INTERACTIVE MEET ON INSIGHTS IN TOXICOLOGY

(IMIT-2019)

- A ToxGurukul Initiative

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

Theme

Risk Assessment for Safety of Personal Care Products Including Cosmetics

Co-sponsored By

Indian Chapter of the Society of Quality Assurance (ICSQA)

L.M. College of Pharmacy, Ahmedabad

AIC-LMCP Foundation

Course Director

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

Course Organizer

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

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The Guru speaks.....

Dear Friends of Toxicology,

It is an honor bestowed on me by the ToxGurukul group of scientists to formally announce the Workshop on "Risk Assessment of Consumer Care Products including Cosmetics" to be conducted on 1st and 2nd March 2019 at the L.M. College of pharmacy in the United Nations Historic city of Ahmedabad, Gujarat, India. This is the second of a series of training workshops that are conducted under the auspices of ToxGurukul in the last two years. The primary objectives of these workshops are to bring in a new generation of toxicologists into the workforce who are ready to take up the challenge 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 in the Government, Academia, and Industry at large.

The two-day Risk Assessment workshop is spearheaded by Dr. Milind Deore of Johnson and Johnson, a leading expert in Risk Assessment in the country.

Risk Assessment topic is of immense importance to inculcate a keen sense of analytical faculty in our scientists to protect our citizens against hazardous chemicals and product. Amongst the products in the universe, most human beings are exposed to more amounts of Consumer Care Products and Cosmetics, more than drugs and pesticides combined. Despite this fact, risk assessment of such products is never taught anywhere in the educational system which is what is needed in the modern work environment in all sectors.

We hope more of our scientific community in all sectors take advantage of this workshop to serve our country more sensibly.

If any of the Sponsors wish to donate any amount (no amount is too small), we welcome your contributions to the success of this epic workshop.

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

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Introduction

Interactive Meet on Insights in Toxicology

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

ToxGurukul

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

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

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

L.M. College of Pharmacy (LMCP)

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

AIC-LMCP Foundation

AIC-LMCP Foundation is one of the At al incubation centres hosted by L.M College of Pharmacy and Supported by Niti Aayog, Govt. of India, tha t provides platform for the innovators, researchers and startups to convert their ideas into successful businesses in the Pharmaceutical and Healthcare Sector.

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Personal Care Products

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

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

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

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

Although Toxicology risk assessment is a relatively new field in India, many, as well as overseas small companies from Europe/USA, are coming to India for getting a risk assessment done on their personal care products. The reason being the availability of talent pool of Toxicologists in a cost-efficient manner. Obviously, these companies do expect an assessment done in a technically sound manner which would cater to international compliant norms and would stand technical scrutiny internationally. Although we have a pool of Toxicologists in India there is a dearth of understanding of the specific requirements for cosmetics and other personal care products.

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

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Schedule

Friday 1st March 2019

Time	Title & Speaker
9:00 am to 9:15am	Inauguration -Course Overview -Dr. Milind Deore, J&J (Mumbai)
9:15 am to 10:00 am	Overview of Risk Assessment Process- Dr.K.S. Rao, Eurofins Advinus (Bangalore)
10:00 am to 11:15am	Risk assessment of Consumer products-Dr.Milind Deore, J&J (Mumbai)
11:15 am to 11:30 am	Tea Break
11:30am to 1:00 pm	Database, Sources of information - Mr. Sampath Kumar, Colgate (Mumbai)
1:00 pm to 1:30 pm	Lunch
1:30 pm to 2:30 pm	Regulatory overview/requirements for cosmetic products, dossiers-Ms. Geeta Bajaj, Estee Lauder Companies (Mumbai)
2:30 pm to 4:00 pm	Risk Assessment of Fragrances and Flavors - Dr. Ravishankar Nagarajan, J&J (Mumbai)
4:00 pm to 4:15 pm	Tea Break
4:15 pm to 5:15 pm	Impurity qualification for Pharmaceuticals (Small molecules)- Dr. Praful Patel, Torrent Pharma (Ahmedabad)
5:15 pm to 6:00 pm	Panel discussion

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Saturday 2nd March 2019

9:00 am	to	9:15 am	Recap of day1 - Dr. Milind Deore, J&J (Mumbai)
9.15 am	to	9.30 am	Sponsor Presentation
9:30 am	to	10:45 am	Alternatives for Animal Testing. – Mrs.Sanghamitra Mishra,Toxminds (Bangalore)
10:45 am	to	11:15 am	Tea Break
11:15am	to	12:15 pm	Read across, QSAR, In silico predictions- Mrs.Sanghamitra Mishra,Toxminds (Bangalore)
12:15 pm	to	1:15 pm	Safety Assessment of Consumer Products as Related to Toys, Detergents Inks, Air Fresheners, and Biocides - Mr.Nishitkumar Kachhela, Intertek Pvt Ltd. (Mumbai)
1:15pm	to	1:45 pm	Lunch
1:45pm	to	2:45 pm	Special Considerations – Botanicals and Aerosols, Dr.Ankushreddy Patil, JnJ (Mumbai)
2:45pm	to	3.45 pm	Documentation- CPSRs/ PSURs/CCDSs/ CTDs etc- Dr.Suresh Pitchaiyan, J&J (Mumbai)
3:45 pm	to	5.00 pm	Case studies- Regimen, PK-PD application - Dr.Ankushreddy Patil, JnJ (Mumbai) and Dr. Ravishankar Nagarajan, J&J (Mumbai)
5:00 pm	to	5:30 pm	Panel discussion and closing ceremony

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

Dr. K.S. Rao is a Board-Certified Toxicologist with more than 40 + years of global experience in safety evaluation. Started his career in 1971 at G.D. Searle and later moved to Dow Chemical and Quintiles, USA. After returning to India, he was heading M/s Jai Research Foundation, Gujarat and Head of Toxicology at, M/s Advinus Therapeutics and M/s Syngene International, Bangalore. Currently, Dr. Rao is Vice President, Subject Matter Expert for Safety Assessment, at Eurofins Advinus Limited. He is an international expert in the toxicological assessment of Agrochemicals, Industrial Chemicals (REACH), Drug Development (small and large molecules) from Discovery Toxicology to IND and NDA filing, Food Additives, Nutraceuticals, Vaccines, Medical Devices and Cosmetic Ingredients. Dr. Rao has been providing guidance on product development to hundreds of companies across the world with major emphasis on testing schemes/strategies and Risk Assessment. He is an Emeritus Member of the Society of Toxicology (SOT) in USA. The first Indian Toxicologist, appointed for this status for being a member of the SOT for 40 years. Dr. Rao is the recipient of the Life Time Achievement award from the Society of Toxicology of India (STOX) for his outstanding contributions in Toxicology. He is instrumental in getting the Diplomate of American Board of Toxicology (DABT) examination to India since 2009. In the last 8 years, 90 candidates have passed the DABT examination from India. Dr. Rao has published and presented papers in international journals and conferences. He is the principal author of more than 500 safety evaluation study reports of various new compounds marketed or to be marketed. These reports are submitted to regulatory authorities of several countries including FDA & EPA (U.S.A), EMA, Japanese Health and Indian Regulatory Authorities.

Session topic : Overview of Risk Assessment Process

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

In general, chemical risk assessment consists of the following three steps:

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

b. Exposure assessment: identifying the extent to which exposure actually occurs. Exposure levels are usually estimated or measured.

c. Risk characterization: combining the information from the hazard characterization and the exposure assessment in order to form a conclusion about the nature and magnitude of risk,and, if indicated, implement additional risk management measures.

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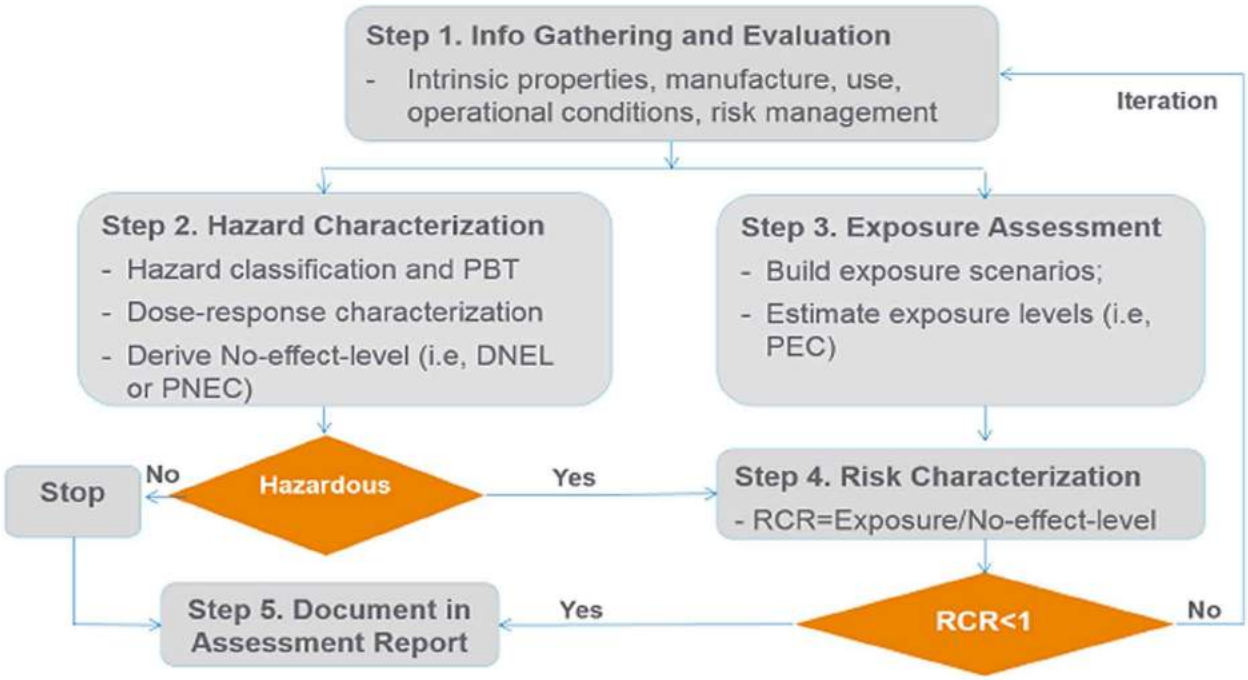
The picture below summarizes the complete procedure of chemical risk assessment.



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

Dr. Milind Deore is an American Board-Certified Toxicologist with over 29 years of experience. He is currently the Senior Director of Toxicology at Johnsons &Johnson, Mumbai and is the Head of Global Toxicology group for its Consumer sector. He is also recognized as Fellow within Johnson & Johnson. Dr. Deore is a veterinary graduate who completed his Masters in Veterinary Pharmacology from Bombay Veterinary College and later received his Ph.D. in Veterinary Toxicology wherein he worked on Selenium toxicity for which he is a recipient of a national award (Jawaharlal Nehru award) for best doctoral research in agriculture and veterinary field in India.

He started his career in poultry industry before switching to academics where he served as a faculty member of Veterinary Pharmacology & Toxicology at Bombay Veterinary College for 15 years during which he was engaged in teaching and research activities. He has guided over 25 students for their Master's and Ph.D. d egrees. He was Principal investigator for two national research schemes and co- investigator on seven national schemes. He has over 25 articles published in National and international journals and over 75 abstracts published in ~ 35 conferences. He has been invited as guest speaker and presented lead papers on more than 20 occasions. He has also authored a chapter in text book for veterinary Pharmacology & Toxicology. He was adjudged as best faculty member on three occasions as nominated by students. He was also a clinician and had a pet clinic for 14 years. In 2007 he shifted to Industry and was involved in Drug Development in Pharma sector. He was Associate Director for Drug Safety Evaluation at Ranbaxy Research Laboratories, and was in-charge of Genotoxicity, Reproductive Toxicology and Safety Pharmacology sections. He was involved in designing preclinical s tudies in rodents and non-rodents, interpretation of studies and taking molecules through different stages of drug development. The studies involved various *in vitro* and *in vivo* studies in GLP environment.Since 2009, at Johnson & Johnson, he is in-charge of the Global Toxicologyand Clinical Safety groupwhich functions from multiple sites – at US, VDR, France and Indiato supportproduct safety evaluation for global launches across Baby, Beauty, Oral care, Topical health and OTC franchises and compliance activities.

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

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Session topic: Risk Assessment of Personal Care Products

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

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

Sampath Kumar is working as Senior Scientist (Team Lead) - Toxicology at Colgate-Palmolive, Mumbai. He is a Regulatory Toxicologist, Chartered Biologist (CBiol) from Royal Society of Biology, and a P harmacologist with diversified experience in he Consumer Good Companies like Johnson & Johnson and Colgate - Palmolive. His expertise is in the area of Product Safety and Risk Assessment of ingredients in Cosmetics (Personal Care, Oral Care), Consumer goods (Home care), and Professional Products. Well versed in conducting the literature search reviews for any of the new ingredients, Safety Assessments,and Complete Product Safety Reports. Sampath is an active member of STOX, India; Society of Toxicology, US; Royal Society of Biology, UK; and The European Society of Toxicology *In Vitro,* EU.

Session topic: Data Bases, Sources of Information

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

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Ms. Geeta Bajaj

Geeta Bajaj works at Estee Lauder Companies (India) as Associate Director – Regulatory Affairs ,and is responsible for all Estee Lauder brands across India and Sri Lanka. Over the last decade she has been actively involved in import registration guidelines and other h armonization initiatives with the Indian authorities. She is also an active member of the technical committee at Indian Beauty and Hygiene Association (IBHA), Cosmetics Europe India taskforce (EU trade body),PCPC Asia subcommittee (US trade body). She also works with FICCI and Indian Society of Cosmetic Chemists (ISCC).

Geeta started her career as a clinical researcher with Derm Expert Paris(India venture with Kaya) and later joined Estee Lauder UK as a Regulatory Affairs Scientist. She has been with Estee Lauder Companies for over 12 years, starting first in UK where she worked on compliance with EU Cosmetics Directive, Dangerous Substances and Dangerous Preparations Directive (CHIP3) and other regulatory affairs for all of Estee Lauder brands across Europe. Since 2009, she started focusing on Middle East and India markets, and now primarily looks after India and Sri Lanka.

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

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

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

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

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

Session topic: Impurity Qualification in Pharmaceuticals

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

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Ms.Sanghamitra Mishra, M.Pharm., ERT

Sanghamitra Mishra is a Senior Consultant at ToxMinds BVBA, Belgium and a Director of its subsidiary ToxMinds India Consulting Pvt. Ltd., with more than 10 years' of research and consulting experience in the human health hazard, ecotoxicology and E-fate, and risk assessment of chemical substances.

Sanghamitra has significant expertise in EU REACH, Classification and labelling and cosmetic regulations. She has successfully prepared more than 100 REACH registration dossiers for several chemical industries and consortiums, including activities such as data gap analysis, critical review of test reports, study evaluation and Klimisch scoring (quality check), robust study summaries preparation using IUCLID software, chemical safety report (CSR) preparation (including DNEL and PNEC derivations) and cost calculations for consortium members based on principles of 'data sharing'. Sanghamitra has also played a key role in preparing critical reviews and assessments of chemical toxicological data in different sectors such as cosmetics biocides, and pharmaceuticals, including safe level derivations, PDE, MoE/MoS calculations, benchmark dose modelling, virtual safe dose or life-time cancer risk calculations using T25 or BMDL10values.

In her curren t rol e at ToxMinds, in collaboration with Dr. Monica Autiero, Sanghamitra has been instrumental in developing the knowledge base inToxMinds in the area of non-animal alternatives, particularly SAR/analogue-based read-across justification and the identification of mechanism-based *in vitro* testing programmes ('AOP') to reduce remaining uncertainties in a proposed read-across approach.

Sanghamitra is a European Registered Toxicologist (ERT) with a M.Pharm in Pharmacology from the Indian Institute of Technology, Banaras Hindu University (IIT BHU), India.

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

In the last decade, the increasing ethical and societal demand for reducing or replacing animal testing in hazard assessment strategies, hasled to significant development and adoption of number of alternate approaches in different regulations. Some of the widely used alternative approaches include use of validated *in vitro* assays for several endpoints (such as dermal absorption, acute toxicity, skin and eye irritation, sensitization, genotoxicity), high-throughput assays from ToxCast program including several mechanistic assays (e.g. endocrine disruption), computational approaches ((Quantitative) Structure-Activity Relationships (Q)SARs) predictions), read across and exposure-based assessments using concepts like TTC or iTTC. Among these options, read-across is at the forefront of prediction of toxicity and has been the "new paradigm" for hazard assessment, specifically for the critical systemic endpoints (e.g. repeated dose, reproductive and development toxicity).

Read-across relies on the ability to identify similar molecules with the assumption that similar molecules will tend to exhibit similar activity or, at least, show similar trends in activity. Although the concept of similarity has growing acceptance for t oxicity prediction, in reality there are still a number of barriers to the acceptance of the predictions, especially for regulatory purposes.

Read across and QSAR (In Silico) Predictions (Cont'd.)

Given these challenges, there have been several efforts from industries and/or regulatory authorities in the form of publications and guidance documents in order to standardize the process ofidentifying and justifying analogue data to be suitable for read-across purposes (e.g. Wu et al., 2010; Blackburn et al., 2011, 2014;Schultz et al., 2015; European Chemicals Agency (ECHA) Read-Across Assessment Framework (RAAF), 2017).

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

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Mr.Nishitkumar Kachhela, M.S.Pharm.

Nishitkumar Kachhela is working at Intertek Pvt Ltd. as an Assistant Manager – Toxicology and leading the team of regulatory toxicologists and MSDS Author which is the part of Intertek's Health, Environmental & Regulatory Services (HERS) business line. The team is a very good combination of knowledge for hazard assessment, risk assessment, and regulatory compliance; majorly working on cosmetic products and other consumer products like Toys, D etergents, Inks, Air Fresheners, Biocides etc. He is in the field of toxicology for more than 7 years now, well-skilled to perform hazard assessments, GHS/CLP classification, risk assessment of consumer products, regulatory consultancy, etc. He has practical experience working for safety and regulatory assessments globally for various countries like the EU, US, Australia, Canada, GSO, ASEAN, India, Israel, Brazil, New Zealand, etc.

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

Dr. Ankush is a Principal Scientist at Toxicology Resource Centre (TRC), Johnson and Johnson Pvt Ltd, Consumer Division, Mumbai, with more than 12 years of combined experience in preclinical, regulatory and consumer Toxicology. He is graduated from Veterinary College, Bidarand finished master's in Veterinary Pharmacology and Toxicology, from Nagpur Veterinary College. He pursued PDCR (Professional Diploma in Clinical Research) from Delhi and MBA in Pharma Marketing from Lucknow. He is a Diplomate of the American Board of Toxicology (DABT) since 2013.

He has been part of the Toxicology J&J from 2011. He currently serves as a Safety Assessor for consumer products and his responsibility include the assessment of Consumer (Skin and hair care and oral care products) & OTC products for the EU Market. This includes hazard assessment of ingredients, risk assessment of raw materials and safety evaluation of final cosmetic products (CPSRs) before release to the market . His responsibilities also include addressing questions posed by regulatory and health authorities, impurity qualification in drug products by data mining and using in silico tools such as OECD QSAR Toolbox, Toxtree and Leadscope. He has worked in preclinical toxicology, product safety and regulatory affairs. He had working experience in the human and environmental safety assessment of chemicals, through their use or presence in consumer products or via the environment, specifically for addressing the REACH& CLP regulation in EU.

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

Suresh Kumar obtained his M.Pharm.Sci in Pharmacology and Toxicology and Ph.D in Pharmacology from The Bombay College of Pharmacy, Mumbai affiliated to the University of Mumbai. He has over 14 years of experience in general toxicology, regulatory toxicology, and product safety. Currently he is working as Senior Manager, Toxicology Resource Center with J ohnson & Johnson's Consumer Product Division, International Technical Centre, Mumbai. He is providing Toxicology supportto business franchises including Over The Counter, Oral care and Topical Healthcare, Adult and Baby Skin care. He is an expertise inin silico and structure activity relationship-based toxicity prediction, risk assessment analysis, designing and managing toxicology studies, as well as preparing and reviewing technical documents for regulatory submissions. Prior to joining Johnson & Johnson, he worked in Drug Discovery program in Discovery Biology function with Glenmark Research Center, Glenmark Pharmaceuticals Ltd., Mumbai and involved in screening of New Chemical Entities for the treatment of asthma, COPD and inflammatory conditions. He has 5 research articles, 1 invited review and 13 abstracts/presentations published in journals and conference proceedings. He is also a reviewer for scientific journals.

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Who should attend?

All professionals in the field of Toxicology (preclinical, regulatory, risk assessment, and so on.)

Registration details*

Registration start date : 09th January 2019
Registration end date : 25th February 2019
**Limited seats available*

Registration fee

Registration fee - Rs.2250*
**For* students, *(Student ID need to be submitted)* registration fee will be Rs.750 per person

How to register for IMIT-19?

Step I

Registration fee shall be transferred to the below-mentioned account of ICSQA

Name of the A/C Holder	: Indian Chapter of the Society of Quality Assurance Trust
Account Number	: **3037 - 6720 - 449**
Name of the Bank	: State Bank of India
Branch	: R T Nagar, Bangalore
IFSC Code	: **SBIN0007982**
MICR Code	: 560002039

Step II

Registration form shall be filled by applicant on the ToxGurukul website, ***www.toxgurukul.org.in (https://toxgurukul.org.in/register-imit-19).***
Details to be filled in the registration form includes:
Name, Gender, Designation, Organization, Email ID, Contact Number (WhatsApp number is preferred), Address for Correspondence, Registration amount, Transaction date(Registration fee), and Transaction ID (Registration fee).

Step III

Applicant shall recieve an email from us regarding confirmation of registration within five working days.

Step IV

Incase the applicant doesnot recieve the confirmation mail within five working days,applicant shall contact ***toxgurukul.india@gmail.com*** *or* ***+91-75728-33104, +91-97454-50045.***

Accomodation

Participants are kindly requested to make their own travel and accommodation arrangements.

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Nearby Accomodations

Name	Address	No. of Rooms	Rating	Double Occupancy (INR)	Triple Occupancy (INR)	Distance from the venue
Category - 1 (Rs.1200-1700 / Night)						
Hotel Apollo	CG Road, Navrangpura, Ahmedabad,(M)085111 51566	12	3 / 5	1300	NA	1.7 Km
Hotel Keshav	4th floor, Om complex, Swastik cross road, C.G. Road, Ahmedabad, (M) 072101 01503	11	3.5 / 5	1200	1500	2.1 Km
Hotel Sunstar	Opposite Sahajanand Apartment Gurukul Road, Ahmedabad,(M)072101 01503	11	4.10 / 5	1300	1700	3.8 Km
Category - 2 (Rs.1800-2500 / Night)						
Hotel Rock Regency	Samartheshwar Mahadev Road, Navrangpura, Ahmedabad, (M) 072101 01503	38	3.7 / 5	1800	2300	1.7 Km
Hotel Vice President	Opp. Bata Showroom, Ashram Road, Shreyas Colony, Navrangpura, Ahmedabad,(M)072101 01503	30	4.20 / 5	2000	2500	2.9 Km
Hotel Kanak	Opposite Gujarat-College, Ellisbridge, Ahmedabad, (M)072101 01503	29	4.10 / 5	1800	2200	3.1 Km
Hotel Rudra Mahal	Capital Commercial Center, Near Sanyas Ashram, Ashram Road, Ellisbridge, Ahmedabad, (M)072101 01503	23	3.60 / 5	1800	2300	4.2 Km
Category - 3 (Rs.2300-3200 / Night)						
Hotel Edition	PanjarapoleChar Rasta, Devang Park, Ambawadi, Ahmedabad, (M)072101 01503	23	4.4 / 5	2300	2900	1.4 Km
Hotel Townhouse	Beside Bharat Petroleum Usmanpura, Ashram Road, Ahmedabad,(M) 072101 01503	40	4.9 / 5	2750	3200	4.2 Km

Disclaimer: Rates are for purpose of guidance and as per information furnished by the respective hotels at the time of brochure preparation.

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About Ahmedabad

Ahmedabad, also pronounced as, Amdavad in Gujarati , is the largest city and former capital of the Indian state of Gujarat. It is the administrative headquarter of the Ahmadabad district and the seat of the Gujarat High Court. Ahmedabad is fifth most populous city in India and located on the banks of the Sabarmati River, 30 km from the state capital Gandhinagar, which is its twin city.

In 2010, Ahmadabad was ranked third in Forbes's list of fastest growing cities of the decade. In 2012, The Times of India chose Ahmedabad as India's best city to live in . Ahmedabad has been selected as one of the hundred Indian cities to be developed as a smart city under Government of India's flagship Smart Cities Mission. In July 2017, the Historic City of Ahmadabad or Old Ahmadabad was declared as India's first UNESCO World Heritage City.

Ahmedabad lies at 23.03°N 72.58°E in western I ndia at 53 metres (174 ft) above sea level on the banks of the Sabarmati river, in north- central Gujarat. It covers an area of 464 km2 (179 sq mi).The area around Ahmedabad has been inhabited since the 11th century, when it was known as Ashaval . At that time, Karna, t he Chaulukya ruler of Anhilwara (modern Patan), waged a successful war against the Bhil king of Ashaval, and established a city called Karnavati on the banks of the Sabarmati.

Some of the most visited gardens in the city include Law Garden, Victoria Garden and Bal Vatika. Law Garden was named after the College of Law situated close to it. Victoria Garden is located at the southern edge of the Bhadra Fort and contains a statue of Queen Victoria. Bal Vatika is a children's park situated on the grounds of Kankaria Lake and also houses an amusement park. Other gardens in the city include Parimal Garden, Usmanpura Garden, Prahlad Naga r Garden and Lal Darwaja Garden. Ahmedabad's Kamla Nehru Zoological Park houses a number of endangered species including flamingoes, caracals, Asiatic wolves and chinkara.

Fabulous Places to Visit in Ahmedabad

Sabarmati Ashram, Jama Masjid, Sarkhej Roza, Swami Narayan Temple, Hutheesing Jain Temple, Kankaria Lake, Bhadra Fort, Manek Chowk, Adalaj Step Well, Lothal, Jhulta Minara, Teen Darwaza, Lal Darwaza, Rani no Hajiro, Calico Textile Museum, Vechaar Utensils Museum, Auto World Museum, Law Garden, Dada Hari Vav, Gujarat Science City, Vastrapur Lake, ISKCON Temple, Sardar Vallabhbhai Patel National Museum, Sanskar Kendra, Nagina Wadi, Sidi Saiyeed's Mosque, Lalbhai Dalpatbhai Museum, Parimal Gardens, Maniar's Wonderland, Rani Sipri's Mosque

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www.toxgurukul.org.in

"This brochure is incomplete, final version will be released soon with all the details."

Companies/Industries interested in sponsoring please contact us
Email: sponsor.toxgurukul@gmail.com, Mob: -91-93128-62512 or +91-93196-74788