

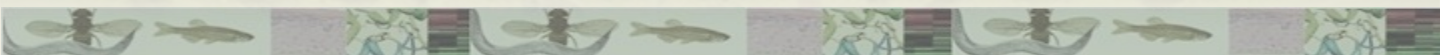
NATIONAL CONFERENCE ON ALTERNATIVES TO ANIMAL EXPERIMENTS (NCAAE-2018)



JAMIA HAMDARD, NEW DELHI
November 27, 2018



BOOK OF ABSTRACTS AND SOUVENIR



About NCAAE-2018

Realising the need for development and validation of alternative models and generating awareness among academics, scientists, policymakers and regulators in India this Conference (**NCAAE-2018**) has been planned. The Conference will also witness launching of the **Society for Alternatives to Animal Experiments (SAAE)**. The Conference aims to discuss the perspectives on the current state of practices and existing strategies to promote the development of non-animal technologies in India. The Conference will be held at **Jamia Hamdard**, New Delhi, a Deemed to be University accredited in category 'A' by the National Assessment and Accreditation Council of India in three consecutive cycles. Jamia Hamdard is an outstanding institution of higher learning with clear and focused academic and research programmes. In the National Institutional Ranking Framework-2018 it was ranked 2nd in the Pharmacy discipline and 23rd in the University category in India. It is one of the few universities in India having an active Department imparting education with cutting edge research in the field of toxicology including *in vitro*, *in silico* toxicity assessments and use of alternative models in toxicology (*C. elegans* and *Drosophila*).

The Organizing Committee invites stakeholders to this Conference and also solicit collaboration and sponsorship from organizations and industry working in the area of alternatives, toxicity testing, method development, regulations and other related fields.

Prof. S. Raisuddin
Organizing Secretary

Themes

- *In silico* approach: Does it replicate the complexity of biological system?
- *In vitro* approach: Opportunities and limitations.
- Alternative model organisms: Fish and other lower vertebrates.
- Invertebrate and non-animal models including engineered tissues.
- Standardization and validation issues.
- Regulatory scenario in India vs. rest of the world.





Professor Dr. Seyed E. Hasnain

Phd, DSc(h.c.), DMedSc(h.c.), FNA, FTWAS, ML, FAAM

Vice Chancellor

Jamia Hamdard

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November 19, 2018

MESSAGE

I am happy to know that a **National Conference on Alternatives to Animal Experiments (NCAAE-2018)** under the 'Pearl Anniversary Celebration' of Jamia Hamdard is being organized at our Campus on November 27, 2018. Alternatives movement is quite prominent in European countries and in those countries, regulatory framework of European Union and OECD has taken firm root. Alternatives including those based on non-animal systems are routinely used with good and reliable data output. In India also this area of research is taking footings and I am sure this Conference will energize the movement. I am also confident that this conference will create awareness about alternatives in India among all stakeholders. I have learned that speakers from Canada, France, Japan, Korea, Switzerland, and USA will be attending the Conference and presenting their perspectives. I am hoping that recommendations of this Conference will be forwarded to regulatory agencies and policymakers of India for their perusal and implementation in the interest of saving the precious lives and our biodiversity.

I wish all the best to Organizers and extend my warm welcome to all delegates to our Green Campus.

Prof. (Dr) Seyed Ehtesham Hasnain
Vice Chancellor



डॉ. रेणु स्वरूप
DR. RENU SWARUP


सचिव
भारत सरकार
विज्ञान और प्रौद्योगिकी मंत्रालय
जैव प्रौद्योगिकी विभाग
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MINISTRY OF SCIENCE & TECHNOLOGY
DEPARTMENT OF BIOTECHNOLOGY
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Lodhi Road, New Delhi-110003

November 19, 2018

Message

I am happy to learn that Jamia Hamdard is organizing a **National Conference on Alternatives to Animals Experiments (NCAAE-2018)** on November 27, 2018. The issue of alternatives in biomedical and biotechnological research has great significance in terms of humane treatment of animals which indirectly contributes to the biodiversity conservation. Although there is enough awareness about concept of alternatives and 3Rs in the west and countries such as Japan and South Korea, there is need of concerted efforts to create same level of awareness in India. Therefore, this Conference is topical and while perusing the programme and profile of speakers it is apparent that the Organizing Committee has made a serious effort to bring various stakeholders at one platform. With technology on our side and latest advent in artificial intelligence I am sure that in foreseeable future we will have alternative available for most of the biological investigations. I am confident that recommendations based on deliberations at the Conference will enable policymakers in India to formulate regulations for biological, toxicological and pharmacological evaluation of drugs and medical devices including biotechnological products.

I convey my all good wishes for the Conference.


(Renu Swarup)



Professor Dr. Ahmed Kamal
FNASc
Pro-Vice Chancellor

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19th November 2018

MESSAGE

I welcome the delegates to this **National Conference on Alternatives to Animal Experiments (NCAAE-2018)** being organized on November 27, 2018 under the 'Pearl Anniversary Celebrations' of Jamia Hamdard. The Organizing Committee has laid out an excellent technical programme, which comprises of plenary lectures, keynote addresses invited lectures and oral as well as poster presentations. This conference has many themes like toxicity and safety assessments using *in silico*, *in vitro*, non-animal and non-mammalian systems. I am pleased to learn that this conference is also being attended by industry representatives and regulatory officials. A pre-conference Hands-on Workshop on Alternatives and Skin Irritation Test According to OECD TG-439 is also scheduled along with NCAAE-2018 a day before that is on November 26, 2018. I am confident that the participants will find these events enriching in enhancing their knowledge and skills and moreover this conference will create awareness about different alternatives that are available for toxicity testing, biomedical research and fulfilment of regulatory requirements.

On behalf of Organizing Committee and my own behalf I would like to welcome the delegates to this conference.

Prof. Ahmed Kamal
Pro-Vice Chancellor
Chairman Organizing Committee
NCAAE-2018



सीएसआईआर-भारतीय विषविज्ञान अनुसंधान संस्थान
CSIR-INDIAN INSTITUTE OF TOXICOLOGY RESEARCH



वैज्ञानिक तथा औद्योगिक अनुसंधान परिषद्
COUNCIL OF SCIENTIFIC & INDUSTRIAL RESEARCH

प्रोफेसर आलोक धावन

एफ एन एस, एफ एम एस, एफ आर एस सी, एटी एस

निदेशक

Professor Alok Dhawan

FNASc, FAMS, FRSc, ATS

Director



Message

It is a matter of immense pleasure that Indian Society for Alternatives to Animal Experiments is organizing its 1st Annual Meeting and National Conference on 'Alternatives to Animal Experiments' at Jamia Hamdard, New Delhi on November 27, 2018.

Efforts are being made globally to minimize the testing on animals and alternatives to animals are now being used. However, a lot needs to be done in this very important area including multi-institutional validation. There is also a need to develop tests, especially in India so that they can be replicated across various laboratories in our country. I am sure that there will be deliberations on the cutting-edge research being done in this area by the experts coming from various institutions.

I compliment the organizers for this important conference and am sure that recommendations emanating from the discussions will be very fruitful for the research institutions as well as regulators.

I wish the conference a grand success.



Alok Dhawan
President

Society of Toxicology (India)

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एनएबीएल द्वारा रासायनिक एवं
जैविक परीक्षण हेतु प्रत्याशित
Accredited by NABL for chemical
and biological testing



विषासता परीक्षण: जीएलपी अनुकूल सुविधा
Toxicity Testing: GLP Test Facility

NATIONAL CENTRE FOR ALTERNATIVES TO ANIMAL EXPERIMENTS (NCAAE)

(Under the UGC-CPEPA Scheme)

BHARATHIDASAN UNIVERSITY

TIRUCHIRAPPALLI - 620 024, INDIA

(Mahatma Gandhi-Doerenkamp Enclave)



Dr.R. THIRUMURUGAN
Professor & Co-ordinator



Message

I am very pleased to extend a warm welcome to the distinguished Scientists, Academic Experts, Scholars and Students on the occasion of National Conference on Alternatives to Animal Experiments (NCAAE-2018) being held at Jamia Hamdard, New Delhi.

The UGC-National Centre for Alternatives to Animal Experiments (NCAAE), the erstwhile Mahatma Gandhi – Doerenkamp Centre (MGDC) founded by Prof. M. A. Akbarsha at Bharathidasan University, Tiruchirappalli, Tamil Nadu, is the pioneer in spearheading the moment of alternatives to use of animals in education and research across India. To enrich multi-disciplinary research in Life sciences and Bio-medical Science, the centre practices and propagates the concept of “3R” – Replacement, Reduction and Refinement - and aims to make India a leader in modern tools of cruelty-free learning and research.

This conference would help to maximize the interchange/exchange of research insights on *in silico* and *in vitro* approaches, opportunities and limitations on alternate model organisms and issues related therewith. The distinguished speakers from renowned Institutes around the globe are going to discuss, generate, share and develop ideas to promote the area of animal alternatives. It is great that this conference will launch the “Indian Society for Alternatives to Animal Experiments (ISAAE)”, an aspect of the National Centre for Alternatives to Animal Experiments. I congratulate all the delegates for taking up new technologies to sustain the concept of “humane science”.

I take this opportunity to thank Jamia Hamdard, New Delhi for igniting the young minds of Indian researchers for the development and validation of alternative animal models by organizing NCAAE- 2018. I am sure the Organizing- and Scientific Committees will put all possible efforts to make this conference scientifically rewarding.

I wish the Conference great success!

R. Thirumurugan

**NATIONAL CONFERENCE ON ALTERNATIVES TO ANIMAL
EXPERIMENTS (NCAAE-2018)**

November 27, 2018

JAMIA HAMDARD, NEW DELHI – 110062
(NAAC A+ Grade Accredited Govt-aided Deemed University)



**Organizing Committee
NCAAE-2018**

Patron

Prof. (Dr.) Seyed Ehtesham Hasnain
Vice Chancellor, Jamia Hamdard

Chairman

Prof. Ahmed Kamal
Pro Vice Chancellor, Jamia Hamdard

Co-chairman

Prof. M.P. Sharma
Dean, SCLS

Organizing Secretary

Prof. S. Raisuddin
Advisor (Research), Jamia Hamdard

Co-organizing Secretary

Dr. Adip Roy
Amway, Gurugram

Jt. Organizing Secretary

Prof. Suheil Parvez
Toxicology, SCLS

Treasurer

Dr. M. Shahar Yar
Pharmaceutical Chemistry, SPER

**Indian Society for Alternatives
to Animal Experiments
(ISAAE)**

President

Prof. Y.K. Gupta
THSTI, Faridabad (formerly at AIIMS)

General Secretary

Prof. M.A. Akbarsha
National College, Trichy



From the NCAAE-2018 Secretariat

I warmly welcome all the delegates to the National Conference on Alternatives to Animal Experiments (NCAAE-2018). The idea of having a conference at Jamia Hamdard was floated by my colleague Dr M.A. Akbarsha and was spontaneously supported by Prof. Y.K. Gupta. Dr Akbarsha is a pioneer in India on the subject of alternatives in biomedical research. He has been among founders of National Centre for Alternatives to Animal Experiments at Bharathidasan University. The Centre is supported by the UGC and Doerenkamp-Zbinden-Foundation (DZF), Switzerland. Jamia Hamdard which is one of leading higher education institutes in India having a full-fledged Department in the subject of Toxicology imparting Undergraduate, Post-graduate and PhD level education. The Department is also well known for its high end toxicology research. For last few years, the Department has been making efforts to establish a laboratory in alternatives and in this direction it has been supported by the DST for research in *Drosophila melanogaster* and *Caenorhabditis elegans*.

The main aim of the Conference is to bring on board all the stakeholders from academia, research institutes, industry, regulatory authorities and social sector in order to generate awareness on alternatives in India and also to facilitate creation of an enabling ecosystem for alternatives. Response from all the stakeholders has been tremendous. A number of international experts including those from industry have come forward to voluntarily attend the Conference and present their perspectives. We have also got valuable support from international faculty and Academies for pre-conference workshops; one at the University of Kerala and another at Jamia Hamdard.

I thankfully acknowledge support and encouragement of our Patron and Vice Chancellor Prof. (Dr.) Seyed Ehtesham Hasnain and the Chair and Co-chair of the Organizing Committee, Prof. Ahmed Kamal and Prof. M.P. Sharma. Besides, I like to acknowledge support of all the Members of the Organizing Committee and Advisory Committee for their support, advice and encouragement.

Valuable sponsorship and collaboration from HSI-India, PeTA India, DZF Switzerland, NCAAE-Bharathidasan University, Indian Pharmacological Society, mediMation (Animation in Medicine) India, J&K Bank and Bank of India, EPISKIN Academy France and OpenTox Switzerland is acknowledged with gratitude.

I once again welcome all the delegates and experts to the NCAAE-2018 and hope their participation experience will be a memorable one.

Raisuddin

Prof. S. Raisuddin
Commonwealth Fellow, FST, FAEB
Organizing Secretary NCAAE-2018

The Conference Secretariat

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Dr Manilal Valliyate
CEO PETA, India



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FOREWORD

On behalf of People for The Ethical Treatment of Animals (PETA), India, I extend my best wishes to the National Congress on Alternatives to animal testing, and the launch of Society for Alternatives to Animals.

PETA India, whose motto in part, reads that animals are not ours to experiment on, welcomes, the launch of society, the scientists, educators and students, participating to discuss the perspectives on the current state of practices and existing strategies to promote the development of non-animal technologies in India. We support the aim of the society to promote adoption of 3Rs (Replacement, Reduction, and Refinement) with the aim to end the use of animals in research, regulatory work and education.

This conference is a step to apprise the researchers, regulators, educators and students with modern updated methods for replacing the use of animals in the field of Biomedical, Pharmaceutical, Life sciences, Veterinary sciences, pesticide testing, and several other fields.

We at PETA India, appreciate the efforts of the Organising Committee, the Organising Secretary and the team of Jamia Hamdard for organising this event. I wish this event a great success.

Kind regards

(Dr Manilal Valliyate)

Affiliates:

- PETA US
- PETA Asia
- PETA France
- PETA Australia
- PETA Germany
- PETA Netherlands
- PETA Foundation (UK)

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**NATIONAL CONFERENCE ON ALTERNATIVES TO ANIMAL
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**JAMIA HAMDARD, NEW DELHI
November 27, 2018**

-- ABSTRACTS --

Keynote Address

-- (KA-01)--

Troy Seidle



Troy Seidle is Vice President, Research & Toxicology at Humane Society International, Toronto, Ontario, Canada. He is an internationally established professional with over two decades of experience in biomedical and toxicological science policy and animal welfare arenas, extensive specialist knowledge of current and emerging testing and research methodologies, legal and regulatory frameworks across numerous countries and sectors, and an expansive network of governmental, corporate, academic and other bioscience stakeholder contacts. A natural leader, strategic thinker and effective, collegial negotiator who thrives on developing innovative solutions to complex scientific and ethical challenges in the health research arena.

Abstract of lecture

A human-focused paradigm in health research: the BioMed21 vision

Troy Seidle

Humane Society International
Research & Toxicology Department
Toronto, Canada
tseidle@hsi.org

The Biomedical Research for the 21st Century (BioMed21.org) Collaboration grew out of a 2015 review publication authored by scientists from Humane Society International in collaboration with a diverse group of stakeholders representing academic, research funding, regulatory, corporate and other communities, which recognized the human relevance and translational limitations of the current paradigm in biomedical research and drug discovery, and the need for change. A cornerstone of the proposed new approach is an organizing framework linking initial molecular events in disease pathways and networks with adverse outcomes, akin to the "adverse outcome pathway" (AOP) approach under development in toxicology. Such a framework could provide a more predictive and effective rubric for understanding disease pathophysiology across levels of biological organization, and for targeting and evaluating new interventions using the growing toolbox of modern, human-specific microphysiological approaches such as 3D tissue models, organoids, organs-on-a-chip and computational systems biology modelling. HSI/India, through the BioMed21 Collaboration, is preparing to launch a funding call to engage Indian health scientists to undertake critical reviews of research progress and barriers in their area of expertise, and convene a national workshop to foster strategic scientific dialogue and identify actionable consensus recommendations as a further step toward a comprehensive Indian roadmap for 21st century, human-specific health research and funding.

Plenary Lecture

-- (PL-01)--

Hajime Kojima, PhD



Dr Hajime Kojima is National Institute of Health Sciences, Kawasaki, Kanagawa, Japan. He is the secretary general of Japanese Center for the Validation of Alternative methods (JaCVAM) and the section chief of Division of risk assessment, Biological Safety Research Center (BSRC) in National Institute of Health Sciences (NIHS) contributing to the identification and evaluation of *in vitro* test methods for their potential validation, in the field of genotoxicity and local toxicity (skin and eye). He holds several publications in refereed journals dealing with *in vitro*

toxicity assay as well as validation study. He is the councilor of the Japanese Society of Toxicology, the Japanese Environmental Mutagen Society and the Japanese Society for Alternatives to Animal Experiments. He is a vice-chair of the Working Group of the National Coordinators for the Test Guidelines Programme and is also an expert of skin & eye irritation, skin sensitisation, validation management group of non-animal for endocrine disrupter in OECD (Organisation for Economic Co-operation and Development). Until now, he has contributed to be approved more than 10 test methods developed by Japanese in the OECD Test Guidelines.

Abstract of lecture

JSAAE Promotion of the 3Rs in Asia

Hajime Kojima¹ and Yasuyuki Sakai^{2, 3}

- 1: Japanese Center for the Validation of Alternative Methods (JaCVAM), National Institute of Health Sciences (NIHS), Japan
- 2: Department of Chemical System Engineering, Graduate School of Engineering, University of Tokyo, Japan
- 3: International Research Center on Integrative Biomedical Systems (CIBiS), Institute of Industrial Science, University of Tokyo, Japan

The Japanese Society for Alternatives to Animal Experiments (JSAAE) has promoted the 3Rs in Japan through a wide variety of domestic activities and international cooperation, such as hosting the 6th Congress on Alternatives and Animal Use in the Life Sciences (WC6: 2007) in Tokyo as well as the First Asian Congress on Alternatives and Animal Use in the Life Sciences (Asian Congress 2016) in Karatsu, Saga, and Fukuoka, Japan. Having already concluded agreements with professional organizations in Korea, the EU, and the USA, the JSAAE is now working to establish a similar relationship with our Chinese colleagues.

This year, JSAAE was supported the International Conference on Toxicity Testing Alternatives & Translational Toxicology and the 2nd Asian Congress on Alternatives and Animal Use in the Life Sciences on October 9th to 11th in Guangzhou, China (<http://www.chntox.org>) and exchanged a memorandum with the European Society of Toxicology In Vitro (ESTIV) on October 16th in Berlin, Germany. The JSAAE is committed to promoting alternative methods to researchers throughout Asia and other places where the concept of the Three Rs is just now achieving penetration and we welcome the activities of National Conference on Alternative to Animal Experiments (NCAAE-2018) in New Delhi, India.

Plenary Lecture

--(PL-02)--

Christian Pellevoisin, PhD



Dr Christian Pellevoisin is Scientific Director, EPISKIN Academy – France. After a PhD in neuroscience at the French National Institute of Health and Medical Research (INSERM) Christian Pellevoisin had a temporary teaching position at the university of Tours (France). He joined L'Oréal in 2000 at the Life Science Research Center where he implemented some *in silico* tools for *in vitro* toxicology. In 2004 he moved to scientific communication in the field of alternative methods and tissue engineering. In 2011 he joined EPISKIN, a subsidiary of L'Oréal, dedicated to development and production of reconstructed human epithelia. He is in charge of EPISKIN Academy, a transversal program to support the use 3D models for efficiency and safety assessment and to relay EPISKIN commitments to 3Rs.

Participating as expert to the ISO TC194 for biocompatibility of medical devices he promotes the development of *in vitro* approaches in this domain.

Abstract of lecture

Reconstructed skin models for *in vitro* hazard and risk assessment of chemicals and cosmetics

Christian Pellevoisin

EPISKIN Academy
Lyon, France

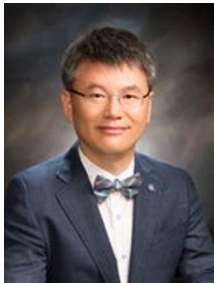
In 2003, the 7th Amendment to the Cosmetics directive introduced in Europe the regulatory framework for the phasing out of animal testing for cosmetics purposes. Since 2013, this testing and marketing ban fully entered in force and is now part of the European Cosmetic regulation. Following this European regulation we observe outside Europe a strong trend for a progressive shift to non-animal methods for safety of ingredients and cosmetics products. Mechanistic approaches to replace the animal are based on *in silico*, *in chemico* and *in vitro* assays that can inform on one or more key events of adverse outcome pathways (AOP). To be as predictive as possible of human being, such individual *in vitro* test systems rely more and more on cells of human origin with a 3D organization which better mimic the *vivo* situation. To this point of view, Reconstructed Human Epidermis (RHE) presents several advantages that make it an alternative method of choice for evaluating some safety endpoints. To date, several alternative methods in toxicology have been developed based upon *in vitro* skin: skin penetration, skin corrosion/irritation, phototoxicity, genotoxicity, sensitization. However, an *in vitro* alternative method must be validated before being recognized by the concerned regulatory bodies. Today, two alternative methods based on *in vitro* skin models have been validated as full replacement methods to animal, the OECD-TG 431 for *in vitro* skin corrosion and the OECD-TG 439 for *in vitro* skin irritation of chemicals. Other methods based on human reconstructed epidermis and full thickness models are at different stage of the validation process for different toxicological endpoints.

This presentation will give an overview of the state of the art in this field and will address future developments.

Plenary Lecture

--(PL-03)--

Eui-Bae Jeung, PhD



Dr Eui-Bae Jeung is Professor of Veterinary Biochemistry and Molecular Biology, and former Dean of College of Veterinary Medicine, Chungbuk National University (CBNU), South Korea. He is a Fellow of the Korean Academy of Science and Technology. Dr. Jeung received D.V.M. and M.Sc. degrees from the Seoul National University, and a Ph.D. in Molecular Endocrinology in 1993 from the University of British Columbia. Following two postdoctoral fellowship at the University of British Columbia, and at the Dept. of Pharmacology and Molecular Biology, Washington University in St. Louis. In 1995, he became the faculty member of CBNU. He has been served as the Director of the Brain Korea 21 Program at CBNU for over 12 years. He has been served as president of Korean Society for Alternative to Animal Experiments and Vice President of Korean Society of Toxicology.

Dr. Jeung received numerous prestigious awards including grand award of veterinary college of CBNU, awards from KST and KSVS. Dr. Jeung has served on the grant committees of the National Research Foundation of Korea. He has served in many international organizations, including as Peer Review Panel of the validation of the Uterotrophic Assay, Hand1-luc screening test in the OECD, Associate Editor of the Journal of Veterinary Science and Editor of Journal of Reproduction and Development, Molecules and cells, BMC Reproductive Biology and Endocrinology (RB&E).

A major focus of Dr. Jeung's research program is in the area of *Alternative Methods to Animal Experiments*, especially on the toxicant screening test without animal use. His research program has received continuous funding from National Research Foundation and Ministry of Food and Drug Safety. Notably, He was establishing new toxicity screening test using mouse embryonic stem cells. Until now, Dr. Jeung's research projects have resulted in the publication of more than 234 papers, 7 book chapters.

Abstract of lecture

Alternative developmental toxicity test with embryonic stem cells

Eui-Bae Jeung

Laboratory of Veterinary Biochemistry and Molecular Biology, College of Veterinary Medicine, Chungbuk National University, Cheongju, Chungbuk 28644
Republic of Korea

In the embryonic stem cell test (EST), differentiation of mouse embryonic stem cells (mESCs) is used as a model to assess embryotoxicity by measuring the half inhibition in viability of mouse embryonic stem cells (ESCs), fibroblasts (3T3 cells) and in cardiac differentiation of ESC. In this study, we suggest the developmental toxicity test method (termed EBT) applying area of embryoid bodies (EBs) instead of cardiac differentiation of EST. In the assessment of 21 substances, EB area was logarithmically decreased in dose-dependent manner. Decline in EB area resulted in decrease of beating ratio during differentiation of ESCs. In classification by the EBT-based prediction model reflecting decline in cell viability and EB area, toxicity for 21 chemicals showed 90.5% accuracy. In the results

of next generation sequencing, reduction in EB area resulted from cell cycle arrest mediated by HDAC2 and CDKN2A. In order to verify the proposed EBT method in this study, intra-laboratory reproducibility (15 substances), inter-laboratory mobility (6 substances), and inter-laboratory reproducibility (20 substances) tests were performed. To ensure reliability of the study results, the tests were conducted using identity-coded test substances. The existing forecasting model included four classifications; non-toxic, weak, moderate, and strong. In this study, we created a new prediction model for only two classifications; non-toxic and toxic. The results of the intra- and inter-laboratory tests were highly accurate (above 80%) when substances were classified using the predictive model. Conclusively, EBT can accurately classify various embryotoxicants in a short time with less effort and greater validation. This research was supported by a grant (17182MFDS487) from Ministry of Food and Drug Safety in 2017.

Plenary Lecture

--(PL-04)--

Albert P Li, PhD



Dr Albert P. Li is the President, CEO and co-founder of In Vitro ADMET Laboratories LLC, Columbia, MD and Malden, MA, USA. He has devoted his scientific career to the development and advancement of scientific concepts and *in vitro* technologies to accurately predict human drug properties including metabolic fate, drug-drug interaction potential, and organ-specific toxicity. His research is focused on the development and application of human-based in vitro experimental models, especially primary cultured human hepatocytes and, most recently, enterocytes, in the accurate assessment of human drug properties including metabolic fate, drug-drug interactions and drug toxicity.

Dr. Li was one of the first scientists to successfully cryopreserve human hepatocytes and enterocytes/intestinal mucosa to retain properties of freshly isolated cells. Dr. Li and his colleagues have developed numerous experimental approaches using cryopreserved hepatocytes and enteric systems to evaluate human specific drug properties including drug metabolism, drug-drug interactions, drug toxicity, and pharmacology.

Dr. Li holds several U.S and international patents, including the QuickRefreeze™ process to produce highly-functional pooled cryopreserved human hepatocytes, the Integrated Discrete Multiple Organ Co-culture (IdMOC™) system, used to co-culture multiple cell types, thus modeling the multiple organs in the human body that are interconnected by the systemic circulation, and the plated hepatocyte relay assay for the evaluation of slowly metabolized compounds. Dr. Li's latest inventions include MetMax™ Human Hepatocytes/Enterocytes and Cryopreserved Human Intestinal Mucosa (both patent pending). MetMax™ Human Hepatocytes has been chosen to be a winner of the US Environmental Protection Agency's Transform Tox Challenge as an exogenous metabolic activation system for in vitro assays. His laboratories continue to develop innovative assays and products to address the unmet needs of the drug discovery and development industry.

Dr. Li is a frequent organizer and speaker at international conferences, and has published over 180 research articles, book chapters, and reviews, and co-edited 5 books in toxicology and drug-drug interactions. He is on the editorial board for various journals, including Current Drug Metabolism, Drug Metabolism Letters, Chemico-Biological Interactions, Journal of Toxicological Sciences, and Toxicology and Cell Biology.

Dr. Li is currently President, CEO and co-founder of In Vitro ADMET Laboratories LLC, Columbia, MD and Malden, MA. Previously, Dr. Li was President and CEO of Phase 1 Molecular Toxicology, Inc. in Santa Fe, New Mexico, U. S. A. (2002-2003), Chief Scientific Officer of In Vitro Technologies, Inc., Baltimore, Maryland, U. S. A. (1995-2002); Research Professor and Director of the Surgical Research Institute, Department of Surgery, St. Louis University Medical School (1993-1995); Senior Fellow and Director, Liver Biology Department, Monsanto Company (1982 – 1993); Group Leader, Cellular and Genetic Toxicology, Lovelace Inhalation Toxicology Research Institute (1979 – 1982); Assistant Professor and Research Scientist, Cancer Research and Treatment Center and Department of Radiology, University of New Mexico (1976 – 1979). Dr. Li obtained his B. Sc. (1972, Chemistry) from the University of Wisconsin, Stevens Point, Ph. D. (1976, Biomedical Sciences) from the University of Tennessee, Oakridge Graduate School of Biomedical Sciences. He received his doctoral training and performed his dissertation research under Professor Abraham Hsie in the Biology Division of Oak Ridge National Laboratory, Oak Ridge, Tennessee, and MBA (2002) from the University of Maryland University College.

Abstract of lecture

***In vitro* hepatic and enteric experimental systems for the evaluation of human xenobiotic metabolism and toxicity**

Albert P. Li

President, CEO and Co-founder
In Vitro ADMET Laboratories LLC,
Columbia, MD and Malden, MA, USA

Because of species difference, laboratory animal results do not always accurately reflect human effects. In our laboratory, primary cell-based systems have been developed to aid the assessment of human xenobiotic metabolism and toxicity. We believe that experimental systems that can predict human effects require to have human-specific as well as organ-specific properties. For safety evaluation, human organ-specific drug metabolism is especially important as it is required for metabolic activation of nontoxic parent chemicals to toxic metabolites as well as metabolic detoxification of toxic parent compounds to less toxic metabolites. The *in vitro* human experimental systems include hepatocytes for hepatic events, enterocytes for intestinal events, as well as the patented Integrated Discrete Multiple Organ Co-culture (IdMOC™) system for the whole human organism.

Plenary Lecture

--(PL-05)--

Dipti M. Kapoor, PhD



Dr Dipti M Kapoor has a PhD in medical biochemistry from the University College of Medical Sciences and Guru Teg Bahadur Hospital, University of Delhi. Her thesis work was on identifying genetic markers for suicidal risks in subjects with stress and associated depression. Dr Kapoor is the science policy adviser at PETA India, working with several government committees and departments to replace animal testing with modern, humane alternatives. She is a member of several government committees, including the sectional committees for cosmetics and surface-active chemicals at the Bureau of Indian Standards and the committee on alternatives to animal

test methods at the Indian Pharmacopoeia Commission. She was also a specially invited to participate on the committee appointed by the Drugs Controller General of India to discuss the feasibility of replacing the Draize test in India with *in vitro*, non-animal methods. She is also a member of the subcommittee created by the pesticide registration committee, which discusses the guidance document that mandates the safety evaluation tests for the registration of chemical pesticides in India— along with other stakeholders, she is working for the adoption of *in vitro* and *in silico*, non-animal tests.

Abstract of lecture

Alternatives to the use of animals in regulatory and biomedical research in India

Dipti M. Kapoor

PeTA India

New Delhi

According to the 2017–18 report of the Department of Science and Technology (which is primarily a policymaking body for India's science and technology sector), the country's gross expenditure on research and development has been consistently increasing over the years and more than quadrupled in just over a decade, from Rs 24,117.24 crores in 2004–05 to Rs 1,04,864.03 crores in 2016–17. Of all the research funding from the Indian regulatory and governing agencies for biomedical research and regulatory policy development, a portion goes towards animal experimentation, even though an increasing number of studies show – and ever more scientists acknowledge – that the results of experiments using animals are often not reproducible or translatable to humans. A great deal of scholarly research shows that animal studies are flawed, diverting economic and intellectual resources from methodologies better suited to curing human disease. While multiple factors contribute to the failure of animal experimentation to predict human outcomes reliably, intrinsic biological and genetic differences between species contribute significantly to problems in extrapolating results from nonhuman animals to humans. A 2014 *BMJ* article by Pandora Pound and Michael Bracken observed that "if research conducted on animals continues to be unable to reasonably predict what can be expected in humans, the public's continuing endorsement and funding of preclinical animal research seems misplaced." Internationally, an evolving trend has shifted efforts away from animal-based research toward the new and rapidly evolving field of human-relevant, non-animal methods.

In this presentation, a number of strategic priorities, which PETA India has already discussed with the union ministers of Science and Technology and of Environment, Forest and Climate Change, will be discussed. The strategic priorities include the following:

- Immediately eliminate animal use in areas in which animals have already been shown to be poor and unreliable predictors for human reactions and have impeded progress.
- Conduct critical scientific reviews of animal use to identify the areas in which their use has failed to advance human health and should therefore be phased out.
- Work with agencies and bodies globally to harmonise and promote international acceptance of non-animal testing methods for regulatory toxicity testing requirements.
- Divert funds from animal studies towards the development of non-animal methods, including areas in which further development, validation, and implementation of non-animal methods are required.

Through these strategic priorities, we offer a robust blueprint to translate the restriction of animal use and an increase in the availability of human-relevant biotechnology into actions aimed at eliminating animal use in regulatory and biomedical research in India.

Distinguished Invited Speakers and their Lectures

--(IL-01)--

Barry Hardy, PhD



Dr Barry J. Hardy is leading Douglas Connect and its team supporting the development of new integrating solutions in industrial safety assessment. An example application is that for integrated testing for skin sensitization available at <https://its.douglasconnect.com/>

He has coordinated the OpenTox project in predictive toxicology and the ToxBank infrastructure development project. He is currently President of the OpenTox Association, founded in 2015 as an international non-profit organisation promoting an open knowledge community approach to new methods in predictive toxicology. He recently led the infrastructure development for the IMI EBiSC stem cell banking project and the eNanoMapper project developing OpenTox solutions supporting nanotechnology safety assessment. New projects include leading OpenRiskNet, knowledge infrastructure development for ACEnano and EU-ToxRisk and translation of research methods to industrial practice within ToxHQ.

He has led the development of research and best practice activities in drug design and toxicology through founding the eCheminfo Community of Practice, InnovationWell and leading the Scientists Against Malaria project. Dr. Hardy obtained his Ph.D. in 1990 from Syracuse University working in computational science. He was a National Research Fellow at the FDA Center for Biologics and Evaluation, a Hitchings-Elion Fellow at Oxford University and CEO of Virtual Environments International. He was a pioneer in the 1990s in the development of Web technology applied to virtual scientific communities and conferences. He has developed technology solutions for internet-based communications, tutor-supported e-learning, laboratory automation systems, and computational science and informatics.

In recent years, he has also been active in the field of knowledge management as applied to supporting innovation, communities of practice, and collaboration.

Abstract of lecture

Collaborative development of predictive toxicology and safety assessment resources - connecting people and data for decision-making

Barry Hardy

President, OpenTox Association and
CEO, Douglas Connect GmbH
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Hochbergerstrasse 60C
CH-4057 Basel/Basel-Stadt
Switzerland

I will discuss experiences and case examples within the history of OpenTox's first decade as we have navigated the journey from a vision of needing interoperability of resources to a developing practice of integrating evidence supporting applications evaluating the safety of new products including drugs, chemicals, cosmetics and new complex materials emerging from nanotechnology research and development. Through OpenTox we have aimed to

provide access to an increasing amount of scientific data, new methods and resources and to bring people, science, technology and data together into a community effort supporting collaborations aimed towards the goal of a "Safer World by Design", combining the design of new and novel products, while simultaneously protecting human and environmental health.

Solving such major challenges today requires the engagement of all stakeholders and greater resources than any of us can wield individually. To do so, we must work together to plan experiments, describe data and how to make it accessible, usable and actionable for specific purposes - ranging from scientific research to industry consortia and regulatory acceptance of information from new methods. Within OpenTox, we collaborate to develop specifications of the open standards and knowledge required to develop integration of resources in predictive toxicology supporting safety assessment applications. We need a common language, formally integrated within an ontology, to achieve semantic interoperability between resources. combined with the provision of distributed data and models aligned according to best practices supported by the international OpenTox community.

In this talk I will provide an overview of:

- A Brief History of OpenTox and its Principles;
- Best practices in Data Management and Harmonisation;
- Learnings on Collaborative Infrastructure Development;
- OpenRiskNet, as a community effort developing an open engineering infrastructure supporting risk assessment;
- European-Japan collaboration as demonstrated by Garuda-OpenTox developments;
- Combination of in silico and in vitro data as integrated evidence associated with Adverse Outcome Pathways;
- Emerging Practices in Evidence-based Assessment;
- Applications supporting drug discovery, cosmetics ingredient evaluation and nanotechnology product design.

Looking forward, I discuss challenges and proposed activities to bring people and diverse resources to the same table to accelerate international collaboration, that will support conversations and knowledge activities, leading to strong and rewarding outcomes.

--(IL-02)--

Indira Ghosh, PhD



Dr Indira Ghosh is Professor and ex-Dean at the School of computational & Integrative Sciences, JNU, New Delhi. Her areas of research include Computational Biology, Chemoinformatics & Systems Biology and its Application to Drug design. Indira Ghosh is working in JNU since 2008 as Dean & Professor to steer the School of Computational & Integrative sciences, which deals with computational approach to Biology, Chemistry, Economics etc. She has nourished the school as Center of Excellence under Department of Biotechnology (DBT), Govt. of India in Computational Biology and initiated a new stream supported by UGC, called Complex Systems, harvesting faculty from Physics and Econophysics.

She has been one amongst the earlier scientists to realize the importance in Bioinformatics and initiated M.Sc courses in Pune University when she joined as Professor in Institute of Bioinformatics & Biotechnology in Pune in 2003. She has completed her M.Sc. in Physics

from Calcutta University and completed her PhD at IISc, Bangalore in Molecular Biophysics in group lead by G.N.Ramachandran under the guidance of Prof. V.S.R.Rao. She had a postdoc experience in University of Houston, USA under Prof. J. Andrew McCammon as Fulbright Scholar during 1983-1986. She then joined CSIR lab at IICB, Kolkata for 2 years as scientist to establish the computational facilities for Biologist & Chemists, then joined AstraZeneca center at Bangalore as Sr. Scientist, which she continued till her come back to academia in 2003. Her research work in form of papers (~65 +4 book chapters) and funded projects (~10), has been contributing in part of Biophysics which later developed in early 90's as Bioinformatics and Computational Biology. She has published one of the first Docking algorithms in early eighties as a part of her thesis and during her post-doc developed novel method for difference in Free Energy of ligand binding to Biomolecules. Her major contributions are in the field of Bio & Chemoinformatics, using Systems Biology approach to find pathway & target enzymes, developing novel tools for molecular simulations and pharmacophore design using known protein structures.

Prof. Ghosh has participated in many projects in AstraZeneca center at Bangalore, involved in infectious disease and leads the team to find target(s) from genome of *M.Tb*, yielded in world patent. Her contribution in AZ in antimalarial project leads to achieve selectivity against *Plasmodium falciparum* vs. human, which was converted into lead molecule investigation. Her academic research group at University of Pune (SBPU) and JNU, has developed many programs and projects on finding Anti-Malarial compounds, Chemical Data-driven anti-Tb compounds and metabolite identification and pathway integration in plants (pfaldb.jnu.ac.in, chemtb.jnu.ac.in & <http://metabolomics.jnu.ac.in/>). Since last 15 years in her academia she has guided 12 PhD, 6 M.Tech & 25 M.Sc students, mentored 7 Research Associates to direct them towards the evolving field of Computational Biology.

She has been contributing immensely in designing courses for many Indian Universities for Bioinformatics & Computational Biology, including a member of core committee for recent release of recommended Syllabus in Biotechnology by DBT, Govt of India (http://www.dbtindia.nic.in/wp-content/uploads/Remodelled-Biotech-Curriculum_MSc-Biotechnology.pdf). During last 15 years she has been servicing as member or chair of Bioinformatics task forces in DBT, ICMR and DeITY (Ministry of Communication & Information Technology) respectively. She also started a course in 2006 in Clinical Data Management to provide skill set to doctors & biotechnologist in Pune with Public – Private Partnership concept. She started in 2006 a certificate examination call BINC under DBT support for providing quality education in Bioinformatics & Computational Biology, which has produced more than 200 certified candidates and nearly 40 PhD, it is presently pursued by BCIL, DBT. Recently she has contributed in development of computational Biology e-course under epg-pathshala (<https://epgp.inflibnet.ac.in/ahl.php?csrno=3>).

Prof. Ghosh has participated in EU commission aided multi-country project since 2008 www.opentox.org, organizer of the Translational Bioinformatics Conference in South Korea, Japan, China & USA, (2011-2017) <http://www.snubi.org/TBC2017/> and Faculty member of research Training on Intracellular Pathogen under U.S.-India Joint Research Training Program(2011-2014) : <http://www.seattle-india-gid.org/> and International Steering Committee member of QCMS (<http://www.qsar.org/>).

Abstract of lecture**Exploring chemical space in predictive toxicology****Rama Kaalia and Indira Ghosh**School of Computational & Integrative Sciences, Jawaharlal Nehru University,
New Delhi 110067. Indiaindira0654@gmail.com

Drug toxicity hinders drug development both at pre-clinical phase and clinical trials. Only 10 % of proposed drug candidates are approved to go for human testing. Even after approval, a drug can be found toxic and withdrawn which is very expensive for industry. To address the challenges of toxicity prediction in a cost-effective, time-saving and efficient way we have established a novel algorithm (Maxtox) to generate chemical descriptors (Maxtox FP) for chemicals using MCS-based (Maximum Common Substructure) approach[1-2] and to develop OECD validated models for toxicity prediction [3] with respect to four endpoint-specific datasets- Mutagenicity, Carcinogenicity, TD-50 and EPAFHM. Our in-silico toxicity prediction models can classify a chemical as toxic or nontoxic on the basis of chemical structural similarity with the compounds known to have toxic activity. We also identified the structural fragments responsible for toxicity. The effect of different parameters (like training set selection approaches and different machine learning methods) on predictive toxicology performances was also studied. We applied our best model of carcinogenicity prediction (MaxtoxRFrep_wholeCarcinogenicity model, 84% accuracy) to predict the carcinogenic activity of drugs used for treatment of diabetes. Out of 45 anti-diabetic drugs from Drugbank, 40% of investigational and 100% of withdrawn drugs were predicted to have carcinogenic effects, emphasizing early filtering of designed chemicals in the field of drug development.

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--(IL-03)--**André Kleensang, PhD**

Dr André Kleensang (M) received his university degree in biochemistry in 2001 from the University of Hamburg (Germany). Between 2003 und 2007 he was responsible for the biometrical and bioinformatics support within several genome wide genetic epidemiological studies at the Institute of Medical Biometry and Statistics at the Medical University of Luebeck/Germany. In 2007 he moved to the European Centre for the Validation of Alternative Methods (ECVAM) at the European Commission Joint Research Centre (JRC) where he was involved as a biometrics and

bioinformatics specialist in the development and validation of in vitro methods on international level. Since 2008 he worked with the same responsibilities for the systems toxicology unit at ECVAM and was until 2010 appointed member of the Institute for Health and Consumer Protection Scientific Committee of the JRC. Currently he works as Research

Associate at Johns Hopkins Center for Alternatives to Animal Testing (CAAT) and is faculty member at the department of Environmental Health Sciences at the Johns Hopkins Bloomberg School of Public Health. His main responsibilities are to combine various data-rich omics approaches to identify pathways of toxicity and developing, implementing and validating novel tools for pathway of toxicity identification. Due to his background in Evidence-based Medicine he supports as well the activities of the Evidence-based Toxicology program.

<Source: <https://www.jhsph.edu/faculty/directory/profile/2604/andre-kleensang>>

Abstract of lecture

Emerging alternatives to animal models for chemical hazard assessment in the 21st century

Dr. Rer. Hum. 13oil. André Kleensang

Center for Alternatives to Animal Testing (CAAT)
Bloomberg School of Public Health
Johns Hopkins University
Baltimore, MD, USA

Conventional toxicity testing typically involves studying adverse health outcomes in animals subjected to high doses of toxicants with subsequent extrapolation to expected human responses at lower doses. The low-throughput of current toxicity testing approaches (which are largely the same for industrial chemicals, pesticides and drugs) has led to a backlog of more than 80,000 chemicals to which human beings are potentially exposed whose potential toxicity remains largely unknown.

This talk will walk the audience over some of the recent developments towards the paradigm shift in human hazard assessment, away from the traditional *in vivo* animal studies towards new approach methodologies (NAMs). This follows mainly the vision of the 2007 U.S. National Research Council (NRC) Report on *Toxicity Testing in the 21st Century: A Vision and a Strategy* (TT21c). NAMs include different approaches such as *in vitro*, *ex vivo* or omic technologies; *in silico* and toxicokinetic modelling. The talk will also address some of the challenging limitations with the integration of NAM data into hazard assessment strategies, in particular for complex endpoints such as repeated dose or reproductive toxicity.

--(IL-04)--

Mohammed Idris, PhD



Dr Mohammed Idris has been working as Scientist at CSIR-CCMB, Hyderabad for more than 18 years. He obtained his Masters in Biochemistry from University of Madras and PhD from Open University, UK. He has been involved in various research program which includes, Molecular Diagnostics, Developmental biology and Neuroscience. His recent research work on Regeneration of tissues in alternate model animals and establishment of Chronic unpredictable stress model in zebra fish are hallmarks for his research work. He has published 45 research article in various journals. He is a recipient of several awards including Indian National award, CSIR- Young Scientist Award for Biology (2010).

Abstract of lecture

Biomechanism of regeneration and degeneration in alternate model animals – A molecular discovery study

Mohammed Idris

CSIR- Centre for Cellular and Molecular Biology
Hyderabad, India

My current research interests concern in understanding the complexity of developmental biology and neuroscience using alternate model animals such as zebra fish (*Danio rerio*), marine chordates (*Ascidian* sp.) and echinoderms (*Asterias* sp.). My research activity mainly focuses in understanding the molecular mechanism of regeneration and degeneration in these model animals involving proteomics, transcriptomics and CRISPR based gene knock down approaches. Regeneration of appendages in zebra fish, nervous tissue in ascidians and arms in echinoderms are the few of my major ongoing research activities. I am also interested in understanding the molecular and functional mechanism of neurodegeneration in zebra fish; due to triplet repeat expansion as like in spinocerebellar ataxia, chronic unpredictable stress as like in anxiety related mood disorders and chemicals as in Parkinson's disease model.

--(IL-05)--

Aamir Nazir, PhD



Dr Aamir Nazir is working as Senior Scientist in the Division of Toxicology and Experimental Medicine at CSIR – Central Drug Research Institute, Lucknow. He has had his education within the field of Toxicology obtaining his Masters and Doctorate degrees from Jamia Hamdard and CSIR-ITRC respectively, followed by a Postdoctoral Fellowship at Medical College of Georgia, USA and advanced research fellowships at University of Nottingham UK and University of Freiburg, Germany. He is currently spearheading the Laboratory of Functional Genomics and Molecular

Toxicology wherein his research team is employing various functional genomics and epigenetics approaches towards understanding the mechanistic aspects of neurodegenerative disease conditions. Employing genetic model system *C. elegans*, his research group makes use of genetics and pharmacological interventions including RNAi induced gene silencing, transgene constructs, Transcriptome analysis, micro RNA expression studies and associated aspects related to protein aggregation, cellular signaling and neuronal cell death, towards understanding mechanistic aspects related to human Alzheimer's and Parkinson's disease. Dr. Nazir has numerous accomplishments to his credit; he has been awarded with prestigious "Raman Research Fellowship", by CSIR, Govt of India, the "India Distinguished Visiting Fellowship" by the University of Nottingham, UK and Young Scientist Award by Department of Science and Technology, Govt of India. Dr. Nazir is an elected Fellow of Society of Applied Biotechnology, India; he serves on Editorial board of several international journals and is associated with multiple scientific societies and other professional bodies. Dr. Nazir is an author on 51 scientific publications and 3 book chapters. The research work from his group has received wide recognition and has been well funded by the Council of Scientific and Industrial Research (CSIR), Department of Science and Technology (DST) and Indian Council of Medical Research, Govt. of India. The aim of Dr. Nazir's research activities is to identify novel genetic modulators of neurodegenerative diseases that could lead towards designing of specific therapeutic agents against these ailments.

Abstract of lecture

Functional genomics and epigenetics studies employing *C. elegans* models of neurodegenerative diseases: Implications for mechanistic understanding and drug discovery efforts

Aamir Nazir, PhD

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Disease research warrants use of efficient model systems that could be beneficially exploited towards assaying specific endpoints relevant to human conditions. Neurodegenerative diseases, that do not find a complete cure yet, have proven to be very challenging to treat because of their multifactorial nature. Immense progress, though, has been made towards understanding the mechanistic aspects of these disease conditions particularly via employing genetic model systems including nematode *C. elegans*. The well deciphered genome, orthology of genes, ease of genetic manipulation, fully described nervous system and multiple technical advantages make *C. elegans* a powerful system for neurobiology and aging studies. We employ various transgenic, RNAi based knockdown and mutant strains in our endeavour of identifying novel genetic modulators of age associated Parkinson's and Alzheimer's disease conditions. In the present study, we report on the association of novel circular RNA molecules with that of Parkinson's disease. Circular RNAs (circRNAs) are a class of non-coding RNAs, which are produced by scrambling of exons at the time of splicing. These molecules are known to act as miRNA sponges thereby modulating the repression function carried out by miRNAs; thus a single molecule affects hundreds of its target genes. Considering the multi-factorial nature of Parkinson's disease, we hypothesize presence of a common circRNA/microRNA trigger for the multiple manifestations of the ailment. We studied these molecules employing transgenic *C. elegans* strain expressing 'human' alpha-synuclein along-with YFP reporter gene. Using the approach of RNaseR-exonuclease treatment of total RNA, followed by amplification using divergent primers, we validated the presence of two very well expressing circRNAs in *C. elegans*. We further went on to validate their sequence and carried out functional genomics studies with their synthesizing genes. Employing RNAi, we studied the associated endpoints of alpha-synuclein aggregation in transgenic *C. elegans* model followed by whole transcriptome analysis employing NextGen sequencing on IlluminaNextSeq 500 platform, which revealed a number of interesting targets thus furthering our understanding of PD via identifying novel circular RNA molecules which could prove to be of immense theranostic relevance.

--(IL-06)--

AB Pant, PhD



Dr AB Pant (FST, FATS, FIAN, FASAW, FAEB, MNASc, MAMS) is a Principal Scientist, System Toxicology & Health Risk Assessment Group CSIR-Indian Institute of Toxicology Research Lucknow Dr Pant is a seasoned toxicologist, started his research career over twenty-seven years back at Central Drug Research Institute, Lucknow, India. He is an alumnus of the Department of Biotechnology, IIT Roorkee, Uttarakhand, India. Since 1997, he is serving at Indian Institute of Toxicology Research, Lucknow, India. In the scientific fraternity, Dr Pant is regarded for establishing the cell based models as alternatives to laboratory animals for neurotoxicity/ developmental neurotoxicity, cytotoxicity, pyrogenicity, phototoxicity,

hepatotoxicity, genotoxicity, oral-toxicity. He has been instrumental in establishing the laboratory for stem cell research in Lucknow and became renowned for his elegant research on application of human cord blood stem cells (hCBSCs) in developmental neurotoxicity (DNT). His research group has demonstrated the mapping of cellular and sub-cellular events of differentiation of hCBSCs into morphological and functional neuronal cells. His DNT research provides deep insights into the complex processes involved in neuronal development, injury and repair mimicking to the human brain during the gestation and early stage of life. More precisely, his work discovered that how the master regulator signalling molecules/ cascades are critical to convert hCBSCs into functional neurons and what exactly happens when things go wrong during the intricate process of neuronal development. In his much-acclaimed research, he has uncovered novel links between the xenobiotic metabolizing capabilities and their regulators in hCBSCs derived neuronal cells all through the differentiation. His work on the developing neurons not only offers a much sought after framework for understanding the neurodegenerative disorders and potential therapeutic interventions, but also is a strong base for future studies aimed at interpreting the human brain specific DNT.

Besides the laboratory work, he dedicated himself to fostering the science among students through public outreach talks and mentoring pre-and post-doctorates. Since 2010 he has also been associated with National GLP Compliance Monitoring Authority of India as GLP Inspector. The accreditation agencies of the country-BIS, DCGI, NABL, Pharmacovigilance, etc. are also utilizing his expertise. He was a member in the draft committee of "National SOP for Patients' Consent in India" developed by the Institute of Medicine & Law, Mumbai. As an International Advisor, he has been instrumental in establishing the WHO funded "Centre of Excellence for Nanotechnology" at Makerere University, Uganda. Recently, he is culminating a task to address the challenges of a neglected neurodegenerative disorder- Amyotrophic Lateral Sclerosis by utilizing an investigator driven federal funding under Indo-Brazilian project. In the acknowledgement of his achievements in the professional career, he has been elected Fellow Several Scientific and Academies bodies, to name a few are: Academy of Toxicological Sciences, USA, Society of Toxicology, India, Indian Academy of Neurosciences, Academy of Sciences for Animal Welfare, India, Academy of Environmental Biology India, etc. Dr Pant is a recipient several prestigious awards such as Shakuntala Amir Chand Prize-2007 (ICMR), Vigyan Ratna Award-2010 (UP-Council of Science & Technology-Uttar Pradesh), National Bioscience Award-2012 (DBT), Prof. KT Shetty Memorial Oration Award-2017 (Indian Academy of Neurosciences), Toxicology Promotion Award (National Academy of Sciences, Allahabad), etc.

Abstract of lecture

Alternatives to laboratory animals: which side of history do we finally want to be?

AB Pant

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The time has come when all the stakeholders must speak in one voice that animal testing would be the "last resort," when alternative methods are available. It will strategize a proactive growth of alternative methods with "fail early, fail cheaply" principle and expedite a way for quick, easy, time and cost-effective means of drug development/ screening/ toxicity testing. Such reproducible, rapid, economical and high-throughput models will not

only generate accurate results but will also be quite instrumental in reducing the clinical trial failure rates and getting rid of the ethical burden of animal euthanasia. Despite these efforts, suitable alternative tests that are already approved in the world are not yet available in all areas of biomedical research in India. Research into the development of alternative approaches have so far resulted in the incorporation of a panel of new cell and tissue culture systems and *in-silico* models, but their maximum utilization have been hampered as regulatory acceptance requires time, prior validation, robust financial and scientific investments. Thus various gaps remain to be bridged when it comes to the transition from conventional into technologically-assisted alternative methods, and a great deal still needs to be done before it will be possible to eliminate animal testing. By channeling funding away from poorly predictive animal models and towards genuinely path-breaking research into human-focused, non-animal technologies, we can both understand human disease biology better and put animal cruelty behind us. Which side of history do we finally want to be?

--(IL-07)--

Brinda Poojary, PhD



Dr Brinda Poojary is the Science Advisor for the Research and Toxicology Department of Humane Society International – India. Dr Poojary has a PhD from Mumbai University in Zoology. Having worked as an embryologist for more than half a decade, her PhD concentrated on the external physical and chemical factors affecting male infertility. Being a proponent of human-centric science from the start, her research was designed to study the effects of various factors only on human spermatozoa, rather than the commonly and widely used mice models. A

firm believer in innovation and the ethical practice of science, she now applies her research knowledge to forward 21st century human-focused approaches to research and toxicology studies and to bring about regulatory changes for the same.

Abstract of lecture

India's roadmap on the alternatives to animal experimentation

Brinda Poojary

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In 2013, a landmark judgement to ban cosmetic testing of animals along with the ban to import animal tested cosmetics made India one of the first countries in Asia to do so. Prior to this in March 2013, European Union implemented its prohibition on animal testing for cosmetics and the import and sale of animal tested cosmetics in the region. This led to companies giving alternative testing methods a serious thought which led to innovation, in turn increasing confidence in validated *in-vitro* and other non-animal methods, invariably increasing the demand for investment from the public and private sector into human-centric technology infrastructures, and continuing education and training to conduct and interpret available and internationally recognized non-animal methodologies. Developed countries like US, UK, and the Netherlands are progressing towards phasing out animal studies and thus have produced strategic roadmaps to achieve this goal. With the advent of the 'Make in India' initiative, the time is ripe for India to invest in progressive science. In addition to investing in research dedicated to 21st century tools in health research and toxicology testing, focus needs to be directed towards training and educating scientists, thus

encouraging the adoption of human-centric research and testing. While a few regulators have paved the path for innovation and investment into these non-animal methods, the biomedical research fraternity hasn't sown the seeds of non-animal technologies yet. While biomedical research and regulatory testing almost seems like a chicken and egg situation, it is imperative for both to go hand in hand for science to advance in India. India must take steps to prevent itself from lagging behind in innovation and technology in the field of biomedical research. Further, a consolidation of this initiative would be to build a committee to validate these developed tools in India to have a self-sustained regulatory system in place.

--(IL-08)--

MA Akbarsha, PhD



Dr MA Akbarsha is currently Coordinator-Research at National College (Autonomous), Tiruchirappalli, India. Formerly, he has been Professor of Animal Science & Biomedical Science; Founder, Director and Chair, Mahatma Gandhi - Doerenkamp Center for Alternatives, Bharathidasan University, Truchirappalli. Specialized in: Alternatives to animal experiments. *In vitro* toxicology. *In silico* toxicology. Animal cell culture techniques. Alternative model organisms. Endocrinology. Reproductive Biology. Cancer Biology. Obesity.

Served as Faculty in Zoology at Jamal Mohamed College, (1970-86); Reader in Animal Science (1986-95), and took to positions such as Professor of Animal Science and Biomedical Science, Director, Center for Distance Education, Co-Ordinator- School of Life Sciences, and Dean- Faculty of Science (1995-2008); More than 250 publications; more than 10 research grants (Rs. 6 crores); Supervised 25 Ph.D. students; Addressed more than 300 National and international conferences; Conferred MRE, FRE and Prof P. Govindarajulu Endowment Gold Medal Oration award of SRBCE; One term President of SRBCE; Editor in Chief, Journal of Endocrinology and Reproduction (2006-till date). Retired from regular service in 2008; Emeritus Professor of Life Sciences (2008-9). In 2009, established the Mahatma Gandhi – Doerenkamp Centre (MGDC) for Alternatives at Bharathidasan University, with full fund support from Doerenkamp – Zbinden Foundation, Switzerland (2009-16). The Center has been propagating the science of alternatives to animal experiments throughout India supported by training to stake – holders in digital, *in vitro*, and *in silico* alternatives and alternative model organisms; attended World Congresses 7 (Rome, 2009), 8 (Montreal, 2011), 9 (Prague, 2014) & 10 (Seattle, USA, 2017) on Alternatives. Addressed Annual meeting of Japanese Society for Alternatives to Animal Experiments (2015) and the Asian Congress of Alternatives Conducted by JSAAE. Conducted 70+ workshops on digital alternatives; 20+ on in vitro toxicology; 5 on handling of 3D reconstructed human epidermis models; one each on Integrated discrete Multiple Organ Co-culture (IdMOC) and Systems Biology. MGDC is now taken over by UGC-funded National Centre for Alternatives to Animal Experiments. Facilitated CPCSEA in organizing programs on alternatives; Editorial Board Member, *ALTEX* (Springer); Spearheading the alternatives movement in India; Initiated effort and formed the team to establish the Indian Society for Alternatives to Animal Experiments (ISAAE). Coordinator- Research, at National College, Tiruchirappalli since February 2018.

He is the main moving force behind NCAAE-2018.

Abstract of lecture

Relevance of invertebrates as alternative model organisms with special reference to Hydra

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Testing of chemical entities in mammalian model organisms is believed as gold standard in pharmacology and toxicology. In the light of emergence of 3Rs from perspectives of ethical considerations as well as species differences, alternative model organisms are strongly recommended. The Tox-21c recommends the use of invertebrate animal models for eco-toxicological investigations. The more recent Frank R. Lautenberg Chemical Safety for the 21st Century Act has advocated a moratorium on the use of vertebrate organisms in toxicity testing, providing scope for invertebrate organisms and *in silico* approaches in the place of vertebrate organisms. We are standardizing methods to develop *Hydra*, a freshwater cnidarian, as model organism for risk assessment of chemicals which pollute the waterbodies. Though simple in organization and biology, it is much complex compared to cultured cells, which make it a suitable organism for eco-toxicity testing. *Hydra* offers advantages such as easy to culture, reproduces fast, cost-effective and highly sensitivity to inorganic pollutants. Whole genome sequencing of *Hydra* has revealed conserved sequences and signaling pathways. The data to be presented here will demonstrate the versatile behavior of *Hydra* and suitability of *Hydra* for toxicity testing of nanomaterials as well as their bulk counterparts. Acute and chronic studies performed with sub-lethal doses of nanoparticles revealed physiological, developmental and behavioral responses in *Hydra*. Metagenome sequencing revealed influence of nanoparticles on commensal bacterial population and the factors that contribute to maintain the bacterial community structure. Molecular studies uncovered the underlying mechanism of toxicity in a manner very precise. TEM analysis revealed sub-cellular alterations and accumulation of nanoparticles within the cells of *Hydra*. The data to be presented will substantiate use of *Hydra* as a model organism for eco-toxicity testing. If validated, *Hydra* as an alternative model organism will be a remarkable contribution from India.

--(IL-09)--

PV Mohanan, PhD



Dr PV Mohanan is Scientist-G & Head at Toxicology Division, Biomedical Technology Wing, Sree Chitra Tirunal Institute for Medical Sciences and Technology (Government of India), Thiruvananthapuram. Dr. Mohanan has immensely contributed in the area of toxicology. He has made significant contributions for the development of medical device industry and medical device regulations in India, and India getting GLP membership in OECD countries. He received certificate of appreciation from the Hon. Minister of Science and Technology, Govt. of India for the contribution to India getting full adherent status on GLP from OECD. Mohanan has been

teaching toxicology to PhD, MPhil, MTech, Postgraduate diploma/certificate courses. He has completed several externally funded research projects as Principal Investigator. He has developed and patented an *In vitro* pyrogen kit for the measurement of pyrogenicity. As a material toxicologist with 30 years of experience, he has been intimately associated with all the medical devices/technologies developed at SCTIMST, Govt. of India. He was a JSPS Post doctoral and Bridge Fellow, He is a visiting Professor and a Visiting Researcher at Toyo University, Japan. He is a Fellow of Society of Toxicology, Fellow of Society of Applied Biotechnology and Fellow of Academy of Sciences for animal welfare. He has authored 175 publications, edited 3 books and 4 conference proceedings.

At present he is the General Secretary of Society of Toxicology (India).

Abstract of lecture

ELISA method for the detection of Interleukin-1 β : An alternative to pyrogen assay

PV Mohanan

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The rabbit pyrogen test based on the intravenous injection of a sterile solution was adopted for many years for the quality control of parenteral preparations. New therapies such as recombinant human proteins or cellular therapeutics, the rabbit pyrogen assay is unviable due to false positives resulting from species specificity in the immunological recognition of these agents. The *in vitro* Limulus Amoebocyte Lysate (LAL) assay, detects only one class of pyrogen, endotoxin from gram negative bacteria, leaving the patients at risk from undetected non-endotoxin pyrogens such as gram positive bacterial toxins, viruses and fungi.

The objective of the present study is to detect the pyrogenicity of five medical grade gelatinous polymer materials, intended for the manufacturing of capsule for pharmaceutical applications, by an indigenously developed ELISA, LAL and rabbit pyrogen assays. The ELISA methodology includes the incubation of the sample extract with blood from a healthy donor at 37°C. Any pyrogen present in the extract induces the Interleukin-1 β (IL-1 β), which can be determined by ELISA. The rabbit pyrogen and LAL assays were performed as per standards.

The result of the ELISA method indicated that all the materials extract induced high level of IL-1 β as a marker for pyrogenicity. The rise in temperature of rabbit pyrogen was above 0.5°C in all materials extract. LAL assay induced an endotoxin level above 0.5EU. All the five polymer materials were found pyrogenic in all the assays. The ELISA method is very sensitive because the lowest limit of detection was 10pg/ml endotoxin. Hence it can be concluded that the ELISA method will be an added advantage for the quality control release of a batch of medical products and improving the existing methodologies in the context of reduction and replacement in the use of animal models.

--(IL-10)--

Vijay Pal Singh, PhD



Dr. Vijay Pal Singh is at present Deputy Director (Risk Assessment Research & Development) in Food Safety and Standard Authority of India, Govt of India. Earlier he served as Veterinarian in CSIR-Institute of Genomics and Integrative Biology and as Assistant Professor in Academy of Scientific and Innovative Research (AcSIR). Dr. Vijay Pal Singh is a Graduate in Veterinary Medicine, Post graduate in Dairy Husbandry and milk processing and Doctorate in Biotechnology. He studied Animal Welfare Ethics and Law from Cambridge University, United Kingdom. Dr. Singh has more than a decade of experience in animal welfare. He has played a pivotal role in conducting 3 international courses on Laboratory Animal Science as a part of improving the research being done on lab animals in a more ethical and humane way possible. He has 31 indexed research articles in indexed journals along with a vast experience of teaching and attending several international courses on lab animal science and animal welfare.

Dr. Vijay Pal Singh is specialist in Lab Animal Science from Utrecht University Netherlands; Adhoc-specialist, International Association for Assessment & Accreditation of Laboratory Animal Care (AAALAC); Ambassador, Systematic Review Centre for Laboratory Animal Experimentation (SYRCLE), Radboud University, Netherlands; Member Electronic Working Group (EWG) - the Joint FAO/WHO Expert Committee on Food Additives (JECFA); Member of the International Scientific Committee (ISC) of the 11th World Congress on Alternatives and Animal Use in the Life Sciences, to be organized in Maastricht, The Netherlands; International Society of Applied Ethology (ISAE) Country Liaison for India.

Abstract of lecture

Risk Assessment of Chemicals/Additive in Foods: Reducing animal usage

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Foods can contain many harmful substances, including pesticides, unhealthy additives or contaminants. Chemicals can end up in our food in various ways. Some trace amounts of chemicals may be used during production, transport, or storage of food products or some trace compounds may get produced during the course of food production or preparation. Chemicals can, however, have a variety of toxicological properties, some of which might cause health effects in humans and animals. Usually, these are not harmful unless exposed to them for a long time and at high levels. Risk assessment is the central scientific component of food safety analysis and was developed primarily because of the need to make decisions to protect health in the face of scientific uncertainty. Risk assessment of food chemicals can be generally described as characterizing the potential hazards and the associated risks to life and health resulting from exposure of humans to chemicals present in food over a specified period. The extent to which a food additive can pose a health risk depends upon its toxicity and the dietary exposure. ADI values are calculated using a safety factor which ensures that if the additive is consumed daily at that level for the rest of one's life, there would be no "noticeable health risk".

Food additives require to undergo a vigorous risk assessment procedure before their approval and entry into the market. Components of the process of risk assessment are hazard identification, hazard characterization, exposure assessment and risk characterization. The scientific process of risk assessment not only estimates human risk associated with consumption of food additives but also assists in arriving at and establishing the ADI values for food additives.

--(IL-11)--

Adip Roy, PhD



Dr. Adip Roy has a Ph.D. in Toxicology and is Head – Regulatory Affairs, at Amway India Enterprises, Gurgaon. Adip did his Ph.D. from ITRC, Lucknow (now Indian Institute of Toxicology Research) where he worked on the restorative potential of neural transplants in chemical induced neurotoxicity. Following his Ph.D, Adip was a Post-doctoral Fellow at the Psychiatric Institute, University of Illinois at Chicago. Adip's Postdoctoral research was on the Neurobiology of Addiction where he looked mainly into the role cAMP dependent signalling pathways in the brain during nicotine and alcohol addiction (tolerance, dependence and preference). Before joining Amway in, Adip was a Lead Toxicologist at Unilever looking after toxicological safety evaluation of new ingredients and pursuing S&T activities on animal alternatives. Currently, Adip leads the Regulatory compliance activities for Amway India for the whole portfolio of products

Abstract of lecture

New frontiers in safety and toxicological assessment

Adip Roy

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As with any material contacted or consumed, there are recognized hazards associated around ingredients that are present in cosmetic products. The erstwhile hazard based principles for managing ingredient safety are not relevant in the current context and a scientifically robust, risk-based approach, which considers both the hazard and exposure scenarios, needs to be adopted for managing safety of ingredient and products.

Risk assessment for ingredients in cosmetics is carried out using a multi-step process viz. Hazard identification, Hazard characterisation, Exposure assessment and Risk characterisation. These steps of risk assessment help in the safety assessment and identification of a safe level of ingredient which can form a part of a cosmetic formulation.

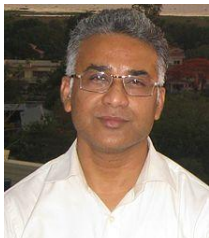
With new regulations around animal testing, assuring consumer safety of novel ingredients without the generation of any animal data is a considerable challenge. Assessing safety using non-animal methodologies implies developing novel toxicological risk assessment strategies and a fundamental change in the way safety assessments are carried out.

To date, there has been considerable progress in the development, validation and acceptance of non-animal approaches for some toxicological endpoints (e.g. assays for skin irritation, eye irritation, skin penetration, skin sensitization, genotoxicity and phototoxicity).

However, assuring consumer safety of novel ingredients without any animal testing remains a formidable challenge. Several private and Government institutions in India are also actively pursuing research for developing alternate methodologies for assuring human safety. We remain convinced that, with continued long-term research investment, this goal is ultimately achievable.

--(IL-12)--

Syed Ziaur Rahman, MD, PhD



Dr. Syed Ziaur Rahman, MD, PhD, FIMSA, MAMS, CMCL-FAIMER Fellow is Professor at Department of Pharmacology Deputy Medical Superintendent, Jawaharlal Nehru Medical College Hospital Aligarh Muslim University Aligarh, India. Prof. Syed Ziaur Rahman believes in the philosophy of '3Rs' of Russell and Burch" on humane experimental pharmacology. He gave series of lectures during 2004 at "Alternatives, Animal Welfare and the Curriculum – A training Seminar and Workshop" in different cities of India. He addressed in the meetings of International Network for Humane Education (InterNICHE) and International Centre for Alternatives in Research and Education (I-CARE). On the recommendation of Medical Council of India (MCI), and after getting survey related to the attitude of undergraduate medical students towards Alternatives to animal testing and Animal experiments, he initiated and established a separate lab on "Alternatives to Animal Experimentation" in the Department of Pharmacology at Jawaharlal Nehru Medical College in 2006. 12 years back, this was a first attempt in any medical college of India to have an exclusive lab where experimental work on animals was demonstrated by Computer aided education. In addition, he edited "A guide to alternatives to animal experiment in pharmacology", which was included in the curriculum of second professional MBBS course. He even translated few papers into Urdu in the field of Alternatives to animal testing.

Abstract of lecture

Teaching and Learning of Experimental Pharmacology by Alternatives

Syed Ziaur Rahman

In-charge, Alternatives to Animal Experimentation Lab
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Animal experiments are an integral part of pharmacology teaching at both modern and traditional medical colleges in India. There have been few studies that have tried to define the relevance of animal experiments in undergraduate teaching and learning including the attitude of the medical students towards them. It has also become difficult to do animal experiments because of issues related to procurement of animals, strict regulations, ethics, change in attitude for animal experiments and finances. Various government agencies and committees including MCI, UGC and CPCSEA issued guidelines and notifications to use alternatives for undergraduate (MBBS/BDS) teaching and learning. Consequentially, many medical colleges in India have either introduced alternatives to these experiments or are debating the issue. The issue of discomfort while teaching with the aid of animal models for training and skills has always been in debate. The issue has been discussed in depth by W.M.S. Russell and R. Burch (1959) in their scientific treatise *The Principles of Humane Experimental Technique*, and these authors brought up the concept of 3Rs- "Replacement, Reduction and Refinement" of animals in experiments. The 3Rs concept is also known as

"alternatives". Thus, there has been intensive research to find alternatives to animal experiments. *In vitro* and *in silico* approaches have been found to be the best alternatives. These alternatives emanate from applications of biotechnology. *In vitro* approach makes use of cell lines that human end points are assessed and precludes the issues of species difference. Depending on the context and relevance, innumerable established cell lines could be used. The present author at his department has been teaching and demonstrating animal experiments through computer based simulators/ software for the last 13 years. The department initiated and established a separate lab on "Alternatives to Animal Experimentation" in 2006. This was a first attempt in any medical college of India to have an exclusive lab where experimental work on animals was demonstrated by computer aided education. There are around 53 software-based pharmacology experiment teaching modules in the Department. Few of these simulators accepted in the revised curriculum and help undergraduate students in learning the basic concept of pharmacology in a better, interactive and user-friendly manner. In addition, the author edited "A guide to alternatives to animal experiment in pharmacology", which is included in the syllabus of second professional MBBS course. In the present paper, author would share his experience in the above discipline.

--(IL-13)--

Subrahmanyam Vangala, PhD



Dr. Subrahmanyam Vangala is the Founder and Chief Executive Officer, ReaGene Biosciences Private Limited. He is an experienced pharma scientist and executive with more than two decades of leadership experience with increasing responsibilities, at global pharma in USA (Wyeth, JNJ, Purdue Pharma and Shire) and Contract Research Organizations in India (Sai Life and Advinus). He received his PhD Degree in Biochemical Mechanisms of Chemical Carcinogenesis from the Department of Biochemistry, Memorial University of Newfoundland, Canada. He conducted his postdoctoral research in Molecular Toxicology department at University of Colorado at Boulder, and continued as a Specialist Scientist (Research Assistant Professor) in Molecular Toxicology at School of Public Health, University of California, Berkeley. His industrial experience was focused on, but not limited to, new drug discovery and development with expertise in DMPK, Bioanalytical, Clinical Pharmacology and Toxicology. Supported more than 30 IND and 10 NDA submissions including ANDAs. Dr. Subrahmanyam to his credit worked in preclinical development programs for marketed new drugs including Zaleplon, Tygacil and Canagliflozin. He has interacted in project teams representing Toxicology, DMPK, Bioanalytical and Clinical Pharmacology research and reviewed data packages of new drug candidates nominated for preclinical development and clinical development. Other areas he gained knowledge include drug-drug interactions, pre-formulation development, drug repurposing, specialty pharmaceuticals, generics, biologics/biosimilars, medical devices, pharmacogenomics, and metabolomics. He participated in several due-diligence activities involving in-licensing activities. He brings with him, unique insights into translational research. He is on the scientific advisory board of Bioagile Therapeutics and on the editorial board of journals related to toxicology and analytical research. He has 50 plus peer reviewed publications in peer reviewed journals including invited book chapters. He has chaired several international symposia in predictive toxicology, idiosyncratic drug toxicity and DMPK.

Abstract of lecture

Could human on a chip end animal testing?

Subrahmanyam Vangala

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Millions of animals are routinely used in agrochemical and pharmaceutical industries to predict safe and/or efficacious doses for humans to prevent any undesirable side effects in humans. Despite the extensive research in animals, more than 90% of clinical trials in humans fail due to unanticipated adverse events or lack of efficacy casting doubt on the value of animal use in predicting human safety. Current regulations by global and regional animal welfare agencies (e.g., AAALAC, CPCSEA) have defined protocols on ethical usage of animals but these guidances have not yet significantly helped in minimizing the animal use in research. Further, regulatory agencies like US-FDA, EMA, ICH have released several guidelines on good laboratory practices and globally harmonized protocols but had little impact on minimizing the animal use in research.

Past couple of decades have seen significant development of alternatives to using animals which include *in silico* models as well as in vitro animal and human systems. Nevertheless, the regulatory mandated animal studies are still the accepted norm for the registration of any chemical prior to their launch in the market.

There is a tremendous opportunity for research companies in India to become global leaders in creating alternative to animal research. In this presentation we will describe some well used *in silico* and in vitro models, their advantages and disadvantages. With the advent of new human on a chip technologies, there is great hope for designing better clinical trials with successful clinical translation and outcomes.

--(IL-14)--

Ekta Kapoor, PhD



Dr. Ekta Kapoor works as Scientist 'E' in the Department of Science and Technology, Government of India and a full time GLP Inspector of National Good Laboratory Practice Compliance Monitoring Authority (NGCMA) of India. She is a Doctorate in Pharmacy (Pharmacology). Dr. Kapoor has over a decade of experience in GLP compliance monitoring and is a 'Lead Inspector' of NGCMA. The committed and sustained efforts of Dr. Kapoor led to the quantum growth and visibility of NGCMA and its activities. She had been instrumental in the rigorous exercise for attaining India a full adherent status to 'Mutual Acceptance of Data' (MAD) in the OECD's Working Group on GLP. Dr. Kapoor represents India in the meetings of the OECD Working Group on GLP. She has conducted the On-Site Evaluation of GLP Programmes of Canada, Japan and Thailand.

Abstract of lecture

**Good Laboratory Practice aspects in toxicology, safety and drug development:
The OECD perspective**

Ekta Kapoor

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Many countries globally mandate conduct of non-clinical and environmental fate studies meant for regulatory submissions in compliance with the quality system of Good Laboratory Practice (GLP). The genesis of the GLP in 1970s and the recommendation of the Organization for Economic Cooperation & Development (OECD) Council for adoption of the Principles of GLP by member countries in 1981 for Mutual Acceptance of Data (MAD) were of great significance in safety evaluation of chemicals and other test items. Since then many OECD member countries started adopting the OECD Council decisions. Considering the importance of the GLP quality system for data generation to meet global requirements, certain Indian industries & CROs established GLP test facilities in early 1990s and received GLP certification from the monitoring authorities of a few OECD member countries namely Germany, The Netherlands, Belgium. The initiatives of the Indian industry in setting up GLP compliant test facilities as well as the OECD Council decision of 1997 concerning the adherence of non-member countries to MAD led the Indian government to establish the National GLP Compliance Monitoring Authority (NGCMA) in 2002 under the Department of Science and Technology. The genesis of the NGCMA and its subsequent role in compliance monitoring, including certification of test facilities in India, provided opportunities for the then existing and new test facilities to conduct studies for global and Indian sponsors. Continuous efforts of the NGCMA resulted in India achieving the coveted global recognition of Full Adherence status for MAD by the OECD Council in 2011. This presentation covers an overview of the importance of GLP, MAD system, genesis of the NGCMA, GLP inspections and growth of GLP test facilities in the country.

Young Scientists' Oral Presentations

--(OP-01)--

A case study approach to next generation risk assessment for consumer safety of cosmetics

Jayasujatha Vethamanickam

Safety and Environmental Assurance Centre
Unilever R&D
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--(OP-02)--

Phase - 0 Studies: An innovative alternative tool to animal experiments

Nusrat Nabi, Arunabha Ray

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Phase 0 trial, also called microdosing studies, was developed as an innovative tool in the drug development process to evaluate new drugs more efficiently and as an alternative to minimise extensive preclinical animal experiments. Such studies explore the pharmacokinetic and pharmacodynamic profile of a drug under investigation in human beings at very low concentration with a non-pharmacologically active dose; involving 1% of the drug required to produce pharmacological effect. In phase 0 trials, the selection of number of subjects, duration of exposure and also the dose (single dose only) for a newer compound with promising pharmacological activity is usually very small. Hence, phase 0 studies aid in reducing the risk of toxicity in humans and requirement of preclinical safety package for the phase I trial. Phase 0 trials are also expected to play a pivotal role in overcoming the major concern of ethics related to animal experiments and few more disadvantages like requirement of skilled manpower, time consuming protocols and high cost. They bridge the gap between traditional preclinical testing and clinical studies and are intended to provide a better understanding of a new compound's pharmacological profile and target localization before initiation of Phase I trials. Phase 0 trials are of particular benefit in oncology to establish at the very earliest opportunity-before large numbers of cancer patients have been accrued and exposed to potential drug-associated toxicity-whether an agent is modulating its target in a tumour, and consequently whether further clinical development is warranted. Although studies are yet to be done for phase 0 trials, it can be recognized that phase 0 trials would provide an opportunity to generate essential human pharmacokinetic and pharmacodynamic data much earlier in a drug development process, thus potentially reducing the requirement of initial preclinical studies and time-to-first-in-human testing.

Unfortunately, in India the process of regulatory reform in drug development process including phase 0 studies or other equivalent exploratory studies has stagnated due to which we are not able to pace with the international drug development process. We hope that this deliberation sensitizes the panel of experts on pharmacology and the august delegates attending the conference and translates into an initiative exploring the phase 0 trials, taking them to their logical culmination.

--(OP-03)--

Neurotoxicity and astrocyte activation: a study on cell-specific responses of rotenone

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Rotenone is a well-known neurotoxic pesticide which inhibits the mitochondrial complex-I and causes toxicity. In the present study, toxic effects of rotenone were investigated on neuronal (Neuro-2A) cells in comparison to non-neuronal (astrocyte C6) cells in vitro. Here we present our findings of involvement of different mechanisms in rotenone-induced neurotoxicity and its comparative profile with rotenone-induced astrocytes activation and toxicity. Study on neuronal Neuro-2A cells showed the involvement of oxidative stress and endoplasmic reticulum (ER) stress in rotenone-induced neuronal death. Increased DNA damage and expression of caspase-12 and 3 confirmed the apoptotic cell death in Neuro-2A cells. Treatment of ER stress inhibitor- salubrinal offered significant protection against rotenone-induced biochemical alterations, ER stress and apoptosis, indicating the key role of ER stress in rotenone-induced neuronal death. Rotenone treatment to C6 cells did not lead to the induction of ER stress, suggesting that rotenone treatment exerts cell-specific toxic effects. However, rotenone treatment to C6 cells caused cytotoxicity, oxidative stress, DNA damage and apoptosis, which were inhibited with melatonin treatment, suggesting the key role of oxidative stress in rotenone induced astrocytes toxicity. Further, rotenone-induced astrocytes activation, observed by GFAP expression in C6 cells, was also prevented by melatonin treatment showing that rotenone causes oxidative stress mediated astrocytes activation. Investigation on neuronal Neuro-2A and astrocyte C6 cells suggested that rotenone exerts cell specific death mechanisms. In neuronal cells the rotenone induced cell death involves both oxidative and ER stress as major events while in astrocyte C6 cells it mainly involves oxidative stress.

--(OP-04)--

Assessment of photosensitization potential via In Chemico Direct Peptide Reactivity Assay

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Gujarat

Chemicals that induce allergic response in skin upon contact are called "skin sensitizers", while those that elicit allergic response only in presence of light are called "photosensitizer". Direct Peptide Reactivity Assay (DPRA, OECD No. 442C) is an in chemico assay used to discriminate between sensitizers and non-sensitizers. DPRA monitors the depletion of model peptides and modified amino acids induced by crosslinking with test chemicals. In order to study combined effect of chemical compound and UV light we modified DPRA (photo-DPRA)

by introduction of photo-irradiation parameter. OECD adopted NRU-3T3 phototoxicity assay is an in vitro assay used to evaluate phototoxicity of test chemicals. Photo-DPRA dependent evaluation of photosensitization potential of the chemicals described in NRU-3T3 PT assay correctly predicted known photosensitizers. Upon irradiation, photosensitizers selectively showed higher depletion of model peptides. In DPRA assay, Cysteine and Lysine peptide synthetic hepta-peptides were incubated with test chemical and each chemical in presence of Cysteine and Lysine hepta-peptides was irradiated with dose of 5 J/cm² UVA_A. These samples were incubated in dark for 24±2 hrs. Post incubation percent peptide depletion was measured by UV-HPLC method at 220 nm. The difference in peptide depletion (Δ) between UV-treated and untreated samples were used to determine the effect of photosensitization. Test chemicals Cinnamaldehyde, Chlorpromazine, Sodium Lauryl sulfate, L-Histidine, Amiodarone HCL, Protoporphyrin IX, Disodium, Anthracene, Hexachlorophene, and Norfloxacin were analysed. Based on the results obtained in the absence of UV exposure, Cinnamaldehyde, SDS, and Hexachlorophene were found to be extreme sensitizers. Protoporphyrin IX, Disodium was found to be Moderate sensitizer. Norfloxacin was found to be mild sensitizer. Upon UV exposure Cinnamaldehyde, Chlorpromazine Sodium Lauryl sulfate, Hexachlorophene, Amiodarone HCL, Protoporphyrin IX, Disodium, Anthracene, and Norfloxacin were found to be extreme sensitizers. Thus, photo-DPRA can serve as an essential non-animal in vitro methods for the identification and assessment of photosensitizers.

--(OP-05)--

Single cell gel electrophoresis for evaluation of genotoxicity of *Vaishavanara Churna* -An Ayurvedic formulation

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Ayurvedic formulations are being used by human since ancient time; recently few questions are being raised by health authorities for the concentrations of heavy metals in these formulations. In the present study the genotoxicity of the Ayurvedic Formulation Vaishvanara Churna was evaluated using Single Cell Gel Electrophoresis. The Concentration of Vaishvanara churna (by dissolving 0.2, 0.4, 0.8, 1.6, 3.2 gram of Churna Preparation in Double distilled water to make up the volume 100 ml) was administered in vitro Peripheral Blood Mononuclear Cells. The Peripheral Blood Mononuclear Cells were separated by using standard protocol. It was found that none of concentration of ayurvedic formulation toxic to Peripheral Blood Mononuclear cells. Single cell Gel Electrophoresis is a simple technique to evaluate the genotoxicity of any drugs on human being and it can be used as an alternative to animal genotoxicity studies.

--(OP-06)--

Chicken-An alternative animal model

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Preclinical evaluation of potential therapies for many human disorders in animal models that mimic the target human disorder as a prelude to the translation of these into clinical trials is important for New Drug Development. Simultaneously the number of animals used in research has gone up with the advancement in medical technology. This increases the pain, distress and death experienced by the animals during scientific experiments which has become a debating issue for a long time. Argument is that being alive, animals have the rights against pain and distress and hence, their use for experimentation is unethical and must be stopped. Moreover, very high cost involved in breeding, housing and lengthy protocols of animal experiments is another drawback. Various alternatives to animal testing were proposed to overcome the drawbacks associated with animal experiments and avoid the unethical procedures. A strategy of 3 Rs (i.e. reduction, refinement and replacement) is being applied for laboratory use of animals. Different methods and alternative organisms are applied to implement this strategy. These methods provide an alternative means for the drug and chemical testing, up to some levels. In such a scenario Chicken (*Gallus gallus domesticus*) could serve as a better alternative and in-particular when it is used as a food in many countries, some of its by-product as ileum could be used in testing many drug activities; which is usually thrown out as waste. This was taken under consideration and an experiment was done to standardize the Chick-Ileum Model on Isolated organ bath using Data Acquisition System in Pharmacology Lab. Unani herbal drug which are stated as antispasmodic in Unani Literature were evaluated using chick-ileum in strict aseptic condition; results were compared with standard drug-Acetylcholine and Histamine. Possible mechanism of action of Unani drugs was evaluated out by which they are effectively being used in many diseases as Irritable bowel syndrome, dysentery etc.

Keywords: New Drug Development, Chicken, Ileum

Poster Presentations

--(PP-01)--

Modern affinity reagents to replace animal derived antibodies

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Modern affinity reagents, recombinant antibodies and aptamers have been extensively used in basic and applied research. The production of animal derived affinity reagents is a growing concern with the aim to reduce the animal experimentation. The need for higher quality affinity reagents has prompted the development of methods that provide scientific, economic, and time-saving advantages and do not require the use of animals. Researchers have reported that animal derived antibodies lack specificity and fail to recognize their targets. On- animal tools offer economic, scientific and time-saving advantages. From a scientific perspective, it is clear that there is a strong need for more reliable, specific, and versatile affinity reagents. Animal welfare principles provide further impetus to the use of rAbs and aptamers because they stress replacement, reduction, and refinement of the use of animals by seeking, considering, and implementing modern alternatives to the use of animals. To take advantage of resources already spent on developing and validating existing hybridoma monoclonal antibodies, existing hybridomas should be sequenced and produced using recombinant technology moving forward. Once technological knowledge and the supporting infrastructure are established, rAbs and aptamers require less time to produce, require less purified antigen, and can be created against a larger number of targets than mAbs .These technologies are the way forward to increased scientific validity and reproducibility and to accelerated research in the life sciences. To help rAb and aptamer developers identify key areas of interest, a list of ascites-produced antibodies purchased by researchers and the justification for using the ascites method of production should be made publicly available. This will allow developers of alternative technologies to focus efforts on the development of these antibodies via recombinant methods.

Key words: rAb, Aptamer, Affinity Reagents, hybridoma technology

--(PP-02)--

Alternative methods in biomedical and behavioral research

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The number of animals used in research has increased with the advancement of research and development in medical technology. Every year, millions of experimental animals are used all over the world. The pain, distress and death experienced by the animals during scientific experiments have been a debating issue for a long time. Besides the major concern of ethics, there are few more disadvantages of animal experimentation like requirement of skilled manpower, time consuming protocols and high cost. Various alternatives to animal

testing were proposed to overcome the drawbacks associated with animal experiments and avoid the unethical procedures. By expanding what is considered to be an alternative to include reductions in the use of animals and refinements in experimental protocols that lessen the pain of the animals involved, the possibility of using alternatives increases. A strategy of 3 Rs (i.e. reduction, refinement and replacement) is being applied for laboratory use of animals. Different methods and alternative organisms are applied to implement this strategy. These methods provide an alternative means for the drug and chemical testing, up to some levels. In addition, the replacement of one animal species with another, particularly if the substituted species is non-mammalian, can be considered another alternative method. An integrated application of these approaches would give an insight into minimum use of animals in scientific experiments.

--(PP-03)--

Analysis of regulatory scenarios of animal experiment models

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The use of animals in scientific research is highly controversial. Older justifications, which referred to an immense gulf between human beings and other animals, can no longer be sustained in the face of a large body of scientific evidence concerning the similarities between human beings and other animals. The Animal House (AH) project is the backbone of research activities of Drug Discovery. The chief mandate of the AH is to breed and maintain different strains of mice, rats, guinea pigs and rabbits, and supply them upon request to institutional researchers. These animals are bred in Animal houses (AH). Animals in research go through many procedures. They are shocked, isolated, subjected to drugs and sacrificed. Animals have to be used under certain regulations. Sustainability is need of the hour. There are international guidelines for use and care of animals in scientific procedures, which references have been made to some of them in this paper. The concern is much more above the guidelines, it is more about the ethical aspect and fulfillment of the regulatory conditions being followed without being hampered. This presentation is analyzing the various responsible bodies work and ethical regulations, which use the animal models for scientific experiments. It also suggests the 3R principle, to be used more profoundly, which has been already in many heads nowadays. The 3Rs, is founding pillars of animal testing studies which stands for Replace (creatures), Reduce (use in minimum amount) and Refine (the manner), must be obeyed to ensure coherent use of animal resources.

--(PP-04)--

In- vitro approach: Opportunities and limitation

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Now days the use of animal experiments are quite being limited in fields of exploring the

right mechanism of action due to exploitation. Thus many alternative methods are adopted for the study which can be physico-chemical, microbiological parts, tissue/organ cultures, computer or mathematical analysis, epidemiological surveys, plant analysis, in-vitro techniques etc. Thus a newer approach like in-vitro studies is looked upon. These studies are conducted using components of an organism that have been isolated from their usual biological surroundings which permits a more detailed or convenient analysis than can be done with whole organisms. However, results obtained from in vitro experiments may not fully or accurately predict the effects on a whole organism as experimental animals. Experimental animal studies should be evaluated as part of hazard characterization to ensure that adequate research has been carried out. The design conduct, interpretation, and reporting should be considered. In any assessment of the reproductive and developmental toxicity potential of exposure to a harmful substance, should be considered, including supplementary data from the experiments and its significance. These systems promote the understanding of mechanisms of toxicity which might be able to take months to come to a conclusion. So in critical aspect the underestimated lining in the recent discussion can be a possibilities and limitations of in vitro systems. Due to complexity, organs have possibilities to compensate stress though alternatives cannot eliminate the need for animals in research domain. Even though no animal model is a complete set of its replication but provides a better model of the complex interaction of the physiological processes.

--(PP-05)--

In Silico Characterization of Diabetic Retinopathy And Uveitis Responsible Proteins

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Two important ocular diseases Diabetic Retinopathy and Uveitis causing severe vision loss or blindness that is highly prevalent across the world are being analyzed in this current study. Diabetic retinopathy (DR) is a major sight threatening complication of systemic diabetes mellitus that causes damage to the blood vessels of the retina. Uveitis is an autoimmune disease that results in chronic inflammation of several parts in the eye. Many proteins have been identified for their pathogenesis. In this report several ocular proteins were retrieved from UniProt database are analyzed and characterized using Bioinformatics tools. An in silico technique was initiated to characterize the properties and structure of the protein. Characterization in terms of molecular weight, atomic composition, isoelectric point, extinction coefficient, aliphatic index, GRAVY, and instability index were obtained using ProtParam. Phosphorylation and signal peptide cleavage sites presence were revealed by NetPhos and Signal P tools. Secondary structure analysis by SOPMA showed that most of the ocular proteins have predominant α -helical structures and rest of the proteins have mixed secondary structure along with very high coil structural content. Protein 3D structures are functionally very important and play a significant role in progression of the disease; hence, these 3D structures are better target for further studies. The 3D structures of ocular proteins were modelled using ExPasy server tool Swiss Model Workspace and Modeller following the approach of Homology Modeling and the structures were validated. Prediction of putative functional sites in the proteins helped in identifying the possible phytochemicals

for the disease. Docking results obtained through AutoDock gave new insights toward the therapeutic treatments for Diabetic Retinopathy and Uveitis.

Key words: Diabetic Retinopathy, Uveitis, ProtParam, NetPhos, Signal P, SOPMA, SOSUI, Swiss Model Workspace, Modeller, AutoDock.

--(PP-06)--

The micro RNA molecules and genes associated with protein quality control machinery, modulate clearance of aggregated proteins in *C. elegans* models of neurodegenerative diseases

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It is well known that the multifactorial neurodegenerative diseases (NDs) have 'protein aggregation' as one of the most critical factors associated with the disease progression and outcome. Misfolded proteins usually expose internal domains which impact their structural stability and molecular partnerships and therefore are very much prone to form toxic aggregates; eg aggregates of alpha synuclein in Parkinson's disease (PD), beta-amyloid and tau in Alzheimer's disease (AD). In order to regulate or prevent protein aggregation, cells have a protein quality control system (PQC). Quality control (QC) pathways inside the cell constantly monitor the protein molecule for occasional damage or errors. In order to maintain cellular homeostasis, aberrant protein should be recognized and either corrected or degraded rapidly. Amongst various mechanistic triggers of protein expression, the microRNA molecules are known to regulate expression of multiple genes which are part of their downstream network. Expression pattern of miRNAs not only varies from organ to organ of an organism but it also varies in normal and diseased conditions. In the present set of studies, we report on our findings from a global microRNA profile of transgenic *C. elegans* strain expressing human α -synuclein (NL5901) and human amyloid β (CL4176) in comparison to wild type strain. We have successfully identified novel microRNA molecules that were previously not known to be related to NDs. We further carried out in silico studies towards identifying their downstream predicted targets followed by functional characterization and validation of genes that find association with the important pathway of protein quality control. We reason that bettering of the clearance of aberrant and aggregating proteins via targeting critical molecules, can aid in curing the NDs. We further extended our studies to assay ROS levels, acetyl choline levels and expression of genes related to apoptosis, autophagy and unfolded protein response (UPR). Our studies are a significant step towards identifying novel modulators of PQC which could be exploited further for targeted cure via bettering of protein clearance in aberrant conditions.

Key words: Neurodegenerative Diseases (NDs), Parkinson's Disease (PD), Alzheimer's Disease (AD), Protein Quality Control (PQC) and Unfolded Protein Response (UPR).

--(PP-07)--**Modulation of Cytochrome P450 enzymes by curcumin and tetrahydrocurcumin using Jrf- 10 in 1 Cocktail Assay****Ashita Desai**, Pooja Desai, Mitiksha Joshi, Rahul Date

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Curcumin, desmethoxycurcumin, and bisdemethoxycurcumin are three principal polyphenolic Curcuminoids found in high concentrations in turmeric (*Curcuma longa*), which are responsible for its distinctive yellow color. Tetrahydrocurcumin (THC) is one of the major metabolites of curcumin, which lacks α , β -unsaturated carbonyl moiety and is white in color. Various comparative studies using curcumin and THC showed their diverse effects in anti-inflammation, anticancer, antiviral, neurological and immunological modulation. CYP enzymes are major players in the oxidative metabolism of a wide range of structurally diverse xenobiotics. Majority of the drugs are metabolized by CYP1A2, 2C9, 2C19, 2D6, 3A4, and 3A5 enzymes. There is limited information available about activity of Curcuminoids on the CYP enzymes. Here, we compared the effect of curcumin and THC on the activity of multiple CYP enzymes with JRF CYP 10 in 1 cocktail assay using tandem mass spectrometry (LCMS/MS). Indicated substrates for the respective CYPs, phenacetin (1A2), coumarin (2A6), bupropion (2B6), amodiaquine (2C8), diclofenac (2C9), omeprazole (2C19), dextromethorphan (2D6), chlorzoxazone (2E1), midazolam and testosterone (3A4/5) were used in this assay. In this study we have also compared the effect of these compounds in 3 different species, Mice, Rat and Human. At 30 μ M concentration curcumin and THC both inhibited the activities of CYP2A6, 2B6, 2C8 and 3A4/5 greater than 50% in mice, rat and human liver microsomes. Moreover, curcumin was more efficient than THC in inhibiting CYP2A6, 2B6, 2C8, 2C9, 2C19, 2D6 and 3A4/5. CYP1A2 and 2E1 were not inhibited by curcumin and THC in rat and human liver microsomes, whereas 60% inhibition of CYP1A2 was observed by curcumin at 30 μ M concentration in mice. Since curcumin and its metabolite, THC, modulate major CYP enzymes involved in metabolism of xenobiotics, interaction of these compounds need to be carefully studied when co-administered with drugs.

--(PP-08)--**Effect of use of social media on CNS****Das Sanjita**, Mazumder Avijit, Mazumder Rupa

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The average teenager spends up to nine hours per day on social media. Social media is the new tribal fire. It is another kind of addiction having no age bar. Facebook, Instagram, Snapchat, Twitter and many more platforms allow people of all backgrounds to have a voice and connect in the virtual world. The present study highlights the effect of use of social media on brain parts and its normal physiology. People who spend more than two hours per day on social media have a higher tendency to report a mental illness. Even without a

mental health disorder, these platforms can make anyone feel negatively about themselves. A human is an organism; the surroundings and conditions a person lives and operates in is his or her environment. The Ventral Tegmental Area (VTA) of the brain monitors social needs by releases dopamine when we achieve social success and inspiring neurochemical deficits when we don't. Tragically, social media is not the VTA's friend. The hippocampus (a memory area in the brain) continuously compares the external world to the brain's core belief of how the world should be. When there is a discrepancy between the external world and the brain's core belief, a threat occurs. Social media plays an important role in this field. Its chronic use gives rise to stress. It leads to chronically elevated blood glucose levels which become insulin resistance, diabetes, obesity and various medical and psychological disorders that have been reliably associated with these conditions. To further complicate matters, primate biology constructed structural brain dynamics to suspend cortical functions, such as thinking, when key subcortical processes, such as the stress response swing into action. The present study concludes that time is the most precious human resource; don't waste it on Twitter wars or Facebook feuds.

--(PP-09)--

Improved safety assessment of chemicals without relying on animal testing

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Nowadays human health becomes a concern in the healthcare system but precisely all the findings does not match with the clinical reports. Thus due to this a preclinical studies are performed by the use of various alternatives in experimental models. Rather than wasting millions of economy and precious time, and bearing the ethical costs of experimenting on so many sentient and intelligent beings, there can be a shift paradigm in humane, human-based science which is more promising, effective, and reliable. Alternatives to [animal testing](#) are the development and implementation of test methods that avoid the use of live animals. Recent advances in toxicological science, bioinformatics, and systems biology have provided means to transform toxicology into a predictive science. There is widespread agreement that a reduction in the number of animals used and the refinement of testing to reduce suffering should be important goals for the industries involved. Replacing animal tests does not mean putting human patients at risk. It also does not mean halting medical progress. Instead, replacing animal testing will improve the quality as well as the humaneness of our science. Development of alternative methods is growing. Due to innovations in science, animal tests are being replaced in areas such as toxicity testing, neuroscience and drug development. But much more needs to be done.

Key words: Toxicology, Replacement, Refinement, Economy.

--(PP-10)--**Design, synthesis and molecular modelling of pyrazole carboxamide derivatives bearing benzene sulphonamide tail as potential anti-cancer agents****Farah Nawaz**, Ozair Alam

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A virtual library of 3783 structurally different pyrazole-4-carboxamide containing derivatives having benzenesulfonamide tail was built with the help of Combiglide using different substituted phenyl methyl ketones and anilines. The virtual screening of the focussed library was carried out and evaluated for binding to the cyclin dependent kinase 2 (CDK-2) enzymes using molecular docking and binding free energy calculations. Based on affinity findings, druggability check and cheminformatic analysis, a series of novel pyrazole-4-carboxamide derivatives bearing benzenesulfonamide moiety was selected, followed by synthesis, characterization and their evaluation for *in vitro* anticancer activity against MCF-7 cell line within the dose range of 2.5 μ M. The potential compounds tested against protein pdb (2VTO) gave diverse docking score ranging from -4 to -9.9 and binding affinity if the same pose ranged from -40 kcal to -82.63 kcal. The promising compounds were then characterized by FT-IR and ^1H NMR. The MTT assay revealed that the derivative (**3111**) had showed the most potent activity (**IC₅₀ 5.8 μ M**) of all the derivatives against the reference standard of tamoxifen (**IC₅₀ 8.1 μ M**). The molecular docking study was carried to understand the possible best binding pose of the ligand by which it could be sorted out for identifying promising leads. Molecular docking studies revealed that derivative (**3111**) binds well to the active site of CDK-2 enzyme and may have potential to be developed as potent CDK-2 inhibitor. The promising derivative was then subjected to check for its stability with the protein using molecular dynamics so as to understand their inter-atomic interaction patterns and stability in the receptor whose biological activity was best among the synthesized compounds were subjected for this study comparatively against the native crystal ligand.

--(PP-11)--**Drug repurposing approach to identify novel inhibitors for targeting DNA gyrase in *Mycobacterium tuberculosis*. Insights from Biophysical and Biochemical Studies****GL Balasubramani**, Rinky Rajput, Manish Gupta, Rakesh Bhatnagar, Abhinav Grover

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Drug repurposing has gained momentum globally and become an alternative avenue for identifying new drugs against tuberculosis (TB). TB can be cured with the use of currently available anti-tubercular drugs, emergence of drug resistant strains of *Mycobacterium tuberculosis* H37Rv (Mtb) and the huge death toll globally, together necessitate urgently newer and effective drugs for TB. To address this problem, we have employed drug

repurposing approach to screen FDA-approved drugs by virtual screening and binding free energy calculations to identify novel inhibitors against Mtb target enzyme, DNA gyrase. Screening of compounds was done against the active site of Mtb DNA gyrase, the region of ATP binding (N-terminal domain) pocket on gyrase B subunit. Here, we identified total of four compounds (Drug97, Drug45, Drug77, Drug38) tightly binds to ATPase binding pocket of gyrase B (MtbGyrB). These compounds were simulated using GROMACS; the results generated were subjected to molecular mechanics-Poisson Boltzmann surface area (MM-PBSA) calculation. Docked results shows binding energy for drugs (Drug97, Drug45, Drug77, Drug38) as -9.94, -9.93, -9.69 and -8.87 kcal/mol. MM-PBSA predicted the binding free energy of the drug97, drug45, drug77 and drug38 to be -1123.18, -1025.211, -1016.250 and -339.745 kcal/mol, respectively. These four compounds showed equilibrium dissociation constant, K_D values of 2.1-53.0 μ M. Among them, drug97 shows K_D values of 2.1 ± 0.17 μ M. Our results suggests that the screened compounds binds to the ATPase domain of gyrase B subunit and inhibits gyrase catalytic cycle. This finding indicates all the identified compounds represent potential scaffolds for further optimization of novel antibacterial agents that can act on drug-resistant strains.

--(PP-12)--

In-silico molecular interaction of Vinclozolin with human androgen receptor

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Vinclozolin is well known dicarboximide that is used to control fungal pests on several crops mostly fruits. Potential of fungicides of disrupting endocrine function and their interaction with nuclear receptors is well reported. In comparison to other fungicides toxicity data on vinclozolin is not extensive. In this study we performed molecular docking to check the binding potency of dicarboximide fungicide (Vinclozolin) on human androgen receptors using Maestro Schrodinger 9.4. It was observed that the ligand of androgen receptors PDB ID: 1GWR exhibited the binding score of 8.6, 8.29, and PDB ID: 2JFA 8.38,8.37. Results indicate that vinclozolin have the toxic potential to disrupt the endocrine function by binding to androgen receptors. We warrant further studies to confirm the biological implications of such interactions.

Key words: Vinclozolin; dicarboximide; androgen; molecular docking.

--(PP-13)--

PPAR γ agonists as antidiabetic regimen: An insight into molecular modeling and Structure activity relationship

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To keep pace with an ever increasing development process, changing lifestyles and loss of physical activity of population throughout the globe has resulted in various lifestyle disorders

among which diabetes has occupied a respectable spot affecting a major section of the society. Diabetes/diabetes mellitus is characterized as a group of metabolic disorder or multifactorial disease affecting glucose, carbohydrate & lipid metabolism etc. Being entitled as a potential epidemic; its incidence is expected to double globally from 171 million (in 2000) to 366 million by the end of 2030 with India as the diabetic capital of the world with 31.7 million cases in 2000 to 79.4 million cases by 2030 followed by China and United States. In order to cope with such a potential burden of this disease, PPARs (Peroxisome proliferator activated receptors) agonist has emerged as the most satisfying option in the present scenario. PPARs are members of nuclear receptor superfamily and its three subtypes with distinct biological profile i.e. PPAR α (fatty acid uptake & activation), PPAR β (controls fatty acids oxidation)& PPAR γ (adipogenesis and glucose metabolism). PPAR γ is the most widely studied PPAR subtype for the treatment of diabetes which is further classified as PPAR- γ agonists, PPAR- γ partial agonists, PPAR- α/γ dual agonists, and PPAR- γ antagonists. This work will provide an insight of PPAR γ agonist along with their recent developments in their design and synthesis along with structure activity relationship and their mechanism to counter this lifestyle disorder.

--(PP-14)--

Ameliorative effect of rosmarinic acid on cisplatin induced nephrotoxicity in HEK293 cells

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Cisplatin is a well known potent anticancer drug used in the treatment of various types of human cancer. Its nephrotoxic side effect limits its use in therapeutic application. Evidence suggests that apoptosis of tubular epithelial cells and renal inflammation mainly determine the progression and outcome of cisplatin-induced nephrotoxicity. Unfortunately, there is currently no effective therapeutic approach to prevent cisplatin-induced nephrotoxicity. Rosmarinic acid is a strong antioxidant agent with promising therapeutic potential. The aim of this study was to investigate the possible protective effect of rosmarinic acid on nephrotoxicity induced by cisplatin in human embryonic kidney (HEK293) cells. *In vitro*, HEK293 cells were treated with cisplatin (5 μ m) with or without rosmarinic acid (16 μ m) administration for 72 hrs. Rosmarinic acid suppressed the mRNA expression of caspase 3 and kim-1 in cisplatin treated HEK293 cells. Also caspase 3 protein expression was found to be downregulated by rosmarinic acid in cisplatin treated HEK293 cells. HEK293 is good cell line model for *in vitro* evaluation of protective effects of natural products against toxic effects of chemotherapeutic agents.

--(PP-15)--

Selectivity and choice of in-vitro technique as a surrogate to animal study for bacterial keratitis animal model: a case study using in-situ ocular nano-suspension of moxifloxacin HCl

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The use of animals in research is essential for enabling researchers to develop new drugs and treatments. Animal models helped to ensure the safety and effectiveness of new treatments. The use of these animals has become an important ethical issue, leading to the promotion of the philosophy of 3Rs (replacement, reduction and refinement) in animals research. The aim of present work is to develop a sustained release ocular formulation for Bacterial Keratitis. The strategy followed for development is screening of formulation attributes through suitable in vitro models, followed by ex-vivo model. The effectiveness of optimized formulation was further verified in rabbit model after development of bacterial keratitis in rabbit eye using bacterial suspension of S.aureus. The nano-suspension formulation was compared with marketed formulation with reduced frequency in developed pharmacodynamic model. Moxifloxacin Hybrid delivery system (solid lipid nano suspension dispersed in in-situ gelling polymer) was prepared using cold homogenization technique. Formulation design and Critical process parameter (CPPs) were optimized using design of experiment studies (DoE). The in-vitro model used for evaluation of critical quality attributes (CQAs) were Drug release, Particle size, Gelling properties Peak positive force, Peak negative force, Peak area, viscosity after application and gelling temperature. Formulations passing criteria in in-vitro studies were then subjected to ex vivo study using goat cornea in Franz diffusion cell. In-vivo studies proved the effectiveness of moxifloxacin hybrid formulation in reducing dose frequency wrt to marketed formulations for bacterial keratitis. The selection of suitable in-vitro and ex-vivo models not only ensured the success of in-vivo studies, but also restrict the use of large number of animal.

Key words: Moxifloxacin, Hybrid delivery system, Quality by Design, Bacterial Keratitis, Solid Lipid Nanoparticles

--(PP-16)--

Three dimensional Organotypic skin equivalents: a comparative analysis with two dimensional cultures

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Recent advances in skin bioengineering have allowed the production of three dimensional cultured epithelial sheets using Two Dimensional (2D) Cultures and establishment of organotypic models, referred to as human skin equivalents having both dermal and epidermal components using Three Dimensional (3D) Cultures. The 3D culture systems have been gaining popularity for their near natural environment as compared to the conventional 2D cultures and contributed to the recent cytotechnological advancement in tissue engineering. In this study, we established both 2D and 3D epidermal cultures and characterized them through cell survival, morphological and immunohistochemical parameters. 3D cultures were prepared by culturing the adult human epidermal keratinocyte cells on collagen matrices populated with growth-arrested Swiss mouse embryonic 3T3 fibroblasts while 2D cultures were established by directly growing the keratinocytes on cell culture treated plastic surfaces in the presence of growth-arrested feeder cells that were generated by pulsed treatment with Mitomycin C. As the growth arrested feeder cells gradually disintegrate with an overall finite life-span and also their population density

regulates keratinocyte turn-over, we first assessed viability of such feeder cells in these two environments. The results indicated that both the culture systems exerted differences in viability of feeder cells. We compared the viability of normal fibroblasts and a Mitomycin C-resistant clone of fibroblasts that were growth-arrested with either irradiation or different concentration-dose combinations of Mitomycin C. We found that the 3D culture system acted like a buffer by slowing down the faster replication of normal/clone cells observed in 2D cultures while reducing the 2D-observed rate of cell death at the same time after induction of toxicity in them by Mitomycin C. There were also specific differences in the expression of epidermal markers between both the culture systems with 3D cultures expressing certain markers somewhat similar to normal skin. On the other hand, the expression level of Keratinocyte Growth Factor by the functionally optimized feeder cells was higher many folds in 2D cultures than in 3D cultures. Further, we ruled out any probable role of trace amounts of Mitomycin C left out in the feeder cells in bringing about these differences by demonstrating the absence of any detectable traces in either the feeder cells or 2D constructed cultured epidermal sheets. The results point out the need to observe caution while deciphering toxicological and pharmacological data from 3D constructs before employing them as alternatives to animal models.

--(PP-17)--

Cytotoxicity of oxaliplatin in Hepg2 cell line

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Chemotherapeutic drugs are able to inhibit cell proliferation and promote apoptosis. Oxaliplatin is an anticancer drug widely used for the treatment of colorectal cancer. It induces oxidative stress leading to toxicity in non-targeted tissues such as neurotoxicity and hepatotoxicity. We studied cytotoxicity of oxaliplatin in HepG2 (human hepatocellular carcinoma) cell line. Cells were exposed to different concentrations of oxaliplatin for 24, 48 and 72 hours. After exposure cell viability was quantified by MTT (3-(4, 5-dimethylthiazol-2-yl)-2, 5-diphenyltetrazolium bromide) a colorimetric assay for assessing cell metabolic activity. Oxaliplatin inhibited cell proliferation in a time- and concentration-dependent manner. Severe effects were observed at 72 hrs of exposure to oxaliplatin. However, higher concentration for exposure time of 24 and 48 hrs also showed 100% cell death. From these results, it is confirmed that oxaliplatin has cytotoxic effect in HepG2 cells and these cells can be used for screening of toxicity of oxaliplatin and other chemotherapeutic drugs. Protective effects of compounds against cytotoxicity of oxaliplatin and other drugs may also be studied using these cells.

Key words: Cytotoxicity, Oxaliplatin, HEPG2 cell line, MTT assay.

--(PP-18)--

Serum EGFR1 and EGFR2 expression in Non Small Cell Lung Cancer patients

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Serum mRNA is promising prognostic tool for non-invasive malignant disease prognosis of disease, and to study serum mRNA may have important role in the prognosis of disease. Histopathologically confirmed 100 NSCLC cases and 100 healthy control subjects were included in study to evaluate the possible prognostic role of serum EGFR1 and 2 mRNA expressions in lung adenocarcinoma patients. Quantification analysis showed 13.54 and 13.92 mean fold increase in serum EGFR1 & 2 expression among NSCLC patients than healthy controls. Patients with larger tumor size had higher EGFR1 & 2 expression which was found to be significantly associated with tumor size ($p=0.02$, 0.01). NSCLC patients who had distant metastases (M1) in organs like brain, adrenal, bone etc showed increased EGFR1 & 2 mRNA expression compared to patients without distant metastases (M0) showed significant difference in expression ($p<0.0001$). With increasing TNM stage of NSCLC, increased serum EGFR1 & 2 mRNA expression was observed ($p<0.0001$). It was found out that a significantly poor overall survival was associated with > 13 fold increase in EGFR1 mRNA expression ($p<0.0001$). It was found that a significantly poor progression free survival was associated with patients with > 13 fold increase in EGFR1 mRNA expression ($p=0.001$). It was found out that a significantly poor overall median survival was associated with patients with > 13 fold increase in EGFR2 expression ($p=0.02$). It was found out that a significantly poor progression free survival was associated with patients with > 13 fold increase in EGFR2 expression ($p=0.001$). ROC curves for EGFR1 & 2 were plotted between early and advanced stage NSCLC patients ($AUC=0.95$, $p<0.0001$, $AUC=0.81$ $p<0.0001$), presence/absence of distant metastases ($AUC=0.81$, $p<0.0001$, $AUC=0.73$, $p<0.0001$) and pleural effusion ($AUC=0.81$, $p0.009$, $AUC= 0.67$, $p=0.03$) respectively. Increased circulating mRNAs expression in serum of EGFR1 and 2 genes was found to be associated with worse overall and progression free survival of NSCLC patients. ROC curve analysis showed circulating EGFR1 and EGFR2 mRNA expression in serum could be useful as important predictive indicators for prognosis of NSCLC patients.

--(PP-19)--

Protection accorded by Curcumin and Quercetin against the lead induced inhibition of Δ -Animo levulinic acid dehydratase and acetyl cholinesterase activity

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Lead has been found in almost all phases of environmental and biological systems. Lead stimulated oxidative stress is a state that involves the generation of free radicals beyond the permissible limits, can deplete at the same time the antioxidant reserves and thus hamper the ability of the biological system to reverse the result. Oxidative stress may also cause the

depletion and changes in the activity of various antioxidant enzymes and markers of lead toxicity such as δ -Animo levulinic acid dehydratase (δ -ALAD), Acetyl cholinesterase. δ -ALAD is a well known marker of lead toxicity in blood. Acetyl cholinesterase is known to be a crucial neuronal enzyme that may serve as an index of neural damage therefore, neuronal damage caused by lead decreases activity of acetyl cholinesterase in animal treated with lead. Curcumin is a yellow-colored polyphenolic compound and the principal active component of turmeric, which is obtained from the plant *Curcuma longa*. Quercetin (3,3',4',5,7-pentahydroxyflavone) is a ubiquitously distributed and comprehensively explored bioflavonoid. The presence of multiple hydroxyl groups in its chemical structure and conjugated electrons account for its antioxidant and metal chelating property. Sprague Dawley (SD) rats were used in the present study. Curcumin and Quercetin accorded protection against lead-induced neurotoxicity in rats as there was significant enhancement in the levels of δ -ALAD in blood and acetyl cholinesterase in the different region of brain and various biomarkers of oxidative stress (GSH, SOD and CAT levels). Therefore the understanding of the interaction between antioxidants and mechanism of lead induced oxidative damage may help to provide an insight into pathogenic processes that contribute to neurological diseases.

Key words: δ Animo levulinic acid dehydratase (δ -ALAD), Acetylcholinesterase (AChE), Reactive oxygen species (ROS),

--(PP-20)--

Zika virus- A global epidemic threat

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Zika virus (ZIKV) is a mosquito-borne flavivirus transmitted primarily by *Aedes* mosquitoes. It was first discovered in 1947 in Zika forest of Uganda in East Africa. From 2007 outbreak of Zika with increasing number of cases most of which includes neurological manifestations had occurred. Virus was active in several countries of Asia and Africa and since 2015 it had also emerged in American countries and Caribbean. According to WHO more than 180 cases of ZIKV had been reported out of which 3 cases were also reported in Ahmedabad in India. Symptoms can be nothing to mild including pain in eyes, joints, fever with chills, rashes which are often misdiagnosed by dengue or chikungunya virus. Reports suggested the transmission of ZIKV through sexual practices with infected person and also transplacentally from pregnant mother to foetus resulting in microcephaly and other brain abnormalities. Currently no effective medical treatments or specific vaccines are available except some broadspectrum antivirals, therefore to combat further threat of Zika virus there is need of implementation of effective preventive measures to prevent the morbidity of complications.

--(PP-21)--

Bridging the gap between *in vitro* and *in vivo* risk assessment of nanoparticles: Emergence of Hydra as a suitable model organism

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The field of nanotechnology is a double-edged sword. Since its introduction as a technology it has received wide range of applications in almost all fields of science and technology and, at the same time, it has raised concerns in view of its negative effects to the humans and animal health through many routes including environmental. Owing to the unique physicochemical properties there is no suitable test system available for risk assessment of nanoparticles. Hence, there has long been a look out for appropriate model systems for toxicity testing of nanoparticles. In this context, we propose Hydra, an aquatic invertebrate which raises little societal and ethical concerns, since it is simple, available in plenty, and feels less or no pain, as a suitable model organism for risk assessment of nanoparticles. Hydra is a diploblastic animal with outer ectoderm and inner endoderm separated by a non-cellular mesoglea. Chemical entities, especially when dissolved in a medium, can very easily enter into the body of Hydra. In addition, many genes in Hydra are conserved, which are not the case even in *C. elegans* and zebra fish. Having already standardized test protocols and toxicity end points in Hydra, we tested two different nanoparticles (cobalt oxide and zinc oxide) for toxicity at cellular and whole animal levels. The study revealed concentration- and duration-dependent effects of the nanoparticles on morphology, physiology and reproduction rate in Hydra. Induction of apoptosis at cellular level was observed in both the treatment groups. Among the two nanoparticles tested, zinc oxide was found to be more toxic than cobalt oxide to Hydra, and the pattern of toxicity was almost similar to higher organisms. This data substantiates the suitability of Hydra as a convenient model organism for nanotoxicity testing.

--(PP-22)--

Molecular docking approach for the exploration of an ungual drug-delivery system for onychomycosis amelioration

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The ultimate success of a formulation intended to be used locoregionally depends in its retention, payload and final disposition. A primary step in the fabrication of an ungual drug-delivery system includes the overcoming of the physical barriers and thereafter the reaching of the drug and its interaction at the site of action. Onychomycosis is a locoregional fungal affliction needing protracted therapy both systemic as well as topical. The conventional treatment modalities available for onychomycosis are associated with pharmacotechnical caveats limiting its technical potential henceforth, the current research aims to design a patient compliant and clinically effective anti-fungal based bilayer nail lacquer, formulated by a combination of various film forming polymers with the incorporation of a permeation enhancer for improved drug delivery, bioadhesion and clinical anti-fungal activity with an additional cosmetic quotient for onychomycosis amelioration. The current research is a humble contribution towards the pursuit of attaining viable solution for the treatment of a difficult to treat disease, onychomycosis. The purported research would be of great interest given the high prevalence and reporting rate of onychomycosis over the last few decades.

--(PP-23)--**Assessment of antimutagenic, free radical scavenging potential and oxidative DNA damage preventive activity of *Trachyspermum ammi* L. (ajowan) seed extracts**

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Oxidation of biomolecules results in generation of free radicals in an organism which is the major cause of onset of various degenerative diseases such as cancer. Antioxidants scavenge these free radicals, thereby protecting the cell from damage. The present study was designed to examine the antimutagenic, free radical scavenging potential and oxidative DNA damage preventive activity of traditionally used spice *Trachyspermum ammi* L. (ajowan). The aqueous, methanolic, and acetonic extracts of *T. ammi* seeds were prepared using soxhlet extraction assembly and subjected to qualitative and quantitative estimation of phytochemical constituents. Free radical scavenging potential was investigated using standard methods, namely, DPPH radical scavenging assay and ferric reducing antioxidant power assay along with the protection against oxidative DNA damage. The mutagenic/antimutagenic activity of extracts of *T. ammi* was determined against indirect acting mutagens viz., 2-Aminofluorene, Benzo[a]pyrene and 7, 12-Dimethylbenz (alpha)anthracene using Ames test by plate incorporation method. The results stated that acetonic seed extracts of spice possessed comparatively high amount of total phenolics whereas methanolic seed extracts were found to have highest amount of total flavonoids. At 1 mg/mL concentration, acetonic extract was recorded with highest FRAP value ($2270.27 \pm 0.005 \mu\text{mol/L}$), and all the extracts have been shown to mitigate the damage induced by Fenton reaction on calf thymus DNA. No mutagenicity of the seed extracts was observed in *Salmonella typhimurium* strains TA98, TA100 and TA102 according to the two-fold rule. From the antimutagenic study carried by Ames assay using plate incorporation method it was concluded that the different extracts were effective in inhibiting the mutagenicity at all dose levels in *Salmonella typhimurium* strains. All the seed extracts expressed weak to strong antimutagenic activity by reducing the number of his⁺ revertants induced by 2-AF, B[a]P and DMBA in *Salmonella typhimurium* strains at different doses. Hence, there was a dose dependent antimutagenic behavior of all extracts indicating that *T. ammi* could be potent antimutagen. All the extracts exhibited comparatively higher and statistically significant ($p < 0.001$ and $p < 0.05$) antioxidant activity than standard antioxidant BHT. Also, the dose dependent and statistically significant ($p < 0.001$ and $p < 0.05$) increase in inhibition percentage in assessment of antimutagenic activity (range from weak to strong inhibition) was recorded by all the samples. Therefore, the study suggests that *T. ammi* seed extracts could contribute as a highly significant bioresource of antioxidants and serve as antimutagenic agents to be used in our day-to-day life to prevent degenerative diseases like cancer, diabetes, aging, inflammation and also in food and pharmaceutical industry.

--(PP-24)--**Gel based solid lipid nanoparticle of an antibiotic drug for ocular use**

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The aim of the present study was focused on the development of solid lipid nanoparticles based gelling system of an antibiotic drug to be administered through ocular route. Four formulations (P1, P2, P3 & P4) of solid lipid nanoparticles were prepared containing prednisolone. Solid lipid nanoparticles were prepared by emulsification followed by sonication method. Prepared prednisolone containing solid lipid nanoparticles were evaluated for particle size, shape, surface morphology, drug content and in-vitro drug release studies. The average particle size was found to be in range 349.2 nm, the particles were uniform, spherical in shape and had 60 to 84.45%w/w of drug entrapped in it. The drug release from solid lipid nanoparticles showed sustained release of drug. All the formulation showed better result in terms of stability. Among the four formulations the best result were found with P1 formulation of Prednisolone. The solid lipid nanoparticles of prednisolone were incorporated in gel so as to make it suitable to be administered by ocular route. Solid lipid nanoparticles containing gel showed drug delivery up to 88.7%. Prednisolone nanoparticles loaded gel showed better result when compared with the prednisolone nanoparticles; because the release rate revealed that the gel gave higher release of drug initially for quick onset of action.

Key words: Solid lipid nanoparticle (SLN), Prednisolone, Ocular route

--(PP-25)--

Assessment of photosensitization potential via novel in chemico amino acid derivative reactivity assay

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Amino Acid Derivative Reactivity Assay (ADRA) is a skin sensitisation method for discriminating between sensitizer and non-sensitizer. ADRA involves 2 amino acid derivatives: N-(2-(1-naphthyl)acetyl)-l-cysteine (NAC) and α -N-(2-(1-naphthyl)acetyl)-l-lysine (NAL), in which each amino-terminal residue is introduced into a naphthalene ring. For ADRA, chemically synthesised naphthalene coupled cysteine and lysine derivatives were dissolved in phosphate buffers of pH 9.5 and 12.0, respectively. Test chemicals were mixed, irradiated with UVA and incubated under darkness for 24 ± 2 hr at 25 ± 2 °C. Post incubation, depletion in amino derivatives was quantified using a high-performance liquid chromatography (HPLC) at 281 nm.

The reactivity was calculated as the percent depletion. The average reduction score was calculated to discriminate between sensitizers and non-sensitizers. The difference in depletion (Δ) between UV-treated and untreated samples were used to determine the effect of photosensitization. Test chemicals like Cinnamaldehyde, Chlorpromazine, Sodium lauryl sulfate, L-Histidine, Hexachlorophene, Protoporphyrin IX, Disodium, Amiodarone HCL, Anthracene, and Norfloxacin were included. In the absence of UVA irradiation, Cinnamaldehyde, Hexachlorophene were found to be extreme sensitizer, Protoporphyrin IX, Disodium were found to be moderate sensitizer, Chlorpromazine was found to be mild sensitizer, Sodium lauryl sulfate, L-Histidine, Amiodarone HCL, Anthracene, and Norfloxacin were found to be Non-sensitizer, . Upon UVA irradiation, Cinnamaldehyde, Chlorpromazine, Amiodarone HCL, Anthracene, Protoporphyrin IX, Disodium and Norfloxacin were found to

have turned to extreme photosensitizers. Thus this assay can be also used as an alternative in chemico assay for predicting photosensitization potential of chemicals.

--(PP-26)--

Genotoxicity assessment by using non animal model

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The *Allium cepa* test ,an alternative to the use of animal model, is being used by many researchers mainly as a bioindicator of environmental pollution, be it testing crude extracts of cyanobacteria or to evaluate the genotoxic potential of medicinal plants because this test uses a model that is adequately sensitive to detect innumerable substances that cause chromosomal alterations. It is an excellent model *in vivo*, where the roots grow in direct contact with the substance of interest (i.e. effluent or complex medicinal mix being tested) enabling possible damage to the DNA of eukaryotes to be predicted. Therefore, the data can be extrapolated for all animal and plant biodiversity. The analysis of chromosomal alterations can be equal to the test of mutagenicity mainly for the detection of structural alterations; however, it is possible to observe numerical chromosomal alterations, as well. The *Allium cepa* test is one of the few direct methods for measuring damage in systems that are exposed to mutagens or potential carcinogens, and enables the evaluation of the effects of these damages through the observation of chromosomal alterations.

Keywords: Genotoxicity, *Allium cepa*, plant model

--(PP-27)--

Assessment of drug permeability via Parallel Artificial Membrane Permeability Assay (PAMPA)

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Various cell-based in vitro methods have been developed for assessment of permeability, in order to predict drug transport properties in humans. Since traditional methods are time consuming and labor-intensive, therefore newer cost-efficient methods have been developed to estimate drug permeability. PAMPA is one such method that measures the permeability of compounds through an immobilized lipid infused artificial membrane. During assay, the drug is added to the donor compartment of the plate, and the acceptor compartment of the plate is kept drug-free. After 5 hours of incubation, plates were separated and amount of remaining drug is measured in each compartment on HPLC. Test chemicals like Atenolol, Carbamazepine, Omeprazole, Verapamil, Diclofenac, Midazolam, Chlorambucil, Phenacetine, Caffeine, Quinine, Dextromethorphan, Sulfaphenazole, Warfarin, and Flurbiprofen were used in the study. In this study, we also used high-throughput method for analysis. In this assay post 5-Hours of incubation, 7-8 compounds were mixed in an appropriate ratio and were co-analyzed with HPLC. Results of the study clearly indicated that individual analysis of compounds as well as analysis in mixture yielded the similar results. Based on results obtained, Carbamazepine, Diclofenac, Omeprazole, Phenacetin, Midazolam, Verapamil,

Caffeine, Quinine, Dextromethorphan, Warfarin and Flurbiprofen were found to be permeable, while Atenolol and Sulfaphenazole were found to be non-permeable. Thus, we propose high throughput PAMPA as an efficient as well as cost-effective method for predicting drug permeability.

--(PP-28)--

Role of invertebrate animal models in experiments

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Abstract: In today's era the use of invertebrate animals are mainly concerned for research and teaching so as to prevent the unwanted decline of vertebrate animals in research. The main fields of concern are biology or the living system and medicines for which they are being tested and approved. Thus the specific use of invertebrates mainly emphasizes on research in drug development, including the invention of bioactive products from terrestrial region and marine invertebrates. They also hold a place in toxicity and efficacy testing of new pharmaceuticals for both human and animal diseases, sparing vertebrate animals from preliminary testing. These animal models serves as an alternative teaching subjects which provides students with opportunities to observe behavior, anatomy, physiological principles, pathology, results of genetic manipulation, and mechanisms of drug actions. To go with hand in hand researchers, veterinarians, and institutional animal care and use committee (IACUC) members keeps on searching for models of specific conditions and diseases. A large number of invertebrates have been used in the developmental process, but the two primary organisms are *Drosophila* and *C. elegans*, with *Drosophila* most often used as because of the close correlation between *Drosophila* and vertebrate cardiogenesis and the conservation of key genes which are responsible. The fly's heart serves as an excellent model of cardiac development and disease. Invertebrates models are used in studying of Neuroimmunology, Memory learning and behaviour, Musculoskeletal, Neural and Neuromuscular system. Other useful area of invertebrate model are Pathophysiology, Aging, Health span of vertebrates, Apoptosis, cancer and also in Toxicological study of vertebrates with five senses. Thus the use of these animal models serves as a boon in medical research field mainly Biomaterials and Biomimetics which helps use to understand the mechanism easily.

--(PP-29)--

Polymorphism of DNA repair gene OGG1: Link with oxidative DNA damage in charcoal workers exposed to PAH

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Human 8-oxoguanine DNA glycosylase 1 (OGG1) removes and replaces the oxidised base 8-oxoguanine, thus repairing oxidative DNA damage induced by several kinds of carcinogens,

mutagens and immunosuppressants. . SNPs in such genes can affect the efficiency of the DNA repair machinery and contribute to genomic instability and cancer development. Biomass fuels such as charcoal and wood are frequently used in small scale industries of developing countries. During the process of charcoal production, charcoal workers are occupationally exposed to polycyclic aromatic hydrocarbon (PAH). PAH exhibit varied toxicity. In this study, we assessed the interactive effect of OGG1 gene polymorphism on oxidative DNA damage in PAH exposed population involved in charcoal production. The population under study included 77 charcoal workers who were exposed to PAH and 79 healthy control subjects who were not exposed to PAH; but belonged to the same age group and socio-economic status as the charcoal workers. Urinary 8-oxodG content (biomarker of oxidative DNA damage) was found to be significantly higher in OGG1 homozygous mutants (mt/mt) (18.81 ± 3.34) as compared to wild type genotypes (wt/wt) (10.34 ± 2.25) and heterozygous (wt/mt) mutants (12.82 ± 2.81) in charcoal workers. 8-oxodG content was found to be significantly lower in OGG1 homozygous mutants (mt/mt) as compared to wild type genotypes (wt/wt) and heterozygous (wt/mt) mutants in control population. So, genetic polymorphism of DNA repair gene OGG1 has great importance in risk assessment of genotoxic/ carcinogenic effects of PAH exposure in charcoal workers. However, more studies need to be carried out for better understanding of gene-environmental exposure interactions in occupational workers.

--(PP-30)--

Estimation of lead toxicity in the National Capital Region by utilizing the unused blood of pathology laboratories; an alternative tool for heavy metal toxicity studies

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The pathology laboratories are widely available in most of the regions of India. The utilization of remaining or unused blood of these pathology laboratories may become a strong tool for the estimation of heavy metals toxicity. Sometimes, there are important reasons (eg, collection tube dead space, variation in hematocrit, repeat analyses, dilutions, and add-on tests etc) for collecting more specimen than the analytic volume. The amount of unused specimen of blood or plasma that remained after testing was completed in pathology laboratories is required to be discarded as per the biomedical waste processing. However, this unused blood sample/ plasma can be utilized in the estimation of heavy metals toxicity and related studies after taking patient consent. The atomic absorption spectroscopy may be utilized for the assessment of heavy metals in these samples for ignition in a flame or furnace at high temperature. The presence of the additives will not affect the quality of the heavy metals estimation as the blood sample is ignited at high temperature approx 2000 °C. In the present study, the authors collected the remaining blood samples from the pathology laboratories of the National Capital Region and carry out the estimation of lead content in the same. Lead estimation has done by method optimized using AAS equipped with Graphite Tube Atomiser. The heavy metals toxicity studies may be performed without using animals by utilising the blood samples remaining after pathology testing in pathology laboratories. The data collected by this mean may be helpful for the particular patient as well as for research purpose, health care authorities and ultimately for the betterment of society at large.

--(PP-31)--

Alternative methods to animal experimentation: Need of an ethical inspection

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Research on laboratory animals has provided valuable information and has been fundamental in the development of vaccines, anaesthetics and antibiotics. Animal experimentation is a debating issue for a long time and rules and regulations have been made to carry out the control over unethical animal experimentation. In the present study, survey was conducted among postgraduate students of biotechnology to find out the acceptance of alternative methods to animals in research. During study 18% of the students were agree that use of animals for experimental purposes is beneficial for human-beings but it violates the rights of animals, 82% postgraduate students suggested the need of alternative methods such as zebra fish, fruit flies and nematodes for research experiments as these are less expensive, efficient and easy to handle. 72% students felt that human volunteers can be used for microdosing experiments as an important alternative. However, some students felt that the use of animals in research should continue to be essential to make progress in the areas of rare diseases, cancer, dementia and viral diseases etc. Different alternative methods such as in vitro cell and tissue culture techniques, synthetic membranes, MRI, computer models and software programmes can predict the properties and action of drug without animal dissection etc. The implementation of alternative methods can reduce animal usage in research but more efforts need to be undertaken to follow four Rs principle (replacement, reduction, refinement and responsibility) to reach the patients more rapidly. Hence, there is an urgent need in revision of curriculum at national level by introducing alternative methods and formulation of guidelines regarding the animal usage for laboratory experiments.

--(PP-32)--

Glial cells and neurodegenerative diseases: Deciphering the functional cues employing genetic model system in *Caenorhabditis elegans*

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Glia are as numerous as nerve cells in vertebrate nervous systems, however the research with glia hasn't progressed as much as the research with neurons has. Part of the complexity has been lack of model systems to study glia. Of late, efforts have been driven in the direction of applying novel approaches towards understanding the biology of glia, particularly in light of human disease conditions. Interestingly, researchers have had success in moving ahead within the field by employing two genetically well deciphered model systems – *Drosophila melanogaster* and *Caenorhabditis elegans*. In particular, *C. elegans* is interesting for its simple nervous system which exhibits complex functions in multiple behaviours. The nervous system of *C. elegans* consists of 302 neurons, 50 glial cells derived from neuronal/epithelial progenitors, and six glial cells that are mesodermally derived. These cells not only run parallel to neurons but also surround the nerve ring which is the central component of nematode nervous system. With an aim of understanding genetic mechanisms

associated with age associated neurodegenerative diseases, we employ various functional genomics tools towards identifying novel genetic modulators relevant to these ailments. In the present study, we carried out a detailed work-up on genes orthologous to human glial cell marker genes olig-2 (oligodendrocyte-2 protein) and PTCHD1 (Patched Domain Containing 1; known gene for Autism disorder) named in *C. elegans* as *hlh-17* (expressed particularly in CEPsh glial cells) and *ptr-10* (global marker of glial cells) respectively. Employing transgenic strain NL5901, that expresses 'human' alpha synuclein, we studied aggregation of alpha synuclein and its associated effects including effects on locomotion, content of reactive oxygen species, expression of dopamine transporter, dopamine associated function and effect on dopaminergic neurons. We further went on to study the expression pattern of *hlh-17* and *ptr-10* across various stages of life starting from pre-reproductive maturity stage of worms till their aged life stage. Our findings reveal a strong correlation between glial cells and neuronal functions. In particular the association of CEPsh cells with dopamine function is interesting in context of Parkinson's disease and opens up interesting avenues for further research in this direction. The studies are a significant step towards understanding intriguing biology of glial cells and their related marker genes which could hold promise in answering important questions related to therapeutic understanding of neurodegenerative diseases.

--(PP-33)--

In chemico assay for evaluating the skin sensitization potencies of triazole

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Recently due to the ban on testing of cosmetics on animals combined with ethical concerns on traditional animal-based assay for testing of cosmetics lead to the development of robust non-animal alternative assays. Skin sensitization is an important toxicological endpoint associated with cosmetic products. This adverse effect results from an overreaction of the adaptive immune system and the key event leading to skin sensitization is well known. Based on this knowledge, two *in chemico* assays the Direct Peptide Reactivity Assay (DPRA) and the Peroxidase Peptide Reactivity Assay (PPRA) have been developed to evaluate skin sensitization potencies of chemical compounds. Both assays involve utilization of synthetic peptides containing either a single cysteine or lysine amino acid as its nucleophilic center for assessing skin sensitization potencies of chemical compounds. Among the two assays, Direct Peptide Reactivity Assay has been evaluated for its reproducibility, transferability, and accuracy under formal validation studies. The present study evaluates 10 commonly used triazoles using the direct peptide reactivity assay. The depletion of the DPRA peptides was used to classify chemicals into four different categories of reactivity allowing discrimination between non-sensitizing and sensitizing chemicals. Among the tested compounds five were tested positive, three were tested negative and two could not be examined due to poor solubility.

--(PP-34)--

Use of alternative methods in animal experimentation

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In the era of scientific applications animal plays a vital role with respect to physiology and drug testing. Due to which many animals like rat, mice, guinea pig, hamster, rabbit and monkey are used at an alarming rate. The popular outcome of animal use has been taken up by many organizations for holding a wide spectrum of views, which ranges from belief in abolition of animal use on moral and ethical grounds to belief in free rein on the use of animals in research, testing, and education. This is because animals are mainly used in dietary, health medications, transportation etc for their needs and they follow the four Rs (Replacement, Reduction, Refinement and responsibility), so to have a concrete approach many amphibians, fishes and birds are also used for experimentation. Being very vital in medication they are also a reach source of antibiotics and vaccines which are dominantly used in diagnosis and treatments. So to have a thrust alternative methods or techniques are used for the same purpose. As they provide accurate, precision result but can provide comparable information about testing of drug. An alternative can even be another in vivo experiment, in which fewer animals are consumed; there is less harm to the animals The number of animals used in research has increased with the advancement of research and development in research technology. The alternative to animal use falls in four categories like: Continued, But Modified, Use of Animals, Living Systems, Nonliving Systems and Computer Programs. Thus various methods are in-vitro, ex-vivo, in-silico and genetically modified organs. So still a thrive is in search for alternatives to animal experimentation, which includes educational aspect, is experiencing intense evolution. Thus these methods can be a choice of animals in biomedical research, testing or teaching.

--(PP-35)--

Protective effect of ginger against experimental induced ulcer in diabetic rats

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To evaluate antiulcer potential of ethanol extract of *Zingiber officinalis* rhizome (EZO) against Pylorus ligation, Aspirin induced ulcer and Indomethacin induced ulcer models in diabetic rats. It has been reported that *Zingiber officinalis* contained presence of flavonoids, alkaloids, tannins, carbohydrates, proteins, amino acids steroids. Rats were divided in seven groups of rats in each medel of experiments. Group I was treaed with normal saline and group II was treated with Normal saline and were diabetic by inducing alloxan. Group three were taken as ulcer induced model in diabetic by inducing the alloxan. Group IV were treated with Metformin in diabetic and ulcerated rats. Group V-VII were treated with EZO (100, 200 and 400 mg/kg, p.o.) in diabetic rats. The parameters of observation were Ulcer index, pH, free acidity and total acidity in pylorus ligated induced ulcer model in diabetic rats. In other two models ulcer index and % protection and antoxident activity were the

parameters of the study. The ethanol extract of *Zingiber officinalis* rhizome were able to inhibit the acid secretion in diabetic rats and were statistically significant ($P < 0.001$) in comparison to control rats with diabetes and ulcers. In other two models ulcer index and % protection and antioxidant activity were the parameters of the study. The ethanol extract of *Zingiber officinalis* rhizome were able to inhibit the acid secretion in diabetic rats and were statistically significant ($P < 0.001$) in comparison to control rats with diabetes and ulcers. In other model the ethanol extract of *Zingiber officinalis* rhizome were also protecting the mucosa in statistically significant count and also possessed antioxidant properties. Conclusively, on the basis of result, the ethanol extract of *Zingiber officinalis* rhizome possessed protective effect against different models of ulcers in diabetic rats and that may be due to presence of flavonoids, tannins and Phenolic compounds. This confirms its usage in traditional medicine.

Key words: *Zingiber officinalis*, Antioxidant, Pylorus ligation, Aspirin induced ulcer, Indomethacin induced ulcer.

--(PP-36)--

Cell line studies in diabetic research as an alternative to animal studies

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Diabetes mellitus is a serious health problem in India nowadays. It affects the quality of life. All socio-economic groups in India are experiencing a rise in living standards and diabetes is a condition in which there is inability to regulate insulin levels which leads to tissue damage and organ failure. It has become country's fastest growing burden over 16 years to 2016. India currently represents 49 percent of world's diabetes burden, with an estimated 72 million cases in 2017, a figure expected to almost double to 134 million by 2025. With this alarming situation there is urgent need to explore more drugs and medicinal plants for its treatment. Animals models have enormously contributed to the study of diabetes mellitus. They have given researchers the opportunity to control in vivo genetic and environmental factors that influence the development of disease and establishment of its complications, and thus gain new information about its handling and treatment in humans. Most experiments are carried out on rodents, even though other species with human like biological characteristics are also used. There are some other methods used in diabetic research which have replaced animal studies. One of them is the use of cell lines in diabetic research. The most widely used insulin secreting cell lines are RIN, HIT, MIN, INS-1 and TC cells. These cells produce insulin and small amount of glucagon and somatostatin. Some of them show poor response to glucose, others respond to glucose well. Despite problems associated with beta cell cultures, these cell lines have provided some valuable information about physiological processes in diabetic research.

Key Words: Diabetes mellitus, Animal models, Cell lines.

--(PP-37)--

Alternatives to animal experimentation in toxicology: Challenges and issues

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A large number of laboratory animals are used in various toxicological, behavioural, and evolutionary studies. Millions of animals such as rats, fish, mice are used all over the world every year. There are several disadvantages of using animals in experiments such as it is very expensive, time consuming and it required skilled manpower. We can also use some smaller animals such as *Drosophila* (Fruit fly), zebrafish etc. for experimentation as alternative. Several alternative methods can be used to lower the cost of experiments include- genetic and stem cell testing methods, *in vitro* test methods, tissue culture, non-invasive imaging techniques etc. These techniques upto some levels are alternatives to animal experimentation in chemical, drug and toxicological testing.

Key words: Animals, experimentation, toxicology

--(PP-38)--

Equilibration of regulatory schemes: Is it imperative or futile?

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Each country strive to protect the welfare of animals, while authorizing the appropriate goals of scientific research to be attained rendering the legal principles, cultures, strengths and constraints of their jurisprudential and societal ethnicities. The adaptation of standard strategies everywhere upsurges the credibility of data and makes it acceptable to regulatory authorities across the world. Every country has their own regulatory bodies for animal welfare, which imposes ethical consideration for the proper care and use of animals by researchers and animal care technicians. For example in developing country like India, Animal welfare Board of India (AWBI) and Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA), National Animal Welfare Advisory Committee (NAWAC), MCI, VCI plays a major role in instigating the rules for the welfare of animal. In developed countries like US, which is more hierarchical and with respect to laws governing animal research which is more traditional, command and control law oriented but Canadian approach is rooted in the concepts of social contracts, with a greater emphasis on guidance and policy and less reliance on legislation, where no federal direct legislation of laboratory animal welfare exists. Legislation for laboratory animal use has been enacted in India and Australia, while animal protection regimes have not yet been enacted in the Middle East and Africa. It is necessary to illuminate the laws and regulations governing animal use, which vary greatly across the globe. International harmonization in terms of regulatory schemes is necessary and it is an important challenge for global scientific community especially to those countries which have not yet developed robust legal systems applicable for animal welfare.

--(PP-39)--

Organ on Chip as an alternative to animal experiments

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The preclinical studies found that the researchers to find the alternatives to animal experiments just because not only to decrease the time but also decrease the number of animals used. That's why alternatives have been devised. Russell and Burch defined these alternatives depend upon three R's- Reduction, Refinement and Replacement. Later on, in 1995 4th R was also added i.e., Responsibility. Based on these one alternative method named "Organs-on-chip" introduced. Clinical studies take year to complete and testing a single compound. Meanwhile, innumerable animals life are lost, and the process often fails to predict human response because traditional animal models often do not accurately mimic human pathophysiology. For these reasons there is need for alternative ways to model human disease in vitro in order to accelerate the development of new drugs and advance personalize medicine. An organ on chip (OOC) is a multichannel 3D micro fluidic cell culture chip that stimulates the activities, mechanics and physiological response of entire organs and organ systems. These micro devices offer a potential alternative to traditional animal testing. Each organ chip is composed of a clear flexible about the size of a computer memory stick that contains hollow micro fluidic channel. Organs that have been stimulated by micro fluidic devices include the heart, the lung, kidney, artery, bone, cartilage, skin and more. And one day they will perhaps abolish the need for animals in drug development and toxic testing.

Key words: Organs-on-chip, traditional animal testing

--(PP-40)--

In vitro vaginal models

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The human vagina represents an ideal and potential route of administration both for local and systemic administration of drug. It offers advantages like larger surface area, rich vasculature, steady drug level, decrease frequency of administration, low dose, avoidance of gastro intestinal route and first-pass effect etc. Although this route has several advantages, efficient drug delivery at vaginal cavity is often challenging owing to its peculiar physiological variations and has remarkable features in terms of secretion, pH, enzyme activity and micro flora. These factors play a vital interaction with the active moiety during study conducted in animal and human model. These complex interactions can be avoided by using in vitro testing of formulations with simulated fluids and simulated tissue models representing, what they encounter within the vagina. This simulant reduces the use of animals and bypasses ethical concerns for the usage of animal and human tissue and cuts down the research

costs. The positive outcomes from this could then be confidently submitted for animal evaluation.

--(PP-41)--

In vitro genotoxic effects of hair dye on peripheral human lymphocytes

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According to the International Agency for Research on Cancer (IARC), some hair dyes are considered mutagenic and carcinogenic in in vitro assays. Different mechanisms such as oxidative DNA damage, interference with DNA repair systems are found to be responsible for genotoxicity and cytotoxicity of hair dye. Epidemiological studies indicate that hair dressers occupationally exposed to hair dyes have a higher risk of developing bladder cancer. Hair dyes and their ingredients have moderate to low acute toxicity. Para-Phenylenediamine (PPD) is found in almost every hair dye formulations and it is the most frequently used permanent hair dye component. PPD containing hair dyes have been associated with cancer and mutagenicity. In our studies, cytotoxicity and genotoxicity of hair dye was assessed by trypan blue assay and comet assay respectively. The hair dye formulated with PPD and resorcinol with hydrogen peroxide induces significant cytotoxic and genotoxic effects in peripheral blood lymphocytes.

--(PP-42)--

In silico and In vitro approach makes theranostics for bone disorders Simpler

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Since science transmute things further than what we know, and technology alters upon what we depend on, research and testing will also switch to embrace and rely on alternatives rather than the use of animals. Using animals for the purpose of research is one crucial attention-demanding subject. The number of animals used in research has ascended with the advancement in medical technology, as animal's trials are cruel, expensive, and many times inapplicable to humans, methods for studying diseases and testing products that substitutes animals have been devised. However, besides great progresses regarding non animal models, the prominence of in silico methods in therapeutics to contribute towards reduction of lab animal usage is scarcely noticeable, which motivated us to follow in silico approach to study the effect of various miRNAs on pathogenesis of osteoporosis. miRNAs are post transcriptional regulators as potential theranostics in numerous bone diseases. Different bioinformatic tools were utilised for osteogenic profiled miRNAs (miR1) to identify biomarkers and therapeutic targets for bone disorders. Initially miRNA target prediction tools viz Targetscan, Tarbase7.0 were used for miR1 which served with putative and validated bone related targets, further we hypothesise that these validated targets will be shared with homolog miRNA, providing novel targets for homolog miRNA, homology prediction tool viz

blastn was applied on miR1, followed sequence retrieval for homolog miRNA from miRBase(Database for miRNAs).Furthermore,tools like RNA hybrid and S fold were employed to acquire specific and promising candidate targets for homolog miRNA. Additionally in vitro studies in combination with in silico approaches, provides a valuable tactic for miRNA therapeutics as alternative to animal exploitations,hence, these targets were further found to be successfully validated in osteoblast cell lines, which sanctions the application of bioinformatic tools in theranostics as a beneficial asset.Therefore, science can and must protect animals survival,environment and encourage better health for humans.

--(PP-43)--

In silico approaches for drug development- alternative tool to Animal Experiments

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The process of drug discovery and development is a time consuming and requires lot of tools and methods to identify a molecule which then comes in to existence as it crosses various phases of inventions. In order to overcome this process in a shorter span the alternative methods are employed so as to rectify the manifestations and disadvantages. A new field which serves the purpose is to apply computational power with respect to chemical and biological space. This will indeed lead to design, development and optimization of molecules Thus in-silico came into existence with its advantages. This field has its own importance in which the different sides of basic research and the practice are combined and inspire each other, modern techniques like QSAR/QSPR, structure based design, cheminformatics, bioinformatics and an increasing number of biological and chemical databases. Methods like Homology modeling, molecular docking, and virtual high throughput screening, comparative molecular field analyses are employed in it. It holds its importance in biomedical arena, computer-aided design to expedite and facilitate hit identification, hit to lead selection, optimize the absorption, distribution, metabolism, excretion and toxicity profile and avoid safety issues. Thus it has been observed that during the process of selection a no a novel drug essential steps are to be looked upon so as to minimize the errors in it. A Regulatory agencies as well as pharmaceutical industry are actively involved in drug discovery and development process which decreases the use of animals and increase predictability. Hence an expected power of CADD will grow as the technology continues to evolve due to drug designing and examine the molecular pathway for its expression and target identification.

Key words: Pharmacophore, CADD, Spatial, in silico discovery

--(PP-44)--**Formulation, characterization and in-vivo pharmacokinetics of casein-based micelles solution for controlled delivery of poorly soluble drug Gliclazide**

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Novel prolonged release casein-based micelles loaded with poorly soluble drug, gliclazide was developed by solvent evaporation technique. An amphiphilic phosphoprotein, β -casein that self-assembled into well-defined hydrophobic core and hydrophilic shell micelles. The solubilization of drug was enhanced by incorporating it inside the hydrophobic micellar core. CAS-micelles were obtained with particle size less than 100nm and zeta potential approx. -30mV. The optimized formulation was characterized by using CCD design, then characterized by in-vitro and in-vivo studies which shows a prolonged release approx. 60% at 24hrs in comparison to conventional drug delivery system shows 96.6% release at 2hs. The stability of micelles was found to be 6 months with no significant variation in drug content. Henceforth, CAS-micelles solution via subcutaneous administration of poorly soluble drug i.e. gliclazide not only prolonged the release of drug but also improve the bioavailability of the drug, avoidance of first pass metabolism, reduce the associated side effect and frequency of dosage form.

--(PP-45)--**Computational studies on CVS acting phytoconstituents**

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Over the past decades, use of traditional medicinal plants in the drug discovery process has been focused due to availability of complementary pharmacological approaches. In silico approaches including virtual screening and network analysis have been widely used to elucidate the pharmacological basis of the functions of traditional medicinal plants. In this work, we first provide a detailed research routine for examining traditional medicinal plants by in silico techniques and elaborate on their theoretical principles. Phytoconstituents of Leek (*Allium ampeloprasum*) have been investigated by molecular docking studies to understand the binding interactions with cardiovascular drug targets. The selected drug targets are G protein coupled receptor kinase-2 and -4, mineralocorticoid receptor (MR), angiotensin-converting enzyme (ACE), and ASK1 for the treatment of hypertension and congestive heart failure (CHF). AutoDock 4.2 program was used to perform docking studies based on Lamarckian genetic algorithm methodology. The selected docking protocol was validated by re-docking the co-crystallized ligands into their original binding pockets. Analysis of binding energy, predicted inhibition constant and hydrophobic/hydrophilic interactions of ligands with target receptors revealed some promising targets.

--(PP-46)--

In-vitro culture as alternative to animal experiments

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The main aim for using an alternative for animal experiment is that there is widespread agreement that a reduction in the number of animals used and the refinement of testing to reduce suffering should be important goals for the industries involved. An alternative for animal experimentation must be introduced in order decrease the death rate of animals which happens due to experiments performed on them. Major alternative to in vitro animal testing is in vitro cell culture techniques. It can be an alternative to animal use in some cases. For example, cultured cells have been developed to create monoclonal antibodies. Human epidermal keratinocytes have been cultured to mimic the human epidermis, and are used to measure skin irritation and dermal corrosion. This method has been accepted by the EU and is intended to replace the Draize rabbit skin irritation test. Pyrogens are most often pharmaceutical products or intravenous drugs that may cause inflammation or fever when they interact with immune system cells. This interaction can be quickly and accurately tested in vitro. The modular immune in vitro construct (MIMIC) uses human cells to create a model of the human immune system on which the efficacy of new vaccines and other compounds may be tested, replacing some steps of the vaccine development process that would otherwise be performed on animals. This process is faster and more flexible than previous methods. Many other methods have been lately added to this in-vitro culture testing which is an alternative to animal experiments.

Key words: alternative for animal experiment, in-vitro animal testing.

--(PP-47)--

Epedermodysplasia verruciformis- A genetic disorder

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Ebola is a viral illness of which the initial symptoms can include a sudden fever, intense weakness, muscle pain and a sore throat, according to the World Health Organization (WHO). Airborne transmission of Ebola virus has been hypothesized but not demonstrated in humans. Ebola is not spread through the air or by water, or in general, by food. However, in Africa, Ebola may be spread as a result of handling bushmeat (wild animals hunted for food) and contact with infected bats. The disease infects humans through close contact with infected animals, including chimpanzees, fruit bats, and forest antelope. Ebola virus can be transmitted by direct contact with blood, bodily fluids, or skin of patients with or who died of Ebola virus disease. As of late October 2014, the World Health Organization reported 13,567 suspected cases and 4922 deaths, although the agency believes that this substantially

understates the magnitude of the outbreak. Experimental vaccines and treatments for Ebola are under development, but they have not yet been fully tested for safety or effectiveness.

Key words: EVD (Ebola virus disease), etiology, clinical features, control measures, transmission

**An *In silico* designing and efficient synthesis of new pyrazoline derivatives:
Search for potential anticancer and EGFR kinase inhibitors**

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A new series of substituted pyrazoline derivatives were synthesized and subjected to in vitro evaluation for anticancer activity and EGFR Kinase inhibition. The synthesized compounds were characterized by IR, NMR, and Mass. All the synthesized derivatives were tested for their in vitro anticancer activities (MTT assay) on two cancer cell lines as HCT116 and A549. Compound 5g showed significant activity against the lungs cancer cell lines, A549 ($IC_{50} = 1.01 \mu M$) and EGFR kinase ($IC_{50} = 2.20 \mu M$) as compared to standard drug. Docking study of all the synthesised compounds were performed using Glide extra precision (XP) Maestro 10.1 Schrodinger software on EGFR Kinase (PDB: 1M17) in order to predict their binding mode. The compound 5g formed strong hydrogen bonds with MET 793 and ASP 800 respectively at active site of EGFR. The docking studies of compound 5g also revealed that the presence of linker moiety between two rings are important for making hydrogen bonding. The binding orientation of titled compounds was found to be same as co-crystal ligand. The results of in-vitro studies prove that pyrazoline derivatives could generate more potent anticancer and EGFR Kinase inhibitors.

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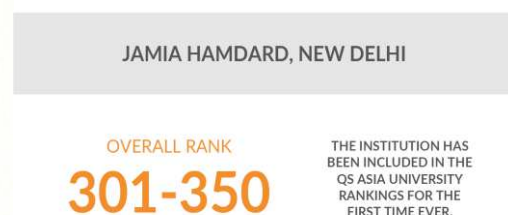
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The Department of Medical Elementology and Toxicology is one of the few Departments in India having full-fledged academic programme at Postgraduate and

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