IMIT-19

Proceedings of Interactive Meet on Insights in Toxicology -2019 – A ToxGurukul Initiative

Risk Assessment for Safety of Personal Care Products Including Cosmetics

Friday 1st and Saturday 2nd March 2019, Ahmedabad, India

Co-sponsored by:
Indian Chapter of the Society of Quality Assurance (ICSQA)
L.M. College of Pharmacy, Ahmedabad
AIC-LMCP Foundation

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Dr.MilindDeore, M.V.Sc., Ph.D., DABT

Course Organizer :
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Message from Patron

Dear Friends of Toxicology,

ToxGurukul concept started off over the WhatsApp chat group consisting of young, vibrant and motivated scientists looking for opportunities to expand their toxicological bandwidth so that they can compete for better job opportunities that are arising in the country. It is almost serendipitous that I got into that WhatsApp group and started learning their aspirations which are no different than any group which sincerely wishes to learn and improve themselves and also help others in the community. ToxGurukul is almost a self-made group with no strongly feelings or attachments to pre-existing dogma, but to improve themselves and help their colleagues. With humble beginning in 2016, I happen to propose to the group that let us organize a "No-Fee" two-day workshop on General Toxicology which consummated in November of 2017 at the KVC auditorium in Bangalore, barely three months from the conception of the idea. The first session was termed as INTERACTIVE MEET ON INSIGHTS IN TOXICOLOGY-2017 (IMIT-2017). Close to 200 attendees participated with voluntary speakers who came out to teach ToxGurukul group. The excitement in the air by the participants was truly magnetic and scintillating. Reverberations from the first meeting in 2017 resulted in establishing multiple WhatsApp Groups due to limitations on the number of participants that are allowed in any one WhatsApp group. Everyone in the group was asking questions to each other on toxicology and answers were forthcoming for most questions within various ToxGurukul groups.

Suddenly one fine morning someone in the ToxGurukul WhatsApp group suggested that we should have one more educational workshop in 2019, which resulted in the present IMIT-2019 on Risk Assessment of Consumer Products and Cosmetics. I happen to tap on the unique niche talent of Dr. Milind Deore, who has established a truly global risk assessment group for Johnson and Johnson in Mumbai which no other company has done in India. Milind was gracious enough to accept my request to lead the session as Course Director, since the cause was just and compelling to develop talent pool in India on Risk Assessment which is sorely lacking. The entire credit must go to Dr. Milind Deore for shouldering full responsibility and recruiting very talented and hands on group of scientists as speakers who are outstanding in their sphere of expertise. Unlike the IMIT-2017, it was decided to charge a nominal fee for each participant in IMIT-2019 and also seek funding from industry to cover the expenses. So far it has worked out very well and we are hoping for a record turnover of candidates considering the narrow niche subject on Risk Assessment of Consumer Products.

The whole dynamism in the ToxGurukul group is self-motivation by volunteers who have no hidden agenda or ulterior narrow motive, except to learn and share among peers which is a noble cause. I suspect the comradery that is developing among the ToxGurukul group is highly contagious (in a positive way) to the extent that all are sticking together and working as a self-propelling locomotive where everyone in the group is an engine by themselves and contributing to the noble cause of toxicology.

I am pleased to advise that we are already working on the next IMIT-2020 and the topic will be "Pathology for Toxicologists" which will be led by Dr. Kalaiselvan P (Syngene International, Bangalore), as Course Director. Speakers are being recruited and the topics have been selected. We are looking for a sponsor to host the session, which will determine the location and timing of IMIT-2020.

I thank the ToxGurukul Team for giving me this honor to serve and nurture the next generation of Toxicologists in the country which undoubtedly will revolutionize the Safety Assessment field, never seen before in India and growing exponentially.

I welcome all the participants to actively devote your valuable two days to learn from the experts and become more valuable to yourselves and to the country at large.

Finally, I wish to thank all the Sponsors who generously donated their hard-earned valuable funds for this worthy cause. We hope there will be more interest from other industry partners to show their moral support by donating to future IMIT meetings.

K.S.Rao, M.V.Sc., Ph.D., DABT
Patron,ToxGurukul Foundation and Course Organizer, IMIT-19

Message from the President

*On behalf of **ToxGurukul**, I am pleased to welcome you all for **IMIT-19** workshop - "Risk Assessment for Safety of personal care products including cosmetics".*

"Risk Assessment" is more than a collection of facts and data. It is an intellectual process. With the modern technology, amount of data describing toxicity of chemicals has grown enormously, and our capacity to interpret this information is a continuing challenge.
*I am very happy that **ToxGurukul** is organizing workshop on very important and demanding topic.*

About ToxGurukul:

In 2016, there were two prominent WhatsApp Groups formed by some toxicologists and they were Toxicology Forum and GLP-SD Team. Though informal, the intent was clear i.e. to share knowledge and discuss and find practical solutions. These two groups then merged and functioned as one for a period of time. Day by day membership started to grow. Discussions, debates, suggestions, solutions etc. were enthusiastically exchanged among the members. It was at this point of time that our now patron Dr.K.S.Rao offered to hold a meeting to collectively discourse about Toxicology and its basic elements, since then I have readily volunteered to support all causes of IMIT held by this group.

*In September 2017, ToxGurukul name was finalized to conduct a workshop. Tox-represents Toxicology, Gurukul represents Gurukulam - a type of education system in ancient India. That was the genesis of '**ToxGurukul', Sōpānapatha (a ladder to knowledge.)***

We decided to have 1st workshop. The dynamic young colleagues were so active and enthusiastic that, what we initially thought- a small workshop of 20 - 30 people, it turned out to be a big workshop of nearly 200 people in Bengaluru in November 2017.

*Suddenly one fine morning someone in ToxGurukul group suggested that we should conduct a Toxicology workshop in Feb/March 2019, which resulted in IMIT - 19. Being a WhatsApp group, **ToxGurukul** had no legal platform and hence couldn't open an account in Bank, so accepting fees, donations was a challenge.*

Incorporation of ToxGurukul Foundation:

*In December 2018, **ToxGurukul Committee** discussed about incorporation of Society, Trust or such similar entities.*

On enquiry with legal experts, it was found that any social, religious or charitable activity can be done by forming either a Trust or a Society or a Company. Each of them has their own legislations for incorporation, administration, working, compliances and dissolution etc.
Since understanding the intricacies of each of them was not an easy task, it was decided to take help of professionals (Practising Company Secretary - CS) who have expert knowledge and experience in this field. After series of exchanges of mail, between Committee members and the CS, it was concluded that forming a Company under section 8 will be more beneficial and easier as compared to a Trust or Society kind of model. The main concern was that, the entity should be able to operate on national as well as international level. Further the entity should be also able to accept donations, subscription, fees from Indian as well as Foreign members, participants, Sponsors.

Considering all the above aspects, time and funds required, it was finally concluded to incorporate a company under Section 8 of the Companies Act, 2013 with the name ToxGurukul foundation. The name ***ToxGurukul Foundation*** *got approved from ROC, Pune on the 20th February 2019.*

Now the documents for obtaining license from the ROC, Pune is in process and the documents are being filed with them. Lot of documents and information is required / asked by the ROC, Pune for granting license. Once the licence is granted, Company has to proceed for obtaining Certificate of Incorporation from the Registrar of Companies (ROC), New Delhi.
It is proposed to register the name and logo under the Trade Marks Act, 1999 to protect the name and design of ***ToxGurukul****. The design of logo* ***ToxGurukul*** *is under process and its registration under the Trade Marks Act, 1999 will be done soon.*

I am proud to be a part of this group. With young enthusiasts like ***Alex, Vamsi, Kruthik, Benita, Deepak*** *and under the guidance of our* ***Guru****,* ***Dr. K. S. Rao Sir****, I believe ToxGurukul will continue to be a lighthouse for the development of toxicology at home and overseas. The ToxGurukul committee is now charged with a number of inspiring activities that will help to build future Toxicologists.*

Mukul Pore, M.V.Sc., DABT, ERT
President, ToxGurukul Foundation

Organizing Secretary's Note

I am very much pleased to associate with ToxGurukul's: IMIT-19 as an organizing secretary and be a part of organizing committee member.

IMIT-19: Risk Assessment for Safety of Personal Care Products Including Cosmetics, a second workshop conducted under the TOXGURUKUL objective of strengthening and endorsing the toxicology knowledge. It was organised in in Ahmedabad. In continuation to IMIT-17 workshop on regulatory toxicology, the IMIT-19 encompassed the applied toxicology stream: Risk assessment sessions and was successfully attended by around 200 scientists from consumer/cosmetic, pharmaceutical, Nutraceuticals industries and academic institutes. Sessions presented by eminent speakers from risk assessment which was efficiently put together by course director Dr. Milind Deore. Sessions emphasized on risk assessment of cosmetics, consumer products, flavors, fragrances, toys, botanicals, aerosols, data bases information and read across strategies, regulatory documentations along with practical training using case studies. Sessions tremendously received best feedback from all scientists who thanked the ToxGurukul for this workshop. I would like to thank and congratulate the Dr. Milind Deore for successful organization and conduct of this course which benefited a lot of toxicologists and pleased to associate with Dr. Milind through this opportunity.

In this occasion, I will join the hands to express the wholehearted thanks to the sponsors for their constant support and guidance for this esteemed workshop.

I also express sincere gratitude to L.M. College of Pharmacy, and Ahmedabad University for support in conduct of this workshop. I congratulate and express sincere thanks to everyone of organizing committee members for the successful conduct of workshop.

Above all, I take this opportunity to convey my heartful thanks to respected Guru Dr. K.S Rao Sir for his eminent vision to amplify the toxicology science and also for giving me this golden opportunity to be part of this workshop.

Looking forward and pleased to be a part of ToxGurukul

VVS Vamsi Mohana Reddy T, M.Pharm.
Organizing Secretary, IMIT-19

Message from Course Director

It is very heartening to know ToxGurukul spreading its wings and taking initiatives to develop Toxicologists in India in different spheres under the strong leadership and guidance of Dr. K.S. Rao. Given the wide scope of field of Toxicology, it is difficult for anyone working in this field to be aware of all the areas in this field. Traditionally in India, the focus in Toxicology was conduct of studies and gaining expertise in several types of studies (Reprotox, mutagenicity, carcinogenicity, safety pharmacology, etc.) and study aspects, viz, pathology, kinetics, in vitro/in vivo techniques, GLP and Quality. However, in recent past the focus has now been shifted to the areas of risk assessment which includes the applied aspect of Toxicology. Risk assessment involves a thorough understanding of all studies and their use for given products like drugs, food, cosmetics, pesticides, environment etc. The area of Risk assessment is a Science which includes technical expertise and also an Art which involves the application for proper use of the data generated. Considering these facts, I am very happy that ToxGurukul is organizing its second workshop to cover risk assessment of consumer and cosmetic products.

Cosmetic and personal care products is a recent addition in the field of risk assessment. Considering the uncontrolled use, variety of products, less stringent regulatory control (as compared to Drugs), the risk assessment of these products is an interesting as well as challenging field. However globally the regulations are now becoming stringent for consumer products owing to which risk assessment of these products is gaining higher importance. In the last decade the demand for toxicologists conducting risk assessment of consumer products has hence increased significantly. Based on the cost-effective expertise available In India, many cosmetic products' organizations are outsourcing the risk assessment of their products to India and is catered by several CROs in India. Besides, the multinational organizations are also establishing their Toxicology units to support risk assessment of their global products. In India as well, the health authorities are having a re-look into the safety of these products revising the regulatory requirements. In addition, the Beauty Industry in India which is currently estimated at USD 950 million is estimated to reach at USD 2.68 billion by the year 2020. Basis these developments and projected growth, the requirement for toxicologists conducting risk assessment of consumer products would increase. I firmly believe that such courses would be required a regular interval to develop talent in India for supporting Indian cosmetic industry and cater the global need.

I am thankful to ToxGurukul for giving me the opportunity to lead and shape the program and hopefully it will be helpful for the participants to get an overview and orientation. I wish

ToxGurukul a continued success in its endeavours and a big thank you to all its volunteers for making this happen. I also wish all the participants a fruitful experience.
Happy learning!

Milind Deore, Ph.D., DABT
Course Director-IMIT-19
Senior Director-Toxicology, Johnson & Johnson

About Us

Interactive Meet on Insights in Toxicology

The key objective of this interactive meet is education through information exchange and knowledge sharing by experienced scientists in the country and from abroad. It is a forum for training our scientists to seek practical knowledge that is not usually taught in our Universities to make the candidates ready to be employed in the industry and a higher calibre of research in national and international institutes.

ToxGurukul Foundation

ToxGurukul is a group of professionals in the field of toxicologywho are in search of a platform to learn and share the vast knowledge in this area. This syndicate belongs to Independent professionals from different backgrounds of toxicology who share their knowledge to un-puzzle the Rubik's cube that each face in their daily work routine.

Indian Chapter of the Society of Quality Assurance (ICSQA) Trust

ICSQA is a Chapter and affiliated to the Society of Quality Assurance (SQA) in the USA. The key objectives of the ICSQA are to facilitate interactions among professionals and provide educational programs for the benefit of the quality assurance and other professionals. Also, associate/co-operate/collaborate with other professional societies, trusts, education and research institutions, organizations, or individuals in carrying out the aims and objectives of ICSQA.

L.M. College of Pharmacy, Ahmedabad University

L.M. College is one of the oldest and the most reputed college of pharmacy and is the most trusted and philanthropic educational trust by Ahmedabad Education Society, Navrangpura, Ahmedabad. LMCP is approved by AICTE and PCI, New Delhi, Government of India and affiliated to Gujarat Technological University, Ahmedabad. It offers a variety of unique courses in pharmacy and technology which makes it excel in the academic community in the country, dedicated to Nurturing the Next Generation of Independent Thinkers since 1947.

Personal Care Products

FMCG (Fast- Moving Consumer Goods) is the key contributor not only to Indian economy but worldwide. In India it is the fourth largest sector which contributes to Indian economy and provides employment to around 3 million people. FMCG can be categorized into four categories-

1. Personal care products (oral care; hair care; skincare; personal wash; cosmetics and toiletries; deodorants; perfumes; paper products);
2. Household care (laundry soaps, detergents, fresheners, etc.);
3. Packaged food and beverages;
4. Spirits & tobacco

Personal care products are the fastest growing markets around the world, including India, even in rural areas. Due to the lack of proper regulations (in particular in the third world), many companies are introducing their products without a proper assessment and the consumers do not have the discriminating capability to understand the risk on usage of such products. Most often price is a major consideration and how often they see the advertisements of such products. Most major top line companies make honest and sincere efforts to undertake an extensive risk assessment before they release their products. By and large, lower tier companies neither have the expertise or the knowledge to conduct the proper risk assessment. In addition, there is a total lack of understanding on risk assessment professionals in the country.

However, of late, the regulations for safety of cosmetic products have become stringent globally. In Europe, US and Brazil, new regulations have come up for personal care products. There is recent guideline for safety of cosmetic products in 2018 in India as well. Hence, moving forward it would be imperative for all companies to abide to strict norms on product safety.

Although "**Toxicology Risk Assessment**" is a relatively new field in India, many multinationals as well as overseas small companies from Europe/USA are approaching India for getting risk assessment done on their personal care products. The reason being is availability of services at CRO's by talent pool of Toxicologists in a cost-efficient manner. Obviously these companies do expect an assessment done in a technically sound manner which would cater to international compliant norms and would stand technical scrutiny internationally. Although, we have pool of Toxicologists in India there

is a dearth of understanding of the specific requirements for cosmetics and other personal care products.

Considering the huge demand and also the gap in understanding risk assessment of personal care products this symposium is intended to focus on the basics of Risk Assessment of personal care products with emphasis on cosmetics. This would help in creating a right talent pool to attract more employment in this sector.

Legends Speak

Message from President of EUROTOX

As President of EUROTOX, I am delighted to hear of your meeting in India and I wish you every success.

With kind regards,

Professor Heather M Wallace PhD, FRCPath, FRSC, FRSB, FBTS, FBPhS
European Registered Toxicologist (ERT)
University of Aberdeen
Institute of Medical Sciences
Foresterhill
Aberdeen AB25 2ZD

Message from Past President STP-I

I am extremely happy that a workshop is being organized under the banner of "ToxGurukul" The topic of the workshop is most appropriate and need of the hour. .

"Risk assessment of safety of personal care products including cosmetics".
The two days speakers are very learned, and I am sure that it would be a scientific feast for the young scientists attending the workshop. When Dr. K.S. Rao is there as an organizing secretary, a doyen in the field of toxicology, there be absolutely no lacunae. The deliberations "personal care products" would be very useful and is of practical importance and also need of the hour especially when market is dumped with all sort of products. But for my preoccupation, I would not have not missed such a workshop.

My complements, appreciation and congratulations for all those who are involved in conducting a workshop of this nature.

I sincerely wish a very fruitful and a successful workshop.
SKV

Dr. S. K. Vijayasarathi, Ph.D., FIATP
Director / Expert Pathologist
Department of Safety assessment
Eurofins Advinus Limited
Bengaluru.

Message from Secretary-General, Society of Toxicology (SOT) India

Happy to know that an 'Interactive meet on insight s in toxicology wil
l be held at Ahmedabad.
I would like to thank the organizers for organizing such a mega event, a congregation of toxicologists. I am sure that the ToxGurukul is the largest forum of toxicologists in the world.
I also got an invitation for this meeting from Dr. Alex. I wanted to be one among you during this meeting. I am not in Ahmedabad because of my prior commitment to other function, in connection with Science day. I take this opportunity to wish you all a very fruitful and enjoyable deliberation.

Thank you all!

Dr. P.V. Mohanan, Ph.D., FST, FASc(Aw), FSAB
Scientist-G & Head, Toxicology Division,
Biomedical Technology Wing,
Sree Chitra Tirunal Institute for Medical Sciences and Technology (Govt. of India)
Thiruvananthapuram

Message from Senior International Consultant

I am greatly privileged to know that the Interactive Meet on Insights in Toxicology (IMIT-2019) will be held on 01 & 02 March 2019 at Ahmedabad, the theme being Risk assessment for Safety of Personal Care Products including Cosmetics, a ToxGurukul initiative, which is cosponsored by the Indian Chapter of Quality Assurance (ICSQA), L M College of Pharmacy, Ahmedabad and AIC-LMCP Foundation. This is the second meet organized by Dr. K. S. Rao, an eminent toxicologist of international repute. For the present programme the Course Director is Dr. Milind Deore, Senior Director of Toxicology at Johnson & Johnson, Mumbai.

Since returning to India Dr. Rao has been associated with renowned toxicology laboratories in the country and started building up human resources in the field of toxicology, the first initiative being many securing Diplomate of American Board of Toxicology (DABT) by appearing for the examination in India. Since then he was responsible for conducting various training programmes and workshops in various fields of toxicology. The founding of ToxGurukul initiative by him with a team of committed toxicologists, is aimed primarily to bring in a new generation of toxicologists who can take up challenges and compete in the global scientific arena. I salute Dr. K. S. Rao for his commitment to train the young force in the country, which is highly commendable and a yeomen service to the advancement and development of the science of toxicology in India.

The topic of the present programe is highly relevant and focuses attention on recent developments in the safety of personal care products as well as cosmetics, which is a different approach when compared with the activities of the present contract research laboratories carrying out studies on agrochemicals and pharmaceuticals in the country.

I wish the meet a grand success and pray to God Almighty to bless ToxGurukul abundantly to conduct such meets and workshops in various advanced fields of toxicology and prepare the younger generation to meet the future demands in safety evaluation of personal care products in the country.

Dr. B. Vasantharaj David, D.Sc., Ph.D., M.Sc.(Ag.)., F.N.A.A.S., F.E.S.I., F.I.A.E., F.P.P.A.I., F.A.Z.R.A., F.G.S.A., F.M.S.F., F.S.B.A., F.N.A.B.S., F.R.E.S.
Chairman, Scientific & Academic Board, IIBAT, Padappai, India
International Consultant- GLP, Rotam Research Laboratory, Kunshan, China

Message from Platinum Sponsor of IMIT-19

It was a pleasure attending the Workshop on,"Risk Assessment for Safety of Personal Care Products Including Cosmetics" organized by ToxGurukul . Personal care products and cosmetics are used extensively in the community and the importance of risk assessment of hazards associated with their use can't be overemphasized. It is also challenging that the methods used should be free from use of animals. Risk assessments are hardly emphasized in toxicology related curricula in the country. In this context, this workshop has been very useful for young aspiring toxicologists both in academia and Industry. The workshop was well organized and the topics covered and the presentations were of exceptional quality. The faculty has been chosen very well. There had been lively discussions at the end of each presentation. I attended all the sessions and found the experience quite rewarding.

My sincere appreciation to ToxGurukul for its pioneering educational activities in toxicology.

With best wishes,

Dr. A. Sankaranarayanan

President, Vivo Bio Tech Ltd

Message from Senior Toxicologist

I am aware of the great contribution of Dr. K. S. Rao as a part of ToxGurukul . I am also aware of previous workshops organised under his leadership. His mission to help our young toxicologists is highly commendable and praiseworthy. He has richly contributed to the growth of toxicology in our country. The programme of the forthcoming workshop at Ahmadabad is well conceived with experts scheduled to deliver talks on diverse fields. I wish all the best for successful deliberations. Also, my best wishes to all the faculty of Tox Gurukul.

P. Balakrishna Murthy, Ph.D., D.Sc.,
Visiting Professor, Hiroshima University, Hiroshima, Japan,
Visiting Professor, SRM University, Chennai,
Plot -14, Lakshmi Nagar, Selaiyur,
Chennai -600073, TN

Message from Senior Toxicologist

Kudos to Dr. K.S. Rao ToxGurukul, Indian Chapter of Quality Assurance Trust, L.M. College of Pharmacy, and Dr. Milind Deore, for organizing training workshop on risk assessment of consumer care products including cosmetics. Educative training in this subject is very much needed at it is not taught in our academics or at workplaces. The faculty of Toxicologists excelled in risk assessment activity at global level, is a boon for our young generation workforce assembled under ToxGurukul roof.

P.Y. Naik
CEO,
IntoxPvt. Ltd, Pune.

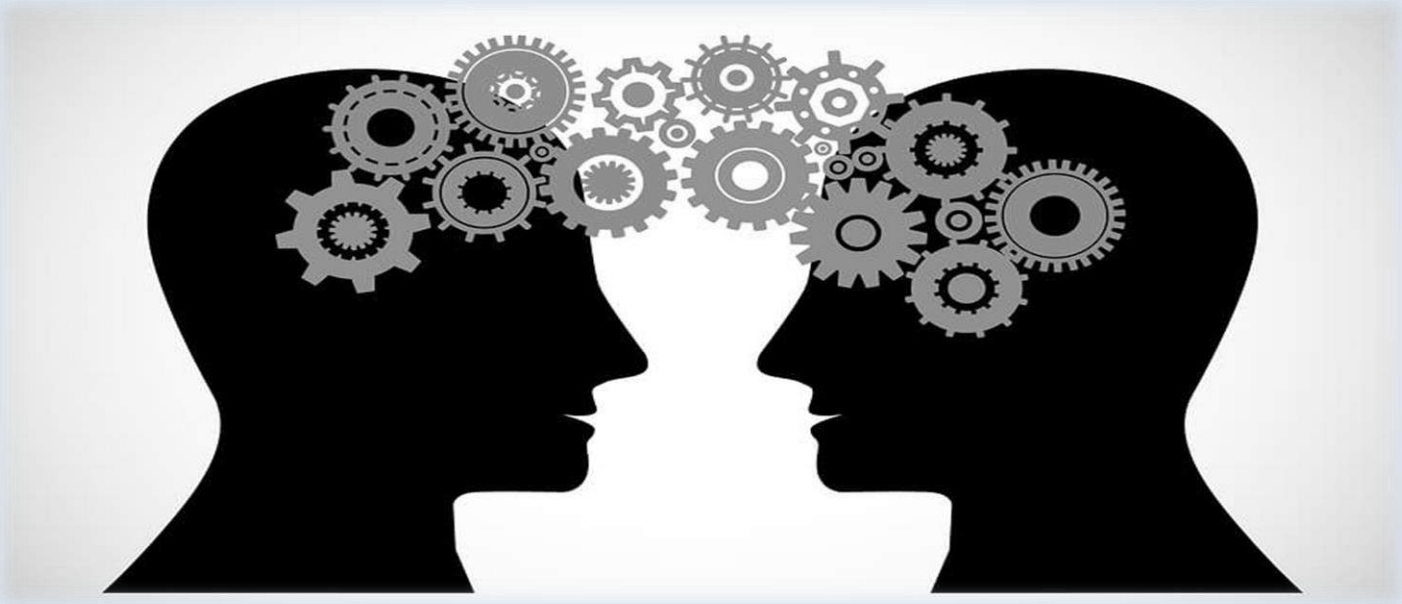
Vivo Bio Tech Ltd.

Your Drug Discovery Partner

Speaker's Profile

&

Abstracts



Summary of Topics Speaker wise and Link to access the presentations

Speaker	Topic
Dr. K.S. Rao, M.V.Sc., Ph.D., DABT	Overview of Risk Assessment Process
Dr.Milind Deore, M.V.Sc., Ph.D., DABT	Risk Assessment of Personal Care Products
Mr. Sampath Kumar M.Pharm., CBiol, MRSB	Data Bases, Sources of Information In the field of Regulatory Toxicology
Ms. Geeta Bajaj	Regulatory overview Requirements for Cosmetics products, dossiers
Dr.Ravishankar Nagarajan, M.V.Sc., DABT, EPLM	Risk assessment of Fragrances and Flavours
Dr. Praful Patel, M.V.Sc., Ph.D.	Impurity Qualification in Pharmaceuticals
Ms. Sanghamitra Mishra, M.Pharm., ERT	Read across and QSAR (In Silico) Predictions
Mr.Nishitkumar Kachhela, M.S.Pharm	Safety assessment of consumer products as related to toys, detergents, air freshners and biocides.
Dr.Ankushreddy S Patil, M.V.Sc., DABT, ERT	Special considerations- Botanicals and Aerosols
Dr.Suresh Kumar, M.Pharm., Ph.D.	Documentation CPSRs/PSURs/CCDs etc.

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Please click below link to access Photos of IMIT-19
Click Here

Happy Learning!

Dr. 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 moved to Dow Chemical and Quintiles, USA. After returning to India, he was heading M/s Jai Research Foundation, Gujarat and Head of Toxicology at, M/s Advinus Therapeutics and M/s Syngene International, Bangalore. Currently, Dr. Rao is Vice President, Subject Matter Expert for Safety Assessment, at Eurofins Advinus Limited. 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 schemes/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. Dr. Rao is the recipient of the Life Time Achievement award from the Society of Toxicology of India (STOX) for his outstanding contributions in Toxicology. He is instrumental in getting the Diplomate of American Board of Toxicology (DABT) examination to India since 2009. In the last 8 years, 90 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.

Session topic: Overview of Risk Assessment Process

The goal of chemical risk assessment is to have a full understanding of the nature, magnitude and probability of a potential adverse health or environmental effect of a chemical. It takes into account of both hazard and exposure. Risk assessment forms the foundation of regulatory decisions for industrial chemicals, pesticides, pharmaceuticals, cosmetics, food additives and food contact substances in developed countries today. In general, chemical risk assessment consists of the following three steps:

a. Hazard characterization: Dose-response determination (LD50/LC50, NOAEL, T25, EC50, NOEC, etc), determining the relationship between the magnitude of exposure to a hazard and the probability and severity of adverse effects.

b. Exposure assessment: identifying the extent to which exposure actually occurs. Exposure levels are usually estimated or measured.
c. Risk characterization: combining the information from the hazard characterization and the exposure assessment in order to form a conclusion about the nature and magnitude of risk, and, if indicated, implement additional risk management measures.

Dr.Milind Deore, M.V.Sc., Ph.D., DABT

Dr. Milind Deore is an American Board-Certified Toxicologist with over 20 years of experience. He is currently the Senior Director of Toxicology at Johnsons & Johnson, Mumbai and is the Head of Global Toxicology group for its Consumer sector. He is also recognized as Fellow within Johnson & Johnson. Dr. Deore is a veterinary graduate who completed his Masters in Veterinary Pharmacology from Bombay Veterinary College and later received his Ph.D. in Veterinary Toxicology wherein he worked on Selenium toxicity for which he is a re of a national award (Jawaharlal Nehru award) for best doctoral research in agriculture and veterinary field in India. He started his career in poultry industry before switching to academics where he served as a faculty member of Veterinary Pharmacology & Toxicology at Bombay Veterinary College for 15 years during which he was engaged in teaching and research activities. He has guided over 25 students for their Master's and Ph.D. degrees. He was Principal investigator for two national research schemes and co-investigator on seven nation over 25 articles published in National and international journals and over 75 abstracts published in - 35 conferences. He has been invited as guest speaker and presented lead papers on more than 20 occasions. He has also authored a chapter in text book for veterinary Pharmacology & Toxicology. He was adjudged as best faculty member on three occasions as nominated by students. He was also a clinician and had a pet clinic for 14 years. In 2007 he shifted to Industry and was involved in Drug Development in Pharma sector. He was Associate Director for Drug Safety Evaluation at Ranbaxy Research Laboratories, and was in-charge of Genotoxicity, Reproductive Toxicology and Safety Pharmacology sections. He was involved in designing preclinical studies in rodents and non-rodents, interpretation of studies and taking molecules through different stages of drug development. The studies involved various *in vitro* and *in vivo* studies in GLP environment. Since 2009, at Johnson & Johnson, he is in-charge of the Global Toxicology and Clinical Safety group which functions from multiple sites - at US, VDR, France and India to support product safety evaluation for global launches across Baby, Beauty, Oral care, Topical health and OTC franchises and compliance activities. He holds permanent

membership of several professional societies within India, was Assistant editor of a scientific journal, was a reviewer for scientific journals and a member of multiple national and international cosmetic industry bodies. He was on advisory board for Establishment for a toxicology center at NIRRH (National Institute for Research in Reproductive health, Government of India)

Session topic: Risk Assessment of Personal Care Products

Looking at the Food, Drugs & Cosmetics Act, major emphasis is laid on the stringent controls and safety assessment of drugs and less on cosmetics and Food. Paradoxically, the exposure to a same chemical entity more uncontrolled and unlimited (as compared to drug) which points to a requirement for a robust safety assessment. Of late, this is recognized and the safety assessments of cosmetics and personal care products have received a fresh outlook from regulators globally requiring more stringent safety norms. A Personal care products (PCP) include a large variety of products ranging from as soaps, shampoos and shower products, sunscreens, skin and hair care products, hair dyes, lip sticks, toothpastes, dental personal hygiene products and other cosmetic products. The exposure is possible through various routes viz., oral, dermal, inhalation, etc., dermal being the most common. Safety assessment of consumer products depend on different exposure scenarios which include type of products, daily use levels, frequency of use, concentration of ingredients/impurities, target population, skin condition and intrinsic hazards of the chemicals. At product level, interaction between these ingredients also needs a separate consideration. Cumulative exposure, aggregate exposure, further complicate the risk assessment process for PCPs. The current challenges mainly involve restrictions or ban on animal testing for cosmetic products. Whereas majority data is based on animal studies. This leads to a paradigm shift in the from traditional Tox studies to use of read -across strategies, validated alternate methods, in vitro models, *in silico* predictions, QSAR techniques, TTC approach etc for safety evaluation of any ingredient/product. These aspects make this domain an intereseting as well as a challenging one.

Mr. Sampath Kumar M.Pharm., CBiol, MRSB

Sampath Kumar is working as Senior Scientist (Team Lead) - Toxicology at Colgate-Palmolive, Mumbai. He is a Regulatory Toxicologist, Chartered Biologist (CBiol) from Royal Society of Biology, and a Pharmacologist with diversified experience in the Consumer Good Companies like Johnson & Johnson and Colgate-Palmolive. His

expertise is in the area of Product Safety and Risk Assessment of ingredients in Cosmetics (Personal Care, Oral Care), Consumer goods (Home care), and Professional Products. Well versed in conducting the literature search reviews for any of the new ingredients, Safety Assessments and Complete Product Safety Reports. Sampath is an active member of STOX, India; Society of Toxicology, US; Royal Society of Biology, UK, and The European Society of Toxicology *in vitro*, EU.

Session topic: Data Bases, Sources of Information In the field of Regulatory Toxicology

The literature search for safety data is the starting point while conducting a risk assessment on a chemical ingredient.A database is an organized collection of data and a literature search is a methodical search for all of the literature published on an ingredient. Due to the high ethical and regulatory standards most of the regions pose restrictions/ban on animal testing for a cosmetic ingredient, this enforces to rely more on the available scientific informationon the chemicals or the related substances for the safety evaluation of an ingredient. An effective search of the literature can be done by identifying the source toxicology databases (PCPC, eChemPortal, EPA, ECHA, SCCS, NTP, ExPub, IARC, HERA, TOXNET, FDA, NICNAS, IRIS, OECD HPV, ACTOR, ScienceDirect, PubMed, Chem View, ChemIDplus etc.) when searched with the right keywords.

Ms. Geeta Bajaj

Geeta Bajaj works at Estee Lauder Companies (India) as Associate Director - Regulatory Affairs and is responsible for all Estee Lauder brands across India and Sri Lanka. Over the last decade she has been actively involved in import registration guidelines and other harmonization initiatives with the Indian authorities. She is also an active member of the technical committee at Indian Beauty and Hygiene Association (IBHA), Cosmetics Europe India taskforce (EU trade body),PCPC Asia subcommittee (US trade body). She also works with FICCI and Indian Society of Cosmetic Chemists (ISCC). Geeta started her career as a clinical researcher with Derm Expert Paris(India venture with Estee Lauder UK as a Regulatory Affairs Scientist. She has been with Estee Lauder Companies for over 12 years, starting first in UK where she worked on compliance with EU Cosmetics Directive, Dangerous Substances and Dangerous Preparations Directive (CHIP3) and other regulatory affairs for all of Estee Lauder brands across Europe. Since 2009, she started focusing on Middle East and India markets, and now primarily looks after India and Sri Lanka. Geeta has a master's degree in Cosmetics Technology and

Diplomas in Clinical Aromatherapy and Reflexology. She has completed Certificate course in "Principle and Practice of Cosmetic Science"by SCS UK She has also completed certificate courses in Toxicology and Classification Preparations organized by CHCS UK and chemical watch. She is currently training to become a Safety Assessor and doing a course in Toxicology organized by German trade body (IKW).She has given lectures and been a speaker on various international platforms.

Dr. Ravishankar Nagarajan, M.V.Sc., DABT, EPLM

Dr. Ravishankar is a veterinary pathologist and graduated from Madras Veterinary College, Chennai in 2002. He pursued an Executive program in Leadership and Management from IIM, Calcutta in 2014 and received his EPLM certification. He is a board-certified toxicologist and passed his DABT exam in 2018. He has an industrial experience of more than 16 years and has served multiple pharma companies such as Zydus, Ranbaxy I abs and Reliance Life Sciences. He has been part of the Toxicology Resource Centre, Mumbai. Johnson and Johnson Pvt. Ltd from 2009. He currently serves as a Risk Assessor for consumer products at and his responsibility is to assess the safety of Oral and Topical Health care products, OTC products and cosmetic products. His regular responsibilities include providing toxicological justifications for product safety in Health Hazard Evaluation cases, compliance issues, qualifying the impurities in drug products by data mining and using *in silico* tools such as Toxtree and Leadscope. He is also involved in the biocompatibility risk assessment of medical devices from multiple Ethicon franchises such as Wound Closure & Reconstruction, Biosurgery and Endosurgery and Depuy Synthes division.

Dr. Praful Patel, M.V.Sc., Ph.D.

Dr. Praful Patel has over 14 years' experience in preclinical drug discovery as a toxicologic and experimental pathologist. He started his career in 2004 at Zydus Research Centre as an experimental pathologist. Currently, Dr. Patel is Scientist -I, In-charge for Preclinical Safety Evaluation at Torrent Pharmaceuticals Limited, R&D Centre. He is actively involved in the field of regulatory toxicology and conducted several toxicity studies towards safety evaluation of New Chemical Entities (NCES), New Biological Entities (NBEs) and Bio-generic molecules for various regulatory submissions. His professional experience as a Toxico-pathologist also involves planning, performing, monitoring, interpreting various nonclinical studies to meet national and international regulatory requirements. He is author of nearly 250 safety evaluation GI Dr.Praful, currently serves as active committee member of Society of Toxicological Pathologists in

India (STP-I) and life member of Society of Toxicology (STOX), India for the benefit academic and industry professionals.

Session topic: Impurity Qualification in Pharmaceuticals, Drug Substance (DS) process development and Drug Product (DP) formulation development are two major areas of the drug development process at pharmaceuticals industries. Impurities/degradants can

be generated in either of the processes, from DS degradation or DS-excipient interaction. These impurities may be nongenotoxic or genotoxic in nature. There arechallenges across all impurity areas some relate to scientific comp regulatory complexity. Food and Drug Administration (FDA) International Conference on Harmonization (ICH) guidelines stipulate that a holistic risk assessment is required, including all potential sources of Impurities. The biggest challenge is taking a guideline that provides a framework in terms of WHAT you need to do and taking this and developing from this a comprehensive and consistent approach, one that defines HOW you practically apply the guideline. Routine impurity analysis in pharmaceuticals requires identification at levels of 0.05 percent to 0.2 percent depending on the daily dose. However, genotoxic impurities can be much harder to detect due to their presence at low ppm levels. The real challenge is how to conduct a risk assessment that, while looking at all risk sources, strikes a sensible balance. Without a risk-based approach it may often lead to exhaustive and unnecessary testing. In principle, genotoxic impurities should not be present in the medicinal product you cannot reduce impurities to zero levels. However, a risk-based approach is needed, particularly in defining what constitutes a probable / likely impurity. There are also specific technical challenges. The workshop will look to outline what these challenges are and practical ways to address them.

Ms.Sanghamitra Mishra, M.Pharm., ERT

Sanghamitra Mishra is a Senior Consultant at ToxMinds BVBA, Belgium and a Director of its subsidiary ToxMinds India Consulting Pvt. Ltd., with more than 10 years' of research and consulting experience in the human health hazard, ecotoxicology and E-fate, and risk assessment of chemical substances. Sanghamitra has significant expertise in EU REACH, Classification and labelling and cosmetic regulations. She has successfully prepared more than 100 REACH registration dossiers for several chemical industries and consortiums, including activities such as data gap analysis, critical review of test reports, study evaluation and Klimisch scoring (quality check), robust study summaries preparation using IUCLID software, chemical safety report (CSR) preparation (including

DNEL and PNEC derivations) and cost calculations for consortium members based on principles of data sharing'. Sanghamitra has also played a key role in preparing critical reviews and assessments of chemical toxicological data in different sectors such as cosmetics biocides, and pharmaceuticals, including safe level derivations, PDE, MOE/MOS calculations, benchmark dose modelling, virtual safe dose or life-time cancer

risk calculations using T25 or BMDL10values. In her current role at Tox Minds, in collaboration with Dr. Monica Autiero, Sanghamitra has been instrumental in developing the knowledge base in ToxMinds in the area of non-animal alternatives, particularly SAR/analogue based read-across justification and the identification of mechanism-based *in vitro* testing programmes ("AOP') to reduce remaining uncertainties in a proposed read-across approach Sanghamitra is an European Registered Toxicologist (ERT) with a M.Pharm in Pharmacology from the Indian Institute of Technology, Banaras Hindu University (IIT BHU), India.

Session topic: Read across and QSAR (*In Silico*) Predictions

In the last decade, the increasing ethical and societal demand for reducing or replacing animal testing in hazard assessment strategies, hassled to significant development and adoption of number of alternate approaches in different regulations. Some of the widely used alternative approaches include use of validated *in vitro* assays for several endpoints (such as dermal absorption, acute toxicity, skin and eye irritation, sensitization, genotoxicity), high-throughput assays from ToxCast program including several mechanistic assays (e.g. endocrine disruption), computational approaches ((Quantitative) Structure-Activity Relationships (Q)SARs) predictions), read across and exposure-based assessments using concepts like TTC or iTTC. Among these options, read-across is at the forefront of prediction of toxicity and has been the "new paradigm" for hazard assessment, specifically for the critical systemic endpoints (e.g. repeated dose, reproductive and development toxicity). Read-across relies on the ability to identify similar molecules with the assumption that similar molecules will tend to exhibit similar activity or, at least, show similar trends in activity. Although the concept of similarity has growing acceptance for toxicity prediction, in reality there are still a number of barriers to the acceptance of the predictions, especially for regulatory purposes.

Given these challenges, there have been several efforts from industries and/or regulatory authorities in the form of publications and guidance documents in order to standardize the process of identifying and justifying analogue data to be suitable for read-across

purposes (e.g. Wu et al., 2010; Blackburn et al., 2011, 2014;Schultz et al., 2015, European Chemicals Agency (ECHA) Read-Across Assessment Framework (RAAF), 2017). Computational or(Q)SAR (*in silico*) tool-based toxicity prediction is another non-animal method, which is often used to complement *in vitro* and *in vivo* toxicity assessments to potentially minimize animal testing, reduce the cost and time, and improve toxicity

prediction and safety assessment. *in silico* toxicology is a predictive technique that helps in retrieving relevant data and/or make predictions regarding the effects of compounds based on descriptors of chemical structure and specific properties. The major *in silico* prediction methodologies include either statistical models (such as QSAR), which use mathematical models derived from a training set of exemplary chemicals or 'expert-rule' based systems, which use structural rules or alerts to make predictions for specific toxicological effects or mechanisms of toxicity. The predictions from these tools maybe dichotomous (e.g. predict mutagenic or non-mutagenic compounds), quantal (e.g. Globally Harmonized System [GHS] Classification and Labeling scheme) or quantitative/continuous (e.g. prediction of median toxic dose [TD50] values). Use of the *in silico* models also have an unique advantage of being able to predict toxicity of chemicals prior to synthesis and to innovate the process of developing new chemical entities with desired properties. With these key facts in mind the session has been designed to provide basic understanding on the two most popularly used non-animal alternative approaches along with the presenter's perspective on the EU Industry's best practices to increase regulatory acceptance. In the first half of the session, the presenter will provide an overview of in silico toxicology, listing of various free and commercial QSAR tools and expert-rule based tools per endpoint, followed by outlining of the key aspects to be considered while performing in silico predictions and its documentation to increase regulatory acceptance. In the latter half, the focus will be to outline the essential steps and tools necessary for implementing read-across, starting with analogue identification using publicly available QSAR tools followed by analogue evaluation and suitability assessment.

Mr.Nishitkumar Kachhela, M.S.Pharm.

Nishitkumar Kachhela is working at Intertek Pvt Ltd. as an Assistant Manager - Toxicology and leading the team of regulatory toxicologists and MSDS Author which is the part of Intertek's Health, Environmental & Regulatory Services (HERS) business line. The team is a very good combination of knowledge for hazard assessment, risk

assessment, and regulatory compliance; majorly working on cosmetic products and other consumer products like Toys, Detergents, Inks, Air Fresheners, Biocides etc. He is in the field of toxicology for more than 7 years now, well-skilled to perform hazard assessments, GHS/CLP classification, risk assessment of consumer products, regulatory consultancy, etc. He has practical experience working for safety and regulatory assessments globally for various countries like the EU, US, Australia, Canada, GSO, ASEAN, India, Israel, Brazil, New Zealand, etc.

Dr.Ankushreddy S Patil, M.V.Sc., DABT, ERT

Dr. Ankush is a Principal Scientist at Toxicology Resource Centre (TRC), Johnson and Johnson Pvt Ltd, Consumer Division, Mumbai, with more than 12 years of combined experience in preclinical, regulatory and consumer Toxicology. He is graduated from Veterinary College, Bidar and finished master's in Veterinary Pharmacology and Toxicology, from Nagpur Veterinary College. He pursued PDCR (Professional Diploma in Clinical Research) from Delhi and MBA in Pharma Marketing from Lucknow. He is a Diplomate of the American Board of Toxicology (DABT) since 2013. He has been part of the Toxicology J&J from 2011. He currently serves as a Safety Assessor for consumer products and his responsibility include the assessment of Consumer (Skin and hair care and oral care products) & OTC products for the EU Market. This includes hazard assessment of ingredients, risk assessment of raw material and safety evaluation of final cosmetic products (CPSRs) before release to the market. His responsibilities also include addressing questions posed by regulatory and health authorities, impurity qualification in drug products by data mining and using in silico tools such as OECD QSAR Toolbox, Toxtree and Leadscope. He has worked in preclinical toxicology, product safety and regulatory affairs. He had working experience in the human and environmental safety assessment of chemicals, through their use or presence in consumer products or via the environment, specifically for addressing the REACH& CLP regulation in EU.

Dr.Suresh Kumar, M.Pharm., Ph.D.

Suresh Kumar obtained his M.Pharm.in Pharmacology and Toxicology and Ph.D in Pharmacology from The Bombay College of Pharmacy, Mumbai affiliated to the University of Mumbai. He has over 14 years of experience in general toxicology, regulatory toxicology, and product safety. Currently he is working as Senior Manager, Toxicology Resource Center with Johnson & Johnson's Consumer Product Division, International Technical Centre, Mumbai. He is providing Toxicology support to business franchises including Over the Counter, Oral care and Topical Healthcare, Adult and

Baby Skin care. He is an expertise *in silico* and structure activity relationship-based toxicity prediction, risk assessment analysis, designing and managing toxicology as well as preparing and reviewing technical documents for regulatory submissions. Prior to joining Johnson & Johnson, he worked in Drug Discovery program in Discovery Biology function with Glenmark Research Center, Glenmark Pharmaceuticals Ltd., Mumbai and involved in screening of New Chemical Entities for the treatment of asthma, COPD and inflammatory conditions. He has 5 research articles, I invited review and 13 abstracts/presentations published in journals and conference proceedings. He is also a reviewer for scientific journals.

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Testimonials

"IMIT-2019 Team ToxGurukul Kudos to you. I am pleased to write this feedback for successful completion of IMIT-2019. I congratulate Dr. K.S. Rao and his entire team for such nicely and smoothly organizing the event. This event was of great success with many distinguished experienced speakers in the field. Listening to Dr. Rao is itself a learning experience. His tireless efforts to make the Indian Toxicological Fraternity visible on global front are commendable. Risk assessment is a vast interdisciplinary area. That has been extracted and delivered to the participants in a easy learning manner. Young professionals will be highly benefited with this type of workshops. I once again thank you all and look forward to be a part of such future events and join hands as a team."

-Sapna Gupta (IMIT-19 Delegate)

Shriram Institute for Industrial Research

"Very good training course material. Very Nice Presentation regarding Risk Management. The trainers were done clarified to all participant on related regulatory aspect. The training is very useful and fantastic for all concern personnel."

-ChandrajeetSingh(IMIT-19 Delegate)

Accuprec Research Labs Pvt. Ltd.

"I really appreciated the opportunity to attend the "Interactive Meet on Insights in Toxicology-2019'' organized by ToxGurukul. Speakers were very knowledgeable, Information they provided was well presented and easy to understand. It was a great success! ToxGurukul did a fantastic job. Congratulations..!! Also congratulations and best wishes for your next meet "Pathology to Toxicologist" Looking forward to attend meet regarding Pharmaceutical Toxicology. My special thanks to Dr K.S.Rao sir for his admirable efforts to upgrade the ground for all fresh players of the toxicology in India by providing support in term of knowledge of toxicology and relevant guidance."

-Dr. Hiren B Parmar, MSc, PhD (IMIT-19 Delegate)

Sun Pharma Advanced Research Company Ltd.

"First of all, thanks to the organizers as their hard work was visible and was vital for smooth functioning of the workshop. This workshop gave us a good platform to meet our old friends and to make new friends in the toxicology world. It was a great learning from all well experienced speakers who are leading in the respective areas of toxicological risk assessment. As a speaker, it was my pleasure to get a chance to interact with these leaders personally. I am thankful to Dr. Milind Sir and Dr. K S Rao Sir for this opportunity and I appreciate ToxGurukul team for all their dedication towards a noble cause. P.S. the auditorium was very nice and I also liked the food given in lunch."

-NishitKachhela(IMIT-19 Speaker)

Intertek

"This is the first time I attended this "Interactive meet on Insights in Toxicology". It is a great eye opener for me and my team. The forum helped to interact with experts of toxicology to on animal free testing. A very useful session."

-Krishnan Subramanian (IMIT-19 Delegate)

JK Helene Curtis Limited

"IMIT- 19 was indeed wonderful experience. Event was organized very well and utilized full two days effectively. Speakers and the topics were in line with the theme of the workshop. Really enjoyed learning from the experts staring from the basics of personal care/cosmetic product safety to the specialized concepts such as spray product evaluation, TTC, impurity qualification and so on. Presentation about in in silico approaches for the safety assessment was informative. I would like to thank speakers for sharing their knowledge generously. Looking forward for such wonderful events in future."

-Sachin Shete (IMIT-19 Delegate)

Colgate Palmolive

I would like to thank you a lot for organizing such a interactive conference related to toxicity studies.The lectures were very informative. We gathered a good knowledge from the conference. Many aspects related to toxicity studies were cleared. It will help us a lot in future.
The hospitality of the volunteers was excellent.

-RumaBaksi, M.V.Sc (IMIT-19 Delegate)

B. V. Patel Pharmaceutical Education and Research Development (PERD) Centre

"IMIT 19 was a grand success! The content of the course was chosen very well. The overview, risk assessment, various in-vitro methods, data base search, regulatory expectation, case studies etc were very well discussed. The speakers were excellent and subject matter expert. The venue and the organization of the conference was great! Congratulations to the IMIT 19 organizing team and hardworking volunteers! Many thanks to Dr. Milling Deore Sir for the course design and Dr. K S Rao Sir for mentoring all of us.. "

-Parimal Solanki (IMIT-19 Delegate)

Sun Pharma Advanced Research Company Ltd.

"Firstly congratulations for the success of beautifully scripting, planning and conducting the conference. It was a holy experience to all the toxicology/regulatory aspirants. Two days flew like few seconds. Knowledgeable speakers and equally enthusiastic listeners made this conference fruitful for all. Thank you to the organizing committee members and his highness Dr. K.S.Rao for this mega event. Looking forward towards more and more such kind of events...."

-Shekhar Shivaji Gaikwad (IMIT-19 Delegate)

Baxter International Inc.

"Conference was very good and nicely arranged. Speakers were good and the topic had been chosen was new for all audience especially cosmetic area of submission.
I congratulate all committee for the same for grand success of this event.
Special thanks to Rao sir for doing such a nice things."

-Dr Ashvin Patel (IMIT-19 Delegate)
Zydus Research Centre

The conference was great, especially the teamwork of organizers and arrangements for participants were nice, so congratulation for good work done. All toxicologist at one place, that is the big highlight of the conference.
Good luck for future endeavors.
-Rita Rana (IMIT-19 Delegate)
Shri B. V. Patel PERD Centre

"Indeed I would agree with you that IMIT-2019 was a grand success!
First of all, I am personally thankful to ToxGurukul for starting this initiative in order to provide a learning platform for all the toxicologists of India. Also, hats off to the dedication and effort put in by all the people of the ToxGurukul organizing committee/volunteers, which facilitated the event to a big success! My special heartfelt gratitude also for Dr. K.S. Rao, who is the driving force behind all this.

Now coming to IMIT-2019, it was a very well designed course by Dr. Milind Deore, who had carefully selected speakers from different Industries…And here again I am thankful to him for inviting me to come over and share my perspectives on the 'alternate to testing' topic! It also felt amazing to see the enthusiasm of the participants, who had gathered for the event from far and near, because of their hunger to learn and understand the subject… This topic of risk assessment for consumer products indeed is a specialized application oriented topic, which is one of the main task expected from the risk assessors of FMCG companies or consultants/service providers, who support them. And I am very sure the course managed to provide that perspective to all the participants! Lastly, the event also provided a good networking opportunity to all participants and speakers working in this domain. In short, the event achieved the objectives what it was designed for!

Looking forward to many more such workshops in India and to learn from each other!

Keep up the excellent work and glad for having being able to contribute a bit to the noble cause!"
*-**Sangamitra Mishra (IMIT-19 Speaker)***
ToxMinds

"Topics picked up for the conference was well chosen and the speakers were exceptionally good and informative. I felt the attendees of the conference were receptive and interactive that had made all sessions lively and interesting. It was a wonderful platform for the grooming toxicologist from both academia and industries as well as to have a complete and detailed overview on risk assessment across different categories. Networking with professionals and subject matter experts during these 2 days has definitely helped in exchanging of intellectual ideas and thought processes.
Overall a great and useful experience – Well organized and Well structured"
- Dr.Gopumadhavan S.
The Himalaya Drug Company

"The IMIT -19 was a wonderful and very well organized workshop, I am very glad to get the opportunity to attend and meet Toxicologists all over India at one place. The course was very well designed, very practical and useful, which are very essential for day to day activities of a Risk assessor. It will help the Toxicologists who are more into Study conduct to understand the Risk assessment process and also help the Toxicologists who are planning to attempt the DABT exam. For freshers or early stage of the career, it will help a lot to get the insights of the Risk assessment process. Personally, I have enjoyed and learned a lot of new things in IMIT-19 workshop.
I want to convey my sincere thanks to Toxgurkul team, Dr. K.S Rao, Dr. Milind Deore, All the respected speaker and all the volunteers/organizers and management of Ahmedabad University for conducting such a great workshop. I will look forward to this kind of great workshops to happen more in the future."
-Anil Kumar Madupu, M.Sc., D.A.B.T.
Johnson & Johnson Pvt. Ltd.

"We from ACS congratulate the organizer team on successful completion of IMIT-19 a ToxGurukul initiative. It was very professionally organized event. Selection of speakers and presentation topics were very much in line with current market scenario and need of the hour. With a desire that more such events will be initiated by ToxGurukul, we wish all the very best to the organization and enthusiastic members."
- Iqbal Gandhi
Animal Care Systems

"Entire 2 day was one of the best I've ever spent. Dr. K. S Rao gave us a nice overview risk assessment process including both hazard and risk assessments. Dr. Milind Deore and other J&J team gave us a nice comprehensive overview of Risk assessment of personal care and cosmetic products. All the speaker was comfortable in his own skin, nothing to prove, no need to hear his own voice, plenty to show and say, doing his best to be of service to the audience.
Thanks for a fab workshop…I came away feeling very educated and inspired to get creative."
-Sandeep P Sarode
Johnson & Johnson Limited Mulund, Mumbai.

"It was an absolutely amazing, enlightening and engaging workshop. The course content was very well-structured- started with an overview, touched all different components of consumer products with respective approaches/methods/tools of risk assessment, regulatory requirements and submissions. I found it really insightful and interesting, as core concept of risk assessment remains same across industries whether pharmaceutical, consumer products, chemicals, food or pesticide. It provided an excellent platform to discuss practical challenges encountered and the solutions adopted in the field of risk assessment. Plethora of information in a short time!"

-Shahnaz Akhtar, PhD, DABT

Sun Pharma Advanced Research Centre

"The complex topic of "Risk Assessment of Consumer Products" was meticulously selected and delivered. Speakers were very good communicators and knowledgeable, Information was well presented and easy to follow. Sessions were interactive and well worth my time.

Hope that next time Risk Assessment in terms of pharmaceutical gets addressed.

Wishing all the best to ToxGurukul for all future endeavors.

And last but not the least thanks to the IMIT-2019 Committee for organizing this Workshop."

-Ashish Kapoor

JDM Research

"I considered it great privilege to be part of IMIT 2019. Firstly thanks for bringing ToxGurukul to Ahmedabad. All session were knowledge sharing and interactive too. Many of the things were not known and the way it was delivered, it was outstanding and energetic. Special thanks to Dr.Milind Deore Sir and Dr. K.S. Rao Sir for their presence and being mentor for all of us. All the arrangements were beautifully organised, thanks to volunteers. Will love to be part of ToxGurukul in future too."

- Dharak N Sharma

Safety and Analytical Research Center LLP

"Conference was awesome and many of the new things I learnt related to cosmetics.

I got an opportunity to meet and listen experienced speakers.

I came to know many things related to toxicology which will be helping us in further studies."

- Riya Agrawal

Maliba Pharmacy College

"It was really a well-organized, interactive workshop and the best of its kind I have ever attended in my professional career. Time management was so excellent to accommodate so many topics in a limited time frame. Although the principles of 'toxicological risk assessment' remain same, however speakers brought in important insights into regulatory framework, execution strategy, key concerns and caveats in respective

areas. Thanks a lot to the course organizer, course director, speakers, the volunteers, sponsors and all who made this workshop happened with a fabulous success and for providing such an opportunity to learn and/or upgrade our knowledge. Let's keep going the generous effort of ToxGurukul group to nurture and disseminate knowledge in the field of toxicology and to take the practice of toxicology in India and its global recognition to a new horizon."

-Dr. Santanu Jana, M.V.Sc (Path.), DABT, DIBTP,

Sun Pharmaceutical Industries Ltd.

"Being a non-toxicologist came out with a confidence of preparing "PRODUCT INFORMATION FILE (PIF)" on Cosmetics after the conference it shows that how good it was, well done everybody and thanks again."

-Venkatesh.B.T.

Botskem Labs

"A Big Thank you to Dr. K.S.Rao and team for successfully organizing the IMIT 2019 Risk Assessment of Consumer Care Products Including Cosmetics Conference, this is the first of its kind conference been held in India to nurture the next generation regulatory toxicologists under the eminent leadership of Dr. Milind Deore. I am thankful to him for inviting me as a speaker. In an era of too many conferences with too little focus, IMIT 2019 stands out as one of the few must-attend shows, which completely focused on the Product Safety of Consumer Goods, this even includes the on-going trend for naturals in the cosmetics. All speakers were top-notch, the sessions were educational and very practical which covers the daily activities of a regulatory toxicologist in the consumer goods industry. This conference also turned to be the best stage, where you can really network with such a concentrated group of toxicologists working across the country in varied industries. Special thanks to Dr. K.S.Rao, hats off to his passion, dedication & implementation of the Toxicology Workshops in India for the development of next-generation toxicologists. I look forward to many more such workshops in India."

-Sampath Kumar, M.Pharm, C.Biol, MRSB

Colgate-Palmolive

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9. **ATNT Laboratories**
10. **Intox Pvt. Ltd**
11. **PRADO**
12. **SA FORD**

BRONZE LEVEL

13. **Kansara Scientific**
14. **National Institute of Biosciences**

1. Vivo Bio Tech Ltd. (http://www.vivobio.com)

Vivo Bio Tech Ltd.
3 Floor, Ilyas Mohammed Khan Estate
8-2-672/ 5 & 6, Road No.1, Banjara Hills
Hyderabad - 500034,
Telangana, India

Vivo Bio Tech Ltd.
Survey # 349/A,
Pregnapur Village, Gajwel - 502311,
Siddipet District, Telangana, India

Vivo Bio Tech Ltd: is a Hyderabad based public listed CRO offering services to biomedical industry worldwide in the areas of in-vitro / in-vivo toxicology, pharmacological investigations, analytical and physico-chemical testing. The company is also the largest supplier of locally bred Specific Pathogen Free laboratory rodents in India. The company's state-of-art 125,000 Sq.ft. preclinical research facility is NGCMA OECD-GLP certified and AAALAC accredited.

Vivo Bio Tech is a full service CRO offering drug development & discovery services to pharmaceutical & biotech companies world-wide in accordance with OECD - GLP, AAALAC & IND guidelines. The company offers services in the areas of *In vivo & In vitro* toxicity studies, Pharmacological investigations, Pharmacokinetic & toxicokinetic studies, Genotoxicity screening, Analytical services etc. Our experienced & talented scientists offer advice on defining drug development paths tailored to specific molecules.

Our Scientific team provides both regulatory and non-regulatory IND enabling preclinical development services. We are capable of screening & evaluating molecules for various pharmacological & therapeutic properties. Specifically for oncology, our scientists can provide design & development of syngeneic / xenograft models for evaluation of anti-cancer agents. Further, our scientists can customize *In vivo* DMPK studies to help profile your drug candidate in both rodent and non-rodent animal models.

Vivo Bio has partnered with Taconic Biosciences for sourcing foundation and expansion colonies of the SPF rodent models and have started in-house breeding & trading. Vivo Bio has also partnered with Cyagen Biosciences to provide easy access to Genomic Technologies to Indian Biomedical R&D.

Vivo Bio Tech Ltd.

Your Drug Discovery Partner

2. Sun Pharma Advanced Research Company (Sparc Ltd(https://www.sparc.life)

17 B Mahal Industrial Estate,
Mahakali Caves Road, Andheri(E),
Mumbai - 400 093.
Tel: +91 22 6645 5645
Fax: +91 22 6645 5685

Sun Pharma Advanced Research Company (SPARC): is a clinical stage bio-pharmaceutical company focused on continuously improving standards of care for patients globally, through innovation in therapeutics and delivery. SPARC was formed in 2007 through a demerger from SUN PHARMA, a global leader in speciality generics. A robust mix of internal ideation and strategic partnering with academic innovators and bio-pharma entrepreneurs fuel our engine with potentially high impact ideas. We partner with thought-leading clinicians across the world for ideas and access. Innovation through integration of partner knowledge and efficient internal execution shapes our future. Our aim is to consistently lower costs and improve operational efficiencies to advance availability and affordability of cures for patients across the world. We realize our dream when we help patients lead more fulfilling lives.

SPARC is a vibrant innovation community spread over three locations globally. We endeavour to develop a meritocracy which takes pride in continuous learning and re-invention. Our aspiration hinges on creating a culture which can attract high quality talent globally, develop them into passionate drug developers & creative problem solvers and empower them with a smart toolset. We are committed to our pursuit of excellence.

SPARC is a responsible public company committed to maintaining highest standards of ethics and transparency. Our accountability to patients we seek to serve and investors who enable us and our commitment to sustainable human progress are key components of our identity – A responsible innovator inspired by life's amazing ability to learn, evolve and survive. We exist because we seek to be part of the solution.

Therapeutic Focus: Oncology, Neuro Degeneration, Ophthalmology, Dermatology, Abuse Deterrent Formulations

3. Toxikon Corporation (http://toxikon.com)

Corporate Headquarters & Laboratory Facilities
Toxikon Corporation
15 Wiggins Avenue
Bedford, MA 01730
United States of America
(781) 275-3330

Toxikon is a leading preclinical contract research organization (CRO) providing in vivo, in vitro, and analytical testing services for the pharmaceutical, biotechnology, and medical device industries worldwide. No matter where you are in the product development lifecycle, Toxikon offers comprehensive high-quality testing to help move your product forward. Collaborating with us provides you access to state-of-the-art facilities and a team of experts experienced in the full range of preclincal testing needed to achieve product safety and regulatory compliance while maintaining the highest levels of manufacturing quality control.

Toxikon provides the qualified, 3rd-party confidence that medical products will perform as expected with minimal risk of adverse effects.

Toxikon is accredited to ISO/IEC 17025, an extensive set of standards confirming our competency as a testing laboratory. Our operations are governed by a rigorous quality management system, ensuring that you can trust the data we deliver in support of your products.

Additionally, we are registered with the United States Food and Drug Administration and the Japan Ministry of Health, Labor, and Welfare for drug and medical testing – and we have demonstrated success with working through these and other worldwide regulatory agencies to complete submissions and, when necessary, defend challenges.

For projects of all types, for companies of all sizes, we can create a testing program that meets your requirements, delivering reliable results on-time and on-budget.

Thought Leadership in Life Science Product Testing

As the both the variety of and complexity of medical devices increases, Toxikon is committed to staying at the forefront of medical device testing by continually evaluating our study methods and research techniques.

4. Ellegaard Göttingen Minipigs A/S (https://minipigs.dk)

ELLEGAARD
GÖTTINGEN MINIPIGS

Göttingen Minipigs now available in India

Göttingen Minipigs are a high-quality large animal model with many similarities to humans and extensively used worldwide for biomedical research.

- **Well-characterized and with lots of background data**
- **Well-defined genetic background**
- **Unique health status**
- **Small size**
- **Easy to handle and with a good temperament**
- **Scientific and technical support**

Studies performed with Göttingen Minipigs are fully recognized by regulatory authorities globally and have supported non-clinical development of a large variety of marketed drug products within many different treatment areas.

Clean Pigs for Clear Results

We strongly believe in the value of animal welfare, quality, respect and collaboration, and we invest many resources in the development and accumulation of new knowledge about Göttingen Minipigs as well as in networking with scientists all over the world working with the animal model.

Read more at www.minipigs.dk

Ellegaard Göttingen Minipigs A/S
Soroe Landevej 302
DK-4261 Dalmose
Denmark

Tel. +45 5818 5818
www.minipigs.dk
ellegaard@minipigs.dk

ELLEGAARD

GÖTTINGEN MINIPIGS

5. Syngene International Ltd,(https://www.syngeneintl.com)

Corporate Office
Syngene International Ltd,
SemiconPark , Tower 1,
Electronic City - Phase-II
Hosur Road,
Bangalore 560 100

Clinical Development Services
Syngene International Ltd,
Biocon Park , SEZ,
Bommasandra Industrial Area - Phase-IV
Bommasandra-Jigani Link Road,
Bangalore 560 099
India

Syngene is a leading contract research and manufacturing organization (CRAMS) in Asia providing end-to-end discovery and development services. Our multi-disciplinary skills in integrated drug discovery and development include medicinal chemistry, biology, in vivo pharmacology, toxicology, custom synthesis, process R&D, cGMP manufacturing and formulation.

Our ability to seamlessly integrate our comprehensive capabilities differentiates us from our competitors. We accomplish this integration by forming multi-disciplinary teams that work cohesively, monitoring projects continuously and proactively addressing and resolving critical issue

<table>
<tr><th></th><th>Discovery</th><th>Development</th><th>Manufacturing</th></tr>
<tr><td>Small Molecules</td><td>Chemistry
Biology
Integrated Drug Discovery</td><td>Drug Substance Development
Drug Product Development
Integrated Drug Substance - Drug Product
Clinical Services (India)</td><td>Clinical Supplies
HPAPI
Speciality Molecules</td></tr>
<tr><td rowspan="2">Large Molecules</td><td rowspan="2">Therapeutic Antibody Discovery & Engineering;
Cell Line Development</td><td>Allied Services</td><td>Commercial Supplies</td></tr>
<tr><td colspan="2">Bioprocess Development | Process Characterization
Clinical Manufacturing (Microbial & Mammalian)</td></tr>
<tr><td>Bioinformatics</td><td colspan="3">Target Dossiers, NGS, Integrated Data Analytics, Modeling,</td></tr>
<tr><td colspan="4">Wide spectrum of services across a range of molecules including Antibody Drug Conjugates and Oligonucleotides</td></tr>
</table>

6. Animal Care Systems Inc. (https://animalcaresystems.com)

Animal Care Systems
1, Khushboo Bunglows, Kajal Park, Inside Ghanchi Hall Road, Juhapura
Ahmedabad, Gujarat 380055
Contact: Iqbal Gandhi
Title: Director of Business Development, India
Phone: +91-9725043010
Mobile: +91-9725043010
Email: igandhi@animalcaresystems.com or iqbal.gandhi@gmail.com

Animal Care Systems: manufactures the only motor-free rodent caging system in the industry. Combining "twice the mice" density with our unique carousel design, our caging provides a microenvironment that is free of noise, vibration and ultrasound, creating a variable-free environment. We have established a stellar reputation for our superior customer service and product support.

Mission

To provide innovative rodent caging systems that save energy and protect animals, their caretakers and the environment.

Animal Care Systems is a member of:

- The American Association for Laboratory Animal Sciences (AALAS) – national, Mile High and many state and regional branch organizations
- Canadian Association for Laboratory Animal Sciences (CALAS)
- Allied Trade Association (ATA)
- We attend and support many other local, regional, and worldwide industry conferences including:
  - Federation for Laboratory Animal Science Associations (FELASA)
  - Association Française des Sciences et Techniques de l'Animal de Laboratoire (AFSTAL)
  - The Society for Laboratory Animal Science (GV-SOLAS)
  - Asian Federation of Laboratory Animal Science (AFLAS)
  - Laboratory Animal Science Association (LASA)
  - Institute of Animal Technology (IAT)
  - Israeli Laboratory Animal Forum (ILAF)
  - Austrialian and New Zealand Laboratory Animal Association (ANZLAA)
  - Society for Neuroscience (SfN)

7. Intertek (http://www.intertek.com)

Intertek, is a leading Total Quality Assurance provider to industries worldwide. Our network of more than 1,000 laboratories and offices and over 43,000 people in more than 100 countries, delivers innovative and bespoke Assurance, Testing, Inspection and Certification expertise for our customers' operations and supply chains.

Industries and Services

Chemicals
Agrochemicals & Pesticides
Basic & Industrial Chemicals
Dyes & Detergents
Lubricants & Greases
Nanomaterials
Petrochemicals
Polymers & Plastics
Specialty Chemicals

Construction & Engineering
Building Products
Hazardous Locations
Industrial, Life Safety & Security
Manufacturing

Energy & Commodities
Agriculture, Biofuels, Coal & Solid Fuels, Minerals, Nuclear, Oil & Gas, Power Equipment, Power Generation, Power Transmission & Distribution, SolarWind, Wave & Tidal

Food & Healthcare
Beauty & Personal Care
Food
Medical Devices
Pharmaceutical

Government & Trade
Customs Services
Import & Export
Public Sector

Transportation
Aerospace
Automotive
Marine
Rail
Space

Products & Retail
Accessories, Appliances
Batteries, Footwear
Furniture, Housewares & Home Decor
HVACR, Information Communications Technology, Internet of Things & Software
Lighting, Machinery & Tools
Medical, Packaging
Retail, Sporting Goods
Textiles & Apparel, Toys & Children's Products, Wireless

- Assurance
  Enabling you to identify and mitigate the intrinsic risk in your operations, supply chains and quality management systems.
- Testing
  Evaluating how your products and services meet and exceed quality, safety, sustainability and performance standards.
- Inspection
  Validating the specifications, value and safety of your raw materials, products and assets.
- Certification
  Formally confirming that your products and services meet all trusted external and internal standards.

8. Sai Life Sciences Ltd.(https://www.sailife.com/)

Sai Life Sciences Ltd.
Office # L4-01 & 02,
SLN Terminus, Survey No. 133,
Gachibowli Miyapur Road,
Gachibowli, Hyderabad 500032,
Telangana, India

Sai Life Sciences delivers advanced Discovery, Contract Development and Manufacturing Solutions, through a broad suite of expert capabilities across the molecular life cycle.
We are an ideal drug discovery, development and manufacturing partner. Our pharma and biotech clients gain clear competitive advantages through shorter time to market and risk minimization using our integrated and high-quality scientific services.
Sai Life Sciences delivers advanced Discovery, Contract Development and Manufacturing Solutions, through a broad suite of expert capabilities across the molecular life cycle.
We are an ideal drug discovery, development and manufacturing partner. Our pharma and biotech clients gain clear competitive advantages through shorter time to market and risk minimization using our integrated and high-quality scientific services.
Sai Life Sciences offers its clients a wide range of services ranging from synthetic and medicinal chemistry, DMPK/Tox, biology, CMC development and cGMP contract manufacturing. Our core expertise and success that when on the highly skilled and motivated talent working at Sai Life Sciences.
At Sai Life Sciences, we believe that the most important elements of a successful partnership are communication and effective program management. To that end, we have built a team with an ingrained culture of supporting our clients, implemented clearly articulated program management processes and developed state-of-the-art tools that enable working together for the successful outcome of every project we work on.

9. ATNT Laboratories (http://atntlabs.com)

10. INTOX Pvt. Ltd.

TOXICOLOGY | MUTAGENICITY | ECOTOXICOLOGY | CHEMISTRY | BIOLOGY

GLP TESTING SERVICES

Crop Protection Products | Pesticides | Biopesticides | Biocides

Pharmaceuticals | Biologics | Speciality Chemicals | Neutraceuticals | Medical Devices

Towards a safer planet...

www.intoxlab.com

OECD GLP CERTIFIED by,
The national GLP Compliance Monitoring Authority,
Department of Science & Technology, Government of India.

The Netherlands GLP Compliance
Monitoring Program, Food and Consumer Product Safety Authority
(VWA), The Netherlands.

intox
QUALITY TOXICOLOGICAL SERVICES

INTOX PVT. LTD., 375 Urawade, Tal. Mulshi, Dist. Pune – 412 115 INDIA
Tel.: +91-20-66548700 (30 Lines), Fax :+91-20-66548799

11. PRADOPvt.Ltd.(http://pradopreclinical.com)

GLP FACILITY CERTIFIED

GLP/C-127/2018

PRADO

advance the safety evaluation

www.pradopreclinical.com

CPCSEA
1723/PO/RcBiBt/
S/13/CPCSEA

Dr. Pralhad Wangikar, Phone: +91-9987001604 Email: pralhad.wangikar@pradopreclinical.com

ABOUT PRADO

PRADO is a Pune-based Preclinical Contract Research Organization, Started providing services since 2014. We have established ourselves as one of the emerging, global, independent market leaders in preclinical services.

Our scientific data is of highest quality and our reports have excellent acceptance record with regulatory agencies, facilitating product registration and approval.

PRADO has technical, research and development expertise and we work closely with our clients to understand their preclinical needs and develop program to meet their goals in timely manner. PRADO can be a strategic and scientific, yet responsive and trustworthy partner for your preclinical needs.

Capabilities

Toxicity Studies

- Acute Toxicity Studies (Single dose),
- Sub-acute Toxicity Studies (Repeated Dose 7/14/28 Days)
- Sub-chronic Toxicity Studies (Repeated Dose 90 Days)
- Chronic Toxicity Studies (Repeated Dose 180 Days)
- Genetic Toxicity Studies
- Reproductive Toxicity studies

Pathology Services

- Histopathology slide preparation and evaluation
- H &E Staining and Special Staining
- Immunohistochemistry
- Hematological analysis
- Clinical Chemistry Evaluation
- Urinalysis

Pharmacokinetics

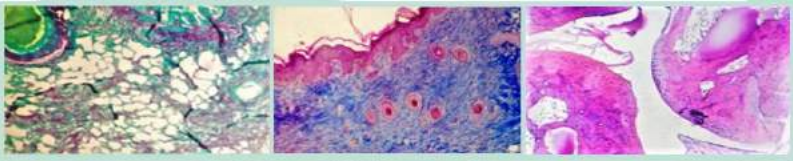
- Custom Designed Rodent Models
- For Pain and Inflammation, Metabolic Disoders,
- e.g. Diabetes, Obesity, Thyroid, Ulcerative Colitis

Biology Studies

- PK by Different Routes of Administration
- In Vitro Permeability Studies
- Drug Distribution in Tissues, Bile and CSF

Industries We Serve

- Pharmaceutical
- Agrochemical
- Biopharma
- Medical Devices



Address: Survey No. 170/1, Punawale Road, Tathawade, Tal- Mulshi, Dist- Pune, 411 033, Maharashtra, INDIA

'Fastest Growing Indian Company Excellence Award 2017 by International Achievers Conference at Bangkok, Thailand'

12. SA-FORD (http://www.sa-ford.com)

sanctuary for research and development

sa-FORD

The one-stop solution for your chemistry and toxicology needs

sa-FORD is a well-known and leading GLP-certified Indian CRO established in 2008 in collaboration with German scientists. With our state-of-the-art animal and lab facilities, we have become the partner of choice for numerous clients from the agrochemical, specialty chemical and pharmaceutical industries, among others.

Under the scope of GLP, we offer the following services and more:

Analytical
Method development/validation, Homogeneity & Stability, CoA, Formulation analysis

Physico-chemical
Absorption spectra, Melting & Boiling points, Vapor pressure, Density, Viscosity, Surface tension, Moisture content, Solubility, Miscibility, Wettability, Flammability, Explodability, Container content capability

5-Batch analysis for impurity characterization

Single dose
Oral, Dermal & Inhalation toxicity, Skin sensitization, Dermal irritation, Eye irritation

Repeated dose
Sub-chronic, chronic, carcinogenicity, developmental neuro- and immuno-toxicity

Reproductive
One and two generation studies, pre-natal

***In vitro* toxicity studies**
including genotoxicity and alternative *in vitro* methods for toxicity testing.

We are in the process of validating various assays that are introduced as alternatives to the classical *in vivo* testing guidelines, and are becoming statutory requirements for some regulatory authorities

sa-FORD works with strict adherence to international regulatory guidelines including OECD, EPA, ICH, EC, EMEA, ABNT, CIPAC, SANCO and others. sa-FORD is also accredited by AAALAC international for its animal care and use program.

lab@sa-ford.com | www.sa-ford.com

Plot V-10, MIDC Industrial Area, Taloja, Dist.: Raigad
Navi Mumbai, PIN: 410 208, Maharashtra, India

13. Kansara Scientific Pvt. Ltd.

14. National Institute of Biosciences (http://nibslab.com)

A Brief Report on

Interactive Meet On Insights In Toxicology (IMIT-19) conducted on 1st & 2nd March, 2019

By ToxGurukul at Ahmedabad, India

Theme

Risk Assessment for safety of personal care products including cosmetics

Course Director

Dr. Milind Deore,

M.V.Sc., Ph.D., DABT

Course Organizer

Dr. K. S. Rao,

M.V.Sc., Ph.D., DABT

Co-sponsored by

Indian Chapter of the Society of Quality Assurance

L.M. College of Pharmacy, Ahmedabad

AIC-LMCP Foundation

Report by

Krutik Andhariya

Joint Organizing Secretary, IMIT-19

PREAMBLE

- ***Dr. K. S. Rao,*** one of the Indian Toxicology legend, is the key person who established ToxGurukul for the development, nurturing and inspiring next generation Toxicologist.
- **With the fruitful success and positive response** of first meet of Toxicology held **in Bengaluru in 2017, he truly vision for the second workshop with different topics of Risk Assessment**, a much important subject to encourage and aware toxicologists.
- His idea and efforts were supported by another Indian Toxicology Legend **Dr. Milind Deore** of Johnson and Johnson, who is leading expert of Risk Assessment in the country, **had enthusiastically taken all responsibility of conducting this course** to deliver guidance and share depth knowledge of Risk Assessment. There the mission started!
- **Within a couple of weeks, they had managed to invite speakers.** These speakers were professionals with strong experience in Risk Assessment. They came from different organizations throughout the India to disseminate the knowledge and train next generation of toxicology.
- **The subject of Risk Assessment was considered for attention due to its indeed awareness to scientists in modern work environment of all sectors.** Risk Assessment topic is of immense importance to inculcate a keen sense of analytical faculty in our scientists to protect our citizens against hazardous chemicals and product. Amongst the products in the universe, most human beings are exposed to more amounts of Consumer Care Products and Cosmetics,

ToxGurukul

- ToxGurukul is extremely delighted **to all Speakers** for taking out time from their exceptionally busy professional schedule to deliver lectures. We are thankful to you for actively sharing a platform to enthusiastic scientists about different aspects of Risk Assessment.
- Significant miscellaneous requirements like demand of the Auditorium Hall, presentation equipment requirement, food arrangement, local volunteering and communication support were proudly handled by **Dr. V.G.S. Sharma and his team**. ToxGurukul is conceitedly thankful of Dr. Sharma for his spearheaded support.
- ToxGurukul is sincere grateful to **L.M. College of Pharmacy, Ahmedabad and Dr. Sharma for arranging auditorium facility at free of cost.**
- ToxGurukul is also sincere thankful of **ICSQA and Team** for its tremendous support as a backbone for handling financial matters. As a treasurer, each work was carried out punctually, without any hesitation and satisfactory to participant and sponsors.
- ToxGurukul is appreciative of **L.M. College of Pharmacy (LMCP),** one of the oldest and most reputed College of Pharmacy, and **AIC-LMCP Foundation** for being as helping hands providing learning platform to budding Toxicologists, Scientists, Innovators and researchers through this workshop.

Day – 1 (1st March, 2019)

REGISTRATION

Program started with formal registration of participants at 08.15 AM. Total three counters with volunteers were set up for easy & quick registration. Around 180 participants took advantage of course.

AUDITORIUM AND PARTICIPANTS

Day – 1 (1st March, 2019)

WARM WELCOME

Around 08.40 AM, Dr. Mukul Pore heartily welcomed all enthusiastic participants followed by 2 minute condolence to Brave Martyrs of Pulwama Terrorist Attack

Dr. Mukul Pore

INAUGURATION

At 08.55AM inauguration was done through lighting Diya by Dr. Mukul Pore, Dr. Milind Deore, Dr. K.S. Rao, Dr. M.T. Chhabaria and Dr. Gaurang B. Shah (From left to right).

COURSE OVERVIEW

At 09.00 AM, complete welcome speech was addressed by Dr. Milind Deore. He welcomed every enthusiastic participant giving a brief overview of the workshop and requested all to achieve opportunities to update their knowledge of Risk Assessment.

Dr. Milind Deore

Day – 1 (1st March, 2019)

“Overview of Risk Assessment Process” by Dr. K.S. Rao

Dr. K.S. Rao is Vice Precident, Subject Matter Expert for Safety Assessment, at Eurofins Advinus. He delivered a wonderful lecture covering different basic aspects like Risk covering, Hazard Identification, Toxicity Endpoints, Dose Response Assessment (DRA), Exposure Assessment, Health based Exposure value derivation.

Dr. K. S. Rao

Dr. Milind Deore

“Risk Assessment of Cosmetics and Consumer Products” by Dr. Milind Deore

Dr. Milind Deore is Senior Director and Global head, Toxicology in Johnson & Johnson, Mumbai. He delivered a delightful lecture on Cosmetics/Personal Care Products (PCP), role of toxicologist for their assessment, Different phases of PCPs Risk assessments, limitations and challenges, Product specific risk characterization methods.

Day – 1 (1st March, 2019)

“Databases, Sources of Information” by Mr. Sampath Kumar

Mr. Sampath Kumar is Senior Scientist (Team Lead)-Toxicology at Colgate-Palmolive, Mumbai. He delivered lecture in depth on available toxicology databases, how to use those, how to search literature using proper keywords, pros and cons of each database. He also delivered demo with few of them to retrieve Toxicological data. All aspirants appreciated his lecture and learnt many aspects.

Mr. Sampath Kumar

Ms. Geeta Bajaj

“Regulatory overview/ requirements for cosmetic products, dossiers ” by Ms. Geeta Bajaj

Ms. Geeta Bajaj is Associate Director – Regulatory Affairs at Estee Lauder Companies. She is actively involved in registration guidelines for cosmetics with strong regulatory background and connections. She delivered brilliant lecture on regulatory requirements and registration guidelines, process, documentation like dossiers, safety reports for cosmetic products. She actively interacted with participants and

Day – 1 (1st March, 2019)

“Risk assessment of fragrances and flavours” by Dr. Ravishankar Nagarajan

Dr. Ravishankar is Senior Manager and Risk Assessor for Oral and topical health care products in Johnson and Johnson, Mumbai. He delivered magnificent lecture on criteria and factors to be taken into account for quantitative risk assessment of fragrance and flavours. He cleared how to qualify fragrance and flavour, requirements and cosmetic product classification according to IFRA, He also cleared calculation of systemic and local effects consideration in fragrance and flavour risk assessment.

Dr. Ravishankar Nagarajan

Dr. Baidyanath Mishra

“Natural Skin Care Design and Selective Active Profile from Botanicals” by Dr. Dr. Baidyanath Mishra

Dr. Baidyanath, an Indian System of Medicine scholar is dedicated to the research and commercialization of the products from Natural Products. He is CEO of Ingex Life Sciences Pvt Ltd. He delivered splendid lecture on Natural Skin Care Design and Selective Active Profile from Botanicals. He incorporated topics like botanicals used in five skin essential- water, hydration, balance, soothe, purification;

Day – 1 (1st March, 2019)

Panel Discussion and Question-Answers

On completion of half day, panel was open for discussion and participants were interacted with questions and answers

Day – 1 (1st March, 2019)

Miscellaneous moments of Day-1

Warm Welcome of Speakers and Delegates

Day – 1 (1st March, 2019)

Miscellaneous moments of Day-1

Messages of Delegates for conference

Day – 1 (1st March, 2019)

Its time for Group Photos !!!

Day – 1 (1st March, 2019)

ToxGurukul Committee Members (from left to right: Krutik, Alex, Dr. K. S. Rao, Dr. Mukul, Dr. V.G.S. Sharma, Vamsi, & Dr.Dipak)

ToxGurukul Committee Members with Speakers

Day – 2 (2nd March, 2019)

“Alternatives for animal testing” and “Read across, QSAR (*In Silico*) predictions” by Mrs. Sanghamitra Mishra

Mrs. Sanghamitra Mishra is Sr. Consultant at Toxmind BVBA, Belgium and Director- Toxmind India. She delivered detailed lecture on alternatives to animal testing methods. She explained each method in easy and understandable way. She added various *in vitro* assays for different endpoints pertaining to regulatory aspects.

Mrs.Sanghamitra Mishra

She also delivered second lecture on concepts like Read across, Quantitative Structure-Activity Relationships (QSAR) *In Silico* predictions for safety assessment of chemicals. She explained that read across is now on priority in prediction of toxicity and hazard assessment. She cleared concepts of QSAR, steps necessary to read-across, advantage of *in silico* methodology in product development, available free and commercial QSAR tools. All participants appreciated her lectures and

Day – 2 (2nd March, 2019)

“Safety Assessment of Consumer products as related to Toys, Detergentts inks, Air freshener and Biocides” by Mr. Nishitkumar Kachhela

Mr. Nishitkumar Kachhela is Assistant Manager –Toxicology at Intertek Pvt. Ltd., Mumbai. He delivered elaborated lecture on safety assessment of toys, categories of toys and hazard to child, regulatory compliance and risk assessments of different consumer products like toys, detergent inks, air fresheners and biocides. He also interacted with aspirants to clear their doubts.

Mr. Nishitkumar Kachhela

Dr. Praful Patel

“Impurity Qualification for pharmaceuticals (Small molecules)” by Dr. Praful Patel

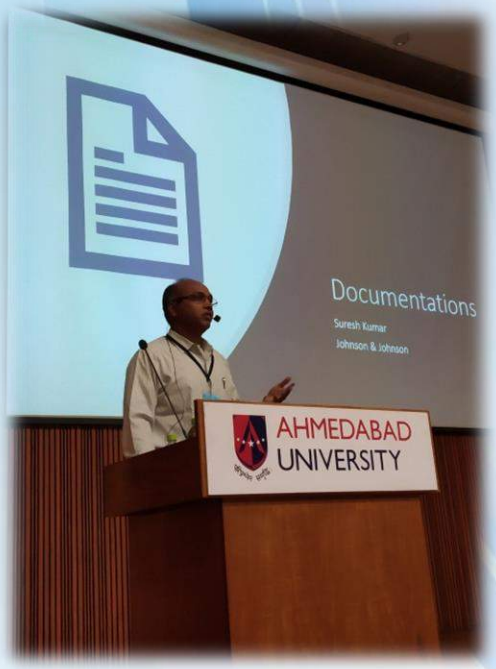
Dr. Praful Patel is Scientist-I, In-charge for Preclinical Safety Evaluation at Torrent Pharmaceuticals Ltd. He delivered attractive lecture on different aspects of impurities like definition, types, toxicological qualifications, classifications, relative guidelines for its qualifications, impurity threshold calculations,

Day – 2 (2nd March, 2019)

“Special Considerations- Botanicals and Aerosols” by Dr. Ankushreddy Patil

Dr. Ankushreddy Patil is Principal Scientist at Toxicology Resource Centre, Johnson and Johnson Pvt. Ltd., Mumbai. He delivered an extraordinary lecture on botanicals and aerosols considerations in cosmetics, their safety assessment, margin of safety calculations for aerosol products like spray, their inhalation safety and evaluation of particle size. All participants appreciate his presentation and content.

Dr. Ankushreddy Patil



Dr. Suresh Kumar Pitchaiyan

“Documentation- CPSRs/PSURs/ CCDSs/CTDs etc” by Dr. Suresh Kumar Pitchaiyan

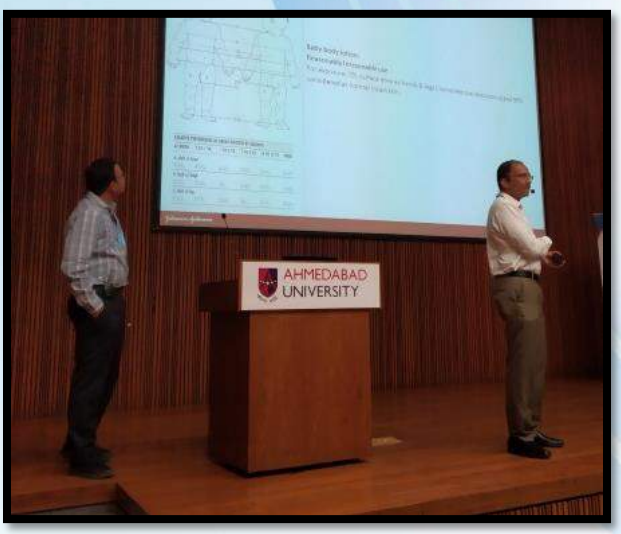
Dr. Suresh Kumar is Senior Manager at Toxicology Resource Centre, Johnson and Johnson Pvt. Ltd., Mumbai. He explained documentation processes for various regulatory report preparations like Cosmetics Product Safety Reports (CPSRs), Periodic Safety Update Reports (PSURs), Company Core Data Sheets (CCDSs) and Common Technical Documents (CTDs). He delivered demo with sample for

Day – 2 (2nd March, 2019)

“Case Studies- Regimen, PK-PD application” by Dr. Ankushreddy Patil and Dr. Ravishankar Nagarajan

Dr. Ankushreddy Patil and Dr. Ravishankar explained some case studies on regimen and PK-PD application for cosmetic products, respectively. Dr. Ankushpatil clarified how to evaluate toxicity and product safety when single product used for multiple purposes like single product as body wash and shampoo. He elaborated body parts consideration to calculate margin of safety of ingredients based on the end product requirement usage.

Dr. Ravishankar clarified how to assess product safety considering critical criteria of Pharmacokinetic and Pharmacodynamics. He elaborated that PK-PD is one of the key factor for safety assessment of cosmetic products.



Speakers were honored with Mementos

Miscellaneous moments captured during workshop

Discussion and expert advise during break time

Say Cheese!!!!


Vivo Bio Tech Ltd.
Your Drug Discovery Partner
DCA
Animal Models


Vivo Bio Tech Ltd.
Your Drug Discovery Partner
DCA
Animal Models


A ToxGuruhut Initiative

At the end, ToxGurukul is thankful of each participants who made this conference success at this level. It was fun to see you all!!!

See you soon at Next IMIT!!!

IMIT-17

IMIT-19

Closing Remarks

It is a great pleasure for me on behalf of ToxGurukul Foundation to express our sincere thanks to our respected Patron and Course Organizer, Dr.K.S.Rao, our eminent Course Director, Dr.Milind Deore for designing such an interactive meet and also for the passionate efforts of our esteemed speakers in delivering interesting topics to us.

We express our sincere thanks to Dr.V.G.S Sharma for local hosting and arrangements including Venue and other logistics, it is only because of his passion and interest we were able to conduct it in Ahmedabad. We thank the Management of LM College of Pharmacy, AIC-LMCP foundation for providing us the auditorium and allowing us to use other amenities.

We express our gratitude to ICSQA for supporting IMIT-19; it is their kind support which helped us a lot for the smooth flow of this event.

Most importantly we express our deepest gratitude towards our sponsors, without their generous contribution this gathering would not have happened.

And a very big thanks you to all the participants for taking part in this great mission and for making it a fabulous affair.

Last but never the least my gratitude to all the committee members and volunteers for all the work done behind the scenes which made this gathering a wonderful and enlightening reality.

This conference in many ways was the game changer for the ***ToxGurukul Foundation*** *in spite of the many shortcomings we faced that made so many of us doubt the successful hosting of this conference. All these uncertainties came to a grinding stop with this dialogue from our patron,*

"Our aim should be empowering Indian Toxicology Community, we need to support toxicologists from all over India, even if only 50 participants I believe it is a success, don't worry about anything I am with you, have the belief that many legends had when the way was not clear, don't look back from now, go ahead without any doubt".

Let us always remember that this foundation was evolved out of a necessity to empower and uplift the toxicology community; making them realize that what they do is not just a regular job for their sustenance but a job that will sustain all beings on this earth.

Kind regards

Alex Thomas, M.Pharm., (Ph.D.)
Vice President, ToxGurukul Foundation

ToxGurukul Foundation

-A National Movement towards Scientific Excellence