



FIRST JOINT SAFETY PHARMACOLOGY WORKSHOP

Bangalore, India

April 13th and 14th 2011

Organized by
Safety Pharmacology Society, USA, Europe and Canada

Indian Chapter of the Society of Quality Assurance (ICSQA)
(Approved Chapter of the SQA, USA)
and
Society of Toxicology of India (STOX)

FACULTY

International Faculty from Safety Pharmacology Society Covering Topics from Cardiovascular
(*in vitro* and *in vivo*), CNS, Respiratory, GI and Renal Pharmacology

Dr. Thomas Beck (Covance)

Dr. Russell Bialecki (Astra Zeneca)

Dr. Alfred Botchway (Xenometrics)

Dr. Mark Holbrook (Pfizer)

Dr. Derek Leishman (Lilly)

Dr. Jean Pierre Valentin (Astra Zeneca)

Dr. Robert Wallis (Pfizer)

Dr. Gareth Waldron (Pfizer)

Venue :

Advinus Therapeutics Ltd.

21&22, Phase II, Peenya Industrial Area
Bangalore 560058, INDIA

For Details Contact: **Dr. K. S. Rao**

Phone No. +91-988-079-9455

Safety Pharmacology Workshop

Bangalore, April 13 and 14 2011

Dear Participants:

This is a Golden Opportunity to listen and learn the Principles and Practical aspects of Safety Pharmacology from the best of the best in the World. Eight World Renowned Safety Pharmacology experts from US and Europe are giving this intensive workshop which is the first of its kind in India. This is a Unique Opportunity and **it may not be repeated in the near future.**

As you know, Safety Pharmacology is an essential component of Drug Development. In fact more drugs are withdrawn in the last 10 years due to Safety Pharmacology concerns than any other single factor. It is imperative that all involved in Biological Sciences, Medical Sciences, Pharmaceutical Sciences must be familiar and fully conversant with the what, why and how of Safety Pharmacology testing.

The course is of utmost importance to all Medical / Veterinary Pharmacologists, Toxicologists, and also to Discovery and Regulatory scientists involved in the industry. It is essential that all academic institute Professors also attend this important workshop so that they can transmit this knowledge to their students who can be "Industry Ready" and be gainfully employed.

Dr. K. S. Rao

Who Should Attend

- | | |
|---|---|
|  Toxicologists |  Health & Safety Professionals |
|  Safety Pharmacologists |  Academicians & Researchers |
|  Regulatory Experts |  Students |

For Further Assistance,

Dr. K. S. Rao M.V.Sc., PhD., DABT

Advinus Therapeutics Ltd

21&22, Phase II, Peenya Industrial Area

Bangalore 560058, INDIA

Tele: +91-80-66553120 Fax: +91-80-2839-4015

Mobile: +91-988-079-9455

Safety Pharmacology Workshop

Bangalore, April 13 and 14 2011

PROGRAMME : DAY 1

08:00	Breakfast	
08:30	Inauguration - Dr. Rashmi Barbhaiya, CEO & MD, Advinus	
09:00	Welcome to meeting and introduction to the Safety Pharmacology Society	-Rob Wallis
09:15	Back ground to Safety Pharmacology: Regulatory guidance and the application of safety pharmacology studies through out the drug discovery and development process	-Rob Wallis
10:15 - 11:00	Understanding sensitivity and specificity, statistical analysis and the use of reference compounds – aspects of best practice	- Derek Leishman
11:00 -11:30	Break	
	<u>Use of in vitro assays in Safety Pharmacology</u>	
11:30 -12:15	Radioligand binding and functional cell-based assays. Study design, strengths and weaknesses. Including case studies	- Gareth Waldron
12:15 -13:15	Lunch	
	<u>QT as a safety issue</u>	
13:15 -14:00	Torsades de Points (TdP) as a safety concern in the clinic. Review of the history of compound withdraws and the use of QT as a biomarker	- Jean Pierre Valentin
14:00 -14:30	In vitro systems: Patch clamp and isolated heart assays. Study design, strengths and weaknesses. Including case studies	- Derek Leishman
14:30 -15:30	In vivo systems: Use of the guinea pig, ferret, dog and monkey to detect QT effects. Study design, strengths and weaknesses. Including case studies	-Alfred Botchway
15:30 -16:00	Break	
16:00 - 17:00	Open Questions for Panel Discussion	
17:00	Close	

Safety Pharmacology Workshop

Bangalore, April 13 and 14 2011

PROGRAMME : DAY 2

08:00	Breakfast	
09:00	Introduction to Day 2	- Derek Leishman
	<u>Central Nervous System</u>	
09:15	CNS FOB: Strengths and weaknesses and review of assays to follow-up on observations in the FOB	- Russ Bialecki
10:00-10:30	Drug - Induced Seizure risk	- Russ Bialecki
10:30-11:00	Studies to detect abuse potential liabilities	- Mark Holbrook
11:00 -11:30	Break	
	<u>Cardiovascular System</u>	
11:30 -12:45	The use of non-rodent species (monkey and dog) to evaluate CV effects of test compounds. Study design, strengths and weaknesses. Including case studies	- Jean Pierre Valentin
12:45-13:30	Lunch	
	<u>GI and Renal System</u>	
13:30-14:00	Studies to define drug effects on the gastrointestinal system. Study design, strengths and weaknesses. Including case studies	-Rob Wallis
14:00-14:30	Studies to define drug effects on the renal system. study design, strengths and weaknesses. Including case studies	-Alfred Botchway
	<u>Pulmonary System</u>	
14:30-15:00	Studies to define drug effects on the pulmonary system. Study design, strengths and weaknesses. including case studies	- Mark Holbrook
15:00-16:30	Incorporating safety pharmacology end points in toxicology studies. Study design, strengths and weaknesses. Including case studies.	- Tom Beck
16:30-17:00	Open Questions for Panel Discussion	
17:00-17:15	Closing Comments - Dr. Nimish Vaccharajani, Advinus	

Speaker Biographies



Russell Bialecki

Dr. Bialecki received his Ph.D. degree in Medical Physiology from the Medical College of Pennsylvania in 1988 with a subsequent Postdoctoral Research Fellowship at Brigham and Women's Hospital and Research Fellowship in Medicine at Harvard Medical School. He is presently Director, Safety Pharmacology North America within the Department of Safety Assessment (US) at AstraZeneca Pharmaceuticals and member of the Board of Directors of the Safety Pharmacology Society. Dr. Bialecki manages preclinical safety programs in support of AstraZeneca Pharmaceuticals discovery and clinical development programs in the US. Dr. Bialecki has engaged in pharmaceutical R&D related to integrative physiology/pharmacology for 18 years with expertise in CNS, respiratory and cardiovascular functional assessments in vivo and in vitro with more than 30 peer reviewed papers and book chapters on these topics.



Derek J. Leishman

Dr. Leishman trained as a pharmacologist and electrophysiologist in Aberdeen, UK. He has 19 years of pharmaceutical industry experience, following his PhD and post-doctoral training. His work has focused on cardiovascular, cardiac, and more general safety pharmacology in positions with Marion Merrell Dow and Pfizer. In 2005 Dr Leishman joined Lilly Research Laboratories as Research Fellow and Global Head of Safety Pharmacology. Dr. Leishman is Vice-President Elect of the Safety Pharmacology Society.



Robert M Wallis

Dr. Robert Wallis obtained his first degree and PhD in pharmacology in the UK and joined Pfizer as a member of the General Pharmacology Team. Whilst at Pfizer he has held roles of increasing responsibilities and is currently Executive Director, Centres of Emphasis (COEs) within Drug safety Research and Development. The CoE groups include Global Safety Pharmacology, Genetic Toxicology, Developmental Reproductive Toxicology and Immunotoxicology.



Jean-Pierre Valentin

Dr Jean-Pierre Valentin is currently Director and, since January 2010, Global Discipline Leader for Safety Pharmacology at AstraZeneca, based at Alderley Park, Cheshire, UK. He has accountability for supporting the entire AstraZeneca R&D portfolio with Safety and Secondary Pharmacology activities as well as for the newly created Safety Screening Centre.

Speaker Biographies



Mark Holbrook

Dr Mark Holbrook is Executive Director and head of Global Safety Pharmacology at Pfizer. Mark trained as a pharmacologist in the UK obtaining his first degree and PhD from Coventry and Liverpool Universities respectively. He has 21 years experience in the pharmaceutical industry working at Celltech and AstraZeneca before joining Pfizer. His career started in drug discovery, primarily in the cardiovascular and respiratory disease areas, before moving to safety pharmacology eight years ago. His department supports projects at all phases from early target identification to registration.



Thomas W. Beck

Dr. Beck is responsible for the scientific leadership and management of the Safety Pharmacology department at Covance, Madison. Dr. Beck received his Ph.D. in Animal Physiology from Michigan State University and was on staff at The Ohio State University, Battelle Memorial Institute, the University of Washington and SNBL USA prior to joining Covance Laboratories.

Dr. Beck is very active with several formative committees for the international Safety Pharmacology Society. He is also a member of the American College of Toxicology and the Society of Toxicology



Alfred Botchway

Dr. Alfred Botchway is President and Founder of Xenometrics, LLC, a non-clinical contract research service provider. Alfred has past experience with academic research, a major pharmaceutical company, a contract laboratory, and teaching medical school students. Alfred's experience includes extensive research in safety pharmacology, and has monitored and conducted numerous studies on behalf of numerous companies. Alfred is also an active member of several international scholastic professional scientific organizations and served on the board of directors of the Safety Pharmacology Society. He holds a Bachelors and a Master's degree in Biomedical Science. Subsequent to a special interest and research in electrophysiological changes associated with regression of left ventricular hypertrophy, Alfred was awarded a Ph.D. from the University of London, UK.



Gareth Waldron

Dr. Gareth Waldron joined Pfizer in 2000 after postdoctoral positions studying vascular smooth muscle electrophysiology and molecular biology at the Universities of Calgary, Canada and Cambridge, UK. Initially in the HTS assay development group he concentrated on plate based assays for ion channel drug discovery before introducing automated patch clamp technology to Pfizer, UK. Gareth then moved to lead the CNS and General Pharmacology Discipline of Pfizer's Global Safety Pharmacology department which resides within Drug Safety Research and Development. Early in 2010 he took the position of Global Discipline Lead for Safety Pharmacology where he is responsible for the forward looking science strategy for Safety Pharmacology within Pfizer.

Safety Pharmacology Workshop

Bangalore, April 13 and 14 2011

PARTICIPANT REGISTRATION

Name Mr. Ms. Dr.....

Company/Institution :.....

Address:.....

.....

.....

Telephone(Landline):..... Mobile:.....

Email:..... Food Preference: Vegetarian Non- Vegetarian

Fee Payment: Mode of payment: Online Cheque/DD

Online Payment :
(Preferred) Indian Chapter of the Society of Quality Assurance Trust (ICSQA) A/C No:
30376720449, State Bank of India Branch R.T. Nagar : Bangalore-560032-IFS Code :
SBIN0007982 Using these details, one can make the payment by online from
anywhere and any bank in india. Please indicate narration as "Safety Pharmacology
Workshop India 2011"

Cheque/Demand Draft: In favour of "Indian Chapter of the Society of Quality Assurance Trust: (ICSQA)
PAYABLE AT BANGALORE

Cheque/DD No. _____ Date: _____

Signature

Date

Place

Registration Fee

Industry/Corporate Sector : Rs. 12,000/-

Non Industry : Rs. 9,000/-

ICSQA Members : Rs. 8,000/-

Send the above completed Registration Form to

To,

Dr. K. S. Rao
Advinus Therapeutics Limited
21 & 22, Phase II, Peenya Industrial Area
Bangalore-560058, INDIA
Mob: +91 988-079-9455
E-mail : ks.rao@advinus.com

ACCOMMODATION



The Beautiful Bangalore

Bangaluru is the capital of Karnataka, located on the southern Deccan Plateau. Bangalore has had many nick names over the years from the 'pensioner's paradise' to the IT capital of India. Bangalore is a thriving business center focusing on information technology (IT), Biotechnology and is considered as IT capital of India, often called the Silicon Valley of India. Today, the city is the nerve centre for many Indian as well as multinational Biotechnology, Information Technology and Pharmaceutical Research and Development Companies.

Bangaluru International Airport (BIAL) is located near Devanahalli, 35 kilometers north of Bangalore city. Airport is served by two major car rental firms, Easy Cabs (080-43434343) and Meru (080-44224422). Bangalore Metropolitan Transport Corporation (BMTc) offers bus facility to all over the city from airport. Within the city, BMTc, Auto and Cabs are also available for transport.

The climate of Bangalore is moderate and pleasant. The city experiences a very favorable weather throughout the year. During the month of April, Summer will be mild with temperature ranging from 28 to 33 °C.

Hotel Reservations

Guest houses (Veterinary University Campus) facilities are limited and would be provided on advance intimation on first come first serve basis. The rest of the delegates will be assisted in getting accommodation in hotels on request. Organizing committee recommends the following hotels at various tariff levels for attendees Transportation will be provided from the below hotels to the venue.

Coraltree by Goldfinch,
RT Nagar Main road,
Bengaluru 560032.
Phone:+91-80-43346600
Email: reserve@coreltree.com

The Solitaire Hotel
3, Kumara Krupa Road,
Madhavanagar,Bangalore-560001
Tel : 91 - 80 – 40443636
email: onlinebooking@thesolitairehotel.com

The Royale Senate
No 24, Bellary Road, Hebbal,
Bangalore – 560024
Ph: 91 80 23439860
email:info@theroyalesenate.com

Hotel Nandhini
No 164, MLA Layout RT Nagar Main Road
Bangalore-560032
Tel : 91 - 80 – 40455555
email: rooms.nandhinirtn@thesolitairehotel.com