..... 7:00 AM–5:30 PM  
 Tuesday, June 23 ..... 7:30 AM–5:30 PM  
 Wednesday, June 24 ..... 7:30 AM–5:30 PM  
 Thursday, June 25 ..... 7:30 AM–12:00 NOON

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### Registration Materials

Badges, event tickets (and ribbons if appropriate) will not be mailed this year. All registered attendees may pick up their badges and other meeting materials at the registration desk (see registration hours on page 8).

### New This Year!



#### Download Abstracts, Attendee List from STP Web Site

In an effort to become more environmentally conscious and also allow STP to redirect funds to enhance Annual Meeting programs, the full *Program*, and *Attendee List* will not be printed this year in the on-site *Program* booklet, but will be available on the STP Web site prior to the meeting. A schedule of events including exhibitor information and sponsor acknowledgements will be available on-site in a smaller booklet format. We also encourage you to bring last year's meeting bag to the meeting this year, as bags will not be provided at registration. Continuing Education books and CD ROMs (CE 1 through 4) will be printed and available in each designated course room.

### Hotel Information

#### MARRIOTT WARDMAN PARK HOTEL

##### Internet Access

High speed Internet access is available for \$9.95 per day, which can be accessed in the lobby and guest rooms. An Internet Café will also be provided in the Exhibit Hall during exhibit hours.

**Marriott Wardman Park Hotel**  
2660 Woodley Road, NW  
Washington, District of Columbia 20008

**Phone:** 202-328-2000  
**Fax:** 202-234-0015

**On-line Hotel Reservations**  
<http://cwp.marriott.com/wasdt/stp/>

PLEASE VISIT THE STP WEB SITE  
For up-to-date hotel information at  
<http://www.toxpath.org/am2009/hotel.asp>.

### About Washington, D.C.

Washington, D.C. is located on the north bank of the Potomac River and is bordered by the states of Virginia and Maryland. As the seat of the U.S. government, it is the home of the President, senators, U.S. representatives, and ambassadors and representatives from nearly every country in the world. It is an intriguing city and also a beautiful one with abundant open spaces and parks and an absence of high rises in the vicinity of the National Mall due to its building height restrictions. Be sure to plan time before or after the meeting to experience the many treasures Washington, D.C. has to offer. Most of the sites below are easily accessible via Metrorail. The Woodley Park-Zoo/Adams Morgan stop is right outside the hotel on Connecticut Avenue (escalator, elevator, and stair entrances).

You are encouraged to plan time before or after the meeting to explore this fascinating and beautiful city. Washington, D.C. offers a tremendous variety of sights and activities for attendees and families and most are just a few subway stops from the Wardman Park hotel via Metro.

The National Zoo (no fee), which is the home of 2,000 animals of 400 different species, is less than a half mile from the hotel. Its best known residents are the giant pandas, Tian Tian, Mei Xiang, and their cub, Tai Shan.

The Smithsonian Institution (no fee) ([www.si.edu](http://www.si.edu)), includes The Air and Space Museum, National Gallery of Art, National Portrait Gallery, Natural History, American History, American Indian Museum, and African Art Museum and 12 other museums. Visit [www.si.edu](http://www.si.edu) for more details. Free highlights tours are offered at most Smithsonian museums.

The International Spy Museum (fee) is the only public museum in the United States solely dedicated to the tradecraft, history, and contemporary role of espionage. Artifacts of international espionage from a 1777 letter by George Washington authorizing a New York spy network to a 1980s coat with a camera concealed in a button bring to life the people and techniques behind some of the most influential espionage actions in world history.

Narrated tours are an ideal way to learn about the history and architecture and visit the many monuments and memorials in the city. Most offer the option to visit sites as long as you would like, then board another tour bus to the next site. Links to tour operators are posted on the STP Web site and information is also available at the concierge desk at the Marriott Wardman Park.

Another popular way to see Washington, D.C. is by boat. Several cruise operators offer afternoon and evening tours on the Potomac River. These are also posted on the Web site.



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*The White House*

Popular sites just outside the city in Virginia, are Arlington National Cemetery, Mount Vernon, George Washington's home, and a number of wineries that are located a 60- to 90-minute drive from the city.

For more information about Washington, D.C., visit: [www.washington.org](http://www.washington.org)

### Washington, D.C. Activities

#### Destination D.C.

The National Zoo (<http://nationalzoo.si.edu/>)

#### Washington Nationals Baseball



The Washington Nationals play the Boston Red Sox on Tuesday, June 23, during the STP Annual Meeting!

#### National Monuments and Memorials

- Capitol Building
- Jefferson Memorial
- Korean War Memorial
- Library of Congress
- Lincoln Memorial
- Washington Monument
- The White House
- World War II Memorial
- Vietnam Memorial

#### Museums (Smithsonian Web site: [www.si.edu](http://www.si.edu))

- Air and Space Museum
- American History Museum
- American Indian Museum
- Holocaust Museum
- International Spy Museum
- National Museum of African History and Culture
- National Museum of Crime and Punishment
- Newseum
- Postal Museum

#### Art Galleries

- African Art Museum
- Hirshhorn
- Freer Gallery
- National Gallery of Art
- National Portrait Gallery
- National Sculpture Garden
- Phillips Collection
- Sackler Gallery

#### In nearby Virginia

- Arlington National Cemetery
- Mount Vernon George Washington's Home
- Udvar-Hazy Air and Space Museum (at Dulles Airport)
- Wineries

#### Tours

- Bike and Roll Washington D.C.
- City Segway Tours
- Historic Tours of America
- Spirit Cruises Washington D.C.
- Tourmobile Sightseeing
- Washington Photo Safari

#### Wolf Trap National Park for the Performing Arts.



Several concerts are scheduled during the STP Annual Meeting. See Web site ([www.wolf-trap.org](http://www.wolf-trap.org)).

#### Web sites about Washington, D.C.

- Smithsonian ([www.si.edu](http://www.si.edu))
- Destination D.C. ([www.washington.org](http://www.washington.org))
- District of Columbia ([www.dc.gov/index.asp](http://www.dc.gov/index.asp))

#### Temperature/Attire

The average June temperature in Washington, D.C., is 84° F (29° C). Casual, comfortable attire is appropriate. Please bring sweater or light jacket for the air-conditioned meeting rooms.

#### Taxes & Tipping

The District of Columbia has a statewide general sales tax rate of 5.75%. A 10% tax rate applies for restaurants and take out.

A 15–20% tip is customary in restaurants if not already included in the bill.

#### Time Zone

Washington, D.C., is on Eastern Daylight Savings Time in the summer.



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### Travel Information

#### Non U.S. Citizens

Please visit <http://travel.state.gov> for current information about requesting documentation for travel to the U.S. Citizens of some countries will require a Visa.

#### New on-line authorization requirement for Visa Waiver Program Countries

Beginning January 12, 2009, all nationals and citizens of Visa Waiver Program (VWP) countries will be required by law to obtain a travel authorization prior to initiating travel to the United States under the VWP. This authorization may be obtained on-line through the Electronic System for Travel Authorization (ESTA™), a free Internet application administered by the Department of Homeland Security (DHS) through a U.S. government Web site.

DHS does not charge VWP travelers a fee for completion of an ESTA™ application. Eligible visitors seeking to travel to the United States under the VWP may apply for travel authorization via the ESTA™ Web site at <https://esta.cbp.dhs.gov>.

### Air, Car, Ground Transportation

#### AIRPORTS

##### Ronald Reagan Washington National (DCA)

9 miles from Marriott Wardman Park

- The hotel does not provide shuttle service.
- Subway service, fee: \$1.35-\$2.55 USD (one way)
- Estimated taxi fare: \$18 USD (one way)

##### SuperShuttle at Reagan Airport

Door-to-door service is available at Reagan Airport. Shuttles operate on a shared ride-on demand basis. For information, call 1-800-BLUEVAN or go to [www.supershuttle.com](http://www.supershuttle.com).

Upon arrival proceed to the outside curb and contact the SuperShuttle representative. After hours, call 1-800-258-3826 and press 1 for dispatch or 2 for reservations.

##### Metrorail from Reagan Airport

The Washington, D.C. Metrorail system has an elevated Metrorail station connected to the concourse level of terminals B and C at Reagan National Airport. Metrorail fare cards may be purchased at machines located at all entrances to the Airport Metrorail station. The station is also fully accessible via elevators.

#### How to access the Metrorail station from the Terminals:

**Terminal B and C:** Use either of two enclosed pedestrian bridges on the concourse level which connect directly to the station.

**Terminal A:** Exit the terminal to the streetside curb, and board any Airport Shuttle bus. At the stops for Parking Garages B and C (bus shelter #3 and bus shelter #5) you may access an enclosed bridge which connects to the Metrorail station.

#### How to access the Terminals from the Metrorail station:

**Terminal C:** Go to the north end of the train platform and exit the station. A pedestrian bridge connects directly to the Terminal's concourse level.

**Terminal B:** Go to the south end of the train platform and exit the station. A pedestrian bridge connects directly to the Terminal's concourse level.

**Terminal A:** Go to either end of the train platform and exit the station towards the parking garage. Take elevator or stairway down to street level and board any "Airport Shuttle" bus.

**Elevator Access:** The elevator is located at the center of the platform. There is a sloped sidewalk at ground level which connects to both pedestrian bridges.

For more Metrorail information, call 202-637-7000; TDD 202-638-3780. Or visit the Transit Authority's Web site, [www.wmata.com](http://www.wmata.com).

#### OTHER AIRPORTS

##### Washington, D.C./Dulles (IAD)

25 miles from Marriott Wardman Park

- The hotel does not provide shuttle service
- There is no Metro stop at Dulles
- Estimated taxi fare: \$55 USD (one way)

##### SuperShuttle at Dulles Airport:

Door-to-door service is available at Dulles Airport. Shuttles operate on a shared ride-on demand basis. For information, call 1-800-BLUEVAN or go to [www.supershuttle.com](http://www.supershuttle.com).

Upon arrival proceed to the outside curb and contact the SuperShuttle representative. After hours, call 1-800-258-3826 and press 1 for dispatch or 2 for reservations.



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### Driving directions from Dulles Airport:

Follow the signs to Interstate 66 East to Washington. Follow I-66 to the Theodore Roosevelt Bridge (US Route 50). Take the Constitution Ave. exit off of the bridge. Continue on Constitution for 6 blocks and make a left turn onto 17th Street. This will change to Connecticut Ave. Continue on Connecticut Ave. for 1 mile. Cross over the William Taft Bridge. Make a left turn at the 3rd light after the bridge onto Woodley Ave. The hotel entrance is on the left.

### Baltimore/Washington International Thurgood Marshall Airport (BWI)

33 miles from Marriott Wardman Park

- The hotel does not provide shuttle service.
- Alternate Transportation: Amtrak to Union Station–Metro to hotel
- Estimated taxi fare: \$60 USD (one way)

### Driving directions from BWI:

Take I-95 South to I-495 West. Take Exit 33, Connecticut Ave. Southbound. Continue on Connecticut Ave. for about 6.5 miles. Turn right onto Woodley Road. The hotel entrance is on the left.

### Ground Transportation

(Distances listed are from the Headquarters hotel)

#### Bus Station:

Union Station (5.0 mi)

#### Train Station:

Union Station (8.0 mi)

#### Metro (subway system):

The Woodley Park Metro stop (Red line) is adjacent to the hotel property.

Metro map and fare and accessibility information:

[www.wmata.com/rail/maps/map.cfm](http://www.wmata.com/rail/maps/map.cfm)

#### Metrorail fares:

Metrorail passes may be purchased from vending machines (small bills) in the metrorail stations, or on-line for U.S. residents. A one-day unlimited pass is available.

Regular fare (In effect on weekdays from 5:00 AM–9:30 AM, 3:00 PM–7:00 PM.)

- \$1.65 minimum
- \$4.50 maximum

#### Reduced Fare (All other times)

- \$1.35 minimum
- \$1.85 mid-range
- \$2.35 maximum

### CAR RENTAL

Major car rental companies are available at all three area airports.

#### Marriott Wardman Park parking fees are:

- On-site parking, fee: \$17 USD hourly, \$31.36 USD daily
- Valet parking, fee: \$36.96 USD daily



Washington, D.C., Tidal Basin

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### Restaurant Guide (Within walking distance from the Hotel)

Average per person for a (3) course dinner: \$ = under \$25 \$\$ = \$25–\$35 \$\$\$ = \$35–\$45 \$\$\$\$ = \$45 and above

Ardeo	\$\$\$	American	3311 Connecticut Ave.	(202) 244-6750
Stone's Throw Restaurant	\$\$\$	American Steak House	2660 Woodley Rd.	(202) 328-2936
Petit Plats	\$\$	French Bistro	2653 Connecticut Ave.	(202) 518-0018
Café Paradiso	\$\$	Italian	2649 Connecticut Ave.	(202) 265-8955
Lebanese Taverna	\$\$	Middle Eastern	2641 Connecticut Ave.	(202) 483-7420
Sake Club	\$\$	Japanese/Sushi	2635 Connecticut Ave.	(202) 332-1115
Taste of India	\$	Indian	2621 Connecticut Ave.	(202) 483-1115
Woodley Café	\$\$	American	2619 Connecticut Ave.	(202) 332-5773
New Heights	\$\$\$	American	2317 Connecticut Ave.	(202) 234-4110
Jandara	\$	Thai	2606 Connecticut Ave.	(202) 387-8876
Mr. Chen's Organic	\$	Chinese	2604 Connecticut Ave.	(202) 797-9668
Rajaji	\$	Shish Keegan	2603 Connecticut Ave.	(202) 265-7344
Murphy's Irish Pub	\$	American	2609 24 <sup>th</sup> St., NW.	(202) 462-7171
Medaterra	\$\$	Middle East	2614 Connecticut Ave.	(202) 797-0400

#### Short cab ride or 10 minute walk North of the hotel Cleveland Park

2 Amys	\$\$	Pizza, Italian	3715 Macomb St., NW	202-885-5700
Buck's Fishing & Camping	\$\$\$	Steaks, American	5031 Connecticut Ave., NW	202-364-0777
Cactus Cantina	\$	Tex-Mex, Mexican	3300 Wisconsin Ave., NW	202-686-7222
Café Deluxe	\$\$	American, Modern	3228 Wisconsin Ave., NW	202-686-2233
*Delhi Dhaba	\$	Indian, Vegetarian/Vegan	4455 Connecticut Ave., NW	202-537-1008
Enology	\$\$	American, Modern	3238 Wisconsin Ave., NW	202-362-0362
Lavandou	\$\$	French	3321 Connecticut Ave., NW	202-966-3003
Nam-Viet Pho 79	\$	Vietnamese	3419 Connecticut Ave., NW	202-237-1015
Palena	\$\$\$\$	American, Modern	3529 Connecticut Ave., NW	202-537-9250
Vace	\$	Pizza, Deli/Quick, Italian	3315 Connecticut Ave., NW	202-363-1999

#### Short cab ride or 10 minute walk South of the hotel Adams Morgan

Al-Khartoum	\$	Ethiopian	1782 Florida Ave, NW	202-986-5031
*Amsterdam Falafelshop	\$	Lebanese, Middle Eastern	2425 18th St., NW	202-234-1969
Bardia's New Orleans Café	\$	Cajun/Creol	2412 18th St., NW	202-234-0420
Bourbon	\$	American	2321 18th St., NW	202-332-0800
Casa Oaxaca	\$	Mexican, South American	2106 18th St., NW	202-387-2272
Cashion s Eat Place	\$\$\$	American, Modern	1819 Columbia Rd., NW	202-797-1819
La Fourchette	\$\$	French	2429 18th St., NW	202-332-3077
Locolat	\$	Belgian Café/Chocolate	1781 Florida Ave., NW	202-518-2570

\*Vegetarian/Vegan







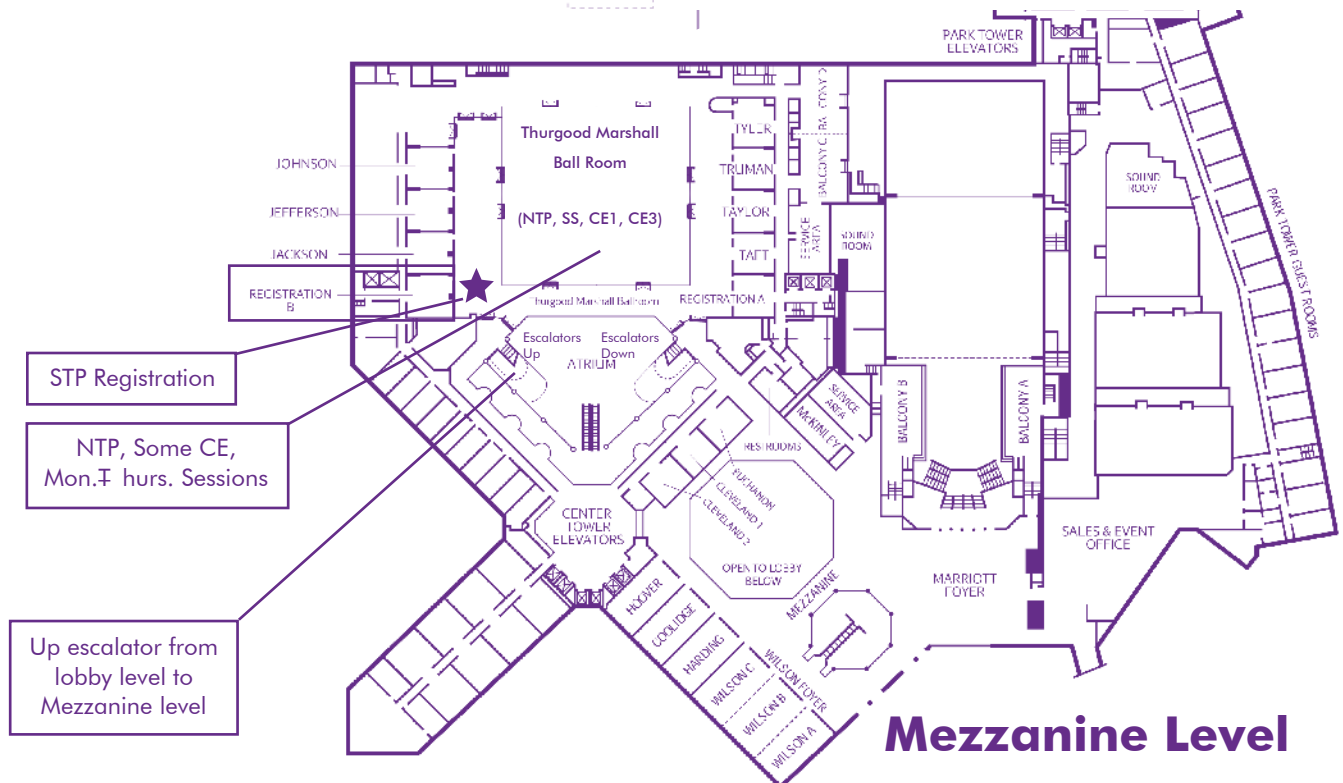
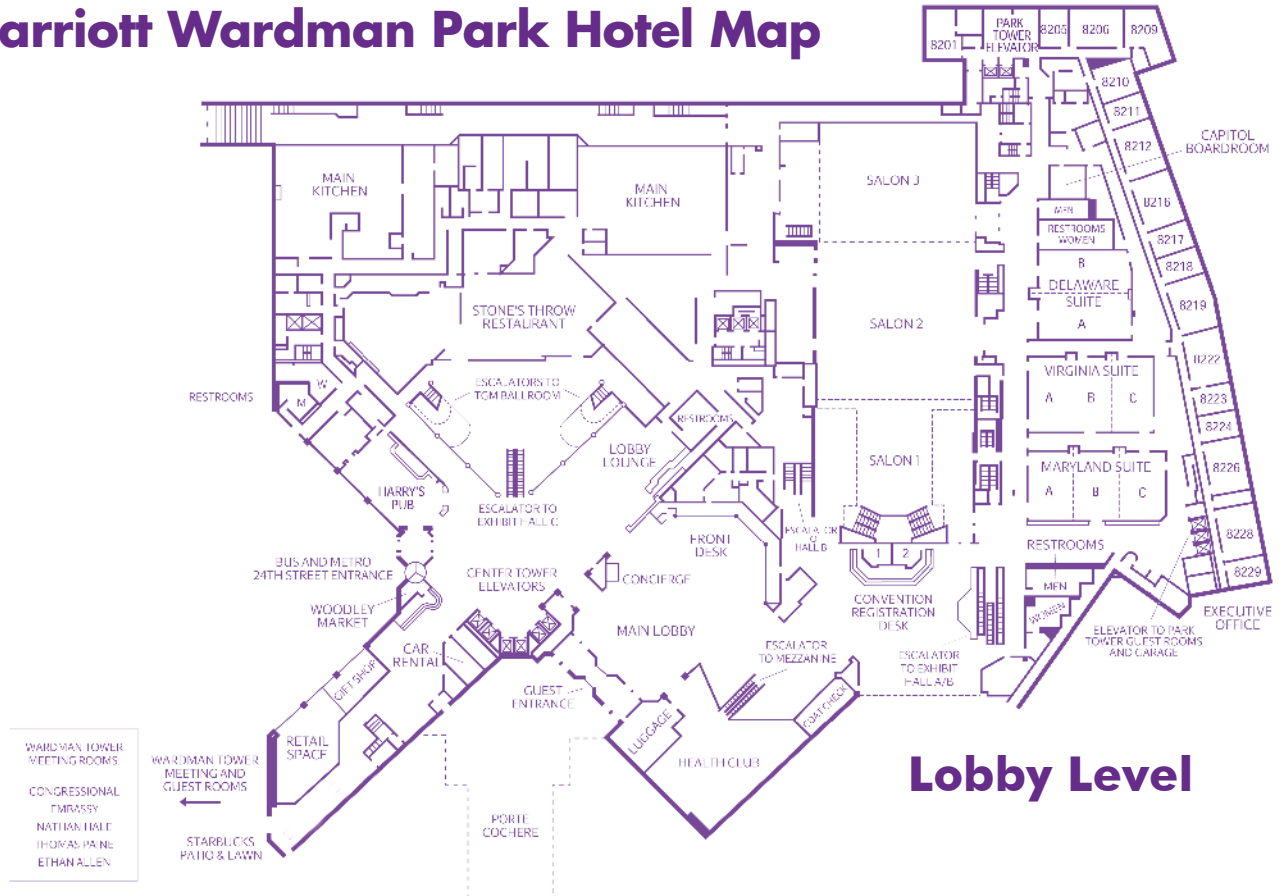
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### Marriott Wardman Park Hotel Map





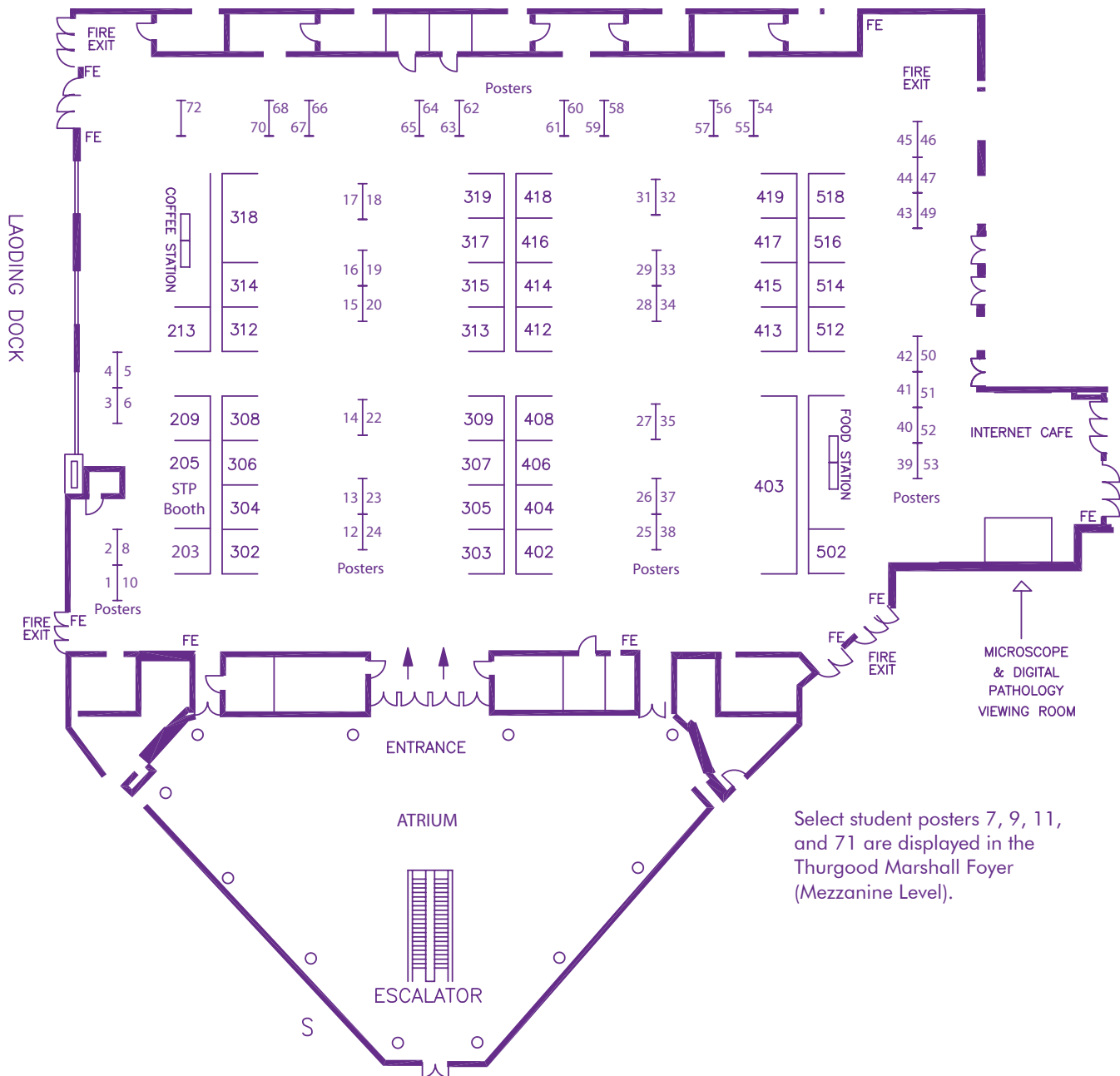
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### Exhibition Hall C

Booths, Posters, Internet Café,  
Microscope and Digital Pathology Viewing Room



Select student posters 7, 9, 11, and 71 are displayed in the Thurgood Marshall Foyer (Mezzanine Level).

# Program

## Symposium: Cancer

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Saturday, June 20

### NTP Satellite Symposium

Thurgood Marshall Ballroom  
9:00 AM-4:30 PM

Free Event; registration required

#### Tumor Pathology and INHAND Nomenclature

Chair: Susan A. Elmore, MS, DVM, DACVP,  
National Institute of Environmental Health Sciences,  
Research Triangle Park, NC

The objectives of this symposium are to provide continuing education on interpreting pathology slides, to generate lively and productive conversation, and to have a good time! The theme for the symposium this year is tumor pathology, corresponding with the STP meeting theme of cancer. We will also include some examples and discussion of INHAND nomenclature as it pertains to neoplastic lesions. During each talk, the speakers will project a series of lesion images on one screen with a choice of diagnoses/answers on a separate screen. Keypads (100) will be distributed at the door on a first come/first serve basis. The members of the audience with wireless keypads will then vote anonymously and the voting results will be displayed on the screen. After each voting session, time is allowed for discussion. The images presented for voting and discussion may represent lesions that are rare and interesting, present a diagnostic challenge, are controversial or have nomenclature dilemmas.

9:00 AM-9:10 AM	<b>Welcome and Introductory Remarks</b> <i>Susan Elmore, MS, DVM, DACVP, NTP/NIEHS, Research Triangle Park, NC</i>
9:10 AM-9:30 AM	<b>Proliferative Lesions of the Adrenal Medulla</b> <i>Georgette Hill, DVM, PhD, Integrated Laboratory Systems, Research Triangle Park, NC</i>
9:30 AM-10:00 AM	<b>The Great Masquerader</b> <i>Rod Miller, DVM, PhD, NIEHS, Hillsborough, NC</i>
10:00 AM-10:30 AM	<b>Knee Jerks Welcomed</b> <i>Dave Malarkey, DVM, PhD, NIEHS, Research Triangle Park, NC</i>
10:30 AM-11:00 AM	<b>Break</b>
11:00 AM-11:30 AM	<b>Hematopoietic Neoplasia in the Tg.AC Mouse</b> <i>Andrew Suttie, BVSc, PhD, Covance Laboratories, Vienna, VA and Ken Latimer, DVM, PhD, DACVP, Covance Laboratories, Vienna, VA</i>

11:30 AM-12:00 NOON	<b>I II Take Spleen for 200</b> <i>Greg Travlos, DVM, NIEHS, Research Triangle Park, NC</i>
12:00 NOON-1:30 PM	<b>Lunch</b>
1:30 PM-1:40 PM	<b>Introduction to INHAND Initiative</b> <i>John Vahle, DVM, PhD, Eli Lilly &amp; Company (GESC Chair), Greenfield, IN</i>
1:40 PM-1:55 PM	<b>Astrogloma, Oligodendroglioma, Glioma Mixed</b> <i>Wolfgang Kaufman, BASF AG, Ludwigshafen, Germany</i>
1:55 PM-2:15 PM	<b>Unusual Proliferative Lesions of the LungA Diagnostic Dilemma</b> <i>Rick Hailey, DVM, GlaxoSmithKline, Research Triangle Park, NC</i>
2:15 PM-2:30 PM	<b>Nong ranular Cell Meningiomas in Rodents</b> <i>Jim Morrison, DVM, DACVP, Charles River Laboratories, Durham, NC</i>
2:30 PM-2:45 PM	<b>Basal Cell Hyperplasia of the Glandular Stomach</b> <i>Thomas Nolte, DVM, PhD, MSc, Boehringer Ingelheim Pharma, GmbH &amp; CO, Biberach an der Riss, Germany</i>
2:45 PM-3:00 PM	<b>Epididymal (Cribriform) Hyperplasia</b> <i>Thomas Nolte, DVM, PhD, MSc, Boehringer Ingel Keim Pharms, GmbH &amp; CO, Biberach an der Riss, Germany</i>
3:00 PM-3:30 PM	<b>Break</b>
3:30 PM-3:45 PM	<b>Pulmonary Mucus Cell Proliferation</b> <i>Susanne Rittinghausen, DVM, Fraunhofer Institute of Toxicology and Experimental Medicine, Hannover, Germany</i>
3:45 PM-4:00 PM	<b>Granular Cell Lesions in the Female Genital Tract</b> <i>Ute Bach, Dr. med. Vet., Bayer Healthcare AG, Wuppertal, Germany</i>
4:00 PM-4:30 PM	<b>Nodular Hyperplasia Revisited</b> <i>Bob Maronpot, DVM, MS, MPH, DACVP, DABT Maronpot Consulting LLC, Raleigh, NC</i>





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### Career Development Workshop

(Free Event, registration required)

#### Toxicologic Pathology in a Multicultural World Washington 1-3

Sunday, June 21, 2009, 8:00 AM-12:00 NOON

*Facilitators:* A. Eric Schultze, Eli Lilly & Company, Indianapolis, IN, and Brian R. Berridge, DVM, PhD, DACVP, GlaxoSmithKline, Research Triangle Park, NC

8:00 AM-8:10 AM **Introduction and Agenda**

A. Eric Schultze, Eli Lilly & Company, Indianapolis, IN, and Brian R. Berridge, DVM, PhD, DACVP, GlaxoSmithKline, Research Triangle Park, NC

8:10 AM- 9:50 AM **China:**  
Vincent P. Meador, DVM, PhD, DAVCP, Amgen, Inc., Seattle, WA, and Helen Han Hsu, DVM, PhD, DAVCP, J&J, Raritan, NJ

9:50 AM-10:20 AM **Break**

10:20 AM-12:00 NOON **India:**  
Kevin Donnelly, DVM, PhD, Covance, Greenfield, IN, and V.J. Reddy, Eli Lilly & Co, Indianapolis, IN

The workshop, organized by the Career Outreach and Continuing Education Committees, will provide interactive sessions covering the challenges of doing business and communicating effectively in two geographical areas of developing business growth; China and India. Presenters include natives of these regions and non-natives with experience interacting in a professional capacity within these cultures. Cultural differences and business styles will be discussed. Differences in the training of professional colleagues, difficulties in scientific translation of reports and messages, and baseline communication skills will be reported. Workshop presenters will offer ways to enhance the interactions of pathologists of different cultures and describe how to prepare pathologists for effective communication in a global world. This interactive workshop will feature speaker and participant discussions of challenging scenarios in Toxicologic Pathology and real life business case examples will be emphasized.

**The Program is sponsored by an educational donation provided by Amgen.**

### Sunday, June 21

#### Continuing Education Courses

*Chair:* Brian R. Berridge, DVM, PhD, DACVP, GlaxoSmithKline, Research Triangle Park, NC

#### CE 1 (Sunday AM) 8:00 AM-12:05 PM

##### Thurgood Marshall Ballroom

#### Cancer Therapeutics, Development Strategies in the Era of Targeted Therapies

*Co-Chairs:* Page R. Bouchard, DVM, DACVP, Archemix Corp., Cambridge, MA, and David Epstein, PhD, OSI Therapeutics, Melville, NY

8:00 AM-8:05 AM **Introduction**

8:05 AM-8:35 AM **Epithelial-Mesenchymal Transition: An Emerging Concept in Cancer Drug Discovery and Development**

David Epstein, PhD, OSI Therapeutics, Melville, NY

8:35 AM-9:05 AM **ICH S9:Nonclinical Development of Anticancer Drugs and Biologicals**

John Leighton, PhD, DABT, U.S. FDA, Silver Spring, MD

9:05 AM-9:35 AM **Safety Assessment Considerations and Strategies for Targeted Small Molecule Cancer Therapeutics**

Richard Westhouse, DVM, PhD, DACVP, Bristol Myers Squibb, Princeton, NJ

9:35 AM-10:05 AM **Break**

10:05 AM-10:35 AM **EGFr Inhibitors and Cancer Lessons Learnt and Future Perspectives**

Jens Oliver Funk, MD, EMD Serono, Inc., Billerica, MA

10:35 AM-11:05 AM **Angiogenesis Inhibitors: Lessons and Surprises**

Donald McDonald, MD, PhD, University of California-San Francisco, San Francisco, CA

11:05 AM-11:35 AM **Immunomodulation: Changing Paradigms for Cancer Therapy**

Jeffrey Schlom, PhD, National Cancer Institute, Bethesda, MD

# Program

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11:35 AM-12:05 PM

### **Inhibitors of the Ubiquitin Proteasome Pathway, Deconvolution of the Biology and Toxicology of a Novel and Pleiotropic Pathway**

*Lee Silverman DVM, PhD, DACVP, Millennium: The Takeda Oncology Company, Cambridge, MA*

## **CE 2 (Sunday AM) 8:00 AM-12:00 NOON**

**Wilson ABC**

### **Drug-Induced Hematotoxicity What's New?**

*Co-Chairs: Nancy E. Everds, DVM, DACVP, Amgen Inc., Seattle, WA, and Frances A. S. Clemons, DVM, PhD, DACVP, Baxter Inc., Lake Bluff, IL*

Hematotoxicity is a common dose-limiting side effect of drugs in preclinical and clinical studies, especially for cancer therapeutics and other drugs that affect cell proliferation. Currently, there are several marketed drugs that are aimed to ameliorate cytopenias in cancer patients through stimulation of hematopoiesis.

This course will cover a range of topics, including fundamentals of hematotoxicity, specialized research tools available to investigate hematotoxicity, mechanisms of management of anemia of inflammation and malignancy, and mechanisms of idiosyncratic hematologic toxicity.

8:00 AM-8:05 AM

### **Introduction**

8:05 AM-8:55 AM

### **General Mechanisms of Hematologic Toxicity**

*John C. Bloom, VMD, PhD, Eli Lilly & Company, Indianapolis, IN*

8:55 AM-9:45 AM

### **Specialized Techniques for Evaluating Drug-Induced Toxicity to the Hematopoietic System**

*Ralph E. Parchment, PhD, National Cancer Institute, Frederick, MD*

9:45 AM-10:15 AM

### **Break**

10:15 AM-11:05 AM

### **The Anemia of Inflammation and Malignancy: The ESA Controversy**

*John W. Adamson, MD, University of California, San Diego, CA*

11:05 AM-11:55 AM

### **Hematological Idiosyncratic Drug Reactions**

*Jack Uetrecht, MD, PhD, University of Toronto, Toronto, Canada*

12:30 PM-1:30 PM

### **Bone Marrow Examination in Non-clinical Toxicology Studies**

#### **Wilson ABC**

(Free Lunchtime Session)

The STP Bone Marrow Working group of the Scientific and Regulatory Policy Committee (SRPC) will present its recommendations on when and how to do bone marrow examination in non-clinical toxicology studies. The draft paper and related documents can be accessed at [www.toxpath.org/membersonly/pos.asp](http://www.toxpath.org/membersonly/pos.asp) (member login required) or [www.toxpath.org/AM2009/agenda.asp](http://www.toxpath.org/AM2009/agenda.asp) (member and non-member attendees can access with login).

## **CE 3 (Sunday PM) 1:30 PM-5:05 PM**

**Thurgood Marshall Ballroom**

### **Unintended Mechanism-Based Adverse Events Associated with Cancer Chemotherapy**

*Chair: Carl L. Alden, DVM, DACVP, Millennium: The Takeda Oncology Company, Cambridge, MA*

The plurality of drugs in development now in the U.S. are targeted in the oncology therapeutic area. With the emerging improvements in cancer therapy an increasing awareness of the toxicities associated with chemotherapy can be anticipated. Examples include long term adverse events such as cognitive function impairment (chemo brain) and congestive heart failure. Equally critical, mechanism based adverse effects may limit the opportunity of the patient to benefit from therapy, such as is the case with chemotherapy induced peripheral neuropathy and drug induced hepatotoxicity. While the oncologist has excellent awareness and ability to manage the traditional cytotoxic chemotherapeutic effects on the gastrointestinal tract and bone marrow, future novel therapeutic targets will hopefully reduce the treatment residua of current chemotherapeutics. The purpose of the course will be to provide an overview of chemotherapeutic drug effects in the brain, peripheral nervous system, liver, and cardiovascular system.

1:30 PM-1:35 PM

### **Introduction**

1:35 PM-2:15 PM

### **Effects of Cranial Irradiation on Neurogenesis and Cognition in Mice**

*Jacob Raber, PhD, Oregon Health and Science University, Portland, OR*

2:15 PM-3:05 PM

### **Chemotherapy Induced Peripheral Neuropathy**

*Lee Silverman, DVM, PhD, DACVP, Millennium: The Takeda Oncology Company, Cambridge, MA*



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3:05 PM–3:35 PM

### Break

3:35 PM–4:15 PM

### Heart Failure and Chemotherapy

Noel Dybdal, DVM, PhD,  
Genentech Inc., South San Francisco,  
CA

4:15 PM–5:05 PM

### Liver Toxicity in Cancer Patients

John Senior, MD, U.S. FDA,  
Silver Spring, MD

## CE 4 (Sunday PM) 1:30 PM–5:00 PM

Wilson ABC

### Drug Development for Pediatric Populations

Co-Chairs: Ian Pyrah, BVMS, PhD, MRCVS,  
FRCPath, Amgen Inc., Thousand Oaks, CA, and  
Kevin S. McDorman, DVM, PhD, DACVP, Charles River  
Laboratories, Reno, NV

Availability of safe and efficacious drugs for children is a current hot topic in society and reflected by increased regulatory demands. The development of drugs for children poses a number of challenges that must be understood and overcome to obtain adequate information in drug safety and efficacy and product labeling. Appropriate preclinical toxicology studies are a component of this package. However, there is limited experience and precedence in the design and interpretation of such toxicity studies in juvenile animals and other systems. This course will provide updated information on regulations and current thinking on preclinical development of drugs for children, providing examples of successful pediatric drug development, as well as examples where concerns for the use of certain classes of drugs exist in the marketplace.

1:30 PM–1:35 PM

### Introduction

1:35 PM–2:05 PM

### Clinical Drug Development in Pediatrics

Jean Temeck, MD, U.S. FDA,  
Silver Spring, MD

2:05 PM–2:35 PM

### Regulatory History and Hurdles of Pediatric Drug Development: Nonclinical Safety Evaluation

Karen Davis-Bruno, PhD,  
U.S. FDA, Silver Spring, MD

2:35 PM–3:05 PM

### Break

3:05 PM–3:45 PM

### Study Design Concepts in Juvenile Toxicity Studies

Shaun Maguire, BSc, MSc,  
GlaxoSmithKline, Hertfordshire,  
UK

3:45 PM–4:35 PM

### Experience of Juvenile Toxicity Studies from a Pathologist's Perspective

Jan Klapwijk, BVSc, MSc,  
MRCVS, FRCPath,  
GlaxoSmithKline,  
Hertfordshire, UK

4:35 PM–5:00 PM

### Round Table Discussion

5:30 PM–7:00 PM

### Exhibits and Poster Sessions Open

5:15 PM–6:45 PM

### Exhibits Opening, Exhibit Hall C

6:45 PM–8:15 PM

### Sponsored Welcome Reception, Salon 1

## Monday, June 22

7:00 AM–8:00 AM

### Continental Breakfast Exhibit Hall C

7:00 AM–11:00 AM

### Exhibits and Poster Sessions

## Scientific Sessions

### Thurgood Marshall Ballroom

Co-Chairs: Jerrold M. Ward, DVM, PhD, DACVP,  
Global VetPathology, Montgomery Village, MD, and  
Kathleen A. Funk, DVM, PhD, DACVP, EPL, Inc,  
Sterling, VA

## Monday Morning

8:00 AM–8:10 AM

### Welcome

Ricardo Ochoa, DVM, PhD, DACVP  
STP President  
Pre-Clinical Safety Inc.,  
Niantic, CT

## Session 1

### Thurgood Marshall Ballroom

8:10 AM–12:05 PM

## Human Cancer

Co-Chairs: Jerrold M. Ward, DVM, PhD, DACVP,  
Global VetPathology, Montgomery Village, MD, and  
Samuel M. Cohen, MD, PhD, University of Nebraska  
Medical Center, Omaha, NE

The first session will review various aspects of the etiology, diagnosis, pathology, treatment, and prevention of human cancers.



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## Symposium: Cancer

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- 8:10 AM-8:15 AM **Introduction to Human Cancer**  
*Jerrold M. Ward, DVM, PhD, DACVP, Global VetPathology, Montgomery Village, MD, and Samuel M. Cohen, MD, PhD, University of Nebraska Medical Center, Omaha, NE*
- 8:15 AM-9:10 AM **Keynote Address: National Cancer Institute's Cancer Therapy Evaluation Program: Translating Science into Useful Treatments**  
*Jeffrey S. Abrams, MD, National Cancer Institute, Bethesda, MD*
- 9:10 AM-10:00 AM **The Molecular Pathology of Colorectal Cancer**  
*Stanley R. Hamilton, MD, University of Texas, MD Anderson Cancer Center, Houston, TX*
- 10:00 AM-10:45 AM **Break**
- 10:45 AM-11:30 AM **Estrogen and Xenoestrogens in Breast Cancer**  
*Jose Russo, MD, Fox Chase Cancer Center, Philadelphia, PA*
- 11:30 AM-12:15 PM **The Impact of High Throughput Pathology: Defining Disease by Protein Expression**  
*Stephen M. Hewitt, MD, PhD, National Cancer Institute, Bethesda, MD*

### Monday Afternoon

- 12:00 NOON-4:30 PM **Exhibits and Poster Sessions**  
Exhibit Hall C
- 12:15 PM-1:30 PM **Lunch Break**

### Session Presented in Spanish

#### Harding

12:15 PM-1:30 PM

#### Estrategias en la Evaluación Pre-clínica de Farmacéuticos

*Roberto Guzman, DVM, PhD DACVP, Division de Patología, Pfizer, Inc., Groton, CT*

**Abstracto:** Se presentará un resumen de el proceso de evaluación de compuestos experimentales en la etapa pre-clínica. Varios ejemplos serán discutidos donde

se describirán resultados de estudios y las técnicas de laboratorio utilizadas para entender mecanismos de efectos toxicológicos y su relevancia en humanos.

#### Hallazgos hematológicos morfológicos en ratones CD-1 y ratas F344 durante dos años de vida

*Armando Irizarry, DVM, PhD, DACVP, Consejero de investigación en Patología y Toxicología, División de Toxicología y Disposición de Drogas, Eli Lilly y Compañía, Indianapolis, IN*

**Abstracto:** Se presentarán hallazgos hematológicos morfológicos ocurridos en ratones y ratas durante dos años de vida. Estos animales solo recibieron comida y agua sin recibir xenobióticos. Se evaluaron frotis de sangre sin evaluar conteos de células.

#### Career Development Lunchtime Series Wilson AB (Free, registration required)

#### Exploring Cultural and Career Diversity in Toxicologic Pathology: A Panel Discussion

Monday, June 22, 2009, 12:30 PM-1:30 PM

This is an informational panel discussion with 4 STP members who will share their diverse cultural and career path perspectives and the experiences gained as a result.

**Moderator:** *Michael Conner, Vice President, Safety Assessment, Theravance, Inc.*

#### Participants:

*Calvert Loudon, DVM, PhD, Senior Director, Pathology, Johnson & Johnson Pharmaceuticals*

*Evelyn Polack, DVM, MS, PhD, DACVP, Principal Investigator, Comparative Pathology, Biogen Idec*

*Dr. Ingrid Pruijboom-Brees, Associate Research Fellow, Pfizer Inc.*

### Session 2

#### Thurgood Marshall Ballroom

1:30 PM-5:05 PM

#### Cancer Biology

**Co-Chairs:** *Robert C. Sills, DVM, PhD, DACVP, NIEHS, Research Triangle Park, NC and Mark R. Simpson, DVM, PhD, DACVP, National Cancer Institute, Bethesda, MD*

The session will focus on the use of mouse models and *in vitro* systems to understand cellular and molecular mechanisms of human cancer and for developing therapeutic strategies.



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- 1:30 PM–2:15 PM **Engineered Cancer Models in Basic and Translational Discovery**  
*Terry Van Dyke, PhD, University of North Carolina, Chapel Hill, Chapel Hill, NC*
- 2:15 PM–2:50 PM **Use of Animal Models in the Development of TGF- $\beta$  Antagonists for Cancer Therapy**  
*Lalage M. Wakefield, DPhil, National Cancer Institute, Bethesda, MD*
- 2:50 PM–3:20 PM **Break**
- 3:20 PM–3:55 PM **Exploiting Genomic Analyses for Pre-Clinical Testing in Mouse Models**  
*Christina N. Bennett, PhD and Jeffrey E. Green, MD, National Cancer Institute, Bethesda, MD*
- 3:55 PM–4:30 PM **Mouse Models of Astrocytoma for Discovery and Translation**  
*Karlyne M. Reilly, PhD, National Cancer Institute at Frederick, Frederick, MD*
- 4:30 PM–5:05 PM **Mouse Models for Cancer Stem Cell Research**  
*Alexander Nikitin, MD, PhD, Cornell University, Ithaca, NY*

### Town Hall Meeting

**Thurgood Marshall Ballroom**

**5:30 PM–6:30 PM**

#### International Recognition of Qualified Toxicologic Pathologists

The topic for this year's facilitated discussion will be "International Recognition of Qualified Toxicologic Pathologists." This forum will consider a draft proposal ([www.toxpath.org/membersonly/pos.asp](http://www.toxpath.org/membersonly/pos.asp) (member login) or [www.toxpath.org/AM2009/agenda.asp](http://www.toxpath.org/AM2009/agenda.asp) (all meeting attendees)) for one such system, which has been prepared by the International Federation of Societies of Toxicologic Pathology (IFSTP) based on negotiations among various toxicologic pathology societies over the last three years. (See page 8 for additional information about this topic.)

- 5:30 PM–5:35 PM **Brief Historical Introduction**  
*Brad Bolon, DVM, MS, PhD, DACVP, GEMpath, Inc., Longmont, CO*

- 5:35 PM–5:40 PM **Comments Supporting the Concept of International Recognition and Specifically by the Proposed Credential Review Format**  
*Jeffery A. Engelhardt, DVM, PhD, DACVP, Consultant, Camarillo, CA*
- 5:40 PM–5:45 PM **Comments Supporting the Concept of International Recognition, but Only if by Objective Examination**  
*Daniel G. Morton, DVM, PhD, DACVP, Pfizer, Groton, CT*
- 5:45 PM–5:50 PM **Comments Against the Concept of International Recognition**  
*Kevin Isaacs, MA, VetMB, MRCVS, FRCPath, Consultant, Harrogate, UK*
- 5:50 PM–6:30 PM **Spirited Discussion**  
Moderator: *Ricardo Ochoa, DVM, PhD, DACVP, Pre-Clinical Safety Inc., Niantic, CT, STP President*

**6:30 PM–10:30 PM**  
**Sponsored Reception, Salon 1**



United States Capitol Building

# Program

## Symposium: Cancer

Washington, D.C.  
June 21-25, 2009

### Tuesday, June 23

- 7:00 AM-8:00 AM **Continental Breakfast**  
Exhibit Hall C
- 7:00 AM-4:00 PM **Exhibits and Poster Sessions**  
Exhibit Hall C

### Tuesday Morning

#### Session 3

**Thurgood Marshall Ballroom**  
8:00 AM-12:00 PM

Free to U.S. government employees, registration required.

#### Alternative Mouse Models for Carcinogenicity Assessment

*Co-Chairs: Daniel G. Morton, DVM, PhD, DACVP, Pfizer, Groton, CT, and James A. Swenberg, DVM, PhD, DACVP, University of North Carolina, Chapel Hill, NC*

The history, rationale for use and selection, design, and interpretation of p53+/-, rasH2, and other alternative mouse models used to support carcinogenicity assessment of compounds for registration will be discussed. Speakers from government and industry will review current and promising future models, the performance of the models in validation studies and studies submitted to support new pharmaceutical products, the use of positive control chemicals, and the need for historical control data. The session will conclude with a roundtable discussion of regulatory acceptance and other questions provided by the audience.

- 8:00 AM-8:05 AM **Introduction**
- 8:05 AM-8:40 AM **An Industry Perspective on the Utility of Short-term Carcinogenicity Testing in Transgenic Mice in Pharmaceutical Development**  
*Richard D. Storer, PhD, Merck Research Laboratories, West Point, PA*
- 8:40 AM-9:05 AM **Alternative Mouse Models for Carcinogenicity Assessment: Industry Use and Issues with Pathology Interpretation**  
*Gerald G. Long, DVM, PhD, DACVP, Eli Lilly & Company, Indianapolis, IN*

- 9:05 AM-9:50 AM **European Perspectives on Alternative Mouse Carcinogenicity Models**  
*Bernard Leblanc DVM, PhD, DACVP, DECVP, Pfizer, Amboise Cedex, France*
- 9:50 AM-10:20 AM **Break**
- 10:20 AM-10:30 AM **The Ito Medium Term Carcinogenicity Model**  
*Hiroyuki Tsuda, MD, PhD, Nagoya City University Medical School, Nagoya, Japan*
- 10:30 AM-11:05 AM **Genetically Modified Mouse Models for Hazard Identification and Risk Assessment in Toxicology and Carcinogenesis: Strengths and Weaknesses**  
*John E. French, PhD, National Institute of Environmental Health Sciences, Research Triangle Park, NC*
- 11:05 AM-12:00 NOON **Panel Discussion: Alternative Models in Carcinogenicity Assessment**  
*John E. French, PhD, National Institute of Environmental Health Sciences; John Leighton, PhD, DABT, U.S. FDA; Bernard Leblanc DVM, PhD, DACVP, DECVP, Pfizer; Gerald G. Long, DVM, PhD, DACVP, Eli Lilly & Company; Richard D. Storer, PhD, Merck Research Laboratories; and Hiroyuki Tsuda, MD, PhD, Nagoya City University Medical School*



Lincoln Memorial





# Program

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### Tuesday Afternoon

Open until 4:00 PM

**Exhibits and Poster Sessions**  
Exhibit Hall C

#### Session 4

**Thurgood Marshall Ballroom**

**1:00 PM–5:00 PM**

Free to U.S. government employees, registration required.

#### Background Pathology in Animal Models of Toxicity: Relevance and Interpretation in Risk Assessment

*Co-Chairs: Dianne Creasy, PhD, FRCPath, Huntingdon Life Sciences East Millstone, NJ, and Brian R. Berridge, DVM, PhD, DACVP, GlaxoSmithKline, Research Triangle Park, NC*

Preclinical animal models are generally considered to be a clean and consistent background of normal anatomy and physiology within which to evaluate the potential toxicity of putative therapeutic agents. But, spontaneous background findings both physiological and pathological manifest in these models and can be quite variable in character, incidence and severity within and between studies. Although an experienced toxicologic pathologist is accustomed to identifying and differentiating these changes from test article-related effects, the distinction is occasionally unclear due to random distribution across dose groups or overlap with those associated with test article treatment. This presentation will describe some of the more common non-proliferative and proliferative background changes in rodent and non-rodent preclinical animal models. The presentation will also outline approaches used by the pathologist to build a weight of evidence for or against attributing the morphologic or clinical pathologic change to administration of the test article. The aim is to provide the regulatory reviewer an understanding of these changes and their context in preclinical safety assessment.

1:00 PM–1:30 PM

#### What Constitutes Background Pathology?

*Dianne Creasy, PhD, FRCPath, Huntingdon Life Sciences, East Millstone, NJ*

1:30 PM–2:30 PM

#### How Normal are Control Animals? Overview of Common Background Changes in Preclinical Studies

1:30 PM–2:00 PM

#### Defining "Normal" in Concurrent Controls: Lesson from Non-Rodent Preclinical studies

*Lauren Tierney, DVM, PhD, DACVP, GlaxoSmithKline, King of Prussia, PA*

2:00 PM–2:30 PM

#### Common Background Findings in Rodents

*Sarah L. Hale, DVM, DACVP, Covance, Vienna, VA*

2:30 PM–3:15 PM

#### Break

3:15 PM–4:00 PM

#### Evaluation of the Male and Female Reproductive Systems in General Toxicity Studies

*Justin D. Vidal, DVM, PhD, DACVP, GlaxoSmithKline, King of Prussia, PA*

4:00 PM–4:30 PM

#### The Histopathology/Clinical Pathology Conundrum

*Vincent P. Meador, DVM, PhD, DACVP, Amgen Inc., Seattle, WA*

4:30 PM–5:00 PM

#### Pieces of the Puzzle: Contextual Interpretation of In Vivo Data

*John L. Vahle, DVM, PhD, DACVP, Eli Lilly & Company, Indianapolis, IN*

### Wednesday, June 24

7:00 AM–8:00 AM

#### Continental Breakfast

Exhibit Hall C

7:00 AM–1:00 PM

#### Exhibits and Poster Sessions

Exhibit Hall C

### Wednesday Morning

#### Session 5

**Thurgood Marshall Ballroom**

**8:00 AM–12:00 NOON**

#### Biological Factors that Impact Assessment of Human Relevance of Animal Neoplasia

*Co-Chairs: James A. Popp, DVM, PhD, DACVP, Stratoxon, Lancaster, PA, and James E. Klaunig, PhD, Indiana University School of Medicine, Indianapolis, IN*

This session will examine several established mechanisms of carcinogenicity in rodents with application to human relevance. A variety of chemical and physical agents have the potential to produce adverse effects by causing heritable changes to the genome. Mutagenesis is not the only mechanism underlying heritable alterations to the genome. Understanding of the epigenetic mechanisms including DNA methylation may play a key role in a variety of chemical-induced toxicities, including carcinogenesis.

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Induction of DNA damage as well as modulation of epigenetic pathways involved in the cancer process has been shown following oxidative stress by chemical and physical agents. Since the same pathways modified in rodents are also the target of oxidative stress in humans, the relevance for this mechanism is important in assessing human risk and relevance. The mechanisms of photocarcinogenesis potentiation and induction by chemical and physical agents will be addressed. Of recent concern is the possible risk of nanomaterials in the induction of photocarcinogenesis. The utilization of transgenic and humanized rodent models in understanding of human clinical response to anticancer drug treatment and genetic and environmental factors involved in the cancer etiology will also be addressed.

8:00 AM–8:10 AM	<b>Introduction</b>
8:10 AM–9:00 AM	<b>Epigenetics in Carcinogenesis</b> <i>Jay I. Goodman, PhD, Michigan State University, East Lansing, MI</i>
9:00 AM–9:50 AM	<b>Oxidative Stress/Damage in Carcinogenesis</b> <i>James E. Klaunig, PhD, Indiana University School of Medicine, Indianapolis, IN</i>
9:50 AM–10:20 AM	<b>Break</b>
10:20 AM–11:10 AM	<b>Photocarcinogenesis</b> <i>Paul C. Howard, PhD, FDA National Center for Toxicological Research, Jefferson, AR</i>
11:10 AM–12:00 NOON	<b>Humanized Mice</b> <i>Clifford R. Elcombe, PhD, CXR Biosciences, Lincoln Memorial Ltd, Dundee, UK</i>

### Wednesday Afternoon

#### Session 6

**Thurgood Marshall Ballroom**  
1:30 PM–5:20 PM

#### Global Regulatory Perspectives on Cancer Risk Assessment Where Are We, Where Are We Heading?

*Co-Chairs: Douglas Wolf, DVM, PhD, FIATP, ATS, U.S. EPA, Research Triangle Park, NC, and Terry Peters, DVM, U.S. FDA, CDER, Silver Spring, MD*

Current approaches for using toxicologic pathology to assist in cancer risk assessment by global regulators include the use of Mode of Action and the Human Relevance

Framework, when applicable. Attention will be paid to understanding cancer pathways and applying new technological approaches to future cancer risk assessment-based research.

1:30 PM–1:40 PM

#### Introduction

1:40 PM–2:20 PM

#### Application of Toxicologic Pathology to Inform Human Relevancy Framework and Mode of Action Analysis

*Vicki Dellarco, PhD, U.S. EPA, Washington, D.C.*

2:20 PM–3:00 PM

#### Cancer Risk Assessment Approaches at the FDA/CDER: Is the Era of the 2-Year Bioassay Drawing to a Close?

*John Leighton, PhD, DABT, U.S. FDA, Silver Spring, MD*

3:00 PM–3:30 PM

#### Break

3:30 PM–4:10 PM

#### Cancer Risk Assessment for Pesticides

*Mary Manibusan, MPH, U.S. EPA, Washington, D.C.*

4:10 PM–4:50 PM

#### The 2-Year Oncogenicity StudyD o We Still Need It?

*Alan Boobis, OBE, PhD, FIBiol, Imperial College-London, Hammersmith Campus, London, UK*

4:50 PM–5:20 PM

#### Panel DiscussionT he Future for Cancer Risk Assessment

*Ron Lorentzen, PhD, CFSAN Cancer Assessment Committee, College Park, MD; Alan Boobis, OBE, PhD, FIBiol, Imperial College London, Hammersmith Campus, London, UK; Mary Manibusan, MPH, U.S. EPA, Washington, D.C.; John Leighton, PhD, DABT, U.S. FDA, Silver Spring, MD; and Vicki Dellarco, PhD, U.S. EPA, Washington, D.C.*

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 Gala Reception

*Salon 1*



# Program

## Symposium: Cancer

### 28<sup>th</sup> Annual Symposium

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### Thursday June, 25

7:00 AM–8:00 AM **Continental Breakfast**  
Thurgood Marshall Ballroom  
Front Foyer

### Thursday Morning

**Session 7**  
Thurgood Marshall Ballroom  
8:00 AM–11:55 AM

#### Pathology of Rodent Neoplasia

*Co-Chairs: Robert R. Maronpot, DVM, MS, MPH, DACVP, DABT, Maronpot Consulting, LLC, Raleigh, NC, and David E. Malarkey, DVM, PhD, DACVP, NIEHS, Research Triangle Park, NC*

This session presents current issues that pathologists and scientists are faced with in efforts to achieve accurate diagnoses and valid interpretations of rodent models of cancer. Cancer progresses through a multistep process with accumulation of molecular alterations often leading to malignant behavior and death. Many factors, including those that are genetic, environmental, and/or inflammatory, can contribute to carcinogenesis. This session focuses on the diagnosis and morphological features of early cancer development and differentiation with elaboration on possible mechanisms of cancer (chemically induced or mediated by inflammation) as well as interpreting rodent-specific neoplasia.

- 8:00 AM–8:05 AM **Introduction**
- 8:05 AM–8:55 AM **Preneoplasia: Acquired or Predestined**  
*Robert D. Cardiff, MD, PhD, UC Davis, Davis, CA*
- 8:55 AM–9:30 AM **Useful Immunohistochemical Markers of Tumor Differentiation**  
*Jon Todd Painter, DVM, PhD, DACVP, Integrated Laboratory Systems, Research Triangle Park, NC*
- 9:30 AM–10:00 AM **Break**
- 10:00 AM–10:45 AM **Chemical Carcinogenesis of the Gastrointestinal Tract**  
*Sundeeep A. Chandra, DVM, PhD, DACVP, GlaxoSmithKline, Research Triangle Park, NC*

- 10:45 AM–11:15 AM **The Role of Inflammation in Murine Intestinal Cancer**  
*Susan E. Erdman, DVM, MPH, DACLAM, Massachusetts Institute of Technology, Cambridge, MA*
- 11:15 AM–11:55 AM **The Relevance of Rodent-Specific Tumors in Cancer Risk Assessment**  
*Douglas C. Wolf, DVM, PhD, U.S. EPA, Research Triangle Park, NC*



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