



## Fifth Conference of Society of Toxicologic Pathology - India

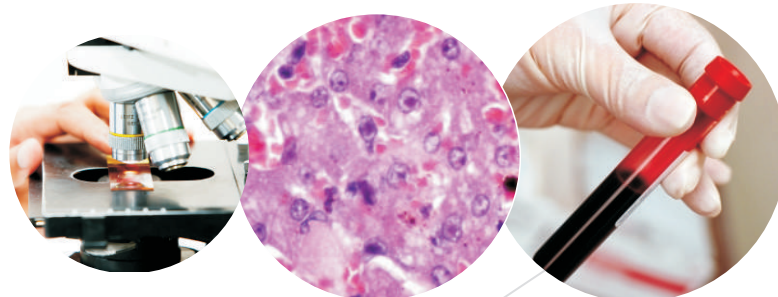
# Continuing Education in Toxicologic Pathology – Endocrine and Gastrointestinal System

Jointly Organized by:

**Society of Toxicologic Pathology - India (STP-I)  
& International Federation of Societies of Toxicologic Pathologists (IFSTP)**

**October 31, November 1-2, 2014**

Venue: “Chancery” The Atria Hotel, # 1, Palace Road, Bangalore - 560 001



*Dear Colleagues and Guests,*

It is a pleasure to invite you to attend Fifth Conference of the Society of Toxicologic Pathology - India on October 31, November 1-2, 2014 at Hotel Atria, Bangalore. This conference is jointly organized with IFSTP. The theme of the conference is “**Continuing Education in Toxicologic Pathology – Endocrine and Gastrointestinal System**”. The organizing committee members have put together extensive three days of technical sessions on toxicology and pathology of Endocrine and Digestive system with half day IATP seminar on Pathology peer review.

The conference organizers are providing exhibit space for companies offering products and services related to the field of toxicology and toxicologic pathology.

## PROGRAMME OVERVIEW

### Day 1: October 31, 2014

**8 am:** Breakfast and Registration

**9 am:** Inauguration

**9.30 am:** High tea

#### Session 1:

Time	Lecture No.	Lecture Title	Speaker
10.00 am	1	Spontaneous and chemically induced pathologies in the gastrointestinal tract	Dr. Thomas Nolte, Boehringer Ingelheim Pharma, Germany
10.45 am	2	Stomach in Preclinical Toxicology	Dr. Kamala K, Advinus Therapeutics Ltd., India
11.30 am	3	Biomarkers for digestive tract toxicity	Dr. Subba R Chintalacharuvu (Chinne)
12.15 pm		Lunch	

#### Session 2:

Time	Lecture No.	Lecture Title	Speaker
1.15 pm	4	Pancreas in Preclinical Toxicology	Dr. Shekar Chelur, Aurigene Discovery Technologies Ltd, India
2.00 pm		Poster presentations IFSTP travel grant trainee award presentations, Young Scientist award presentations	
2.45 pm		Short Break	
3.00 pm	5	Immunohistochemistry as confirmatory tool for malignancy	Dr. Julie Randolph-Habecker, Fred Hutchinson Cancer Research Center, USA
3.45 pm	6	Spontaneous and chemically induced pathologies in the gastrointestinal tract	Dr. Thomas Nolte, Boehringer Ingelheim Pharma, Germany
4.00 pm	7	Digestive tract carcinogenic toxicity in rodent models	Dr. Masumi Suzui, Nagoya City University, Japan

**Day 2: November 1, 2014****8 am:** Breakfast**Session 3:**

Time	Lecture No.	Lecture Title	Speaker
8.30 am	8	Thyroid follicular and C cells in preclinical toxicology	Dr. Tom Rosol, Ohio State University, USA
9.15 am	9	Pituitary in preclinical toxicology	Dr. S. K. Vijayasarathi, Advinus Therapeutics, India
10.00 am		Short Break	
10.15 am	10	Practical approaches for endocrine toxicity in preclinical safety assessment	Dr. Akira Inomata, Eisai Co., Ltd. Japan
11.00 am	11	Importance of immunohistochemistry in endocrine pathology	Dr. Julie Randolph-Habecker, Fred Hutchinson Cancer Research Center, USA
11.45 am	12	De-risking strategy of pancreatic effects caused by a novel CCK-1 receptor agonist	Dr. Chandi Elangbam, GSK, USA
12.30 pm		Lunch	

**Session 4:**

Time	Lecture No.	Lecture Title	Speaker
1.30 pm	13	Adrenal cortex and medulla in preclinical toxicology	Dr. Tom Rosol, Ohio State University, USA
2.15 pm	14	The importance of endocrine tumors in rodent bioassays	Dr. C. Gopinath, Toxicologic Pathology Consultant, UK
3.00 pm		Short Break	
3.15 pm	15	Species specific adrenal toxicity investigation, a case study	Dr. Venkatesha Udupa, Glenmark Pharmaceuticals Ltd, India
4.00 pm	16	Frontloading safety assessment in drug discovery at lead optimisation stage: A case study	Dr. Sowmya Bharath, AstraZeneca, India
4.45 pm		Award ceremony	

**Day 3: November 2, 2014**

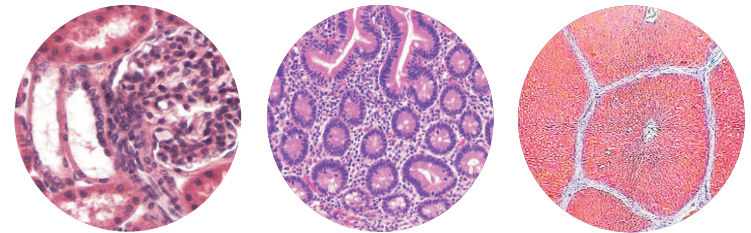
**8 am:** Breakfast

**Session 5:**

Time	IATP seminar	Speaker
8.30 am to 12.30 pm	<p><u>Speakers</u></p> <ul style="list-style-type: none"> <li>•Jerry Hardisty, DVM, DACVP, Fellow IATP, Experimental Pathology Laboratories, Inc., USA</li> <li>•Peter Mann, DVM, DACVP, Fellow IATP, Experimental Pathology Laboratories, Inc., USA</li> <li>•Lila Ramaiah, DVM, Ph.D, DACVP, Huntingdon Life Sciences, USA</li> <li>•Sabine Francke, DVM, PhD, Fellow IATP, CFSAN, FDA, USA</li> <li>•P Kalaiselvan, B.V.Sc, M.V.Sc, DICVP, DABT, Syngene international limited, India</li> </ul>	<p><u>Session chairs/Panel moderator:</u></p> <ul style="list-style-type: none"> <li>•Kamala Kannan, B.V.Sc, M.V.Sc, DIBTP, Advinus Therapeutics Ltd., India</li> <li>•Yogesh Kumar Murkunde, B.V.Sc, M.V.Sc, Ph.D, DIBTP, IIBAT, India</li> <li>•Bhanu Singh, B.V.Sc, MS, DACVP, DABT, Fellow IATP, Janssen R&amp;D, USA</li> </ul> <p><u>Organizing Committee:</u></p> <ul style="list-style-type: none"> <li>•S.K. Vijayasarithi, M.V.Sc, Ph.D, DIBTP, Advinus Therapeutics Ltd.</li> <li>•Bob Maronpot, DVM, MPH, DACVP, DABT, Fellow IATP, Maronpot Consulting LLC, USA</li> <li>•Bhanu Singh, B.V.Sc, MS, DACVP, DABT, Fellow IATP, Janssen R&amp;D, USA</li> <li>•Takanori Harada, DVM, Ph.D, The Institute of Environmental Toxicology, Japan</li> </ul>
12.30 pm	Lunch	
	Meeting adjourned	



The Awards Ceremony will take place on November 1, 2014.



**GENERAL BODY MEETING**

The Society's Business Meeting will be held on 31st October evening.

## SUBMISSION OF ABSTRACTS FOR YOUNG SCIENTIST AWARD

Professor M. K Shingatgeri Memorial Young Scientist Award is instituted by Dr. Vyas M Shingatgeri, Vice President, Drug Safety Evaluation, Ranbaxy Laboratories Ltd., R&D, Gurgaon, in memory of Late Professor M. K Shingatgeri, Former Dean of Bombay Veterinary College and Professor and Head of the Department of Pharmacology and Toxicology. The award is restricted to the subject/topic of Toxicologic Pathology only. The award consists of a Certificate and cash of Rs. 3000.

All member of the society aged less than 35 years can participate in this competition. Oral presentations shall be for 12 minutes with question and answer session for 3 minutes. The abstract of oral presentation of about 250 words should include title, authors, address, purpose of study, methods, results and conclusions. The name of the presenting author should be underlined. A registered delegate can present a maximum of one original work. Abstract with email address should be submitted preferably through E-mail (not as an attachment file but as a body of the mail) to the Organizing Secretary Dr. Shekar Chelur (E-mail: stpi.india@gmail.com) latest by October 10, 2014. Total number of presentations is restricted to eight.

## IFSTP TRAINEE AWARD

IFSTP (International Federation of Societies of Toxicologic Pathologists) is a confederation of ten national and regional societies of toxicologic pathology (STPs) representing scientists from around the globe. Society of Toxicologic Pathology - India is member of IFSTP. The IFSTP's stated role is to build, integrate and set standards in toxicologic pathology through member societies around the globe. In concordance with their commitment and goals, IFSTP is sponsoring travel grant of USD 200 each (equivalent in INR) for five PhD students who are interested in toxicologic pathology, completing their research work and writing thesis related to toxicologic pathology or in a closely related area. Travel grant is expected to adequately support students travel/accommodation/meeting registration fee. All interested students pursuing their doctoral research should send detailed CV and work report of about 300 words, attested by their Research Guide and Dean of College to the organizing secretary, Dr. Shekar Chelur latest by October 10, 2014. Poster presentation of research work must be presented at the conference. A panel of experts will evaluate work report and presentation and the winners will be awarded a certificate along with travel grant at an Award ceremony at the conference.

## CHARLES CAPEN TRAINEE AWARD

The International Academy of Toxicologic Pathology will fund two awards in the amount of 200USD each (equivalent in INR) for MVSC & PhD students for travel and registration costs to attend STPI conference. The successful applicant will have demonstrated achievements in the field of toxicologic pathology including but not limited to:

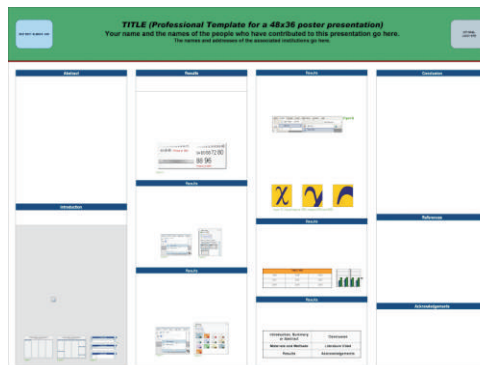
- Research contributing to public safety as it relates to the adverse health effects of xenobiotics;
- Establishing test methods and standards that enhance the field of toxicologic pathology; and/or
- Developing new or novel uses of toxicologic pathology in safety research.
- The applicant must submit abstract, CV and any other supporting document authorised by the major advisor and dean of college to organizing secretary by October 10, 2014. . A panel of experts will evaluate work report and presentation and the winners will be awarded a certificate along with travel grant at an Award ceremony at the conference.

## SUBMISSION OF ABSTRACTS FOR BEST POSTER PRESENTATION AWARD

The award is restricted to the subject/topic of Toxicologic Pathology only. The award consists of a Certificate and cash award of Rs.1500.

## POSTER PRESENTATION

The abstract of poster presentation of about 250 words should include title, authors, address, purpose of study, methods, results and conclusions. The name of the presenting author should be underlined. A registered delegate and member of the society can present a maximum of one original work.



Abstract with email address should be submitted preferably through E-mail (not as an attachment file but as a body of the mail) to the organizing secretary Dr. Shekar Chelur (E-mail: stpi.india@gmail.com) latest by October 10, 2014. Total number of presentations is restricted to ten. Poster shall be of size 48 inches (Width) x 36 inches (Height). General template given below may be followed.

## SOCIAL EVENTS

All registered participants, sponsors, organisers will receive social event passes for dinners on 31st October and 1st November 2014.

## MEETING MATERIALS

All registered attendees can pick up printed program books, badges and social event passes at registration desk.

**Dr. Sowmya Bharath, MVSc, DABT**

Gold medalist in MVSc Pathology, Dr. Sowmya Bharath started her career in Rallis Research Center in 1993. She served for 5 years as study pathologist for several short term and Long term studies. In 1998, she moved to AstraZeneca India Pvt Ltd, which was dedicated in research for neglected diseases viz., Tuberculosis and Malaria which predominantly affects the third world countries. She was part of the team which established efficacy models: Aerosol murine model for TB which is a specialized work to be carried out in BSL-3 facility and Peter's test- a 4 day murine model for malaria. Along with this, Sowmya contributed in frontloading the toxicology and Pathology in early drug discovery.

With all these efforts, her team has taken one molecule into Phase II clinical trials for treating Tuberculosis. The other achievements are: They have one molecule for TB and one molecule for Malaria as candidate drugs. Pathology and along with toxicology has been extensively studied by her and has given a boost in her career of drug discovery. She has published many research papers in international journals.

**Dr. Shekar Chelur, M. V. Sc, DABT, DIBTP**

Dr. Shekar Chelur graduated in 1996 and completed his Master's in Veterinary Pathology from Bangalore Veterinary College in 1999. He has worked at Jai Research Foundation,

Torrent Research Centre and Zydus Research Centre before joining Aurigene Discovery Technologies Ltd in 2004.

Shekar has been extensively involved in safety evaluation of NCE's in the area of Metabolic Disorders (Diabetes and Obesity), Oncology (Protease and Kinase inhibitors), Pain & Inflammation, Immunomodulators, Musculoskeletal disorders and anti- Apoptotic therapy. He is recipient of several merit scholarships including senior research fellowship from Indian Council of Agricultural Research. He is co-inventor of 3 international patents.

**Dr. Subba R Chintalacheruvu, Ph.D.**

I have over fifteen years' experience in the both pharmaceutical industry and Contract Research Organization, focused on lead optimization and clinical development of small and large molecules. Expertise in drug hunting skills, forecasting, data analysis, issue resolution and proposing comprehensive strategies-

to address efficacy and safety studies in autoimmune, bone and renal diseases. Strong expertise in pharmacology and immunology while functioning as the lead pharmacologist for numerous Cytokine/Chemokine, Kinase and Steroid programs at Eli Lilly and Company. As the scientific Lead of Inflammation, Renal and Bone at Covance, I have provided consulting in the selection of efficacy and safety packages for over 75 different clients in Asia, Europe and US.

**Dr. Chandhi S. Elangbam, B.V.Sc, M.V.Sc, PhD, DACVP, DABT**

Dr. Elangbam is currently a Director of Pathophysiology at GlaxoSmithKline, Research Triangle Park, North Carolina, USA. He provides specialized expertise in early drug discovery programs, animal models of human disease, pathologic evaluation and interpretation of target biological profiling in support of novel drug discovery and development. Previously, Dr. Elangbam has had a variety of roles and positions, including Director, Regulatory and Discovery Pathology (2001-2003), GlaxoSmithKline, Research Triangle Park, North Carolina, USA; Senior Principal Pathologist (1998-2001), GlaxoWellcome, Research Triangle Park, North Carolina, USA; Senior/Staff Pathologist (1991-1998), WIL Research Laboratories Inc.,

Ashland, Ohio, USA; Visiting Instructor, Department of Pathology, Oklahoma State University (1990-1991), Stillwater, Oklahoma, USA; Research Assistant (1982-1985), Toxicology and Pathology Department, CIBA-GEIGY Research Center, Goregaon (East), Bombay, India; and Assistant Professor/Pathologist (1981-1982), Department of Pathology, Bombay Veterinary College, Parel, Bombay, India.

Dr. Elangbam received his B.V.Sc. (1979) and M.V.Sc. (1981) from Bombay Veterinary College, Bombay, India; and completed his Residency and Ph.D. in Veterinary Pathology (1990) from Oklahoma State University, Stillwater, Oklahoma, USA. Dr. Elangbam has specialty board-certification in Veterinary Pathology (Diplomate, ACVP; 1994) and Toxicology (Diplomate, ABT; 1996). He has served on the Editorial board of Toxicologic Pathology (2002-2005) and published more than 57 publications, including invited reviews, and received the Centennial Research Excellence Award, Oklahoma State University, 1990. Presently, his research interests include use of transcriptomic (gene) signals in drug discovery and potential biomarker for drug safety and liabilities of anti-obesity therapeutics.

**Dr. Chirukandath Gopinath, B.V.Sc; PhD; FRCPath; FIATP**

Currently a Consultant in Toxicology & Pathology working independently from Alconbury, Cambridgeshire, UK. Has experience of well over 40 years in toxicologic pathology. Worked in academia, pharmaceutical and contract research organisation, holding senior positions mainly in UK and Europe. Dr Gopinath worked as a lecturer in veterinary pathology at Kerala veterinary college, Mannuthy, India and later as a veterinarian with Kerala government in India. He then went to British Guiana as a veterinary officer.

Dr Gopinath had worked as lecturer in veterinary pathology at University of Liverpool, UK, head of pathology, drug safety laboratories, Organon, Holland and as director of pathology and chief scientific officer at Huntingdon Life Sciences, UK. He was past president of British Society of Toxicologic Pathology and International Federation of Societies of Toxicologic Pathologists and past European director of International Academy of Toxicologic Pathology.

Also held senior academic role as chief examiner of veterinary pathology at the Royal College of Pathology, London. He has published extensively in peer reviewed journals on several topics in toxicologic pathology. He has also edited/ authored text books in the field. Recent publications included Toxicologic Pathology nonclinical safety assessment eds Sahota, Popp, Hardisty and Gopinath in 2013 and Atlas of Toxicological Pathology ed Gopinath & Mowat in 2014.

Dr Gopinath took his veterinary degree from Kerala Veterinary College, Mannuthy in 1959 and he was amongst the first batch of veterinarians qualified at Mannuthy. Dr Gopinath has organised and operated several educational modules in toxicologic pathology in different countries including India, China and Brazil.

**Dr. Julie Randolph-Habecker, Ph.D**



Dr. Julie Randolph-Habecker received her Master's of Science in Clinical Chemistry from The Ohio State University in 1993 and a doctorate in Pathobiology from The Ohio State University in 1998. Dr. Randolph-Habecker did her postdoctoral fellowship with Dr. Beverly Torok-Storb at the Fred Hutchinson Cancer Research Center. Drs. Habecker and Torok-Storb studied cytomegalovirus in the marrow microenvironment and strived to understand virulence factors in transplant patients. Dr. Randolph-Habecker became the Director of Experimental Histopathology Shared Resource in 2003.

Her laboratory provides pathology, histology, immunohistochemistry/immunofluorescence, laser capture microdissection, and digital pathology services for Hutch investigators as well as collaborators from other institutions and companies. The lab currently collaborates with about a third of the faculty at the Hutch.

Dr. Randolph-Habecker teaches classes at FHCRC including Fundamental of Immunohistochemistry and Cancer Fundamentals as well as classes for the National Society for Histotechnology on subjects consisting of immunofluorescence staining techniques, immunohistochemistry of animal tissue, and bringing innovation to research histology. She has co-authored a number of publications and was a contributor to the Comparative Anatomy and Histology Atlas.

**Dr. Akira Inomata, D.V.M., Ph.D., D.J.S.T.P.**



Dr. Akira Inomata is a veterinary/toxicologic pathologist who has worked on drug safety research since 1993. He received his D.V.M. (1993) and Ph.D (2003) from Nippon Veterinary and Life Science University and is a Diplomate of the Japanese Society of Toxicologic Pathology.

The first 10 years of his career were spent at Nippon Roche Research Center where he specialized in toxicologic pathology and in vivo/in vitro animal disease models. In 2003, he moved to Eisai where he is a preclinical safety lead of several global projects and currently a head of the pathology group at Drug Safety Tsukuba. His expertise and interest lies in drug induced target organ toxicity, particularly endocrine and GI toxicity.

**Dr. K. Kamala, B.V.Sc, M.V.Sc, DIBTP**



Dr. K. Kamala obtained her B.V.Sc from Madras Veterinary College and Masters Degree in Veterinary Pathology from University of Agricultural Sciences, Bangalore, India. She is working as Group Leader - Pathology in Advinus Therapeutics Ltd., Bangalore.

She has around 14 years of experience in the field of Toxicological Pathology with strong base in Good Laboratory Procedures to handle the regulatory Toxicology studies.

Involved in the conduct of gross and histopathology evaluation for all toxicity studies in rodents and non rodents including the carcinogenicity studies in rats and mice, also conducts peer reviews for the regulatory toxicology studies. She is author for around 150 regulatory toxicology study pathology reports including several chronic studies in rats and mice and transgenic mice.

**Dr. Thomas Nolte, Dr. med. vet., M.Sc, F.I.A.T.P.**



In 1988, Thomas Nolte received his DVM from the University of Veterinary Medicine of Hannover, Germany, where he also successfully completed his postgraduate study in veterinary pathology until 1991. Jointly with the Fraunhofer Institute of Toxicology and Aerosol Research in Hannover he conducted his doctoral thesis on the histogenesis and human relevance of pulmonary squamous cell carcinomas induced by airborne toxicants in rats in 1991. After three years attending a modular training in Applied Toxicology at the University of Surrey, Guildford, UK, he received his MSc in Applied Toxicology in 2005.

Thomas is German Board Certified Veterinary Pathologist and Toxicologic Pathologist.

In 1992, after one year as staff pathologist at the Fraunhofer Institute in Hannover, Germany, he started his career in pharmaceutical industry by joining ASTA Medica in Halle/Westfalen, Germany, as Principal Scientist.

In 2001 he moved to Boehringer Ingelheim Pharma, Biberach, Germany, where he works now as Scientific Expert in toxicologic pathology. Thomas now has responsibility for carcinogenicity testing and as member in several research and development teams for overall nonclinical safety testing.

Thomas is co-founder of the INHAND initiative of global harmonization in toxicologic pathology and is member of the INHAND Global Editorial and Steering Committee. In addition to membership in several INHAND working groups he chairs the Digestive Tract Organ Working Group. Since 2003 he chairs the industry-sponsored RITA project, and since last year he is co-organizer of the annual symposium "Classic Examples in Toxicologic Pathology".

#### **Dr. Thomas Rosol, DVM, Ph.D**



Thomas Rosol, DVM, PhD is a professor of veterinary pathology at The Ohio State University, diplomate of the American College of Veterinary Pathologists and senior advisor for technology commercialization in life sciences at OSU. He has served as dean of the College of Veterinary Medicine and vice president for research at OSU and on advisory boards to the National Institutes of Health, United States Department of Agriculture, American Veterinary Medical Association, and Morris Animal Foundation. Rosol serves as a consultant for industry in preclinical safety in the areas of endocrine, bone, and reproductive pathology and animal models of cancer. The Rosol laboratory investigates the pathogenesis of cancer-associated hypercalcemia, mechanisms and treatment of bone metastasis, animal models of human cancer, and endocrine-responsive cancers.

Recent work focuses on prostate, breast, and head and neck cancer. Rosol has served as the mentor for over 40 PhD graduate students and postdoctoral trainees. The laboratory specializes in mouse and dog imaging using bioluminescence, microCT, high resolution ultrasound, and MRI. Rosol is a fellow of the American Association for the Advancement of Science and was recognized by Ohio State University as a Distinguished Scholar, which is one of the universities' highest honors.

#### **Dr. Masumi Suzui, M.D., Ph.D.**



Professor of Department of Molecular Toxicology, Nagoya City University Medical School, Nagoya, Japan.

Specialty and present interest: carcinogenesis and cancer risk assessment, molecular cancer therapeutics and cancer prevention by natural and synthetic compounds.

#### **Dr. Venkatesha Udupa M.V.Sc (Path), M.Sc (Tox), DABT, DIBTP**



Dr. Venkatesha Udupa is currently working as General Manager – Toxicology and Vivarium at Glenmark Pharmaceuticals Ltd, Mumbai. In this role, Dr. Udupa supports drug discovery and development for several unprecedented targets by providing scientific input in the design and execution of early discovery and nonclinical toxicology experiments that focus on characterizing the safety of the candidates and/or understanding potential mode of action for toxicity in pre-clinical studies.

He also provides investigative guidance and scientific leadership in toxicology and pathology to drug discovery teams and support teams on laboratory animal resource.

Dr. Udupa has immense interest in drug development and safety evaluation of new chemical or biological entities especially in identifying mechanism of toxicity and overall risk assessment. He has worked in the targets related to metabolic disorders, infectious diseases, urinary incontinence, pain and inflammation etc.

Dr. Udupa completed his Pathology training at Veterinary College, Bangalore. He is a recipient of Overseas Development Administration Shared Scholarship Scheme (ODASSS) by the Association of Commonwealth Universities in the United Kingdom for Master's program in Toxicology at University of Surrey, UK. He is a Diplomate of American Board of Toxicology (DABT) and Indian Board of Toxicological Pathologists (IBTP) and actively involved in various professional activities of STPI or IBTP. He has 14 international publications in peer reviewed journals and 16 national publications, co-inventor in couple of patents and a coauthor for a book chapter on topics in Discovery and Regulatory Toxicology in Pharmaceutical Industry.

#### **Dr. S.K. Vijayasarithi, M.V.Sc, Ph.D, DIBTP**



Dr. Vijayasarithi (B.V.Sc., M.V.Sc., Ph.D) has over 45 years of experience in the field of pathology. He first joined University of Agricultural Sciences, Bangalore India, in 1969 and served in various capacities and superannuated in 2004 as Head of the Pathology Department. During this period he was involved in teaching of Undergraduate and Postgraduate courses leading to award of B.V.Sc/M.V.Sc and Ph.D degrees. He was the Major supervisor for 29 Master's and Doctoral students and Advisor for more than 150 graduate students.

He was the principal investigator for several federal and private funded research projects. He has nearly 80 scientific publications to his credit and has presented several research paper at National and international conferences. He is recipient of many awards for his scientific achievements. Presently he is the President of Society of Toxicologic Pathology and India and also life member of many scientific organizations.

Simultaneously he was also consultant pathologist for several GLP certified laboratories which were actively involved in safety assessment of NCEs. He joined as Head of Pathology at, Advinus Therapeutics Limited Bangalore, India in 2007. He is involved in study designing, conducting and histopathological evaluation of the toxicological potential in variety of animal models. He is the author of nearly four hundred safety evaluation study reports including more than 25 carcinogenicity studies. In addition he has peer reviewed several studies. These reports are submitted to various regulatory authorities of several countries, including FDA & EPA (U.S.A), European and Japanese Health – Indian Regulatory Authorities.





## Pathology Peer Review

Sponsored by IATP, IFSTP, STP and STP-I

**November 2, 2014, Bangalore, India**

As part of our international outreach and educational initiative, the International Academy of Toxicologic Pathology (IATP) is organizing a half-day seminar at Bangalore, India on November 2, 2014. This seminar is sponsored by IFSTP, Society of Toxicologic Pathology (USA) and Society of Toxicologic Pathology India (STPI). This is the first IATP seminar in India.

Pathology peer review verifies and improves the accuracy and quality of pathology data and interpretations. Pathology peer review is a critical phase when important risk assessment or business decisions are based on nonclinical studies. A recent OECD advisory document “Draft OECD Guidance on the GLP Requirements for Peer Review of Histopathology” is under discussion with various Tox Path societies worldwide. The following topics will be covered and discussed in the seminar:  
The seminar will be concluded with a panel discussion on Pathology peer review practices.

- ✓ Roles of the Study Pathologist, Peer Review Pathologists, Pathology Working Groups
- ✓ Peer review of clinical pathology data
- ✓ Regulatory perspective on pathology peer review
- ✓ Perspective of a Pathologist on peer review in Indian CRO

## Organizing Committee:

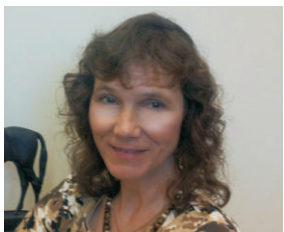
- S.K. Vijayasarithi, M.V.Sc, Ph.D, DIBTP, Advinus Therapeutics Ltd., India
- Bob Maronpot, DVM, MPH, DACVP, DABT, Fellow IATP, Maronpot Consulting LLC, USA
- Bhanu Singh, B.V.Sc, MS, DACVP, DABT, Fellow IATP, Janssen R&D, USA
- Takanori Harada, DVM, Ph.D, The Institute of Environmental Toxicology, Japan

## Session chairs/Panel moderator:

- Kamala Kannan, B.V.Sc, M.V.Sc, DIBTP, Advinus Therapeutics Ltd., India
- Yogesh Kumar Murkunde, B.V.Sc, M.V.Sc, Ph.D, DIBTP, IIBAT, India
- Bhanu Singh, B.V.Sc, MS, DACVP, DABT, Fellow IATP, Janssen R&D, USA

## Seminar Speakers

### Dr. Sabine Francke DVM, Dr Vet Med, Ph.D, Fellow IATP, CFSAN, FDA, USA



Dr. Sabine Francke is the Senior Pathologist of the Center for Food Safety and Applied Nutrition (CFSAN) of the Food and Drug Administration (FDA) in the Office of Food Additive Safety (OFAS). Dr. Francke functions as the Agencies recognized Expert for Toxicologic Veterinary Regulatory Review Pathology and serves all FDA Centers and other Government Agencies by addressing controversial pathology issues of regulatory submissions and supporting pathology related regulatory research efforts.

Dr. Francke conducts independent slide reviews and participates in international Pathology Working Groups (PWG) to provide a regulatory perspective to global complex preclinical safety issues.

Dr. Francke is a recognized Fellow and the current President of the International Academy of Toxicologic Pathologists (IATP), a “past-president” of the Association of Government Toxicologists (AGT), Member of the North American Society of Toxicologic Pathology (STP) and the European STP (ESTP). Dr. Francke functions as Regulatory Liaison to the Science and Regulatory and Policy Committee (SRPC) of the STP. In this role, Dr. Francke has served on many STP working groups and has co-authored several best practices papers. Dr. Francke is also a member of the CFSAN Cancer Assessment Committee (CAC), Science Council, Redbook committee and chairs the Immuno-toxicology Redbook committee.

Before joining FDA in 2001, Dr. Francke worked as staff pathologist in preclinical safety for the Pharmaceutical Industry and as immuno-pathologist for a contract research organization. Dr. Francke completed her PhD / residency in applied veterinary pathology at The Ohio State University, Columbus Ohio, USA. Prior, Dr. Francke defended her Dr. Vet. Med. thesis after she graduated as D.V.M. from the Justus Liebig University, Giessen, Germany.

### Dr. Jerry Hardisty, DVM, DACVP, Fellow IATP, Experimental Pathology Laboratories, Inc., USA



Dr. Jerry F. Hardisty is the Chief Executive Office of Experimental Pathology Laboratories, Inc. (EPL®). He graduated from Iowa State University College of Veterinary Medicine and received his pathology training in the U.S. Army Preceptorship Program. He joined EPL as a staff pathologist in 1976. He has been a Diplomate of the American College of Veterinary Pathologists since 1976. Dr. Hardisty is an Adjunct Assistant Professor with the North Carolina State University College of Veterinary Medicine. In 2005, he was awarded the Stange Award for Meritorious Service by the College of Veterinary Medicine at Iowa State University.

Dr. Hardisty has worked with the NCI/NTP Carcinogenesis Testing Program closely for over 30 years. He has participated in the publication and presentation of significant results of the NCI/NTP Pathology Quality Assessment Program and of several specific carcinogenesis bioassay tests. He has coauthored several publications in experimental pathology, pathology quality assessment and pathology peer review. He has served on the Editorial Board for Toxicologic Sciences, Toxicologic Pathology and Experimental and Toxicologic Pathology. He specializes in the conduct of Pathology Peer Review of subchronic and carcinogenicity nonclinical toxicology studies. He also organizes and chairs Pathology Working Groups and Scientific Advisory Panels in the US, Japan and Europe.

Dr. Hardisty is active in the Society of Toxicologic Pathologists (STP) as member of Executive Committee (1994-1998), Standard Systematized Nomenclature and Diagnostic Criteria Committee (SSNDC) (1984-2000), liaison with the American College of Toxicology (1998-2000), as President-Elect (199-1999), President (1999-2000) and as Past-President (2001-2002). He has also served as the chair of the STP nominating and fundraising committees. In 2011, he was received the Society of Toxicologic Pathology Achievement Award. He is a member of the International Academy of Toxicologic Pathologists and has served as the North American Director of the IATP.

**Dr. P Kalaiselvan, B.V.Sc, M.V.Sc, DICVP, DABT, Syngene international limited, India**



Dr. P. Kalaiselvan is currently working as senior research scientist in the pathology section of Safety Assessment department, Syngene International limited, Bangalore, India. In this role he is responsible for managing pathology group and also involving as study pathologist for various repeat dose toxicology studies. Prior to Joining Syngene, Kalai has worked in Drug Safety Evaluation of Ranbaxy Research Laboratories, Gurgaon, India and IIBAT, Chennai. In these roles he served as study pathologist for toxicology studies involving NCEs, generic pharmaceuticals and agrochemicals.

Kalai is a diplomate of Indian College of Veterinary Pathologists (DICVP) and American board of toxicology (DABT). He is veterinarian by training (obtained from Madras Veterinary College, India) and has Master's degree in Veterinary Pathology (obtained from College of Veterinary Sciences, Thrissur, Kerala). He is a recipient of ICAR's research fellowship for his Master's degree. He has experience in toxicologic pathology for the past 10 years.

**Dr. Lila Ramaiah, B.Sc, DVM, Ph.D, DACVP, Huntingdon Life Sciences, USA**



Dr. Lila Ramaiah is a board certified veterinary clinical pathologist with more than 6 years of experience in toxicologic clinical pathology. She is director of clinical pathology (safety assessment) at Huntingdon Life Sciences. She has co-authored five book chapters and a best practice paper for clinical pathology in industry. Dr. Ramaiah is the current chair of the ASVCP Regulatory Affair Committee, has been an active leader in the STP Clinical Pathology Interest Group.

She has presented in SOT and ASVCP scientific meetings, has moderated a panel discussion on pathology peer review between FDA and industry pathologists, and has co-chaired a number of continuing education courses for the STP, ACT and FDA. In addition, Dr. Ramaiah is past treasurer of the AACC Division for Animal Clinical Chemistry (DACC).

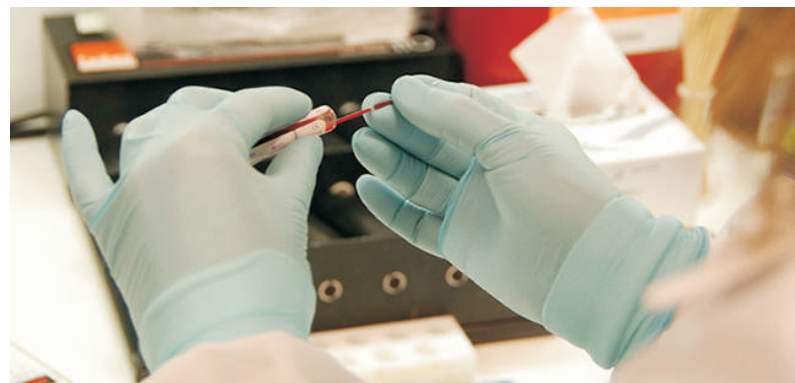
At HLS, Dr. Ramaiah provides scientific expertise and acts in a scientific advisory capacity to Huntingdon Life Sciences and its Clients on all aspects of clinical pathology in the regulatory environment, including study design and biomarker test implementation, and in-depth interpretation of clinical pathology and biomarker data. In addition, Dr. Ramaiah serves as scientific reviewer of Regulatory Toxicology Reports, evaluates peripheral blood and bone marrow smears for hematotoxicity, and provides scientific and interpretive support for assays involving cytology, cytokine and complement analysis and flow cytometry. Dr. Ramaiah holds a B.Sc. (Honors) in Molecular and Cellular Biology, a D.V.M. (veterinary medical degree Laboratory Animal Medicine track) and a Ph.D. in Pathology.

**Dr. Peter Mann, DVM, DACVP,  
Fellow IATP Experimental Pathology Laboratories, Inc., USA**



- Bachelor's Degree in English Literature, Washington University, St. Louis, Mo, 1970
- DVM – University of Missouri, Columbia, 1979
- Residency in Comparative Pathology, National Zoological Park, Washington DC, 1979-82
- Senior Lecturer, Pathology, University of Pennsylvania School of Veterinary Medicine, 1982-1985
- Pathologist, ICI Americas (now Astra Zeneca), Wilmington, DE, 1985-1989

- Pathologist, Manager, Experimental Pathology Laboratories, Inc. (EPL), 1989-present
- Areas of Interest: Peer Review, Carcinogenesis, Transgenic models, primate pathology
- Society of Toxicologic Pathology: Committee Chairs, Executive Committee, President, Chairman of INHAND initiative
- Birdwatcher, Lives on a boat in Seattle, WA, with his wife Dr. Nancy Everds, well-known clinical pathologist





### **ABOUT BANGALORE**

The capital of the state of Karnataka, Bangalore is situated halfway between the east and west coasts in Southren India. The city was founded in the 16th century and was ruled by great southern dynasties like the Kadambas, the Hoysalas and Vijayanagar Empire. Legend has it that the name Bangalore comes from "boiled beans" (Benda Kaluru), which was served by a humble old lady to a hungry ruler in the 10th century.

Bangalore is also called "the Garden City" thanks to its many parks and flowering trees. Thanks to many local parks, along with pink cassias, golden acacias, golden tabebuias, blue jacarandas and flaming gul mohars, which bloom throughout the city.

Many international visitors come to Bangalore for its IT industry and prestigious research institutes, such as the Indian Institute of Science, Indian Institute of Management, etc. While enjoying the pleasant weather year-round, tourists can also use the city as a central base for day trips to other Karnataka attractions.

### **TRANSPORTATION**

Bangalore international airport is located at Devanahalli, 35 kilometers from Bangalore City. Most U.S. and many international airlines offer direct flights to Bangalore.

#### **Transportation from the Airport**

##### **Car Rental**

Bangalore International Airport (<http://www.bengaluruairport.com>) is served by Three major car rental firms. Mega Cabs – 4747 4747, Meru - 4422 4422, KSTDC- 4466 4466 24 hour service (Rs 17.50/- per kilometer). The Citywide public transportation agency is Bangalore Metropolitan Transport Corporation (BMTC) connects BIA to major routes through Vayu Vajra bus services.

#### **Local Transportation**

Conference organizers will provide transport from Veterinary University guest-house, Karnataka Veterinary Council Guest House and IVRI Guest House to conference venue. The Citywide public transportation agency is Bangalore Metropolitan Transport Corporation (BMTC). Auto Rickshaws and City Taxis are other means of transport.

### **HOTEL INFORMATION / RESERVATIONS**

STPI has reserved limited number of rooms at discounted rates at the Hotel Atria, Hotel Ashraya International and Hotel Nandhini. Delegates are requested to contact the hotel directly. Please remember to refer to the "Society of Toxicologic Pathology - India" meeting in order to receive the discounted rates (maximum 20%). It is important to make reservations as soon as possible to assure availability. All cancellations and changes should be made directly with the hotel. The discounted rates are mentioned below:

#### **1. The Atria Hotel (Conference venue)**

No. 1, Palace Road, Bangalore - 560001,  
Ph: 91-080-22205205, Fax: 91-080-22256850  
Room Tariff: Rs.3500 (Standard room single) to Rs.6100 (Lifestyle room double) + Tax,  
E-mail: [rooms@atriahotel.com](mailto:rooms@atriahotel.com), Web: [www.atriahotel.com](http://www.atriahotel.com)

#### **2. Ashraya International Hotel (5 minutes walk)**

149 Infantry Road, Bangalore 560 001,  
Phone: +91-80-40355999, +91-80-22261921,  
+91-80-51148484, Fax: +91-80-22263982  
Room Tariff: Rs. 2000 (Standard room, Single) to Rs.3000 (Superior room, double) + Tax  
Email: [ashraya.hotel@gmail.com](mailto:ashraya.hotel@gmail.com) / [booking@ashrayahotel.com](mailto:booking@ashrayahotel.com),  
Website: [www.ashrayahotel.com](http://www.ashrayahotel.com)

#### **3. Hotel Nandhini (15 minutes drive)**

# 164, MLA lay out, R.T Nagar Main Road,  
Bangalore-560032,  
Ph: +91 80 22178900 Fax; +91 80 22178951  
Room tariff: Deluxe AC, Rs-1200 (single), Rs.1500 (double),  
Comfort class - Rs.1400 (single) , Rs.1600 (double)  
Email: [rooms.nandhini@rediffmail.com](mailto:rooms.nandhini@rediffmail.com),  
Website; [www.nandhini.com](http://www.nandhini.com)

### **ACCOMMODATION**

Limited accommodation will be available in the Veterinary University guest-house, Karnataka Veterinary Council Guest House and IVRI Guest House on first come/informed basis to the delegates. Average room rates per day on twin sharing basis will be Rs. 150 to 300. The rest of the delegates will be assisted in getting accommodation in hotels if they can let us know in advance. For further details, contact Organizing Secretary, Dr. Shekar Chelur at [stpi.india@gmail.com](mailto:stpi.india@gmail.com)

**Fifth conference of  
Society of Toxicologic Pathology - India**

**“Continuing Education in Toxicologic Pathology –  
Endocrine and Gastrointestinal System”**

October 31, November 1-2, 2014

“Chancery” The Atria Hotel # 1, Palace Road, Bangalore - 560 001

**REGISTRATION FORM**

Name: \_\_\_\_\_

Designation: \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Phone / Fax: \_\_\_\_\_ E-mail: \_\_\_\_\_

STP-I membership #: \_\_\_\_\_ Amount: \_\_\_\_\_

Draft/cheque No. : \_\_\_\_\_ Bank: \_\_\_\_\_

Date: \_\_\_\_\_ Signature: \_\_\_\_\_

Registration fee	Before October 1	Spot registration fee
STP-I member	Rs. 4000	Rs. 4500
Non member	Rs. 5000	Rs. 5500
Students	Rs. 2500	

**Online transfer details:** Axis Bank Ltd, Electronic City, A/C name: Society of Toxicologic Pathology – India, A/C # 912010024584538, IFS Code: UTIB0000677. Intimation of online transfer with filled registration form e-mailed to [stpi.india@gmail.com](mailto:stpi.india@gmail.com)  
At par cheque/draft to be drawn in favour of Society of Toxicologic Pathology - India (STP-I), payable at Bangalore sent to Dr. Shekar Chelur, Aurigene Discovery Technologies Ltd. 39-40, KIADB Industrial Area, Electronics City Phase II, Hosur Road, Bangalore - 560 100, Phone (O): 080-6620 4390, Mobile: +91 98802 37237



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Advinus Therapeutics Limited, Bangalore

### Vice President

Dr. B. K. More, M.V.Sc., Ph.D  
Department of Veterinary Pathology,  
Shirwal Veterinary College, Pune

### General Secretary

Dr. Shekar Chelur M.V.Sc, DABT, DIBTP  
Aurigene Discovery Technologies Ltd, Bangalore

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International Institute of Biotechnology and Toxicology (IIBAT), Chennai

### Treasurer

Dr. Jomy Jose M.V.Sc., DIBTP  
Vimta Laboratories Limited, Hyderabad

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Sun Pharma Advanced Research Co. Ltd, Vadodara

Dr. P Kalaiselvan, M.V.Sc, DICVP, DABT,  
Syngene international limited, India

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Zydus Reseach Centre, Ahmedabad

### Special Advisor

Dr. S. J Seshadri, M.V.Sc., FIAVP  
Bangalore

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Department of Veterinary Pathology,  
Shirwal Veterinary College, Pune

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Advinus Therapeutics Ltd, Bangalore

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International Institute of Biotechnology and Toxicology (IIBAT),  
Chennai

Dr. Jomy Jose M.V.Sc., DIBTP  
Vimta Laboratories Limited, Hyderabad

Dr. Sathish Panchal, M.V.Sc.,  
Sun Pharma Advanced Research Co. Ltd, Vadodara

Dr. P Kalaiselvan, B.V.Sc, M.V.Sc, DICVP, DABT,  
Syngene international limited, India



Society of Toxicologic Pathology - India  
29, 1st cross, Malleshwaram  
Bangalore - 560 003, Karnataka, India  
e-mail: [stpi.india@gmail.com](mailto:stpi.india@gmail.com)  
Website: <http://www.toxpathindia.com>