INTERACTIVE MEET ON INSIGHTS IN TOXICOLOGY
-A ToxGurukul Initiative
25th to 26th November, 2017, Bengaluru, India

Karnataka Veterinary Council
Veterinary College Campus
Hebbal, Bengaluru-24

Course Director and Organizer
K. S. Rao, M.V.Sc., Ph.D., DABT
ToxGurukul

ToxGurukul is a group of professionals in the field of toxicology who were in search of a platform to learn and share the vast knowledge in this area. This platform does not belong to any company or organization. It is a forum where professionals from different backgrounds of toxicology share their knowledge to un-puzzle the Rubik’s cube that each face in their daily work routine.
Organizing Committee

Patron
Dr. K.S.Rao  Advinus Therapeutics, Bengaluru

Chairman
Mr. Alex Thomas, IIBAT, Chennai

Vice Chairman
Ms. Benita Saklani Maindola, Advinus Therapeutics, Bengaluru

Organizing Secretary
Dr. Mukul Pore, Intox, Pune

Joint Organizing Secretary
Dr. Pise Pravin, ADTL, Bengaluru

Members
Dr. Jagadeesh S.Sanganal, Bengaluru
Dr. B.V.Ravichandra, Dr.Reddy's Laboratories Ltd, Hyderabad
Mr. Krutik Andhariya, iMED Global, Bengaluru
Dr. Sowmya Bharath, Intox, Pune
Mr. Deepak Ujaawane, JRF Global, Gujarat
Mr.V.V.S Vamsi Mohan Reddy, Stelis Biopharma,  Bengaluru

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## Course Schedule

### DAY 1 (25.11.2017)

<table>
<thead>
<tr>
<th>Time</th>
<th>Title &amp; Speaker</th>
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<tbody>
<tr>
<td>09.00 am</td>
<td>to 09.15 am* Introduction to the course and overview - Dr. K.S. Rao, Advinus Therapeutics, Bangalore.</td>
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<tr>
<td>09.15 am</td>
<td>to 10.30 am* Basic Principles of Toxicology - Dr. Prakash Nadoor, Veterinary College, Bangalore.</td>
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<tr>
<td>10.45 am</td>
<td>to 12.00 pm* Basic ADME and DMPK - Dr. Prasad S, Anthem Biosciences, Bangalore.</td>
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<tr>
<td>12.00 pm</td>
<td>to 01.00 pm* ToxQuiz</td>
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<tr>
<td>01.30 pm</td>
<td>to 02.45 pm* Advanced DMPK - Dr. Sanjeev Giri, Aurigene, Hyderabad</td>
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<tr>
<td>02.45 pm</td>
<td>to 04.00 pm* Exploring Regulatory Toxicology - Dr. Rajesh Eshwarappa, Aurigene, Hyderabad.</td>
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<tr>
<td>04.15 pm</td>
<td>to 05.30 pm* What is considered as Adverse Effect? - Dr. Mukul Pore, Intox, Pune.</td>
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<tr>
<td>05.30 pm</td>
<td>to 06.15 pm* Interactive Session</td>
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*Tea break - 10.30 - 10.45am & 04.00 - 04.15pm; Lunch Break - 01.00 - 01.30pm

### DAY 2 (26.11.2017)

<table>
<thead>
<tr>
<th>Time</th>
<th>Title &amp; Speaker</th>
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<tbody>
<tr>
<td>08.15am</td>
<td>to 10.00 am* Small Molecule Drug Development - Dr. Venkatesha Udupa, Glenmark Pharmaceuticals, Mumbai</td>
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<tr>
<td>10.15 am</td>
<td>to 11.30 pm* Large Molecule Drug Development - Dr. Praveen Reddy, Biocon, Bangalore.</td>
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<tr>
<td>11.30 pm</td>
<td>to 12.45 pm* Impurity Qualification - Dr. Ramesh Subramani, Dr. Reddy’s Lab, Hyderabad.</td>
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<tr>
<td>01.15 pm</td>
<td>to 01.45 pm An overview on Endocrine Disruptors - Dr. N.Subashini, IIBAT, Chennai.</td>
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<tr>
<td>01.45 pm</td>
<td>to 02.15 pm Anesthesia and Euthanasia in Laboratory animals – Dr. Yogeshkumar Murkunde, Sri Ramachandra University, Chennai.</td>
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<tr>
<td>02.15 pm</td>
<td>to 04.30 pm Interactive Session - Participants</td>
</tr>
</tbody>
</table>

*Including discussion; Tea break-10.00 -10.15am & 03.30 -3.45pm; Lunch Break -12.45 -01.15pm
K.S. Rao, M.V.Sc., Ph.D, DABT

Dr. K.S. Rao is a Board Certified Toxicologist with more than 40 years of global experience in safety evaluation. Started his career in 1971 at G.D. Searle and later moving to Dow Chemical and Quintiles, USA. After returning to India, he was heading M/s Jai Research Foundation, Gujarat followed by Head of Toxicology, M/s Advinus Therapeutics and M/s Syngene International, Bangalore. Currently Dr. Rao is the Senior Director, Strategic Business Development with M/s Advinus Therapeutics. He is an international expert in the toxicological assessment of Agrochemicals, Industrial Chemicals (REACH), Drug Development (small and large molecules) from Discovery Toxicology to IND and NDA filing, Food Additives, Nutraceuticals, Vaccines, Medical Devices and Cosmetic Ingredients. Dr. Rao has been providing guidance on product development to hundreds of companies across the world with major emphasis on testing scheme/strategies and Risk Assessment. He is an Emeritus Member of the Society of Toxicology (SOT) in USA. The first Indian Toxicologist, appointed for this status for being a member of the SOT for 40 years. He is instrumental in getting the Diplomate of American Board of Toxicology (DABT) examination to India since 2009. In the last five years, 68 candidates have passed the DABT examination from India. Dr. Rao has published and presented papers in international journals and conferences. He is the principal author of more than 500 safety evaluation study reports of various new compounds marketed or to be marketed. These reports are submitted to regulatory authorities of several countries including FDA & EPA (U.S.A), EMA, Japanese Health and Indian Regulatory Authorities.
Prakash Nadoor, M.V.Sc., Ph.D., F.NASc.(AW)

Dr. Prakash Nadoor is Professor and Head in the Department of Pharmacology & Toxicology at Veterinary College, Bangalore, a constituent professional institution under Karnataka Veterinary, Animal & Fisheries Sciences University (KVAFSU). He is basically a pharmacologist actively engaged in teaching undergraduate and post-graduate students in the subject of veterinary pharmacology and toxicology. He is Advisor to several students of Master’s and Doctoral degree programme in the University for the past 23 years. His special areas of interest include execution of pharmacokinetic studies in animals and residue toxicology of drugs and agrochemicals in foods of animal origin. He is a member of the editorial board of ISVPT and LASA (India) and referee for many elite scientific journals. He is also serving as Main Nominee of CPCSEA, Ministry of Environment, Forest & Climate (MoEF&C), Govt. of India for several educational and research organizations.

Prasad Shivardraiah, M.V.Sc., Ph.D.

Dr. Prasad started his career with Aurigene Discovery Technologies Limited (A Dr. Reddy’s company), where he was involved in integrated discovery projects in therapeutic areas of cancer, metabolic disorder and inflammation from major pharma companies. Before joining to Anthem biosciences, he worked for Evolva Biotech and Biocon-Bristol Myer Squibb research Centre. Where he was involved in preclinical candidate optimization for NCEs from multiple therapeutic areas. At Anthem Biosciences, Dr. Prasad is heading DMPK and Toxicology department a GLP and AAALAC certified facility based in Bangalore. Instrumental in implementation of Good Laboratory Practice (GLP) principles and certification in a short time at Anthem Biosciences.
Sanjeev Giri, M.Sc., Ph.D.

Dr. Sanjeev Giri is currently leading DMPK and Pharmaceutical Development department at Aurigene Discovery Technologies Ltd. He has over 15 years of experience in managing a scientific portfolio of drug discovery & development projects of diverse therapeutic areas, and designing preclinical and clinical pharmacokinetics studies leading to product registration. Prior to joining Aurigene, he has worked in Jubilant Biosys Bangalore, Reliance Clinical Research Services, Mumbai and Cadila Pharmaceuticals, Ahmadabad. His current responsibility at Aurigene includes identification, selection of clinical candidates, designing strategy for preclinical development, CMC and IND filing. Sanjeev’s research interest includes regulated bioanalysis, biotransformation, pharmacokinetics/toxicokinetics, PK/PD modeling, CMC, FIM predictions.

Dr. Rajesh Eswarappa M.Sc., Ph.D., DABT, ERT

Dr. Rajesh Eswarappa possesses 22 years of experience in preclinical toxicology. He started his career as a toxicologist at Rallis Research Centre, Bangalore; subsequently he worked with multiple toxicology contract research organizations (CROs) and pharmaceutical R&Ds including Jai Research Foundation, Lupin Pharmaceuticals Ltd., Advinus Therapeutics Ltd and Kemin Industries, where he established GLP certified toxicology facility and contributed for safety evaluation of new chemical entities/Agrochemicals/industrial chemicals. Currently, Rajesh is heading the preclinical safety evaluation department in Aurigene discovery technologies, Hyderabad. Where, he is involved in preclinical development of new chemical entities.
M. P. Pore, M.V.Sc., DABT, ERT

Dr. M. P. Pore is one of the founders of INTOX, and is the Lifetime Director of INTOX Pvt. Ltd. He looks over the responsibility of the Test Facility Management in the GLP organization. Dr. Pore has designed and conducted toxicology studies for diverse kind of products - Pharmaceuticals, Agrochemicals, Biotechnology Products, Specialty chemicals, Vaccines, Medical Devices, Industrial chemicals etc. during his experience of over 27 years in regulatory toxicology. Also active in Animal Welfare issues, he is a Fellow & Associate of 'Academy of Sciences for Animal Welfare, India' and is an Ad Hoc Specialist for AAALAC International, USA (2010 – 2013; 2013-2016; 2016-2019). He is a member of Society of Toxicology (STOX), Chinese Society of Toxicology, Japanese Society of Toxicology (JST), UK Registry of Toxicology, Laboratory Animal Scientists Association of India. Dr. Pore received the 'Fellow of Society of Toxicology' (FST) award by Society of Toxicology (STOX), India for year 2009.

Venkatesha Udupa, M.V.Sc., M.Sc., DABT

Dr. Venkatesha Udupa, is currently working as Senior General Manager-Toxicology 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 and late stage nonclinical toxicology evaluations and risk assessment of new chemical entities. He has immense interest in drug development of small and large molecules, impurity qualification and assessment of manufacturing safety of pharmaceuticals products. He is a ‘Trainer’ for GLP by the WHO and has 16 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.
Praveen Reddy, DVM, M.Sc., DABT

Praveen Reddy is working as Scientific Manager in Drug Discovery and Development toxicology. He served as Study Director / Study Monitor for approximately 65 toxicology studies both GLP and Non GLP (Includes NCE’s, NBE’s Generics, Herbal drugs and Biosimilar’s). He was involved in filling 3 IND’s, 6 ANDA’s and 2 Para IV infringement at Dr Reddy’s Laboratories and Ranbaxy Laboratories. Recently, he was involved in IND filling of 3 New Biologics at Biocon Research Limited. The experience pans over Designing, developing and standardizing new toxicological and efficacy animal models. Designing, developing and validating 2D and 3D cell culture systems for assessing the efficacy and safety of NBE’s. Designing and developing animal models for assessing the efficacy of NBE’s. Assessing the genotoxic potential of impurities found in Generic drugs/NCE/NBE by in silico (DEREK) analysis and in vitro Genotoxicity studies. Estimating starting dose in humans using PKPD modelling.

Dr. S. Ramesh, DVM, DABT, ERT, RAC (US)

Dr. Ramesh started his career in 2007 at Advinus Therapeutics Ltd, Bangalore as a Study Director for conducting Preclinical Toxicological studies in rodents & non-rods for IND/NDA filing in compliance with the principles of GLP, covering OECD GLP, FDA GLP and EPA GLP, later moved to Vivo Bio Tech, Hyderabad. After that he moved to Dr. Reddy’s Laboratories, IPDO, Hyderabad, currently working as Senior Scientist (Regulatory Toxicologist). His work experience includes Toxicological/Risk Assessment of Pharmaceuticals, Biologics, Generic Drug Development [NDA (505b2), ANDA (505j)] and as a Study Director for IND and NDA toxicological studies with Agrochemicals, Pharmaceuticals, Biologics, Industrial chemicals, Medical Devices and others.
N. Subashini, M.Sc., Ph.D.

Dr. N. Subashini is currently working as Senior scientist-toxicology at IIBAT, Chennai. She has got more than 14 years of experience in the field of toxicology. Her expertise is in the area of US FDA/OECD/CIB regulations and related toxicity studies. She has expertise in conducting inhalation toxicity, reproduction toxicity and developmental neurotoxicity studies. She has done research works in toxicity profile of pesticide mixtures, transplacental carcinogenesis, endocrine disruptor chemical assays, and also in Comet assay & other Genetic toxicity studies. She is a member of STOX and SNCI, LASAI and also a Fellow of Animal Welfare Science.

Yogeshkumar Murkunde, M.V.Sc., PhD, DIBTP

Who should attend?
All professionals in the field of Toxicology (preclinical, regulatory and so on.)

Registration Fee
There is no registration fee to participate in this interactive meet.

Queries
 toxgurukul.india@gmail.com

“Ask the right questions, and nature will open the doors to her secrets”
-C V Raman