ToxGurukul
- Sōpānapatha

PATHOLOGY FOR TOXICOLOGISTS

Proceedings of IMIT SEP -2019
A ToxGurukul Initative

20th & 21st Sept.2019
Dr Reddy's Laboratories Ltd
Auditourm-Leadership Academy
Bachupally,Quthbullapur
Hyderabad, Telangana 500072

Course Director:
Dr. P.Kalaiselvan,

M.V.Sc., DICVP, DIBTP, DABT

Course Organizer:
Dr. K.S.Rao,
M.V.Sc., Ph.D., DABT

Venue:
Dr. Reddy's Laboratories Ltd
Auditorium-Leadership Academy
Bachupally, Quthbullapur
Hyderabad, Telangana 500072

Organized By:
Tox Gurukul
Foundation

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  - Dr. Pise Pravin, M.V.Sc, DIBTP

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Message from Patron

Dear Friends of Toxicology:

It is an honor bestowed on me by the ToxGurukul group of scientists to welcome you all at the workshop on "Pathology for Toxicologists" conducted on 20th and 21st September 2019 at the Campus of Dr. Reddy's Laboratories, Bachupally, Quthbullapur, Hyderabad. This is the third in a series of training workshops that are conducted under the auspices of ToxGurukul Foundation in the last two years. The primary objectives of these workshops are to bring in new generation of toxicologists into the workforce who are ready to take up the challenges from the beginning and compete in the global scientific arena. The topics covered at these workshops are primarily designed to sharpen the skills of younger toxicologists who can occupy higher positions over time in the Government, Academia and Industry at large.

The two-day workshop on Pathology for Toxicologists is spear headed by Dr. Kalaiselvan (Syngene International Ltd.) who has over 15-years of Industrial experience and is a leading expert in Toxicopathology of laboratory animals in the country. Everyone working in the field of toxicology must have a working knowledge of organ pathology as it pertains to normal and abnormal lesions in laboratory animals and their associated terminology for Integrated Interpretation of Toxicologic Data with Organ Pathology Lesions. An intelligent and credible determination of No Observed Adverse Effect Level (NOAEL) following treatment with the test agent (drug, pesticide, industrial chemical etc.) to laboratory animals by the study director or toxicologic investigator can only be done if the investigator has a sound understanding of both toxicology and organ pathology. The proposed two-day workshop on Pathology for Toxicologistsis designed to impart working knowledge of pathology to toxicologists which will make them an all rounded toxicologists, which is a real gap that exists in the country.

I express my heartfelt gratitude to Dr. Reddy's laboratory for letting us conduct this workshop and use their facilities for workshop on "Pathology for Toxicologists" on 20th and 21st September 2019 being organized under able guidance of Dr. Kalaiselvan and entire organizing committee. I'm failed to fulfill my duties if I do not thank our Sponsors who donate any amount (no amount is too small) and contributed for the success of this maiden workshop which goes a long way to improve the cadre of toxicologists in the country. I congratulate and welcome all the audiences who participated to take advantage of this maiden workshop which was never conducted so far in the country.

Dr. K.S. Rao, M.V.Sc., Ph.D., DABT
Patron
ToxGurukul Foundation

Message from Vice President

Dear Participants, Speakers and organizers of the IMIT SEP 2019 "Pathology for Toxicologists" Conference,

I would love to express my heartfelt thanks to each of you who participated in IMIT SEP 2019 "Pathology for Toxicologists" Conference in Hyderabad conducted on 20th – 21st September. Over 270 persons from 56 organizations and colleges gave their time and resources to attend and to contribute in conference. You made IMIT SEP 2019 a success and it was a great pleasure to see so many of you there! Hopefully, you might have enjoyed both the scientific part and the social program and that you used the opportunity to extend your existing networks. I am sure that the cooperation with most of you will continue in the near future. It is also fair to conclude that the conference was a great success! So many people have contributed in so many ways to turn this event into a smoothly running conference with very interesting presentations and a very good atmosphere for discussion and networking. I would like to give special thanks to the Speakers of the conference and to the Dr.Reddy's Laboratories (DRL) for hosting us during the event. Furthermore, I owe much gratitude to effective teams: ToxGurukul team, DRL Staffs, Auditorium team and camera team who did outstanding work in organizing the event and to reach it on incomparable height. All those who contributed to the conference: Thank you all for your excellent work!

Best wishes,
Krutik Andhariya
Vice President

Message from General Secretary

As always, it brings me immense pleasure to show gratitude through this IMIT-Sep'19 proceeding report.

It's great when things seen microscopically from macroscopic understanding, like way pathology and its applications making the toxicological sciences strongest by playing a pivotal role in identification of adverse effects from non-adverse effects.

To make our toxicologists more strengthen on pathology knowledge, our esteemed guru DR.K.S.RAO initiated and lead everyone to the successful conduct of conference "Pathology for Toxicologists (IMIT-Sep'19)" spearheaded by ***Dr. Kalaiselvan*** *as course director.*

250+ participants, 56 organizations/colleges, 12 speakers, 6 sponsors and 1 registered foundation make this conference trim and stain well to a most successful conference in pages of toxicology and toxicopathology.

I sincerely thank course director ***Dr. Kalaiselvan*** *for selection and conduct of timely needed sessions through eminent speakers.*

In this occasion, I also thank all the speakers for all their knowledge enriching sessions varied from different organs pathology to risk assessment.

Above all, I thank ***DR. REDDY'S LABORATORIES*** *from the core of heart and ToxGurukul Foundation also as this support boosted up conference very much and written a memorable milestone for the foundation.*

I also thank every sponsor for their constant encouragement to ToxGurukul Foundation in the conduct of knowledge sharing sessions like this.

It's my sincere regards to the army of co-committee members for their tireless work during conduct of this conference.

I sincerely grateful to Dr. K.S.Rao for constant efforts in toxicology and very much pleased to associate with and give my contribution through this foundation.

Let's Learn, Prosper and Be the Best Toxicologist.

Best Wishes
V V S Vamsi Mohana Reddy T, ERT
General Secretary
ToxGurukul Foundation

Organizing Secretary's Note

It is my great pleasure and honor to represent the organizing committee of ToxGurukul Foundation as 'Organizing Secretary' and hosting this premier National event of 3rd Interactive Meet on Insights in Toxicology (IMIT-Sep-2019) at Dr.Reddy's Laboratories Ltd., Hyderabad. Under the strong and dedicated leadership and guidance of our Indian Tox Guru (Dr. K.S. Rao) and Course Director (Dr. Kalaiselvan), the ToxGurukul organized this unique and first of its kind themed workshop - "Pathology for Toxicologists". The workshop witnessed over 300 active and enthusiastic participants from all parts of India and around 12+ speakers across Indian Pharmaceutical industry and academic institutes discussing applied pathology relating to the Toxicology. We are glad that you chose to travel to this beautiful setting and participate in this IMIT edition. The organizing committee began preparation for this workshop over three months ago and has spent countless hours working to create what we feel was an outstanding workshop. This edition also focused on digitalization of several activities easing and making the event more systematic. Special sessions on Impurity qualification by Dr. Anirban Thakur, Toxicological Risk assessment by Dr. Sebastian and Nonclinical drug development – 505(b)(2) application by Dr. Balaji M.R. were of special interest to the audience of Dr. Reddy's Laboratories Ltd. involving Toxicologists and professionals from Clinical, Regulatory affairs, Analytical, Formulation and API teams.

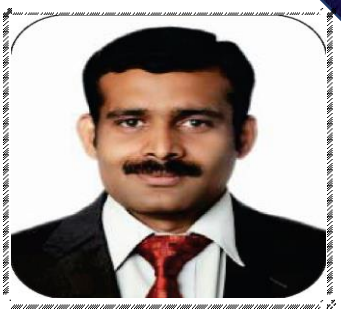
Special thanks go to all core committee Board of Directors - ToxGurukul Foundation, key speakers, the active audience and all the staff of the Dr.Reddy's Laboratories Ltd. for their outstanding service and contributions toward making this Workshop possible and a grand success. ToxGurukul Foundation continues to strive to provide a unique, effective platform for Toxicologists to learn and share their knowledge, and to advance their professional careers.

ToxGurukul Foundation is grateful to Dr. Reddy's Laboratories Ltd. for their generous support and sponsoring the event helping in providing the auditorium, food and other amenities to use. On behalf of ToxGurukul we appreciate your participation in these 2 days of scientific exchange and trust you had found this meeting intellectually stimulating, socially rewarding and culturally revealing.

As always if you have comments or would like to be more involved in this Indian Toxicology Revolution, please contact the ToxGurukul Foundation Executive Office. We are sure that this IMIT had left you invigorated and inspired to continue the important work of our field. Thanks to each one of you again and look forward to associate again in next ToxGurukul event. Cheers…!

Organizing Secretary IMIT SEP 19
ToxGurukul Foundation.
Dr. B.V. Ravichandra, M.V.Sc.
Preclinical Expert- Global Clinical Management
Dr. Reddy's Laboratories Ltd., Hyderabad.

Message from Course director



Toxicologists play a key role in the discovery & development of new compounds and they work in diversified fields such as pharma, agrochemical, industrial chemical, medical devices and biopharmaceuticals, to name few and play a critical role in hazard identification and risk assessment. Although the field of in-vitro toxicology is evolving, in-vivo studies are critical for the discovery and product development wherein the toxicologist shoulder the responsibilities of conducting complex toxicology studies. In GLP terms, the toxicology study director is the key personnel responsible for the conduct of regulatory toxicology study. Toxicologists integrate contributing scientists reports such as from formulation analysis, toxicokinetic analysis and pathology report to prepare a comprehensive toxicology report for regulatory submission. Apart from in life data, the key parameters which decide the outcome of the study and determination of NOAEL lies with pathology part. Understanding of background findings, toxicant induced changes, species differences, adaptive changes and adverse outcomes will help the toxicologist to integrate the pathology data to the toxicology report and aid them to derive the defendable NOAEL. The objective of this workshop is to discuss the anatomy, histology, physiology, background observations, induced changes, species differences, adverse vs adaptive changes, stress induced changes in various organ systems and correlation of pathology findings to in-life data, etc. This workshop is designed to provide basic knowledge in toxicologic pathology to the participants. For the general interest of toxicologists, this workshop also covers the topics of impurity qualification and risk assessment.

Dr. P. Kalaiselvan, M.V.Sc., DICVP, DIBTP, DABT
Course Director

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Introduction

GENESIS OF TOXGURUKUL

ToxGurukul Foundation a non-profit organization for Toxicologists across globe. It is a forum for professionals in the field of toxicology, 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 everyone faces in their daily work routine.

Akin to how in ancient times there were ashrams for students to learn an all-round education, today through means of modern technology and communication systems, we are evolving our education and making it a continuous process. Accordingly, Tox-represents Toxicology, Gurukul represents Gurukulam - a type of education system in ancient India, Sōpānapatha (a ladder to knowledge).

The Genesis of ToxGurukul Foundation is an interesting story, groups on social media viz; Toxicology Forum and GLP SD Team merged in the year 2016 with a vision to promote knowledge sharing among toxicologists. Dr. K. S. Rao (Guru of Indian Toxicology) was introduced to the group on September 07, 2017 and he realized the potential of this small group, on September 23, 2017 he proposed:

"I have a proposal for this most interactive group. I propose that we as a team meet once a year for two days. We can choose speakers among ourselves and also consider having one or two outside speakers. Objective is simply educating each other. My ultimate objective few of you will be motivated to consider taking DABT exam. I realize fully well that one meeting per year is not enough but can be a start. If most of you agree I am willing to host the first meeting in Bangalore at my expense. No registration fees for this meet. Simply show up in Bangalore. We can work up logistics if more members agree on this concept is some variation thereof."

ToxGurukul

On September 23, 2017, Dr. K. S. Rao had proposed some ground rules for the *2-day self-teaching course* at Bangalore

- *No opening dignitary lecture, no flower bouquets, no mementos etc. But simply lectures by few selected speakers within the group to teach each other.*
- *No CRO ads, no sponsors and no collection of any money from anyone. Simply treat this* **""Toxicology Gurukula"**

Also “If all of you come to Bangalore, I will try to arrange it at Veterinary College where hostel facilities are available. I am ok for any place that is agreed upon by majority in the group”.

The first meet

- Aspiring scientists of that group took it up immediately and in an unbelievable speed they started working for the first conference entitled “Interactive meet on insights in Toxicology” at Veterinary College, Bangalore and over 200 scientists attended the conference from across INIDIA. Slowly, the group had overflowing response and more groups were added with subsequent names to accommodate 1000+ scientists.

Second Meet

- ToxGurukul website was launched, after first conference, which was designed and developed by toxicologists themselves. The second conference on “Risk Assessment for Safety of Personal Care Products Including Cosmetics” was held on 1st to 2nd March 2019 at Ahmedabad, India, spearheaded by Dr. Milind Deore, M.V.Sc., Ph.D., DABT (J&J, Mumbai) with 200+ scientists take part in this meet.

Incorporation of ToxGurukul Foundation:

- In December 2018, ToxGurukul committee discussed about forming society, Trust or such similar entities. After discussion with legal experts, it was realized 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. However, understanding the legal intricacies of trust or society was a tough task it was decided to seek professional help (Practicing Company Secretary - CS) who have expert knowledge and experience in that domain. After series of exchanges of emails, between the committee members and the CS, decision was made to register:
- ToxGurukul as a Company under section 8 will be more beneficial and easier as compared to a Trust or Society. The main concern was that, the entity should be able to operate globally. Further, the entity should be also able to accept donations, subscription fees from members across the globe, participants and 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 and registration on 19th March 2019.

IMIT Sep 19, Pathology for Toxicologists is ToxGurukul's third conference spearheaded by Dr. Kalaiselvan P, Syngene International, Bangalore.

Dr. Reddy's Laboratories Ltd

Dr. Reddy's Laboratories Ltd. is an integrated pharmaceutical company, committed to providing affordable and innovative medicines for healthier lives. Through its three businesses -

Pharmaceutical Services & Active Ingredients, Global Generics and Proprietary Products -Dr. Reddy's offers a portfolio of products and services including APIs, custom pharmaceutical services, generics, biosimilars and differentiated formulations. Our major therapeutic areas of focus are gastrointestinal, cardiovascular, diabetology, oncology, pain management and dermatology. Dr. Reddy's operates in markets across the globe. Their major markets include – USA, India, Russia & CIS countries, and Europe.

Legends Speak

Wishes

It gives me immense pleasure to congratulate the IMIT team for arranging this 3rd workshop on Pathology for Toxicology. I also congratulate and thank ToxGurukul for providing such a platform which can be used for learning and sharing knowledge. I wish to see many more such interactions that will benefit the coming generations to gain from the experience of established toxicologists.

My sincere felicitations to all participants and wish them all the success.
With Best Regards

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It gives me immense pleasure to congratulate the IMIT team for organizing such a wonderful event. It is good platform for all to come together and share their knowledge and experience.
I am sure there will be many more events organized by the team for the benefit of the scientific community in India. I once again congratulate all for coming together.

Best Regards,

Dr. Atoshi Mukherjee| Test Facility Management
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I am extremely happy to know of the 3rd workshop on Pathology for Toxicology being organized by ToxGurukul. It's a wonderful idea to bring together people from all walks of our community and share ideas and experience on a platform such as this. This is indeed an inspired decision which, in my opinion, will pay rich dividends in time to come.

I wish all participants a highly stimulating workshop and would love to see this interdisciplinary symposium growing steadily over the coming years. Having had a look at this year's program, I am convinced that you are in for numerous inspiring key notes, lectures, and discussions.

I send you all my best wishes and wish the workshop a grand success

Dr. Manu Jaggi,
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I congratulate the IMIT team for organizing this wonderful & timely event. It is a very vibrant platform for toxicologists and pathologists to come together and enhance their knowledge in this field.
I trust that we will see many more such events that bring together scientists with a common goal to enhance the standards of toxicology in India. Congratulations and good luck for the event ahead!

Best Wishes,

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The Indian Chapter of the Society of Quality Assurance (ICSQA) congratulates the ToxGurukul Foundation for organizing the Interactive Meet on Insights in Toxicology (IMIT) programs for sharing knowledge of professionals with the community of people in order to have greater learning and understanding on current topics that are relevant to the community of toxicologists. The proposed program on the theme "Pathology for Toxicologists" during September 20-21, 2019 is excellent. We wish a great success of this event!

Best Regards,

Dr. Natesan S., PhD, RQAP-GLP
President, ICSQA
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Toxicology plays a crucial role in drug discovery and development of NCEs. It is a backbone of safety assessment process in the field of pharmaceuticals, agrochemicals and medical devices. This diversified area includes discovery, exploratory, non-regulatory and regulatory toxicology. It conglomerates the related domain like dose formulation, toxicokinetic and impurity characterization. To study about these facts will certainly help to understand induced findings from background findings, toxicant induced changes, species differences, adaptive changes and adverse outcomes thus will help to establish NOAEL. The emerging field of in-vitro toxicology is evolving and complementing to in-vivo studies to elucidate the complexity in toxicology studies. I am happy to know that ToxGurukul is one stop solution for these facts will provide basic knowledge in entire spectrum of toxicology to the readers.

I congratulate the entire team of ToxGurukul for organizing this workshop as "Pathology for Toxicologists" and wish them great success.

R. Madheswaran, M.V.Sc. DABT
Assistant Professor
Department of Veterinary Pathology
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9488585638

*I have great pleasure to know that **ToxGurukul is holding Workshop in 2019** which is an excellent platform for the toxicologists/scientists to exchange their views and aspects of toxicology/poisoning related issues. I hope deliberations of the workshop will be very beneficial to the enthusiastic community of the toxicologist to update their knowledge and progress in the field. The need of the hour is to appreciate the priority chosen by the youngsters in the advancement.*

I convey my best wishes for grand success of the workshop and sincerely hope that participants return from the conference rejuvenated and invigorated to meet every professional challenge.

Thanking You.

Dr. A. K. Jaiswal

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Toxicology and careers in toxicology are undergoing rapid and dramatic changes as new discoveries, technologies, and hazards advance fast. There are new demands on toxicologists to keep pace with increasingly complex threats to public health. These demands must be met with new paradigms that require advanced and continuing education in toxicology. ***ToxGuruku****l is indeed doing a great service to toxicology, by bringing Indian toxicologist under one umbrella, encouraging communication among them and imparting training. I wish this conference all success!*

D. Suresh Kumar
Head R&D
Cymbio Pharma, Bangalore

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Speaker's Profile
&
Abstracts

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Summary of Topics Speaker wise and Link to access the presentations

Topics	Speaker
Inauguration & Course Overview	Dr. K.S Rao Mr. Sauri Gudlavalleti Dr. Siddharth Chachad
Role and Significance of Pathology in Preclinical Toxicology Studies	Dr. P. Kalaiselvan
Hepatobiliary System	Dr. Jayachandra K.C.
Urinary System	Dr. Pankaj Shelar
Respiratory System	Dr. Madhusudan P.G.
Reproductive System	Dr. Shekar Chelur
The Art of Impurity qualification: A scientific approach	Dr. Anirban Thakur
Risk Assessment	Dr. Sebastian Joseph
Preclinical Development of Small Molecule Oncology Drugs	Dr. Shekar Chelur
Toxic response of skin	Dr. P.C Prabu
Nervous System	Dr. Selvam G
Immune system	Dr. Sowmya Bharath
Endocrine system	Dr. Jomy Jose
Cardiovascular System	Dr. Pankaj Shelar

LINK TO ACCESS THE PRESENTATION

https://drive.google.com/folderview?id=1dYxWO9uCfxyDWw2pb0ZDgmHreumn8lr5

Message from Speakers

Dr. P. Kalaiselvan, **M.V.Sc., DICVP, DABT, DIBTP**

Dr. P. Kalaiselvan is a Veterinary Pathologist, currently working as Senior Principal Scientist in Safety Assessment department, Syngene International limited, Bangalore, India. In this role he is responsible for managing pathology group, involve as study pathologist and peer review pathologist for various repeat dose toxicology studies. Prior to Joining Syngene, Kalai has worked in Drug Safety Evaluation of Ranbaxy Research Laboratories, Gurgaon, India and IIBAT, Chennai. In these roles he served as study pathologist for toxicology studies involving NCE's, generic pharmaceuticals, biologics and agrochemicals. Kalai is a diplomate of Indian College of Veterinary

Pathologists (DICVP), Indian Board of Toxicological Pathology (DIBTP) and American board of toxicology (DABT). He has obtained his bachelor's degree in Veterinary medicine from Madras Veterinary College, India and master's degree in Veterinary Pathology from College of Veterinary Sciences, Thrissur, Kerala. He is a recipient of ICAR's research fellowship for his master's degree. He has experience in toxicologic pathology for the past 15 years.

Session Topic: Role and Significance of pathology in preclinical toxicology studies

Toxicologic pathology is the study of molecular, cellular, tissue or organismal response to xenobiotics which play critical role in discovery and development of pharmaceuticals, biologics, vaccines, medical devices and agrochemicals. At the discovery stage, pathologists are involved in animal model development and efficacy studies in preclinical species. During development, pathology evaluation starts form early exploratory studies to pivotal GLP studies. Toxicologists and pathologists work together in the design and conduct of preclinical studies. Number of pathology parameters viz, hematology, coagulation, clinical chemistry, urinalysis, blood and bone marrow smear evaluation, gross pathology, organ weights and histopathological evaluation (about 40 tissues) are involved in the characterization of toxicity of a compound. Role of the pathologist is to identify the test compound related changes, describe using standard terminologies and interpretation of pathology findings (clinical pathology, gross pathology, organ weight and histopathology). Pathologist often needs to correlate the pathology findings with in-life and toxicokinetic data. At the end of pathology evaluations, the findings are classified as test item related or not, primary effect of test item administration or secondary to stress. If the findings are test item related, then the findings are further categorized as adaptive, adverse or non-adverse which is one of the critical aspects in defining NOAEL/NOEL for the compound under investigation. Hence, pathology is an essential component of hazard identification, dose response establishment, and risk characterization essential for risk assessment and risk management. Having knowledge in pathology helps the toxicologist to integrate the morphological, clinical pathological and functional changes in a logical manner with respect to their biological significance and help them in appropriate evaluation of toxicity and risk assessment of compounds under investigation.

Dr. Jayachandra K. C., M.V.Sc., DABT

Dr. Jayachandra is currently a Principal Scientist at Eurofins Advinus. In this role, at Eurofins Advinus, he provides GLP Pathology support for pharmaceutical, medical device and chemical industries. Dr. Jayachandra supports safety assessment department by providing scientific inputs in the design and conduct of toxicology experiments that focus on characterization and safety of novel test compounds and/or understanding potential mode of action for toxicity in preclinical studies. He obtained his bachelor's degree in veterinary science and animal husbandry from UAS, Bangalore in 2004 and Master's degree in Veterinary

Pathology from KVAFSU, Bidar in 2006. After finishing master's degree, he worked at Primate Research Lab, Dept of MRDG as Senior Research Fellow in Medhamurthy's Laboratory. Dr. Jayachandra has been engaged in the field of toxicologic pathology for 12 years at Eurofins Advinus and Syngene International. He is a diplomate of American Board of Toxicology (DABT) and member of Society of Toxicologic Pathology (STP) and Society of Toxicology (SOT) USA.

Session Topic: Hepatobiliary System

Drugs continue to be pulled out from the market with disturbing regularity because of late discovery of hepatotoxicity. Such unexpected toxicities appear to be the consequence of the unique vascular, secretory, synthetic, and metabolic features of the liver. About 75% of hepatic blood comes directly from the gastrointestinal viscera and spleen via the portal vein. Portal blood brings drugs and xenobiotics absorbed by the gut directly to the liver in concentrated form. Drug metabolizing enzymes detoxify many xenobiotics but activate the toxicity of others. Hepatocytes are highly reliant on ATP for ureagenesis, gluconeogenesis, and fatty acid metabolism among many other metabolic processes. Hepatocytes with low hepatic glycogen content, hypoxia, mitochondrial inhibition and damage to mitochondrial DNA lead to hepatocellular necrosis.

The liver synthesizes, concentrates, and secretes bile acids and excretes other toxicants, such as bilirubin. Drug-induced injury to hepatocytes and bile duct cells can lead to cholestasis. Cholestasis, in turn, causes intrahepatic accumulation of toxic bile acids and excretion products, which promotes further hepatic injury. Fortunately, the liver has enormous regenerative capacity, but regeneration of hepatocytes lost by necrotic and apoptotic cell death may mask detection of drug-induced injury. Furthermore, the active proliferative response of hepatocytes makes the liver an important target of carcinogens. The goal of this presentation is to discuss how assessment of hepatobiliary toxicity is done based on clinical chemistry, gross pathology, organ weight and histopathology. This presentation will emphasize important injury mechanisms, which can be a consequence of metabolism and/or direct cell toxicity of chemicals.

Dr. Pankaj Shelar; B.V.Sc., M.V.Sc., DICVP, DIBTP

Dr. Pankaj Shelar graduated from Bombay Veterinary College and earned his master's in Veterinary Pathology from the same institute wherein he worked on Chromium toxicity in rats and dogs for which he is a recipient of 'Young Scientist Award' instituted by Society of Toxicologic Pathology India (STPI). He is a dual board-certified toxicologic pathologist with experience spanning over more than a decade in non-clinical safety assessment of novel biopharmaceuticals. He was employed by Ranbaxy, Daiichi-Sankyo, Sun Pharma and currently affiliated with Lupin, and has shouldered responsibilities of increasing magnitude. He has authored more than 100 GLP-compliant pathology phase reports for non-clinical safety evaluation studies conducted on rodents and non-rodents, submitted to international regulatory agencies. Moreover, he has several publications in peer-reviewed journals of international repute including Toxicologic Pathology and lead authorship of an international patent. He has been an active member of Society of Toxicologic Pathology-India (STP-I) and Indian Association of Veterinary Pathology (IAVP) and is a certified diplomate of Indian Board of Toxicologic Pathology (IBTP) and Indian College of Veterinary Pathologists (ICVP). Also, he holds an invited full membership of Japanese Society of Toxicologic Pathology. He has been invited as lead speaker and session examiner for various workshops and conferences organized by IAVP/ICVP and Society of Toxicology-India (STOX). His routine responsibilities include supervising GLP-compliant histopathology and immunohistochemistry laboratories, performing histopathology evaluation, conducting formal and informal peer reviews and writing/reviewing pathology phase reports. His research interests include immunopathology and onco immunopathology in particular.

Session Topic: Toxic Responses of the Urinary System: 'Keeping it Renal'

The mammalian urinary system consists of kidneys, ureters, urinary bladder and urethra. Kidney consists of numerous cell types organized into 'nephron' which is the basic structural and functional unit. Overall functional integrity of the kidney is pivotal to complete body homeostasis as it plays quintessential role in excretion of metabolic waste, regulation of electrolyte composition, maintaining acid-base balance and maintaining extracellular fluid volume. Additionally, it synthesizes, releases and metabolizes hormones and vitamins such as renin, erythropoietin and active vitamin D3 form. Kidney is especially poised to toxic insult as it receives a significant percentage of cardiac output and robust blood filtration regularly exposes it to drugs and drug metabolites. Acute Kidney Injury (AKI) is the foremost common manifestation of nephrotoxic damage induced by a variety of drugs classes, chemicals and biological toxins. Site specific AKI may result into a spectrum of cellular and molecular responses manifested as functional and structural changes e.g. decline in glomerular filtration rate (GFR) and renal tubular epithelium (RTE) injury, histologically seen as degeneration/necrosis of RTE. Chronic Kidney Disease (CKD) may result from progressive deterioration of renal function with long term exposure to drugs/chemicals and culminate in end-stage renal disease. Therefore, timely assessment of renal function with the help of biomarkers coupled with precise pathological examination can prevent exacerbation of renal injury and its systemic adverse effects.

Session Topic: Toxic Responses of the Cardiovascular System: 'Pathology beyond Rhythm'

The components of cardiovascular system (CVS) are susceptible to a wide spectrum of insults from natural disease and xenobiotics including drugs. Accurate and precise histopathological description coupled with elaborate functional assessment are important for comprehensively understanding the pathogenesis and mechanisms involved in CVS toxicity. Responses of CVS to the injury may reflect functionally as decreased cardiac output and peripheral tissue hypoperfusion resulting from perturbations in biochemical, energy metabolism, electrophysiology pathways and contractility of the heart. The functional and morphological alterations induced by a toxic insult are collectively referred as toxicological cardiomyopathy. Although responses to injury by the CVS are similar in nature to those of other organs, it is noteworthy that minimal and/or insufficient regenerative capacity of cardiomyocytes to replace significant loss of cardiac tissue marks it as an exception. Pathogenesis of xenobiotic-induced vascular injury may be due to immunologic, biochemical or direct cellular cytotoxicity. Direct cytotoxicity and biochemical mechanisms are predominantly seen in laboratory rodents while immune-mediated vasculitis is more common on clinical side. Spontaneous or non-drug induced vascular lesions may pose interpretive challenge, however differentiation by considering incidence, dose-response and historical experience with spontaneous disease can be made.

Dr. Madhusudan P.G. M.V.Sc, PhD, DACVP, DABT

Madhusudan P. G is currently working as a senior principal scientist in the Department of Safety Assessment at Syngene International Limited, Bengaluru. He has approximately 10 years of combined experience in diagnostic and toxicologic pathology. He is the only American College of Veterinary Pathologists (ACVP) certified pathologist working in India. Prior to joining Syngene, he worked in one of the top CROs in US (Covance Laboratories) for approximately 4 years as a veterinary pathologist in preclinical safety assessment. He did anatomic pathology residency training at College of Veterinary Medicine, Kansas State University in US, followed by passing ACVP certification exam in 2013. He has two years of postdoctoral training in respiratory toxicologic pathology at National Institute for Occupational Safety and Health (NIOSH) in US, where he worked on elucidating the mechanisms of respiratory toxicity induced by artificial butter flavorings. He has bachelor's degree in Veterinary Science from Bengaluru and master's degree in Animal Biochemistry from National Dairy Research Institute (NDRI), Karnal. He obtained PhD degree in reproductive physiology from West Virginia University in 2009, where he researched on cellular mechanisms of differential sensitivity of bovine corpus luteum to prostaglandin F2 alpha. He has presented his research findings in many international conferences and published several research articles. He has extensive diagnostic pathology experience in diseases of various domestic and pet animals and pharmaceutical industry experience in histopathology evaluation of several subacute, chronic and carcinogenicity studies involving multiple laboratory animal species including rats, mice, primates, rodents and rabbits.

Session Topic: Respiratory System

Respiratory system is in direct interface with the environment and therefore constantly exposed to contents in the air through inhalation. Respiratory toxicity can result from either exposure through inhalation or blood. Some understanding regarding gross and microscopic anatomy with subtle differences among species are essential to understand and interpret toxic response of respiratory system. Respiratory system has an inherent defensive and repair mechanisms to prevent and protect against exposure to injurious agents, which when overwhelmed can to lead to pathologic changes in the respiratory changes. This pathologic response of respiratory system to toxins can be assessed by gross and microscopic pathology, which can provide information on mechanism, severity, and reversibility of toxic responses. Assessment of pathology endpoints by specialized techniques can provide insight into mechanisms of toxicity, which can be effectively utilized in experimental toxicology pathology. Animal models of human respiratory diseases provide relevant information on safety and efficacy of new therapies. Knowledge of common diseases of respiratory system in laboratory animals is essential to undertake preventive animal husbandry practices in the vivarium. Importantly, an appropriate use of diagnosis and terminologies by pathologist in toxicology studies and effective communication with the toxicologist or study director is essential to make a clear distinction between adaptive versus adverse findings in the respiratory system.

Dr. G. Selvam, M.V.Sc., PhD, DICVP, DIBTP, DABT, PGDRM, FASc (AW)

Dr. G. Selvam received his B.V.Sc. degree from Madras Veterinary College followed by his post-graduation (M.V.Sc. & A.H.) degree from Jabalpur Veterinary College, Madhya Pradesh and Doctoral degree from University of Madras, Chennai. Besides, he holds related specialty board certifications in Veterinary Pathology (Diplomate, ICVP), Toxicologic Pathology (Diplomate, IBTP) and Toxicology (Diplomate ABT). To fill his penchant towards stem cell research and tissue engineering, he completed a Post Graduate Diploma course in Regenerative Medicine (PGDRM) from Madras Veterinary College, Chennai. As a Toxicologic Pathologist, he has 12 years of experience in risk of assessment of chemicals and has been presently working as Senior Scientist / Head In-charge of Pathology division at International Institute of Biotechnology and Toxicology (IIBAT), Padappai, Tamil Nadu. He has worked in several regulatory toxicity studies and has actively participated in various basic science / academic researches concerned with engineered nanoparticles like MWCNTs, amorphous silica and various metal oxide nanoparticles. By virtue of these research endeavors he has published research articles in various, well-acclaimed, peer reviewed journals. His expertise and interest lie in inhalation toxicology, nanotoxicology, neurotoxicology and regenerative medicine.

Session Topic: Nervous System

Risk assessment for the neurotoxicity potential of a chemical or drug, demands an integrated, multidisciplinary approach where the entire assessing unit is expected to be thorough with the basic principles, concepts and technical procedures in designing the experiment with appropriate endpoints, obtaining the intended information as accurate as possible and in evaluating the data. This approach involves specific aspects on behavior, neurochemistry, neurophysiology and neuropathology. Several factors, like superlative degree of complexity in the wiring pattern of the near and distant neurons that act in a coordinated fashion, high lipid content and energy demand, restricted regenerative capability, to name a few, predispose the nervous system to be extremely vulnerable to certain chemical insult. Further, the manifestation of the nervous system to the toxic insult is highly unpredictable where, in certain circumstances, the erratically triggered communication mechanism leads to overt clinical signs and even sudden death. In contrast, in other situations, the toxicity is exhibited in a very subtle manner that could be detectable only in the advanced stages, for example, in case of altered cognitive functions. Thus, the understanding of the animal behavior and cognition, neurochemistry, neurophysiology, neuroanatomy, and principal techniques used for evaluating the selected endpoints are considered as a paramount prerequisite in the risk assessment of neurotoxicity in a preclinical set-up.

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

Dr. Shekar Chelur graduated in 1996 and completed his Master's in Veterinary Pathology from Bangalore Veterinary College in 1999. He has worked at Jai Research Foundation, Torrent Research Centre and Zydus Research Centre before joining Aurigene Discovery Technologies Ltd in 2004. He is a Diplomate of American Board of Toxicology (DABT) and Indian Board of Toxicologic Pathology (IBTP). He is currently Vice President of Society of Toxicologic Pathology- India (STP-I), Registrar of Indian Board of Toxicologic Pathology (IBTP) and actively involved in various professional activities of STP-I and IBTP.

Shekar has been extensively involved in safety evaluation of NCE's in the area of Metabolic Disorders (Diabetes and Obesity), Oncology (Kinase inhibitors, protease inhibitors, hormone receptor modulators, epigenetic targets, TLR pathway inhibitors, PROTAC's), Pain & Inflammation, Immunomodulators, Musculoskeletal disorders and anti-Apoptotic therapy. He is recipient of several merit scholarships including senior research fellowship from Indian Council of Agricultural Research. He is co-inventor of 3 international patents. He is author of 15 publications and co-author of three chapters in 2019 reference book “The Illustrated Dictionary of Toxicologic Pathology and Safety Science”.

Session Topic: Preclinical Drug Discovery and Development of Small Molecule Oncology Drugs

Abstract: Cancer is the second leading cause of death and was responsible for 8.8 million deaths globally in 2015 (WHO Cancer Fact sheet, February 2017). There are more than 200 anticancer drugs currently in the global market and still there is unmet medical need for treatment of several cancer types. The pharmaceutical companies and regulators worldwide follow different approach for oncology drug development vs development of drugs for non-life-threatening diseases. Phase 1 clinical trials are conducted in patients with non-responsive late stage disease with mean life expectancy of three to five months. Phase 2 trials are conducted in late stage disease with mean life expectancy of only one to two years excluding few cancer types such as, hormone-dependent metastatic prostate cancer, breast cancer. US Food and Drug Administration (FDA) terms oncology drug development as a “Permissive Process” and advocates fast-track mechanisms, including accelerated approval with phase 2 data, priority review, and orphan drug status, more recently breakthrough therapy for approval of new anticancer molecules.

Newly identified targets in tumors and cancer cell lines holds great promise for oncology therapy. Molecules directed at a novel target has only about an 11% chance of success after entering first in human trials and the probability for novel oncology drug success is even less (less than 5%). Risk lies with the fact that novel targets, by definition lack validation through proof of efficacy in the clinic and they rapidly move through drug candidate selection and enter development well before the function of the target in normal tissues and physiology is fully understood.

Outcome of preclinical toxicology studies are both subjective and context dependent. Several factors must be considered sufficiently to halt progression of an anticancer compound to human subjects based on a toxicology finding.

- Are toxicities consistent with mechanism of target inhibition?
- Are PK-PD-Toxicity inter-relationship well established?
- What is the severity and reversibility of the finding?
- What is the margin between the concentrations of the compound at which toxicity is observed compared with the concentration needed to show beneficial effects (also known as the therapeutic index)?
- What is the risk–benefit ratio in the intended disease setting?
- What is the likelihood of such an effect translating to humans?
- the ability to monitor and treat any subsequent consequences?

Decision to stop an oncology drug candidate for toxicological reasons is both a complex and nuanced judgement. Mechanism based toxicities in preclinical species are now shown to have considerable correlation to modulation of pharmacodynamic biomarkers and clinical efficacy of Oncology molecularly targeted therapies. Success of Drug Discovery and Development of Small Molecule Oncology Drugs at the preclinical stage depends on a. understanding of adequate target/s knowledge through “target safety assessment profile” which helps to understand potential liabilities of inhibition of a certain target and to understand the risk tolerance for liabilities based on the intended therapeutic use, b. validation of target to help define the physiological function of a target, as well as potential adverse effects resulting from inhibition of the target, characterization of candidate's molecular properties to help target validation and eventually influencing compound developability. more importantly, understanding and managing toxicities than trying to reduce or eliminate toxicities which are more commonly futile in cancer therapeutics.

Session Topic: Reproductive system

Xenobiotic induced effects on the reproductive system can be pivotal in development of drugs and chemicals as human fertility is considered too fragile to compromise. Reproductive tissues in both males and females are assessed by several evaluations including weights of testes, epididymis, and accessory glands; ovaries and uterus, sperm morphology, motility, and concentration; estimation of hormone hormones and impact on fertility, but histopathology evaluation is essential for safety assessment and for elucidation of mechanism of action. Background pathology, knowledge of reproductive endocrinology, development, and comparative biology and species differences are also important for evaluation. The reproductive system also has several unique features that require special attention, including regulation by hormones from the hypothalamus, pituitary, and other endocrine organs; stress related changes, age-related dynamic changes at puberty and senescence and stage aware evaluation of spermatogenesis in the males. Use of mature animals in studies is prerequisite for effective risk assessment of reproductive toxicants. This is a greater problem in dogs and non-human primates than in rodents, which mature at about 8-10 weeks of age. Organ weights (particularly of the testes and epididymis), sperm analysis, endocrine hormone estimation and fertility assessment can be more sensitive than histopathological evaluation. Prostate and seminal vesicle weights can be more useful to evaluate xenobiotic induced effects on hormone levels than histopathological examination.

Dr. Jomy Jose, M.V.Sc., DIBTP, DABT

Dr. Jomy Jose is currently heading the Pathology group at RCC Laboratories India Ltd, Hyderabad. In this role she supports evaluation of toxicity of environmental chemicals and safety assessment of pharmaceutical compounds. She is a toxicopathologist with 16 years of experience and prior to this she was associated with Vimta Labs and Advinus Therapeutics. She is a Diplomate of Indian Board of Toxicologic Pathologists and an American Board-Certified Toxicologist. Being a member of national and international professional societies for pathology and laboratory animals she had served as executive committee member and treasurer for the Society of Toxicologic Pathology-India. Currently she is one of the board of directors for Indian Board of Toxicopathology

Session Topic: Pathology of Endocrine system

A vast number of critical biological processes are regulated by the endocrine system and hence regulation of hormonal activity is critical to all biological systems in their quest for biological homoeostasis. Because of the structural similarity to certain hormones, some toxic substances interfere directly with the glands that synthesize and secrete hormones. The chemical vulnerability of the endocrine system is exacerbated by the tier and feedback systems of many hormones. In effect, the glands producing the regulatory hormones are also target organs of the primary hormone; hence every cell in the endocrine system is chemically linked to every other cell within the sphere of influence. The effects can be widespread and can be life threatening if they do not function in synchrony. Interestingly, chemically induced changes in the endocrine system are not always considered undesirable. The lecture on endocrine system focuses on some effects of pharmaceutical compounds and environmental chemicals on various aspects of the system's function. Mechanistic information is included whenever possible to aid in the interpretation of findings and to assess their potential for human risk.

Dr. P.C.Prabu, M.V.Sc., Ph.D., DICVP, DIBTP

Dr. P.C.Prabu, hailing from a small town of Erode, is a Dual Board Certified Veterinary Pathologist (Diplomate ICVP (Indian College of Veterinary Pathology)& Board certified Toxicologic Pathologist - Diplomate IBTP (Indian College of Toxicologic Pathology), currently working as Assistant Professor at the Madras Veterinary College, TANUVAS Chennai. He is one of the Directors of the prestigious Indian Board of Toxicologic Pathology. He has more than 10 years of experience in preclinical research at various levels as Lab Animal Veterinarian, study pathologist, study director and deputy technical manager. He has served as Research Scientist under DST Animal Facility Project and was involved in the establishment of the Laboratory Animal Facility including the transgenic facility as a Lab Animal Veterinarian at the Central Animal Facility, SASTRA University. He has also established the Histopathology and Clinical Pathology Laboratories. In 2014, all these laboratories were accredited by NABL (ISO: IEC 17025) for Biological Testing. He has been primarily, a study pathologist and have done slide reading for 200 + studies including both toxicology and pharmacology studies as per the regulatory guidelines (OECD, Schedule Y, WHO and ISO). He has served as the Member Secretary of the IAEC, SASTRA for 11 years involving more than 350 animal projects. The drugs / compounds evaluated were herbal medicines, biofilms, and nano-drugs / nanomaterials. He has been the Principal Investigator / Co-investigator of several projects funded by MHRD, ICMR, SASTRA University, etc., to the tune of 1 crore. He has to his credit more than 23 international papers in peer reviewed journals of repute with a cumulative impact factor above 65 and h index of 10. He is a recipient of several National and International Awards including the coveted IFSTP (International Federation of Society of toxicologic pathologists) Student Travel Grant Award (2012) for best Ph.D work in Toxicologic Pathology and Charles Capen Trainee Award (2014) for demonstrated achievements in the field of toxicologic pathology awarded by the International Academy of Toxicologic Pathology.

Session's Topic: Toxic responses of skin

Skin guards the internal organs against external injuries and plays vital role in the maintenance of internal homeostasis. Its biological sophistication allows it to perform a myriad of functions above and beyond that of a suit of armor. However, its large volume and high accessibility to different chemicals makes it the most affected organ particularly through topical route. The National Institute of Occupational Safety and Health (NIOSH) considers disorders of skin as the most pervasive occupational health problems and has been placed in the top 10 leading work-related diseases. The major mechanisms by which skin is injured by chemicals include systemic toxicity via skin absorption, direct effects that damage the skin and immune-mediated responses to chemicals that contact the skin. In this brief presentation, normal anatomy / physiology of skin, mechanisms of dermal toxicity, types of dermatitis, photo toxicology, pigmentary disturbances, neoplasms, etc., are discussed.

Dr. Soumya Bharath M.V.Sc., DABT, DIBTP

Sowmya Bharath received veterinary degree from University of Agricultural sciences, Veterinary College, Bangalore, then she also completed master's in veterinary Pathology with gold medal. In 1993 she joined Rallis Research Center (Advinus) as Research Officer- Pathology in Histopathology department where she was responsible for evaluation of molecules in GLP setup. In 1998 she moved to AstraZeneca Bengaluru and served for 16 years where she was responsible for efficacy studies initially and safety support in drug discovery for Tuberculosis and Malaria later on. A Diplomate of American Board of Toxicology, she established the safety criteria for TB and Malaria along with Global safety assessment of AstraZeneca. Currently Dr. S. Bharath is working in a CRO "INTOX Pvt. Ltd" as Head of Section-Histopathology and Clinical pathology. She is responsible for evaluation of molecules in 28-day/90-day repeat dose toxicity studies under the principles of Good Laboratory Practice (GLP) following OECD guidelines. She recently got certified as Diplomate Indian Board of Toxicologic Pathology. She has coauthored more than 15 papers in reputed international journals. She has also authored a chapter in a colour atlas.

Session Topic: Immune system

Thymus, spleen, lymph node, bone marrow and mucosa -associated lymphoid tissue (MALT), and other lymphoid tissues like serosa -associated lymphoid clusters (SALC) and tertiary lymphoid structures (TLSs) form haematolymphoid system. These haematolymphoid organs produce and maintain the cells of acquired and innate immunity and immune responses (lymphocytes, monocytes, macrophages, dendritic cells and granulocytes) and they also produce the cells that carry blood gases (erythrocytes) and maintain vascular integrity (megakaryocytes). The hematolymphoid organs are the organs of the immune system and they collectively produce the lymphocyte repertoire, conduct immune surveillance and mount immunologic reactions. The classic primary or central organs are the bone marrow and thymus where lymphocyte proliferation and maturation take place independent of stimulation by exogenous antigens. The spleen, lymph nodes, MALT and SALC are secondary lymphoid organs where exogenous antigen dependent lymphocyte development and proliferation take place. TLS are tertiary lymphoid tissues that are induced in non-lymphoid organs.

A key feature of the hemato-lymphoid organs is that blood cells can move from one organ to another using the blood and lymph for transportation. Mature naïve lymphocytes are particularly mobile and constantly cycle through secondary lymphoid organs in their continual search for cognate antigens. Erythrocytes, monocytes and platelets are also stored in the red pulp for ready release. The level of background activity or each strain and group of animals is influenced by nutritional status, antigen load, age, genetics, spontaneous lesions, steroid hormone status and infectious agents (opportunistic, incidental or noncurrent). Data from standard toxicity studies should be evaluated for signs of immunotoxin potential. Histomorphology assessment of the immune system is a recognized cornerstone in identification of immunotoxicity. Drug or drug-protein adducts might also be recognized as foreign and stimulate an antidrug response. Subsequent exposures to the drug can lead to hypersensitivity (allergic) reactions.

The purpose of this presentation is to provide standardized nomenclature for classifying changes observed in hematolymphoid. This will also introduce to conventional terms which were used earlier. Differentiation and identification of background, individual, local or systemic effects require accurate description and interpretation of histological findings in conjunction with ancillary data such as clinical history, clinical pathology, organ weights and gross observations

Dr. Sebastian M.V.Sc., DABT

Dr. Sebastian is a Veterinarian and Certified Toxicologist (Diplomat of American Board of Toxicology/European Registered Toxicologist), and currently working as Director and Principal Consultant-Development Consulting and Scientific Affairs at PharmaLex India Private Limited. Dr. Sebastian has close to 14 years of industrial experience that includes drug discovery, non-clinical development, experimental toxicology and pharmacology, Good Laboratory Practices (GLP), computational toxicology, human health risk assessment, environmental risk assessment, and medical writing. In his past assignment at Dr. Reddy's Laboratories Ltd., and Aurigene Discovery Technologies Ltd., he gained hands-on experience in design, conduct, review, analysis, interpretation, and reporting of in-vitro and in-vivo (rodent and non-rodent) toxicology and pharmacology experiments. He established and validated number of in-vitro and in-vivo safety pharmacology models and contributed significantly in establishing an integrated safety pharmacology facility. He has extensive knowledge of OECD principles of GLP, its implementation and application in a regulatory environment for the safety evaluation of pharmaceuticals. He functioned as study director for toxicology and safety pharmacology studies and also as study monitor for outsourcing key investigational new drug (IND) application enabling studies.

Dr. Sebastian is currently involved in strategic development and consulting services in pharmaceutical product development with special reference to non-clinical and toxicological requirements; non-clinical evaluation strategy in support of IND and NDA; risk assessment of pharmaceutical active ingredients and excipients; impurity qualification of API's and drug products; risk assessment and derivation of permitted daily exposure (PDE) and occupational exposure limit in support of GMP manufacturing; environmental risk assessment of pharmaceuticals; provide expert review of investigator's brochure, non-clinical and clinical overview of CTD modules; author/review briefing book for regulatory consultation; respond to regulatory queries as appropriate; and toxicological risk assessment and safety evaluation of cosmetic ingredients/products, medical devices, and consumer products.

Session Topic: Toxicological risk assessment

Fundamental principle of toxicology assumes that every chemical is a poison; there is none that is not a poison. However, all chemicals won't result in harm in all situations; adverse effects occur only under certain specific situations. The risk assessment attempts to find out the possibility of occurrence of harmful effects under certain specific conditions. An adverse effect to a chemical is likely to occur when the chemical is inherently toxic (hazard) and when the exposure is sufficiently high to cause an adverse effect. Irrespective of type of chemical for which the assessment is done, the human health risk assessment comprises of hazard assessment, dose-response, exposure assessment, and risk characterization. The hazard data required for a risk assessment comes principally from the experimental study reports. The most critical information the risk assessor looks at in the study reports is the NOAEL and LOAEL values. An incorrectly defined NOAEL/LOAEL can dramatically alter the course of the risk assessment. Therefore, it is important that Study Directors critically evaluate the study findings and draw conclusion based on the expert judgement. In a typical risk assessment, potential adverse effects on all health end points are considered. Broadly, they can be categorized into effects which show a 'threshold' and those which do not show a typical threshold; accordingly, the risk assessment methodology also varies. This concept is applicable to all areas of risk assessment– pharmaceutical, medical device, industrial chemicals, environmental pollutants, food contaminants, cosmetics, consumer products, etc. This presentation covers the application of basic concepts of toxicological risk assessment to address chemical safety related issues that affect these industries, but with special focus on pharmaceuticals. It also deals with the most common challenges in the risk assessment such as data gaps and route-to-route extrapolation using illustrations that include case studies.

Dr. Anirban Mallik Thakur, B.V.Sc & A.H., M.V.Sc.

Anirban is currently working as Functional Head for Toxicology and Preclinical Research for Cipla Ltd. and has over 15 years of experience in different Pharmacology and Toxicology Labs as a researcher, study director and monitoring scientist. He has hands in experience of more than seven years in OECD GLP certified toxicology laboratories. He has more than 10 years of experience calculating and deriving different toxicological values and health-based exposure limit calculation. He also has experience handling pharmacology, pharmacodynamics and toxicity study of small to large molecules, biotechnology derived products, biosimilar, stem cells, medical devices, veterinary products etc. He also has rich experience in in-vitro biowaiver studies. He has the experience of working on the global development of Veterinary pharmaceuticals. He has the experience of attending many interactions with regulatory agencies.

Session Topic: The Art of Impurity qualification: A scientific approach

In pharmaceutical industry impurity/ extractable/ leachable poses a great challenge in timely approval. There are many guidelines available which helps in mitigating the challenge. However, because of diverse nature of the impurities, extractable and leachable, its many time poses great challenge. Many times, late stage identification of impurities at three-month stability data makes the things more complicated. There are many unknown territories like peptides, fermented products, biosimilar posed additional challenge where the guidelines are scant.

Impurity qualification itself is a great art, with umpteen numbers of approaches with last resort of conducting a toxicity study. There are many in-silico tools, smart data mining, taking help from analytical colleagues can lead to successful time efficient paper-based justification.

Last but not the least, toxicity study gives assurance about impurity qualification. However, there are many approaches needed to consider like selection of species, umber of groups, inclusion or exclusion of toxicokinetic groups etc. Proper strategy is the need of the hour to smooth approval.

In short, it's an art of drawing a collage to sail through the approval process without compromising the quality of product and as a toxicologist assuring patient safety.

Dr. Balaji M R, M.V.Sc

Dr. Balaji M R is currently working as Senior Director and Head of Toxicology at Dr. Reddy's and has over 22 years of experience as a drug discovery and regulatory toxicology and development of new chemical entities in pharmaceutical industries. Vast experience in the development of preclinical strategy, development of target product profile, drug target assessment, risk assessment, study design, conduct, reporting and evaluating safety data for new chemical entities, impurities in drug substance/products and bridging toxicology studies; extensive experience in regulatory filing of repurposed products 505 (b)(2); in training and managing staff; in dealing with regulatory bodies, contract research organizations; in writing investigational new drug application toxicology summaries; Author , review and approve nonclinical sections for regulatory submissions including IBs, INDs, annual reports, CTAs, MAAs & NDAs. Analyze & integrate toxicology reports & other documentation in support of regulatory submissions. Non clinical strategy, execution and filing of 6 NDA's 505 (b)(2) for repurposed products at Dr.Reddy's Laboratories in the last 8 years. All the 6 NDA's were approved by FDA in the first cycle review.

Session Topic: Exploring 505 (b)(2): An Abbreviated pathway for Repurposing of Existing Drugs with special reference to topical product development

Drugs are approved by the FDA by three main regulatory pathways: (I) 505(b)(1) new drug applications (NDAs); (ii) 505(b)(2) NDAs; and (iii) 505(j) abbreviated NDAs (ANDAs). Various aspects govern the drug development through 505(b)(2) pathway. The appropriate pathway depends on the active ingredient, already approved drug products, drug formulation, clinical indication, route of exposure, among other factors. A 505(b)(2) application is one for which one or more of the investigations relied upon by the applicant for approval "were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted" .The 505(b)(2) NDA pathway is a regulatory approval pathway that allows sponsors to use existing public data in lieu of conducting studies; thus, potentially offering significant drug development and marketing advantages. Nonclinical testing programs for 505(b)(2) submissions are often reduced and, in some cases, are not even required. For 505(b)(2) NDA drug development, the nonclinical program typically focuses on: (i) filling any nonclinical data gaps (ii) justifying the safety of any differences between the new drug product and the Listed drug (e.g., justifying the local safety of a new route of administration); (iii) justifying the safety of the excipients; and (iv) qualifying impurities and degradants. The nonclinical development program for a 505(b)(2) NDA drug product is highly drug-product-dependent and many factors enter into whether nonclinical testing is required and the number and types of studies that might be needed. The FDA has issued a guidance document that provides general information on the types of nonclinical studies that might be required for reformulated drug products and drug products administered by an alternate route. Nonclinical development of a topical (dermal) product for 505(b)(2) application is highly complex and needs careful assessment of dermal toxicity and may require extensive evaluation including carcinogenicity in some instances.

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ToxGurukul
- Sōpānapatha

A Brief Report

- Introduction
- Sessions and Discussion: Day 1
- Sessions and Discussion: Day 2
- Learning’s and Takeaway’s

This report is based on a conference "Interactive meet on the insights of Toxicology-Pathology for Toxicologists" held on 20th and 21st September 2019, that was organized by ToxGurukul foundation and was cosponsored by Dr. Reddy's Laboratories. The conference was co-chaired by Course Organizer Course Organizer Dr. K.S. Rao, M.V.Sc., Ph.D., DABT and Course Director Dr. P. Kalaiselvan, M.V.Sc., DICVP, DIBTP, DABT. Staff support was provided by, Mrs. Benita Saklani Maindola, M.Sc. for Advertisement & Sponsorship Coordinator; Mr. Krutik Andhariya, M.Sc. as a Treasure; Mr. G.Hanumanth, M.Pharm as a Joint Treasurer. Furthermore, Advertisement & Sponsorship Coordinators were Mrs. Benita Saklani Maindola, M.Sc.; Dr. Kanthi Kiran, Ph.D., MBA; Dr. Bhaskaraiah Nagoju, Dr. Mukul Pore, M.V.Sc., ERT, DABT; Mr. V V S Vamsi Mohana Reddy T, Pharm, ERT; Dr. Sowmya Bharath, M.V.Sc., DABT, DIBTP; Mr. Alex Thomas, M.Pharm. (Ph.D.); and Dr. Pise Pravin, M.V.Sc, DIBTP.

We would like to especially thank the invited speakers and the participants for their valuable time in this intensive two day) conference. We also thank our sponsors, Dr. Reddy Laboratories, Intox, Aurigene, Syngene, Vivo Biotech and ToxMinds for their generous support and gratitude to this noble purpose of training young and emerging toxicologists.

This is the third in a series of training workshops that are conducted under the auspices of ToxGurukul Foundation in the last two years. The primary objective of this two-day conference was to impart basic knowledge in toxicologic pathology for an integrated interpretation of toxicologic data and endpoints associated thereof .The sessions of this conference were based on pathology of each organ encompassing the aspects of anatomy, histology, physiology, background observations, induced changes, species differences, adverse vs adaptive changes, stress induced changes in various organ systems and correlation of pathology findings to clinical scenarios. Exclusive sessions on impurity qualification and risk assessment were conducted with the intention to impart basic knowledge to the participants on the emerging areas of regulatory toxicology.

Report Prepared by:
Dr. Dhanya Nair
Cipla Ltd. Mumbai

Day 1

Day one sessions commenced by the inauguration followed by brief description about the conference by Dr. K.S Rao from Eurofins Advinus, Mr. SauriGudlavalleti and Dr. Siddharth Chachad from Dr.Reddy's Laboratories Ltd .

The introductory talk was followed by the first technical session by Dr. P. Kalaiselvan from Syngene International Ltd on Role and Significance of Pathology in Preclinical Toxicology Studies. Dr. Kalaiselvan threw light on various aspects that a toxicologist needs to consider when correlating the pathology findings with in-life and toxicokinetic data. He explained the identification of appropriate adverse effects and their classification and further emphasized on the fact that the accurate classification of all the adverse effects, technical session was conducted by Dr. Jayachandra K. C., M.V.Sc., DABT from Eurofins Advinus on Hepatobiliary System. Dr. Jayachandra focused his talk on the importance of the Hepatobiliary system as one of the essential organs in determining the toxicity profile a compound. As the portal blood absorbs the xenobiotics into the liver in concentrated form for the process of metabolism. This may lead to lethal synthesis reactions or oxidative damage to the liver. Dr. Jayachandra briefed the different mechanisms of hepatotoxicity and the pathological changes associated with the toxicities. He explained the various parameters that are useful in identifying and categorizing the severity and extend of Hepatotoxicity.

The third technical session was conducted by Dr. Pankaj Shelar; B.V.Sc., M.V.Sc carries prime importance in defining NOAEL/NOEL for the compound under investigation.

Dr. Pankaj Shelar M.V.Sc., DICVP, DABT, DIBTP from Lupin Ltd briefed us on Toxic Responses of the Urinary System. Dr. Pankaj described the basic anatomy and physiology of the urogenital system with special emphasis on nephrons. He explained the different mechanisms of xenobiotic induced nephrotoxicity and the biomarkers that would help in identifying the toxicity. He further emphasized the importance of identifying a potent nephrotoxic agent while conducting routine toxicity studies

The fourth session was conducted by Dr. Madhusudan P.G. M.V.Sc, PhD, DACVP, DABT, from Syngene International Limited on the Respiratory system. He explained in detail the inherent defensive and repair mechanisms of the respiratory system to prevent and protect against exposure to injurious agents. He further threw light on the pathologic response of respiratory system to toxins and their identification through gross pathology and microscopic pathology. Dr. Madhusudan briefed about various animal models, specialized techniques and the assessment of pathology endpoints with respect to the respiratory system specialized techniques and the assessment of pathology endpoints with respect to the respiratory system.

The fifth session was conducted by Dr. Shekar Chelur from Aurigene Discovery Technologies Ltd on the pathology of reproductive system. Dr Shekar explained the significance of evaluating the effect of drugs on human fertility (both male and female), embryo-fetal development and post-natal development. Dr. Chelur highlighted certain key features that would be useful in evaluating the effects of xenobiotics on reproductive system.

The sixth session was conducted by Dr. Anirban Mallik Thakur, B.V.Sc & A.H.; M.V.Sc. from Cipla Ltd. on the art of Impurity qualification. Dr. Anirban threw light on various aspects of impurity qualification and gave examples of approaches that were successfully adopted to qualify higher levels of impurity.

The seventh session was conducted by Dr. Sebastian M.V.Sc., DABT, from PharmaLex India Private Limited on Toxicological risk assessment wherein he explained the concepts of hazard identification, hazard characterization and exposure assessment and its role in risk assessment. Dr. Sebastian threw light on the aspects of PDE (Permissible exposure levels) and NESIL (No expected sensitization induction level).

The Day 1 sessions were concluded by case discussion/ panel discussion

Day 2

The day 2 Sessions started with the presentation by Dr. shekar on Preclinical Drug Discovery and Development of Small Molecule Oncology Drugs. Dr. Shekar briefed about molecularly targeted therapies in the field of oncology and the factors that would determine the success of Drug Discovery and Development of Small Molecule Oncology Drugs at the preclinical stage.

The second session was session was conducted by Dr. P.C.Prabu working as Assistant professor in Madras Veterinary College, TANUVAS Chennai. Dr. Prabhu's talk focused on Toxic responses of skin. Dr. Prabhu explained the significance of toxicity to the skin with respect to an occupational safety. He further briefed the major mechanisms of skin injury and hypersensitivity.

The third session was conducted by Dr. G. Selvam, M.V.Sc., PhD, DICVP, DIBTP, DABT, PGDRM, FASc (AW) from International Institute of Biotechnology and Toxicology (IIBAT) on Nervous system. Neurochemistry, Neurophysiology and Neuropathology were the key areas that Dr. Selvam focused in his session. Various mechanisms of neurotoxicity and the importance of understanding the animal behavior and cognition along with neurophysiology were specifically emphasized by Dr. Selvam.

The fourth session was conducted by Dr. Soumya Bharath M.V.Sc., DABT, DIBTP, from INTOX Pvt. Ltd on pathology of immune system. Dr. Soumya explained the anatomy and physiology of the hematolymphoid organs and role of immune system in different xenobiotic induced toxicities. Dr. Soumya threw light on standardized nomenclature for classifying changes observed in hematolymphoid.

The fifth session was conducted by Dr. Jomy Jose from RCC Laboratories India Ltd on pathology of endocrine system.

Dr Jomy focused on the effects of drugs and environmental chemicals on endocrine system and the key histopathological findings that a toxicologist should consider while evaluating endocrine disrupting chemicals.

The sixth session was conducted by Dr. Pankaj Shelar; B.V.Sc., M.V.Sc., DICVP, DIBTP on Toxic Responses of the Cardiovascular System. Dr. Pankaj emphasized on the susceptibility of the cardiovascular system to a wide spectrum of insults from natural disease and xenobiotics including drugs. He further threw light on histopathological considerations in evaluating cardiotoxicity. He also made it pertinent to mention that non-drug induced vascular lesions may pose interpretive challenge.

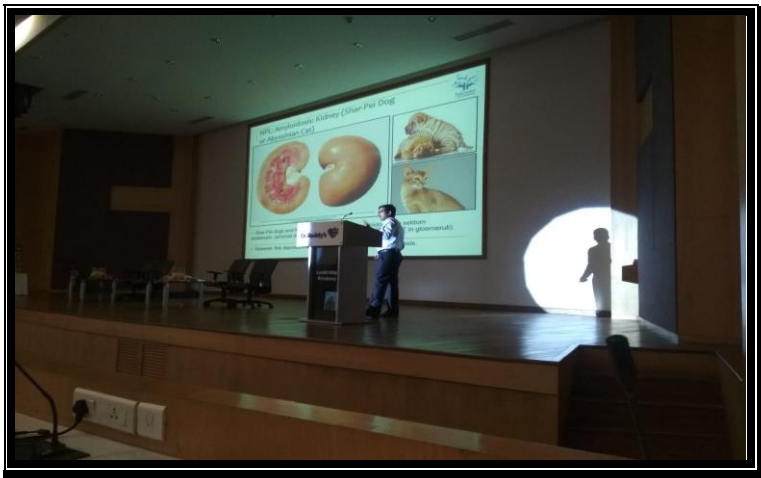
The seventh session was conducted by Dr. Balaji M R, M.V.Sc. from Dr.Reddy's Laboratories on Exploring 505 (b)(2): An Abbreviated pathway for Repurposing of Existing Drugs with special reference to topical product development. Through this session Dr. Balaji explained the basics of 505 (b)(2) regulatory pathway in drug development and threw light on the various regulatory guidance's one has to follow to bring a 505 (b)(2) into the market.

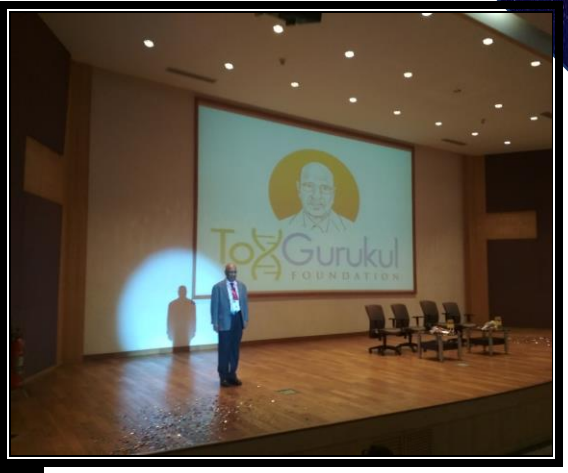
The Day 1 sessions were concluded by case discussion/ panel discussion.

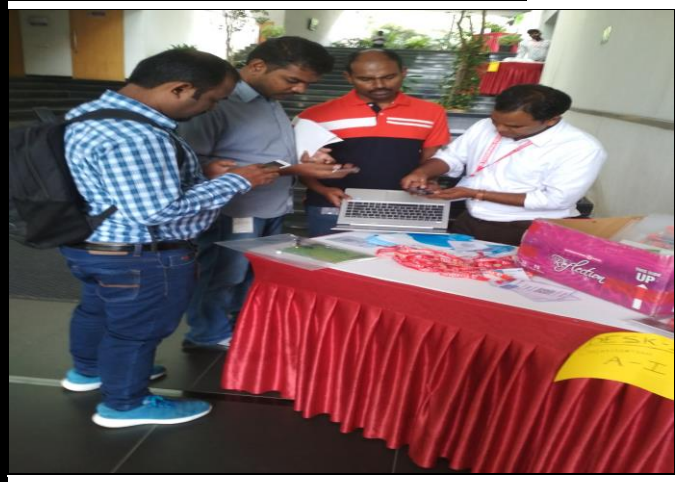
Knowledge of pathology undoubtedly stands utmost important in analyzing and deriving accurate conclusions from toxicological studies. Hence it is pertinent that every toxicologist must possess basic working knowledge of pathology. This would help them not only in arriving at an appropriate endpoint (NOAEL/LOAEL) but also to assess the impact of pathological findings during risk assessment of chemicals and pharmaceuticals.

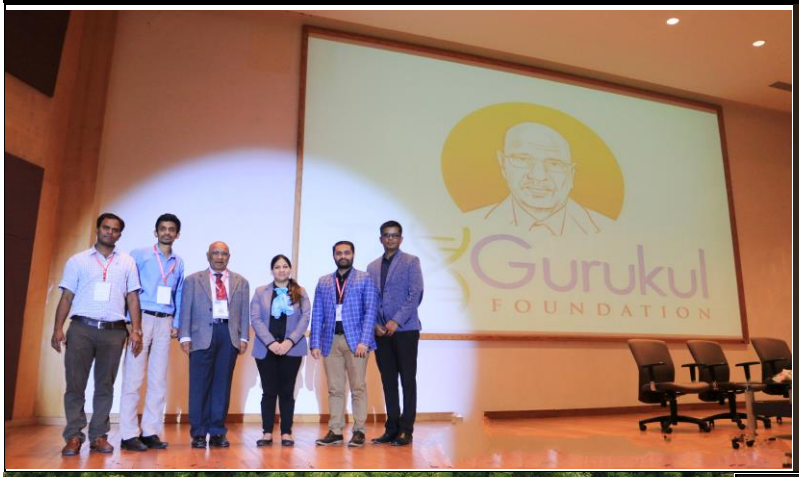
The two- day conference conducted by ToxGurukul was successful in imparting understanding about the concepts of pathology to the toxicologists through its knowledge oriented technical sessions and post session elaborate discussions.

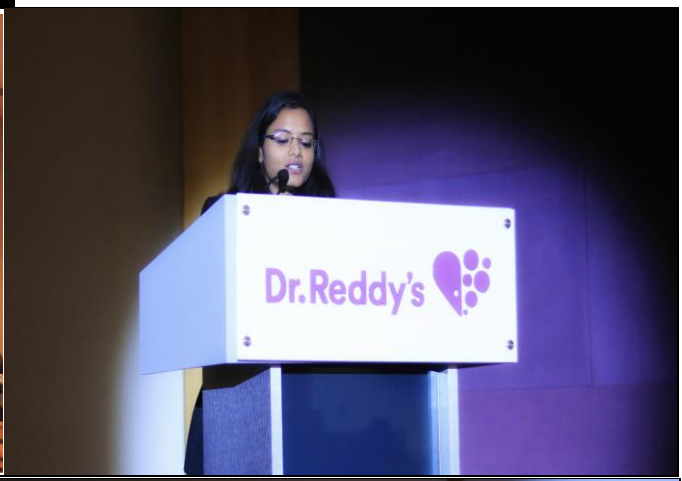
And Here comes some Precious Moments from IMIT SEP-19

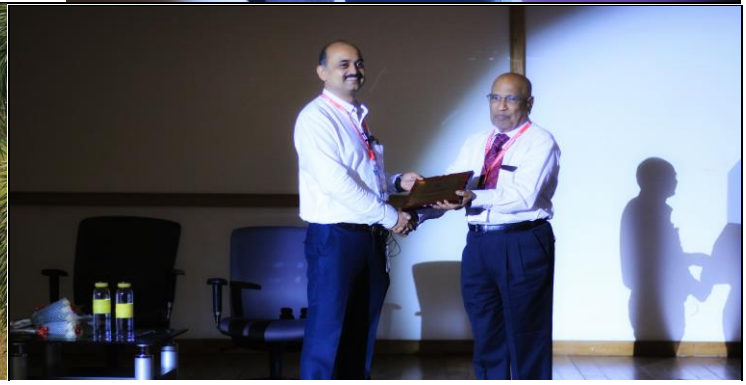






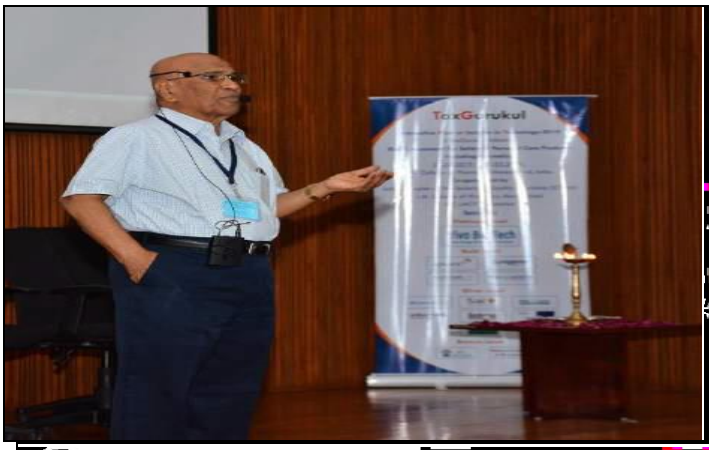


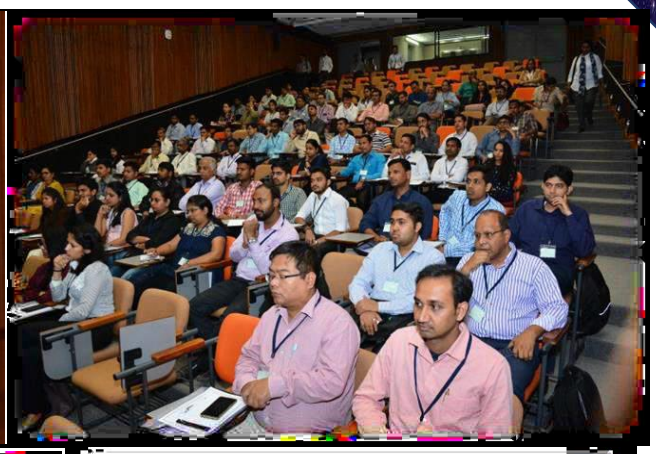


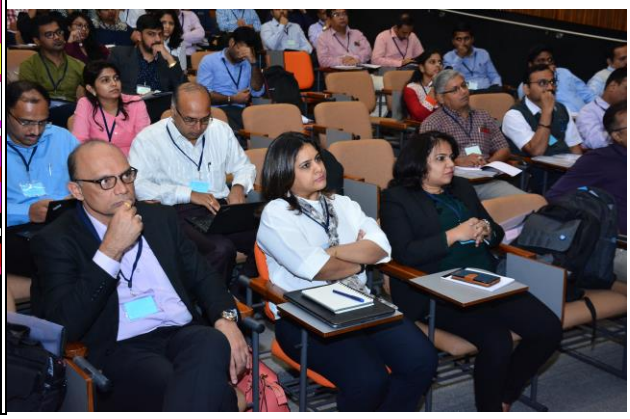


Highlights of Past Workshop

IMIT MAR-19







IMIT- NOV-17

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SPONSORS AND PARTNERS

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- Vivo Biotech

SILVER SPONSORS

- ToxMinds

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INTOX (www.intoxlab.com)

With a mission to provide high quality, reliable research and testing services in the field of product safety assessment to clients throughout the world, INTOX was founded in India in year 1995 by a dedicated group of qualified and experienced Toxicologist.

Trusted R & D Partner:

A Contract Research Organization (CRO), INTOX performs a wide range of studies, including Toxicological, Mutagenicity, Ecotoxicological and Chemical, for Pharmaceutical, Crop Protection / Agrochemical, Biotechnological, Chemical and Medical devices industries which wish to obtain National and International registration of their new products, with the respective Governmental regulatory authorities.

Today, INTOX is one of the most trusted names in safety assessment, with its GLP compliance been endorsed by regulators from India and Europe.

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intox
QUALITY TOXICOLOGICAL SERVICES

Services at a Glance

Regulatory Guidelines:

Testing programs can be designed to support product registration as per International and National requirements recommended by OECD, US FDA / EPA, EMEA, ICH, EC, ISO, USP etc. and authorities in India (DCGI / DBT / CIB).

Studies Offered:

General Toxicity:

- Acute Toxicity
- Repeated Dose Toxicity
- Chronic Toxicity
- Carcinogenicity

Reproductive Toxicity:

- Fertility Studies
- Developmental Toxicity
- Perinatal and Postnatal Studies
- Multigeneration Studies

Special Toxicity Studies:

- Skin / Eye Irritancy
- Sensitization
- Neurotoxicity
- Other protocol specific studies

Genetic Toxicity:

In-vivo and in-vitro studies such as

- Ames Test
- Micronucleus Test
- Chromosome Aberration Test
- Mammalian Cell Gene Mutation Test

Environmental Toxicity:

Studies on aquatic and terrestrial organisms:

- Alga, daphnia, fish, honeybees, earthworm
- Chicken, pigeon, quail...
- Studies on behavior in Water, Soil and Air; Bioaccumulation

Biocompatability Studies for Medical Devices

Experimental Systems

Rat, Mouse, Guinea pig, Rabbit, Farm Animals, etc.

Routes of Exposure:

Oral, Dermal, Parenteral, Inhalation etc.

Other Studies:

- Health monitoring studies on human volunteers for household pesticides & crop protection products.
- Health monitoring studies on livestock for crop protection products.

Chemistry Services:

- Physical - chemical studies
- Five Batch Analysis / Impurity profile
- Kinetic studies - PK / TK
- Method development and validation
- Residue studies

REACH Compliance:

- Physical-chemical studies
- Toxicity / Mutagenicity studies
- Ecotoxicity studies

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AURIGENE

Accelerating Discovery

Aurigene (https://www.aurigene.com) is a Drug Discovery Services company committed to the vision of being the most respected and valued scientific collaborator in India.

Based in Bangalore, Hyderabad and Kuala Lumpur, Aurigene has fully integrated Drug Discovery infrastructure from Hit Generation to Pre-clinical development.

Aurigene has pioneered customized models of Drug Discovery collaborations with large-pharmaceutical, mid-pharmaceutical companies and Biotechs

In over 12 years of working with Pharma, Biotech and Academic partners, in a variety of Therapeutic Areas, Biologies and Chemistries and over 75 integrated Drug Discovery projects, Aurigene has contributed to delivering over 15 small molecule and peptide drug candidates to its biotech and pharmaceutical partners.

In addition, Aurigene's stand-alone Services partnerships have contributed to many projects in areas of Medicinal Chemistry, Crystallography, ADME/ PK, Process Development and non-GMP Scale-up

Aurigene is a profitable company that has continuously invested in its people resources, infrastructure and expertise over the years.

Research Services Overview

OVERVIEW

Aurigene uniquely has

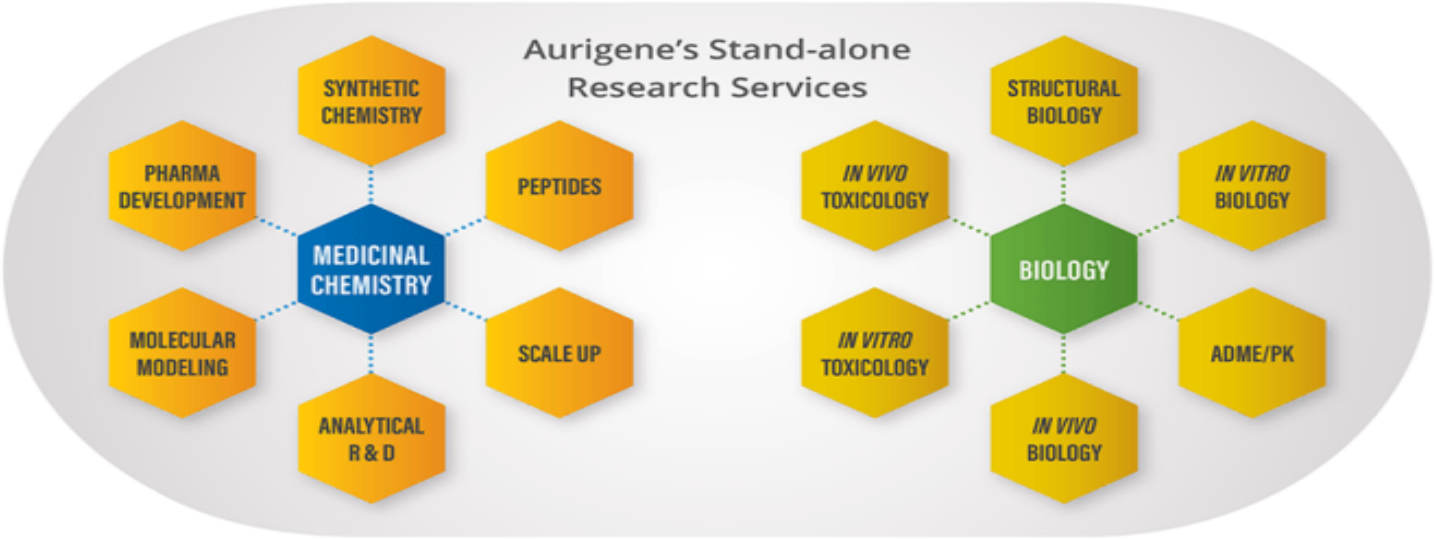
- A track-record of having executed >70 discovery programs using small molecule, peptide and peptidomimetic approaches
- Over the past 10 years, delivered fifteen (15) clinical programs, currently in Phase I/ II global clinical trials.

In addition:

- Aurigene's 500+ scientific team and 40+ leadership team has a strong scientific and academic background with rich drug discovery experience; most senior scientists have spent over 10 years in the company. This stable team provides leadership and strategic oversight to the discovery collaborations
- Experience with diverse biologies across multiple therapeutic areas and with different scientific approaches across biotechs to large pharma
- Experience spanning from target validation through hit development, lead generation and all the way to candidate nomination

All of the above combine to make Aurigene a unique Drug Discovery partner of choice to venture-funded startups, biotechs, collaborators from academia and pharma companies.

Aurigene undertakes integrated discovery collaborations and also provides stand-alone research services (chemistry, peptides, DMPK, structural biology and others).



In addition to Integrated Drug Discovery collaborations, Aurigene also offer Stand-alone Drug Discovery Services (SDDS). These SDDS are offered in Synthetic chemistry (Small molecules and peptides), Scale up, molecular modeling, Protein production and Structural biology/ Crystallography, DMPK, in vivo Pharmacology, Toxicology and Pharmaceutical development.

Details of the capabilities and services offered are provided below:

- Small Molecule Chemistry & Scale up
- Peptide Synthesis
- Structural Biology & Protein Production
- In Vitro ADME, PK/PD
- IND/CTA Enabling Studies
- Pharmaceutical Development

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Syngene

A Biocon company

Syngene International Ltd, https://www.syngeneintl.com

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

Clinical Development Service
Syngene International Ltd,
Biocon Park , SEZ,
Bommasandra Industrial Area - Phase-IV
Bommasandra-Jigani Link Road
India

Syngene is a leading contract research and manufacturing organization (CRAMS) in Asia providing end-to-end discovery and development services. Our multidisciplinary 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>Discovery</th><th>Development</th><th>Manufacturing</th></tr>
<tr><td>Chemistry</td><td>Drug Substance</td><td>Clinical Supplies</td></tr>
<tr><td rowspan="2">Biology</td><td rowspan="2">Drug Product</td><td>HPAPI</td></tr>
<tr><td></td></tr>
<tr><td colspan="2">Safety Assessment</td><td>Specialty Molecules</td></tr>
<tr><td>Integrated Drug Discovery</td><td>Human Pharmacology Unit (Phase 1)</td><td rowspan="3">Commercial Supplies</td></tr>
<tr><td rowspan="3">Therapeutic Antibody Discovery Engineering; Cell Line Development</td><td>Bio Analytical Lab (Large Molecules)</td></tr>
<tr><td>Stability Services</td></tr>
<tr><td colspan="2">Bioprocess Development, Process Characterization, Clinical Manufacturing (Microbial & Mammalian)</td></tr>
<tr><td colspan="2">Bioinformatics: Target Dossiers, NGS, Integrated Data Analytics, Modeling, System Biology, DILI, Drug Repurposing</td><td></td></tr>
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Vivo Bio Tech Ltd.

Your Drug Discovery Partner

Vivo Bio Tech Ltd.
Your Drug Discovery Partner

Vivo Bio Tech Ltd. www.vivobio.com

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

ToxMinds (https://toxminds.com/services/) are specialised in ensuring product safety and compliance

Services

- **Chemical and product safety**

  Ensuring chemical and product safety with passion for (eco)toxicology using emerging technology and state-of-the-art risk assessment practices.

- **Regulatory strategy and compliance**

  We help you to meet the regulatory demands and to stay compliant with EU Regulations.

- **Product stewardship**

  Ensuring publicly acceptable products – We help you to communicate the safety of your product to the public.

- **QSAR Modelling**

  Predicting toxicity, identifying suitable analogues for read across and select lead candidates through combined use of public and commercial QSAR tools.

- **Endocrine disruption**

  Identifying and assessing the evidence for chemicals to cause endocrine disruption in humans and the environment.

- **New risk assessment methodologies**

  Identifying and applying new methodologies and risk assessment approaches to support chemical safety without animal testing.

Toxicology Educational Seminars in India Conducted

by

DR. K.S. Rao

No.	Name	Course Director	Year
1	Mid America Toxicology Course, Bangalore, India	Dr. Curtis Klaassen	Oct 2007
2	First DABT Exam Started in India, Bangalore, India	Dr. K.S. Rao	Oct 2009
3	Safety Pharmacology Workshop, Bangalore, India	Dr. Derek Leishman	April 2011
4	Study Director Training Course, Bangalore, India	Dr. William Brock	Oct 2012
5	Toxicity, Safety, Biocompatibility Evaluation of Materials, Medical Devices, and Combination Products, Thiruvathapuram, India	Dr. Shayne C Gad	Nov 2013
6	Comprehensive Toxicology, Bangalore, India	Dr. Wally Hayes	Jul, y 2015
7	Risk Assessment Seminar, Bangalore, India	Dr. Shayne C Gad	Feb 2016
8	Insights in Toxicology, Bangalore, India	Dr. K.S. Rao	Nov 2017
9	Risk Assessment of Personal Care Products and Cosmetics, Ahmedabad, India	Dr. Milind Deore	Mar 2019
10	Pathology for Toxicologists, Hyderabad, India	Dr. P. Kalaiselvan	Sept 2019

LIST OF DIPLOMATES OF AMERICAN BOARD-CERTIFIED TOXICOLOGIST IN INDIA

Sl. No.	Name of the Diplomate	Employer Name & Location	Year of Passing DABT	e-mail ID	Contact No.	State	Subject/ Profession
1	K.S. Rao	Eurofins Advinus Bangalore	1980	toxrao@gmail.com	7337830074	Karnataka	Veterinary Nutrition/ Toxicology
2	Deepak Agarwal	Formerly, IITR, Lucknow	1984	Deceased			
3	Shivaputrappa Ganiger	Eurofins Advinus, Bangalore	2009	shivaputhrappa.g@advinus.com	9448776111	Karnataka	Veterinarian/ Toxicology
4	Venugopala Rao	Eurofins Advinus, Bangalore		venugopala.rao@advinus.com	9880711044	Karnataka	Veterinary Pharmacology & Toxicology
5	Prabhakar Bhoite	Syngene International Ltd, Bangalore		pybhoite@gmail.com	9945496560	Karnataka	Veterinary Pharmacology & Toxicology
6	Pralhad Wangikar	PRADO Pvt Ltd, Pune		pralhadwangikar@gmail.com	9987001604	Maharashtra	Veterinary Pathology
7	Krishna H	Abbott Healthcare Ltd. Mumbai		krishnaalse98@gmail.com	9967543135	Maharashtra	Toxicology
8	Venkatesh Udupa	Glenmark Pharmaceuticals Ltd., Mumbai		venkatesha.udupa@glenmarkpharma.com; udupa02@yahoo.com	9819518642	Maharashtra	Veterinary Pathology
9	Mukul. P. Pore	Intox Ltd, Pune		mukulpore3@gmail.com	9822024836	Maharashtra	Veterinary Pathology
10	Sivanesan. P	CellixBio, Hyderabad	2010	sivanesanvet@yahoo.co.in	9323661981	Tamil Nadu	Veterinary Pathology
11	Narendra Sampatrao Deshmukh	Intox Ltd, Pune		narendra_deshmukh@hotmail.com	9822056023	Maharashtra	Veterinary Pathology
12	V. Chandrashekara	Syngene Interanational Ltd. Bangalore		chandrashekar.vishwanath@gmail.com	7799222006	Karnataka	Biology
13	M. Praveen Kumar Reddy	Biocon, Bangalore		**praveen.reddy@biocon.com**	9663474683	Karnataka	Veterinarian
14	Girish, B. Chandrashekaraiah	Hassan Veterinary college		**girishbekkare@gmail.com;**	9663303688	Karnataka	Veterinary Pathology
15	Milind Devdas Deore	Johnson & Johnson, Mumbai		MDeore@its.jnj.com	9920701520	Maharashtra	Veterinary Pharmacology & Toxicology
16	S.M. Sulaiman	Eurofins Advinus, Bangalore		syed.sulaiman@advinus.com	9880722994	Karnataka	Veterinary Pharmacology
17	Santhosh C.R.	Bangalore Veterinary College,		crsanthosh@rediffmail.com	8722100419	Karnataka	Veterinary Pharmacology & Toxicology
18	Shekar S. Chelur	Aurigene, Bangalore		shekar_chelur@hotmail.com	9880237237	Karnataka	Veterinary Pathology
19	Pradeep Kumar G.B.	DuPont , Hyderabad		pradeep736@gmail.com	9900106160	Andhra Pradesh	Veterinary Pharmacology & Toxicology

Sl. No.	Name of the Diplomate	Employer Name & Location	Year of Passing DABT	e-mail ID	Contact No.	State	Subject/ Profession
20	Minakshi Singh	Lupin Limited, Pune	2010	minakshisingh@lupinpharma.com	9890307434	Maharashtra	Toxicology
21	Krishnappa. H	Eurofins Advinus, Bangalore		krishnappa.h@advinus.com	9880733118	Karnataka	Veterinary Pharmacology & Toxicology
22	Prathap Kumar, S.M.	AbbVie Pharmaceuticals, Chicago		drprathapk@gmail.com	806-7736948	Karnataka	Veterinary Pathology
23	Srinivasan M. Rajaram	TANUVAS, Chennai		seenubioinfo@gmail.com	7401043980	Tamil Nadu	Veterinary Pharmacology & Toxicology
24	Salim Ramjan Tamboli	Lupin Limited, Pune		salimtamboli@lupinpharma.com	9970172981	Maharashtra	Veterinary Pathology
25	Mathiyazhagan R	Bioneeds, Bangalore		mathidr73@yahoo.co.in	9880365032	Karnataka	Veterinary & Genomics
26	Rajesh Eswarappa	Aurigene, Hyderabad	2011	rajesheswarappa@yahoo.co.in	9941077752	Karnataka	Zoology, Toxicology
27	Kamala Venkatesh Palanisamy	BBRC, Bangalore		pkvenkatesh79@gmail.com	9686576147	Karnataka	Veterinary Pathology
28	Mohamad Sadik Mullah	Vimta Labs, Hyderabad		al_sadikmulla@yahoo.co.in	9619017466	Telangana	Veterinary Pathology
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Votes of Thanks

WE VALUE OUR SPONSORS!

On behalf of ToxGurukul Foundation, I would like to express our deep gratitude for the unconditional support of Sponsors of IMITSep-2019: Dr. Reddy Laboratories, Intox, Aurigene, Syngene, Vivo Biotech and ToxMinds.

Dear Sponsors, you are great leaders and reformers who believe in contributing and supporting for the good cause. We are really proud to see your repeated Sponsorship for IMIT's. Words are really less to express our heartiest gratitude for us you are not just Sponsors you are the Lifeline of ToxGurukul Foundation. Day by day we are improving with your monetary, moral support and guidance and the way our Indian toxicologists are getting benefitted by series of IMIT is remarkable.

We are grateful to you and appreciate your kind cooperation. In nutshell, you have given wings to ToxGurukul foundation to think high and fly!

We are sure that your contribution and support is making Indian toxicologists more efficient. We wish to have same support from your side for upcoming meets too.

Thanking you once again on behalf of each and every Toxicologist and ToxGurukul foundation!

With lots of heartiest regards and gratitude.

Benita Saklani Maindola
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Message from Editorial Team

Dear Readers,

Toxicology is an interdisciplinary science that helps us understand the harmful effects that chemicals, substances, or situations, can have on people, animals, and the environment. Toxicology had always been a subject of interest since very old times (Socrates) as "Science of Toxins". However, modern toxicology is often referred as the "Science of Safety" it has evolved from a science focused on studying poisons and adverse effects of chemical exposures, to a science devoted to studying safety and Risk assessment.

Toxicologists play an important role in this arena and play a critical role in hazard identification and risk assessment. In order to do that, a Toxicologist needs to master upon many scientific areas such as chemical analysis, toxicokinetic, ADME reports and Histopathology, to prepare a comprehensive toxicology report for regulatory submission and other understandings. Therefore, this workshop had been designed and organized to bring all the pathological interactions, basic knowledge in toxicological pathology, impurity qualification and risk assessment to the participants.

ToxGurukul is a common platform shared by early career, mid-career and late career Toxicologists to share their knowledge and ask their doubts for a better future of Modern Toxicology in India. All the workshops organized by ToxGurukul open a new avenue and concludes with a learning experience for all, especially for new budding Toxicologists. I am heartily thankful to the ToxGurukul Foundation for giving me this opportunity to be a member of Editorial team.

It gives me immense pleasure to unveil the vast knowledge shared by our speakers during the workshop and personal discussion sessions. I am grateful on behalf of Editorial Team to all the authors who trusted us with their work; without them there would be no conference. The final result would not have been possible without the dedication and hard work of our organizing teams in form of workshop and entire Editorial team. Special thanks are due to ***Dr. K.S. Rao*** *patron of the workshop,* ***Dr. P. Kalaiselvan*** *the Course director,* ***Dr. Reddy's laboratory and management*** *for providing us the facility to organize this workshop. I'll be failed to serve my duties if I don't acknowledge the so & so of Toxicology from all over India who spared their times and send good wishes to us. Lastly, I'm thankful to* ***Dr. Alex Thomas*** *for the quality and depth of the reviews, and their sense of responsibility and responsiveness under very tight deadlines.*

Editor Team
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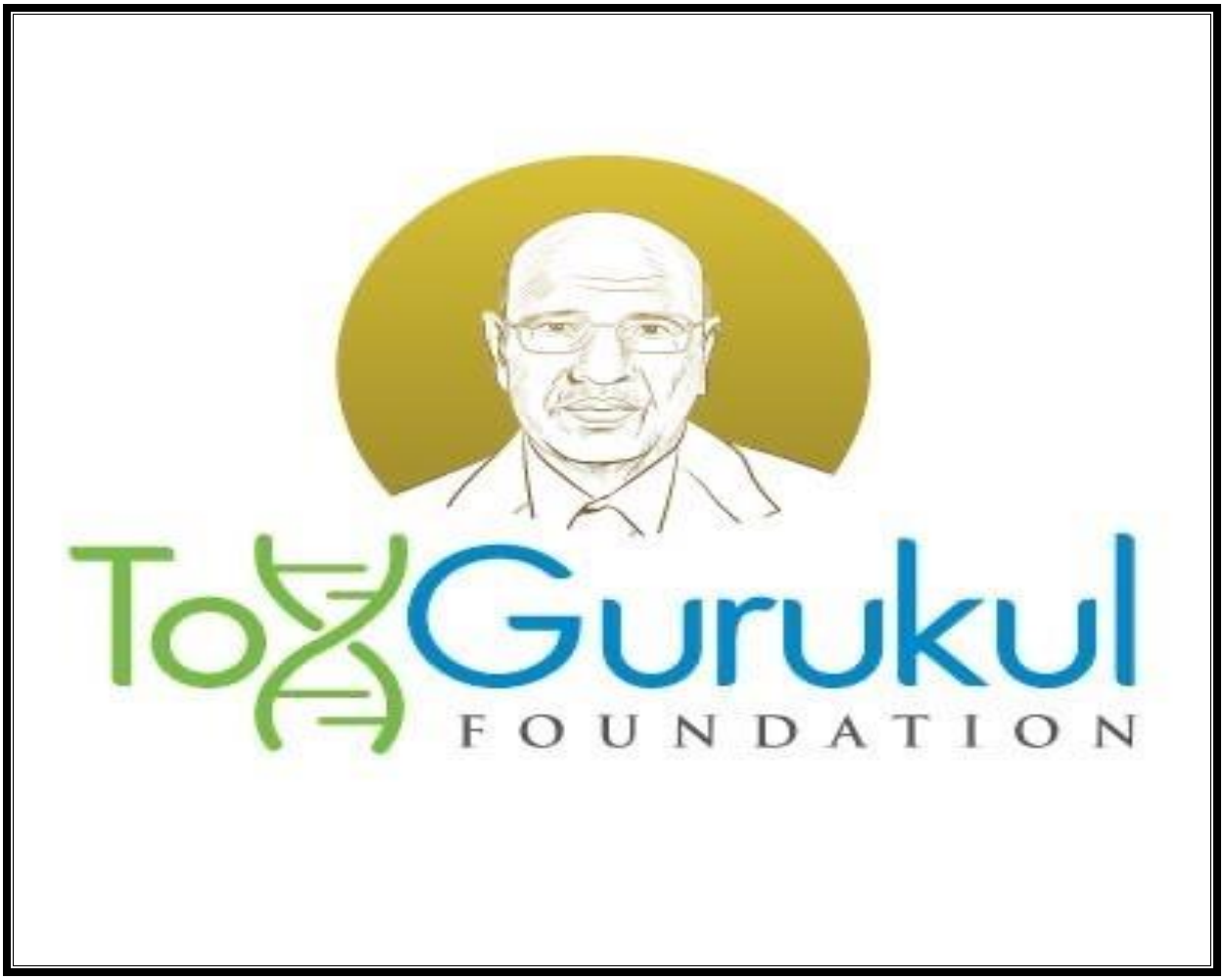

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Mahatma Gandhi