

7TH

EDITION OF GLOBAL CONFERENCE ON

PHARMACEUTICS AND NOVEL DRUG DELIVERY SYSTEMS



VIRTUAL EVENT

SEPT 08-09

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**BOOK OF
ABSTRACTS**

**7TH EDITION OF GLOBAL CONFERENCE ON
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ABOUT MAGNUS GROUP

Magnus Group (MG) is initiated to meet a need and to pursue collective goals of the scientific community specifically focusing in the field of Sciences, Engineering and technology to endorse exchanging of the ideas & knowledge which facilitate the collaboration between the scientists, academicians and researchers of same field or interdisciplinary research. Magnus group is proficient in organizing conferences, meetings, seminars and workshops with the ingenious and peerless speakers throughout the world providing you and your organization with broad range of networking opportunities to globalize your research and create your own identity. Our conference and workshops can be well titled as 'ocean of knowledge' where you can sail your boat and pick the pearls, leading the way for innovative research and strategies empowering the strength by overwhelming the complications associated with in the respective fields.

Participation from 90 different countries and 1090 different Universities have contributed to the success of our conferences. Our first International Conference was organized on Oncology and Radiology (ICOR) in Dubai, UAE. Our conferences usually run for 2-3 days completely covering Keynote & Oral sessions along with workshops and poster presentations. Our organization runs promptly with dedicated and proficient employees' managing different conferences throughout the world, without compromising service and quality.



ABOUT PDDS 2022

Magnus Group welcomes you to our Online Event entitled “7th Edition of Global Conference on Pharmaceutics and Novel Drug Delivery Systems” PDDS-2022 scheduled on September 08-09, 2022. with the theme “To foster the strategies of Pharmaceutics and Novel Drug Delivery Systems”.

The two-day conference is designed to maximise collaborations and innovation, with pharma and technology presentations, interactive sessions, oral and poster sessions, and visionary keynote sessions by professionals from industry and academia. Join us at PDDS 2022 to meet scientists from around the world and to learn how to move pharma from the bench to the market.



KEYNOTE FORUM

DAY 01

7TH EDITION OF GLOBAL CONFERENCE ON
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08-09 SEPT



Victoria Demina*, Katja Kossmann, Marcus Stapf,
Anke Hermann, Jonas Kosten, Oliver Ernst, Heiko Manninga
Neuway Pharma GmbH, Germany

Drug delivery to the brain using engineered protein capsules (EnPCs®)

The blood brain barrier (BBB) is both a blessing and a curse: On the one hand, the tightly connected endothelial cells covering the cerebral blood vessels protect the brain from harmful large molecules. On the other hand, they are the obstacle to treat severe central nerve system (CNS) diseases. The limiting factor is not the absence of active compounds, but to facilitate their passage through the BBB. To achieve this goal, NEUWAY Pharma GmbH develops a next-generation, proprietary CNS drug delivery platform technology enabling drug transport across the BBB for a broad spectrum of therapeutic compounds, such as small molecules, nucleic acids (incl. mRNA or plasmid DNA, oligonucleotides) or proteins (incl. antibodies). The cargo molecules are encapsulated in the lumen of biotechnologically manufactured and purified Engineered Protein Capsules (EnPCs®), which are derived from the shell of the common John Cunningham Virus (JCV) maintaining its CNS tropism. The resulting stable protein nanoparticles are very well characterized, stable, protect the cargo molecules against detrimental environmental effects such as degradation and overcome two physiological barriers, i.e. BBB and cell membrane of target cells.

Here we present different strategies for Drug Delivery applying EnPCs®:

- Packaging different modalities into EnPCs® and their delivery (proteins, antibodies, ASO, siRNA)
- Intense focus onto data for EnPCs® loaded with mRNA. As example, mRNA encoding for luciferase and the therapeutic protein arylsulfatase A (ASA) to treat Metachromatic Leukodystrophy (MLD) were encapsulated into EnPCs® and delivered in vitro and in vivo in the mouse disease model
- Using various in vitro cell models, including blood brain barrier (BBB) transwell model, we demonstrate trafficking of EnPCs® through BBB cells and transfection of CNS cells in the abluminal compartment (also in cooperation with AbbVie Deutschland GmbH & Co. KG., published at Nanoscale Advances, 2021). In vivo experiments in mice show delivery of mRNA and expression of functional protein after delivery into the brain via intravenous (i.v.) injection. This approach with NEUWAY's proprietary CNS drug delivery platform technology has the great potential to be the key to successfully treat severe CNS diseases with very high medical need

Audience Take Away Notes:

- The advantages of Engineered Protein Capsules (EnPCs®) used as next-generation drug delivery technology for delivering drugs to the brain
- EnPCs® are able to load a broad spectrum of cargo molecules (nucleic acids, proteins, small molecules), facilitate passage through blood brain barrier (BBB) and delivery of functional cargo molecules to the brain
- Safety advantages of EnPCs®, e.g. intravenous injection omits surgical procedures and circumvention of the disadvantages associated with viral vectors such as AAVs or lentivirus
- Scalable production and purification process of EnPCs® in combination with a scalable, universal encapsulation process for drug encapsulation
- Open to collaborate on or co-develop optimized cargos for brain delivery

Biography:

Victoria Demina studied Biology at the Novosibirsk State University, Russia and graduated as MS in 2007. After graduation she came to Germany and since then worked in different biotechnological companies and institutions. Viktoria Demina is a co-founder of NEUWAY Pharma GmbH and works as Head of Production and Manager R&D. She published a high number of different papers and patents over the last 13 years.



Cornelia Braicu^{*1}, Lavinia Lorena Pruteanu¹, Maria-Ancuta Jurj¹, Lajos-Zsolt Raduly¹, Oana Zanoaga¹, Iulia Neamtiu², Eugen Gurzau², and Ioana Berindan-Neagoe¹

¹Iuliu Hațieganu University of Medicine and Pharmacy, Romania

²Environmental Health Center, Romania

Arsenate target specific cell death mechanism in normal and tumoral breast cancer cell lines

Arsenate was demonstrated to be implicate in a wide range of cellular and molecular pathways. These multiple actions of Arsenate highlight the need for additional mechanistic studies to determine which actions mediate the diverse biological effects of this compound as environmental toxic agent or therapeutic target. Our study was focused on the evaluation the response to a low dose (50nM) of arsenate in a panel of normal (HMEC) and tumoral breast cancer (MCF7, Hs578T and MDA-MB-231). Microscopy results showed that arsenate induced cytoskeletal alteration, as well as increased autophagy and apoptosis rate in the breast cancer cell lines, none of which was seen in the normal breast cell line. Arsenate treatment specifically induces autophagy, apoptosis and cytoskeletal alteration, these effects being more pronounced on tumor cells than in the of the normal breast cancer cell line. Additional gene expression microarray evaluation (Agilent technology) was done, showed that arsenate induced important alteration on transcriptomic pattern, these being cell type specific. These alterations were related to autophagy, apoptosis, epigenetic alteration and DNA damage signaling. Furthermore, we revealed an activation of a panel of genes responsible for promoting drug resistance. Our study provides new insights on mechanistic understanding of the toxicity of arsenate and might have an important role on the development of more effective therapeutic interventions.

Audience Take Away Notes:

- The description a fundamental study related to the mechanism of action of arsenate on tumor and normal breast cancer cell lines
- Discussion related to the biological significance of using small doses of arsenate (environmental toxic agent or therapeutic agent), emphasis the originality and the limitation of the study

Biography:

Cornelia Braicu is a researched at Research Center for Functional Genomics, Biomedicine and Translational Medicine, "Iuliu Hațieganu" University of Medicine and Pharmacy. Dr. Braicu has a background in translational medicine, the major field of interest being functional genomics and she has over 130 ISI papers, of which 35 as first author, h-index.



Miroslav Radenkovic* and Ana Jakovljevic

University of Belgrade, Serbia

Cardiac myosin inhibitors – New pharmacological approach for obstructive hypertrophic cardiomyopathy treatment

The modern knowledge of hypertrophic cardiomyopathy (HCM) rapidly evolved over the past twenty years, where the thorough understanding of HCM pathophysiology, combined with innovative therapeutic solutions, finally allowed us to achieve some excellent outcomes, including in obstructive HCM (oHCM). Currently, septal reduction therapies are largely confined to patients with oHCM who have advanced symptoms, as defined by New York Heart Association (NYHA) Class III or IV. Unfortunately, worldwide, many patients with oHCM are managed in institutions with limited or no expertise in septal reduction therapies. The initial approach to treatment of symptomatic patients with oHCM includes beta blockers, non-dihydropyridine calcium channel blockers, and disopyramide. Although generally effective, all these agents are commonly associated with specific adverse drug reactions. Therefore, the development of pioneering, disease-aimed therapies, represent a major chance for oHCM patients. It was recently confirmed that HCM-associated mutations affecting sarcomere protein genes most probably cause myocardial hypercontractility, due to excessive availability of myosin heads ready to form cross-bridges with actin, with a reduced proportion remaining in the energy-sparing super-relaxed state not available for engagement. Consequently, cardiac myosin inhibitors (CMI) represent a new class of medications being developed for patients with oHCM. The first one just recently approved was mavacamten, which reduces cardiac muscle contractility by inhibiting excessive myosin-actin cross-bridge formation. The main objectives of this presentation will be to clarify pharmacological properties of mavacamten, including pharmacodynamics, pharmacokinetics, indications and contraindications for use, adverse drug reactions, as well as the most important drug interactions. This will provide better understanding of this ground-breaking drug for oHCM, thus helping clinicians in appropriate prescribing and its adequate clinical use.

Biography:

Miroslav Radenkovic, MD, MS, PhD, a full-time professor at the Department of Pharmacology, Clinical Pharmacology and Toxicology, graduated from the Faculty of Medicine – University of Belgrade (FMUB) in 1995, and from 1996 he is working at the FMUB. He received an MS from pharmacology, board certified in Clinical Pharmacology, PhD from Medical Sciences, and a sub-specialization degree in Clinical Pharmacology - Pharmacotherapy in 1999, 2000, 2004, and 2016 respectively, from the FMUB, as well as Bioethics MS in 2021 from the Clarkson University, NYC, USA. From 2002 Dr. Radenković officially participated in several scientific projects supported by the Ministry of Science – Serbia; the Austrian Science Fund; as well as the NIH Fogarty International Center Project, USA. Dr. Radenković is a member of the Ethics Committee of Serbia.

SPEAKERS

DAY 01

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**Heema Desai¹, Kaushal Kapadia²**¹Texilla American University, India²Clinical Research Professional, India**Development and evaluation of structured strategic approach for successful accomplishment of risk-based monitoring model from clinical trial inception to completion at clinical trial organization**

International Conference on Harmonization guideline E6 requires clinical trial sponsors to conduct monitoring oversight to ensure protection of rights, safety and welfare of the clinical trial subjects. In 1988, the FDA released a guideline for Monitoring of Clinical Investigations. This guideline states that ‘The most effective way to assure the accuracy of the data submitted to the FDA is to review individual subject records and other supporting documents and compare those records with the reports prepared by the investigator for submission to the sponsor’. The 1988 guidelines led to a common consent that most of the industry that SDV of up to 100% of all entered data was required to comply with the FDA requirements for data quality and integrity. The guidelines advise the sponsors to generate an adequate level of monitoring, which is inclusive of alternative monitoring methods other than SDV, combined with a risk identification and risk mitigation process for the entire duration of the trial. SDV method proves to be costly and account for an average of 25% of the entire clinical trial budget. In the past two decades, the industry has seen a tremendous increase in number of global clinical trials and their complexity. These changes create new challenges with respect to clinical trial oversight, difference in clinical investigator experience, site infrastructure, treatment patterns, standard of healthcare and geographic variance. Additionally, increased use of electronic systems, improvements in statistical assessments creates a pathway for alternative monitoring approaches which can improve the quality and efficient of sponsor oversight. The previously available literature suggests that though we have guidance available from the regulatory agencies the sponsors and CRO are still trying to trace a pathway for successful implementation. This study tries to understand challenges in implementation and possible solutions to these challenges, developing correct and selecting right systems that is compliant to regulatory requirements and is easily adoptable by users. Additionally, the study tries to understand if the adoption of RBM model can be cost effective compared to traditional monitoring methods and ultimately leads to reduction of time. 54.6% (279 participants) respondents believe that RBM model helps reduce the time taken to review the EDC. 45.6% (233 participants) strongly agrees that mindset change is the first step towards RBM implementation. 42.9% (219 participants) agree that new mobile technologies like smart phone and fit bits to collect patient data can become a new operational excellence in RBM closely followed by 42.5% (217) participants who strongly agree to this ideology. 51.1% (261 participants) agree that RBM is all about targeted, efficient and intelligent monitoring and e-consenting is an example of intelligent monitoring. 39.1% (200 participants) are of opinion that mixed SDV strategy helps in reduction of overall cost and time. 40.9% (209 participants) opine that incorporating RBM in protocol and study design is important for implementing RBM. Implementation of RBM system needs data analytics hence having expertise in IT and clinical operations are paramount. Using risk-based monitoring technique as alternative monitoring method reduces the overall cost of the trial. However, risk-based monitoring will not reduce the importance of sponsor representative visiting the site.

Audience Take Away Notes:

- It will help the clinical research professionals to implement the risk-based monitoring model to the clinical trial. It addresses the common challenges faced, while RBM implementation and how to overcome those challenges. Additionally, it answers how efficient the remote monitoring can be in preventing the risk at first hand
- With the shift in traditional monitoring practice every clinical research professional at some point must get acquainted with the remote monitoring or centralized monitoring. This presentation tries to answer how designing of protocol plays a major role in RBM model
- It provides on-job solution for management to address the issues like mind shift change, training of personnel etc. The audience gets chance to understand basic concepts of what risk are, how risk can be identified and prevented.

- The current research is primary in nature and includes responses from industry personnel having five years of RBM experience. This research tries to touch the base all aspects of the RBM like project management, cost management, Quality management, etc. Any individual researcher can opt to deep dive and conduct research only on one parameter of the RBM model. Research can also be done only on the teams involved 100% in the RBM to give further refined knowledge of the RBM model
- The presentation provides a reason why an organization is not prepared for RBM implementation alongside provides solution to perceived barriers to RBM implementation
- The presentation helps the audience to understand how and why risk-based monitoring is gaining importance. It addresses how implementing the RBM right from the start of the trial proves to be an efficient way in identifying and preventing the risk
- The other benefits include in-depth understanding of which technological systems should be used in RBM, how those systems should be developed and what are the general expectations of the user from these systems

Biography:

Heema Desai is a Ph. D. student at Texila American University pursuing her doctorate the field on healthcare management. She has completed her master's in business management. She is a clinical research professional with core clinical experience of 9 years.

**Neha Agarwal**

University of Lucknow, India

Latest trends in bio-degradation of xenobiotics for cleaning up the environment

The release of Xenobiotics into the environment is a matter of global concern, as the harmful chemicals when reach in the environment; are stable over a prolonged period resulting in their accumulation in the environment. A gargantuan acceleration in the release of xenobiotics in the last decade has raised concerns over their occurrence in the soils and wastewaters posing imminence to the general public health and environment. Pharmaceuticals, pesticides, dyes are one of the major contributors to the unsustainable environment because they are malignant and hardly biodegradable in nature. To ensure the safe disposal and clean-up of environment the cost-effective and ecofriendly remediation technologies for degradation of these toxicants are urgently required. With the recent advances in biodegradation; researchers are showing interest in exploring bio-degradation techniques due to their efficiency, cost effectiveness and eco-friendly nature in combination with physio-chemical remediation techniques. Therefore, it's extremely important to focus on various types of remediation processes available for the removal of xenobiotics with a special attention towards biodegradation for a green and sustainable environment.

Audience Take Away Notes:

- An understanding of the persistence, accumulation and toxicity associated with the release and accumulation of xenobiotics in the environment
- Present and future challenges associated with their accumulation in the environmental
- Bioremediation potential for degradation of xenobiotics for a green, economically viable and sustainable remediation technique and their other wide applications
- Knowledge of various sources of accumulation of xenobiotics in environment and their serious post effects as threats to global environment
- Further research areas and treatment techniques for a safe and healthy environment and can work for developing sustainable and green environment
- As a career option for future research and teaching

Biography:

Neha Agarwal had been awarded Ph.D. in Chemistry at the University of Lucknow, Lucknow, India, in 2017 and qualified UGC-CSIR-NET Chemical science in 2013. She then joined the Navyug Kanya Mahavidyalaya, a leading women's college; associated with the University of Lucknow in 2019. She is presently giving her services as the Head of Department of Chemistry in Navyug Kanya Mahavidyalaya as a permanent faculty. She had published many research papers on the mechanism of oxidation of Pharmaceuticals in journals of National and International repute. She is an active member in the field of chemical science and an editorial board member of World Journal of Pharmaceutical Research (ISSN 2277-7105), and Pharmaceutical Drug Regulatory Affairs Journal (ISSN-2642-6315) open access, peer reviewed international journal of high repute. She is an active member of SNIC (Singapore), ACT, CRSI (India).

**Mirjana B. Colovic***, Danijela Z. Krstic

University of Belgrade, Serbia

Acetylcholinesterase and ATPases: targets of biologically active compounds

Acetylcholinesterase is a serine hydrolase whose key biological role is the termination of impulse transmission at cholinergic synapses by rapid hydrolysis of the neurotransmitter acetylcholine. The reversible inhibition of brain acetylcholinesterase is the major therapeutic target in the treatment of Alzheimer's disease associated with loss of cholinergic neurons in the brain and the decreased level of acetylcholine, whereas toxic effects are related to irreversible modulators of the enzyme activity. Na⁺/K⁺-ATPase is a transmembrane protein regulating many cellular functions, involving those associated with tumor cell growth. In addition, particular Na⁺/K⁺-ATPase subunits are expressed in some cancer cells and changes in Na⁺/K⁺-ATPase activity and relative subunit abundance were detected in various carcinoma cell lines. Accordingly, design and synthesis of novel compounds have been directed towards new modulators of Na⁺/K⁺-ATPase, which selectively target these cellular abnormalities. Ecto-nucleoside triphosphate diphosphohydrolases (ENTPDases) are plasma membrane bound enzymes representing the major part of purinergic signaling. Increased E-NTPDases levels were observed in cancer cells due to their abnormal cellular growth and proliferation. Accordingly, the decrease of E-NTPDase activity could be regarded as a new approach in the development of antitumor drugs. This presentation will be focused on metal-based compounds such as polyoxometalates which are discrete, negatively charged metal-oxo clusters of early d-block metal ions in high oxidation states, surrounded by oxygen atoms. These compounds were approved to exhibit a variety of biological actions such as anticancer, antimicrobial and antidiabetic properties. However, the mechanism of their bioactivities has not been completely understood yet. It has been assumed that polyoxometalates interact with different enzyme families extracellularly located on the plasma membrane such as phosphatases and ecto-nucleotidases. This presentation will primarily be directed to acetylcholinesterase, Na⁺/K⁺-ATPase and E-NTPDases as potential targets of polyoxometalate pharmacological and toxicological activities.

Audience Take Away Notes:

- The audience will achieve knowledge about promising new-generation drugs
- Other scientific institutions could use the results to expand their research
- The results present a good platform for design and synthesis of new more efficient and less toxic anticancer and anti-Alzheimer's therapeutics.

Biography:

Mirjana B. Colovic, a senior research associate, has been employed at University of Belgrade, Serbia, from 2005. Her research activities are in the field of enzymology, toxicology, biosensors, physiologically active compounds and their interactions with biomolecules. She published over 100 scientific contributions including 48 papers in impacted international journals, 4 chapters in books, 3 articles in national scientific journals, and over 70 abstracts in scientific meetings. She served as a reviewer in over 30 international journals and 9 foreign projects, and as an editorial board member in 2 international journals. Her papers are cited over 2000 times.

**Tanvi S. Kabre¹ and Kaushal Kapadia²**¹Texila American University, India²Clinical Research professional, India**Understanding the issues with recruitment in pediatric clinical trials in India as cited by key stake holders and to draw down the strategies for better recruitment**

A steep rise is seen in conduct of clinically trials not just globally but in India as well over the years. Through this pharma industry is striving to serve high quality treatments and procedure options catering to all class of populations and including those for complex diseases at affordable prices. Being said these trials in pediatric population still remains a challenge as major reason for which is low recruitment and retention rates. For prolonged times pediatric population have been excluded from clinical trials conducted globally as well as in India. It was observed that various treatments and procedures which are used for pediatric population have not undergone clinical trials. In recent times various regulations and guidelines have been laid to conduct clinical trials in pediatric population. Despite of this the major reasons disturbing or delaying enrollment in clinical trials is that the parents or legal guardians being primarily involved in decision making, concerns also arises with regards to the safety and benefits to the participating child in the study. Researchers have also identified certain other factors like study design, procedures involved, indication for the development of study drug, patient characteristics that contribute to low recruitment as well. It is necessary to overcome the enrollment issue to conduct an appropriate clinical trial which would further help in having the right effective treatments to pediatric population. Understanding the said situations, the study was designed to understand the concerns and prospective as well as the reasons from various group to evaluate the problem and filter down to the solution. A survey was designed to understand the barriers and facilitators responsible for enrollment in pediatric clinical trials. One of the groups for the study was of clinical research (CR) professionals who are in forefront of planning and execution of trials. Next was of site personnel who have firsthand experience with the management of subject population and the final group of parents with children less than or below 12 years of age as they would be the decision takers. The data was collected and analyzed, and it was observed that 100% of site and CR personnel found pediatric recruitment challenging. More than 70% CR & site professionals agreed that limited scientific literacy in general population is responsible for narrowing the chances of patient enrollment in the pediatrics trials. More than 80% of CR & site personnel see moderate to very high chances of child's primary physician referring their pediatric patients to a clinical trial but being said this around 80% consider informed consent and assenting process to majorly impact pediatric recruitment. Media is considered to have positive to extremely positive impact as per 50% site personnel. 75% of parents agreed to having heard about clinical research of which 61% parents would allow then child to participate in a trial provided the child in willing to participate on its own. Overall, it was understood that more awareness in general population will help in better recruitment and retention in pediatric clinical trials

Audience Take Away Notes:

- The data analyzed in this research study will help audience to identify various challenges and barriers observed during enrollment in pediatric trials and facilitators or measures that can incorporated in improving the recruitment and retention rate. In addition to this the audience will also learn on the understanding of what parents have about clinical research and their willingness to allow their child for participation in the trial
- The professionals from clinical research domain can apply the learnings when designing the protocol for pediatric trials. They can try designing the trial considering the barriers and discuss the same with their preferred sites. Including the factors that motivates parents for enrolling their child in trials will lead to smooth execution with low dropouts and also provide quality data during analysis
- The data analyzed for this research study can surely be a steppingstone for improving the recruitment and retention in pediatric trials. This can be researched further in-depth, and we can have problems identified in recruitment for various trials using the same survey or by modifying it as per the type or trial or identified issue

Biography:

Tanvi Kabre is a research student at Texila American University, pursuing her Doctorate in Clinical Research. She has completed PG Diploma in Clinical Research and Master's in Biochemistry from Mumbai University. She has 7+ years of experience across multiple domains in clinical research. During this tenure she has worked at clinical trial site and also couple of Global CROs & Multinational pharmaceutical organizations.

**Deepinder Singh Malik* and Ravi Goyal**

Chitkara University, India

An insight to anti-acne potentials: In-vitro, ex-vivo and in-vivo models

Acne is the 8th most commonly prevailing chronic skin disorder affecting more than 9.4% population worldwide. Its pervasiveness has been predominant in juveniles especially in males during adolescence. However, acne dominance in females is higher during adulthood. The market today is flooded with the pool of anti-acne medications (allopathic/herbal; oral, topical/systemic) that contain either single therapeutic agent or multi targeted agents acting over multiple pathological factors. Conversely, incidence of bacterial resistance, drug targeting, skin penetrability, toxicity and other pharmaceutical issues limits the clinical applicability of these commercial therapies. Thus, the therapy opted besides considering drug therapeutic and safety profile should take into account patient's related factors i.e. lesion type and severity, pre-existing medical conditions, patient's endocrine history and the desired treatment mode. This warrants the extensive understanding and research of skin physiology under normal and diseased condition so that newer, safer and effective medication could be devised. In order to ensure the safety and efficacy of innovative cosmeceuticals/drugs for acne, various acne models are implemented and analyzed. This review is an attempt to provide insight of various acne models and would provide the researcher with the varied evaluation parameters for formulating palliative acne therapies and comparative profiling of test formulation with standard commercial preparations.

Audience Take Away Notes:

- Audience will get the basic information regarding various models for evaluation of Anti-acne potential
- It will assist in determining various in-vitro, ex-vivo and in-vivo model employed for analysis of anti-acne activity of formulation and its comparison with other preparations available commercially
- Is this research that other faculty could use to expand their research or teaching? Yes
- Does this provide a practical solution to a problem that could simplify or make a designer's job more efficient? Yes
- Will it improve the accuracy of a design, or provide new information to assist in a design problem? Yes
- The content will provide an insight to various feasible practical approaches for evaluation of anti-acne potential of their test preparation
- Will assist in comparative profiling of their test formulation with the commercially available preparations

Biography:

Deepinder Singh, Studied Pharmaceutics at the Punjabi University, Patiala and graduated as B. Pharm in 2011. He then continued his higher qualification (M. Pharm, PhD) in former institute. He received his PhD degree in 2019 in the same institution. Later to that, He joined Chitkara College of Pharmacy, Chitkara University, Punjab, India as Assistant Professor and serving the same till date. He has published 12 Scopus indexed papers in National and International journals.



Gil Goncalves

University of Aveiro, Portugal

Advanced cancer diagnosis and therapy using carbon nanodots/tetrapyrrolic macrocycles conjugates

Carbon is one of the most relevant elements on earth to all forms of life and presents a wide range of natural allotropic forms with high economic potential. Inspired by nature, Scientists started to design synthetic strategies for the development of novel allotropic carbon nanomaterial. Harry Kroto et al. are considered the pioneers in this field with the discovery of fullerenes in 1985, which culminated with the attribution of the Nobel Prize in Chemistry in 1996. Recently, the remarkable discovery of graphene Nano sheets by Andre Geim and Konstantin Novoselov, that resulted in the first ever isolation of a 2D crystal with atomic thickness under natural conditions, culminated in the attribution of the Nobel Prize in Physics in 2010. Carbon atoms' versatility in establishing various chemical interactions between them has enabled the development of novel nanostructured materials in all dimensions (0D, 1D, 2D, and 3D). Indeed, it was realized that the control of carbon chemical structure offers a wide range of optical, chemical features for the development of novel biomedical hybrid materials with high performance. I will present my current research on the design of novel synthetic routes for the conjugation of carbon dots with different tetrapyrrolic macro cycles. Additionally, they will be discussed in terms of their performance in terms of cancer bio imaging and the agnostic. Finally, I will provide my view on their application in the exciting and fast-growing field of biomedicine.

Audience Take Away Notes:

- Historical overview about the development of carbon nanostructures
- Novel synthetic methods for the preparation of carbon dots hybrids
- Conjugation of photodynamic and bioimaging agents tetrapyrrolic macrocycles
- In vitro cancer cell studies with the developed hybrids

Biography:

Gil Goncalves received his PhD in Mechanical Engineering at the University of Aveiro with a thesis dedicated to Nano composite materials for biomedical application. After obtaining a Marie Curie research fellowship in 2016, he started working at the Institute of Material Science of Barcelona-High Council of Spanish Research (ICMAB-CSIC). Currently he is working at TEMA - University of Aveiro (Portugal), as a researcher on the development of new graphene-based Nano composite materials for environmental, structural, and biomedical applications. Dr. Gil has (co-)authored numerous scientific papers and communications in national and international conferences (61 published documents; h-index 25 and >2800 citations). He is member of the editorial board of Scientific Reports (Nature Publishing Group) in the field of Chemical Physics.

**Samir Haddouchi**

Sotax Pharma Services, France

API characterization – why dissolution testing can help you learn more about Active Ingredient

Sotax Pharma Services, France, Dissolution is a critical parameter of pharmaceutical dosage forms. It is indeed an extremely powerful tool to acquire knowledge about pharmaceutical products. The dissolution techniques can also be used to learn more about the properties of the Active Pharmaceutical Ingredient (API). 2 techniques are used: the intrinsic dissolution using the stirring mechanism concept and the apparent dissolution using the flow through cell dissolution concept (known as USP4). Both techniques bring different information, but it is important to proceed with such API characterization. Such knowledge may obviously guide the development of a new formulation but can also be very valuable during the life cycle of any product, when considering post approval changes such as new sources/ suppliers of raw material and its possible impact on the performance of the drug product. During this webinar, these 2 API characterization techniques will be explained in detail, showing some clear case studies.

Biography:

Prior to joining SPS, Samir spent more than 10 years at Sandoz and Novartis, in Switzerland and France, participating to the development of analytical methods for agrochemical and pharmaceutical compounds and formulations. In 2005, he resigned from Novartis to create SPS Pharma Services which is the first and only CRO specialized in Dissolution and Release Testing. In April 2013, SPS moved to a new larger facility in Orleans (France) to provide a broader range of services to its clients, including cGMP routine testing. The facility has been successfully inspected by US FDA and is registered as Pharmaceutical Establishment for both US and Europe. Since beginning of 2022, SPS is fully integrated within SOTAX Group and Samir is now in charge of the business segment Pharma Services, which comprises of 3 sites located in Europe, America and Asia.



Hilal Erdogan

Nevsehir University, Turkey

Chlorine dioxide as root canal irrigation solution in endodontic treatment

Root canal treatment applied to inflamed teeth is a dental treatment method that aims to keep the natural tooth in the mouth by fulfilling its functional, phonetic, and aesthetic functions. For this purpose, the removal of all vital or necrotic tissues, microorganisms, and microbial by-products from the infected root canal system is important in the success of endodontic treatment. Irrigation is very important in achieving chemomechanical debridement, as the complex anatomy of the root canal system limits effective cleaning and disinfection. There are many root canal irrigation solutions with different contents and properties in endodontics. Sodium hypochlorite, which has widespread use as an irrigation solution in endodontics, has features such as a strong antimicrobial effect, easy accessibility, tissue dissolving capacity, and low viscosity. However, due to the chemical and cytotoxic effects of sodium hypochlorite, the search for alternative irrigation solutions is still ongoing. Chlorine dioxide (ClO₂) is considered a possible root canal irrigation alternative to sodium hypochlorite due to its broad spectrum of antimicrobial activity, tissue dissolution, and smear layer removal properties. ClO₂ is a biocompatible disinfectant, oxidizing agent, and bleaching solution used in many fields. It is used in the veterinary, medical, food industry, water treatment, surface disinfection, and dental care products. It has bactericidal and virucidal activity, and it is stated to be a powerful antiviral agent that may be useful in reducing COVID-19 infection. It is suggested in the therapy of numerous diseases such as COVID-19, cancer, malaria, and autism but careful use is emphasized regarding its potential clinical harms. This presentation aims to review the properties of chlorine dioxide as an endodontic root canal irrigation solution, with an emphasis on its benefits, drawbacks, and clinical applications.

Audience Take Away Notes:

- To provide participants with an update on the conventional and alternative root canal irrigation solutions
- To summarize the properties of an ideal root canal irrigation solution
- Explain to participants the benefits, shortcomings, and clinical applications of chlorine dioxide as an alternative root canal irrigation solution
- Propose rational indications for these irrigants based on available information
- To raise awareness of participants about the importance of endodontic irrigants for treatment success in clinical practice

Biography:

Hilal Erdogan graduated from Selcuk University Faculty of Dentistry, Konya Turkey, and obtained her Doctor of Dental Surgery (DDS) degree in 2009. Subsequently, she completed a Ph.D. program at Selcuk University Faculty of Dentistry Department of Endodontics, Konya, Turkey in 2016. She worked at the Ministry of Health Oral and Dental Health Hospitals as an endodontist until 2019. She has been working as an Assistant Professor Doctor in the Department of Endodontics, Faculty of Dentistry, Nevsehir Haci Bektas Veli University, Nevsehir, Turkey since 2019 and the head of the endodontics department. She is a member of the Turkish Endodontic Society. Dr. Erdogan has publications in national and international journals related to her specialty and attends many national and international conferences.

**Tarek Aboul-Fadl**

Assiut University, Egypt

Prodrugs of non-steroidal anti-inflammatory drugs (NSAIDs) and amino acid esters as novel non-cyclooxygenase inhibitors for colorectal cancer chemoprevention

A structure-based medicinal chemistry strategy was applied to design new NSAID prodrugs that show growth inhibitory activity against human colon tumor cells through a cyclooxygenase (COX)-independent mechanism. In vitro testing of the synthesized compounds against the human HT-29 colon tumor cell line revealed enhanced growth inhibitory activity compared to the parent drugs. Selectivity of the most active tested molecules was investigated against a panel of three tumor and one normal colon cell lines and showed up to six times less toxicity against normal colonocytes. The tested molecules were shown to induce dose-dependent apoptosis of HT116 colon tumor cells as evidenced by measuring the activity of caspases-3 and 7. None of the synthesized prodrugs showed activity against COX-1 or COX-2 isozymes, confirming a COX independent mechanism of action. The synthesized prodrugs were found to have no ulcerogenic effect in rats as indicated by electron microscope scanning of the stomach after oral administration. A pharmacophore model was developed for elucidating structure–activity relationships and subsequent chemical optimization for this series of compounds as colorectal cancer chemo preventive drugs.

Audience Take Away Notes:

- Potential of Structure based drug design for drug discovery and development
- How to improve the activities of the current clinically approved drugs
- Opening the windows for global scientific collaborations
- Improvement of the accuracy of drug design and provide new information to assist in solving drug design problems

Biography:

Tarek Aboul-Fadl has completed his PhD in Medicinal Chemistry from Assiut University, Egypt (1994) under the channel system and joint supervision scheme between Assiut University and Josai University/Japan. He performed his postdoctoral training as a postdoctoral research fellow and scientist of Pharmaceutical and Medicinal Chemistry at University of Vienna, Austria (1997- 1998), Friedrich-Alexander-Universität, Erlangen-Nürnberg, Germany (1999 and 2013) and University of Utah, USA (2001-2002 and 2004-2005). He has over 77 publications and 4 patents that have been cited over 1934 times, and his publication H-index is 23. He awarded ACDIMA Research Award for the Best Scientific Research in Arab World, 2012.

**Alena Korbut* and Linzi Allen***

Cherokee Nation Outpatient Health Center, USA

Continuous glucose monitors impact on glycemic control among American Indian and Alaskan natives: Single center, pre- post- comparison

Continuous glucose monitors (CGM) technology provides insight into a complete picture of a person's blood glucose levels throughout the day and the full effect insulin has on the blood glucose trends. The data generated by CGM can be used to make real-time therapeutic adjustments and facilitate improved patient outcomes. To assess how professional CGM assisted pharmacists in clinical decisions making and how CGM helped American Indian and Alaskan Native (AI/AN) patients with insulin-treated Type 2 Diabetes Mellitus achieve targeted A1C control in an outpatient pharmacy-based clinic. Intensive Diabetes Management Services (IDMS) is a clinic run by pharmacists within an outpatient health center that provides comprehensive diabetes services under a collaborative practice agreement that includes prescriptive authority, ordering labs, and referrals. Indian Health Service setting provides pharmacists the opportunity to use their medication expertise to its fullest capacity. Pharmacists utilize CGM technology to provide detailed data on the glucose trends over a wider time range vs finger stick blood sugar to optimize patient medication therapy. Pharmacists who are involved in IDMS have an opportunity to integrate CGM as part of their clinical decision-making. This study involved retrospective chart review from June 2017 through February 2019. Inclusion criteria: Patients greater than 18 years old with uncontrolled insulin-treated type 2 Diabetes Mellitus enrolled in IDMS and prescribed CGM for 14 to 28 days of use. Exclusion Criteria: Patients with missing A1C results, failure to attend appointments, an allergy to adhesives, pregnancy, repeated monitor adhesive failure, or CGM data collection less than 72 hours. The primary outcome measure was a change from baseline in A1C after 3 months. A t-test was used to compare the differences between the two means. Initial data collection identified 71 AI/AN patients met initial inclusion criteria. Following chart review, 21 patients were excluded due to CGM adhesive failure, failure to attend appointments and missing initial or follow-up A1C. The remaining 50 patients were used for Dependent T-Test. The results from the pre-test ($M = 9.58$, $SD = 1.38$) and post-test ($M = 8.42$, $SD = 1.11$) indicate that CGM use resulted in an improvement of A1C, $t(49) = 6.06$, $p = 1.87 \times 10^{-7}$. There was a significant reduction in A1C following CGM utilization compared to patient data at baseline. Average A1C reduction was [1.2%] yielding average A1C change from [9.6%] at baseline to [8.4%] at study conclusion. Results demonstrated that CGM was an effective tool in improving blood glucose levels and lowering A1C. Furthermore, it provided the ability for pharmacists to individualize medication treatment plans to patients with the correct dose of insulin promptly and facilitate discharge from the clinic due to patients reaching target A1C faster than patients not using CGM. Even though the study examined limited patients ($n=71$) from a specialized clinic, CGM proved to be a useful tool in identifying hypoglycemia and optimizing therapeutic decisions for hyperglycemia.

Audience Take Away Notes:

- Describe the impact of Continuous Glucose Monitors (CGM) on achieving glycemic control
- Identify ideal candidates for utilization of CGM
- Identify strategies on how to communicate with and educate people with diabetes about CGM to make informed self-management decisions
- Compare CGM to traditional Intensive Diabetes Management Services (IDMS)

Biography:

LCDR Korbut was born and raised in Belarus, and moved to the United States in 2003. In 2017 graduated with Doctor of Pharmacy Degree and was accepted into Indian Health Service Post-Graduate Pharmacy residency program at Cherokee Nation W.W. Hastings Hospital in Oklahoma where she also joined the US Public Health Service Commissioned Corps. In 2019, LCDR Korbut received her Board Certification in Pharmacotherapy and currently working as a clinical pharmacist as well as managing local diabetes clinic. In 2021, LCDR Korbut received her Master's in Healthcare Administration to further her career. CDR Linzi Allen studied pharmacy at the University of Oklahoma, United States and graduated with her Doctor of Pharmacy degree in 2010. Following graduation, CDR Allen completed a post-graduate pharmacy residency at the Phoenix Indian Medical Center in 2011. She has completed additional training and has been awarded a Master's in Healthcare Administration in 2017 from Oklahoma State University and a Graduate Certificate in Global Health and Global Health Engagement from the Uniformed Services University of the Health Sciences. Currently, Linzi works for the United States Public Health Service Commissioned Corps and is stationed in Tahlequah, Oklahoma with Cherokee Nation Health Services.

**Deepika Raina^{*1}, Vishakha jaiswal²**¹Graphic Era Hill University, India²BBDNIIT, lucknow, U.P, India**Formulation and evaluation of Escitalopram loaded bio nanosuspension for brain specificity**

In the United States, it is estimated that depression costs the country over \$210 billion each year in lost productivity, health care costs, and absenteeism. It is estimated that between 1 and 3 percent of adults suffer from depression, while about 6 percent suffer from major depression at some point in their lives. While antidepressants are not universally effective yet, research is revealing important information about their use that may help to limit the limitations of the current treatment approach. In the current research, Nano formulation was formulated with a novel biopolymer. Because of their unique shape, nanoparticles are not usually absorbed by the body on their own. Ten formulations were prepared to vary the polymer ratio. The prepared formulation was evaluated for content uniformity, pH, in-vitro drug release Ex-vivo, and stability. The results revealed that the (1: 1) ratio was the best formulation on the basis of the response obtained.

Audience Take Away Notes:

- Depression is a common problem whose treatment and cause is unknown, audience will have insight of both these things and also about the dose related side effects caused due to therapy and how to overcome all these problems
- This will help researches to carry out research on decreasing the dose and frequency of the antidepressants
- Is this research that other faculty could use to expand their research or teaching? Yes
- Does this provide a practical solution to a problem that could simplify or make a designer's job more efficient? Yes
- Will it improve the accuracy of a design, or provide new information to assist in a design problem? Yes
- Lowers side effects, dosing frequency, less mortality rate after discontinuation of the therapy

Biography:

Deepika Raina studied B. Pharmacy at the RKGIT Ghaziabad, India and graduated in 2009. I then joined the research group of Prof. Satheesh Madhav at the DIT University, India. I received my PhD degree in 2018 at the same institution. In 2018 I was appointed as an Assistant Professor at DIT University, and then joined Chitkara University Punjab. Currently I am working as an Associate Professor in Graphic Era Hill University. I have published more than 15 research articles out of which 5 of them are indexed in SCI(E) or scopus journals.



Andre Luiz Pereira

Hemominas Foundation, Brazil

Medicine waste pollution: A Brazilian view about pharmacopollution and public health

Parmacopollution is a public health and environmental outcome of some active pharmaceutical ingredients (API) and endocrine-disrupting compounds (EDC) dispersed through water and/or soil. Its most important sources are the pharmaceutical industry, healthcare facilities (e.g., hospitals), livestock, aquaculture, and households (patient's excretion and littering). The last source is the focus of this presentation. Household Waste Medicine is part of the emerging contaminants, such as steroid hormones, pharmaceuticals and personal care products (PPCP), industrial chemicals, and pesticides. The Brazilian HWM case is remarkable because it is the fourth pharmaceutical market (US\$ 65,971 billion), with a wide number of private pharmacies and drugstores (3.3:10,000 pharmacy/inhabitants), self-medication habits. The HWM generation is estimated in 56.6 g/per capita, or 10,800 t/year. National take-back programs were recently implemented.

Biography:

Pereira has a Ph.D in Sanitation, Environment and Water Resources (Federal University of Minas Gerais – UFMG, Brazil), Master in Administration – reverse logistics (FUMEC University), and bachelor in Administration (UESB). Author of international articles, such as Environ Sci Pollut Res and others. Author of “Reverse Logistics and Sustainability” (Cengage) and “Solid Waste Management and Management” (Juris Lumen). Top 6 Fedex Reverse Logistics Professional 2014 Award and Top 3 9th Public Management Award. Dr Pereira also has experience in Germany and Brazil. Dr Pereira is Springer Nature, Pan American Journal of public Health Journal and Waste Management reviewer.

**Ruchika**

University of California San Francisco, United States

Understanding ABC transporters to navigate human disease

Membrane proteins constitute 30% of genome in organisms and are involved in numerous physiological processes. ABC transporters is a class of membrane proteins which are ubiquitously present in all organisms, bind and hydrolyze ATP to power the solute transport and are associated with several human diseases like multidrug resistance in cancer, macular degeneration, cystic fibrosis, retinitis pigmentosa etc. ABC transporters consists of two transmembrane domains (TMDs), which form the permeation pathway and nucleotide binding domains (NBDs) to bind and hydrolyze ATP and follow alternating access mechanism. Bacterial ABC transporters like binding-protein-independent mutant of maltose transporter, MalG511 from E.coli and FtsEX-PcsB from S. pneumoniae have been characterized biochemically and biophysically to study mechanism and future higher resolution studies. Oral excipients were screened against P-gp using calceinAM fluorescence assay and digoxin flux assay were found to be inert for their effect on P-glycoprotein. beta-Cyclodextrin and light green SF yellowish were found to be inhibitory at high macromolecular range in digoxin flux assay. This information will be helpful in preparing novel generic formulations.

Audience Take Away Notes:

Audience will learn about the ABC transporters, their function and how these sciences can be used for human welfare

Biography:

Ruchika has BSc (H) Biochemistry from University of Delhi and MSc. Biotechnology from Indian Institute of Technology Roorkee, India and received her PhD from Purdue University where she was trained as a Membrane Protein Biologist. Afterwards, she pursued her postdoctoral training at UCSF. She focused on ABC transporters all the way in her scientific training. She is very much passionate in elucidating in mechanistic underpinning of membrane proteins using biochemical, biophysical and structural biology approaches, which could help to rationally design novel pharmacological tools to modulate the function of membrane proteins altered in disease.



**Amira Zaky^{*1}, Eman Khaled¹, Mayssaa M. Wahby¹,
Ahmad Bassiouny¹ and Marc Landry²**

¹Alexandria University, Egypt

²University of Bordeaux, France

APE-1 redox activity inhibition impacts dopaminergic system in inflammatory pain condition

Apurinic/Apyrimidinic Endonuclease 1/Redox Effector- 1 (APE1/Ref-1) is a negative regulator of inflammatory response via several mechanisms in neuronal cells. APE1's redox activity stimulates the DNA-binding activity of several transcription factors. We investigated targeting the APE1 redox activity that might influence the neurotransmitters and related receptors by intradermal injection of E3330 (selective redox inhibitor of APE1) in formalin- induced rat inflammatory pain model. Accumulating evidence has shown that dopamine systems in the brain are also involved in the central regulation of chronic pain. Most importantly, descending dopaminergic pathways play an important role in pain modulation. Therefore, we tested the effect of APE1 redox activity on the regulation of dopaminergic signaling pathway. We determined the index of pain through behavioral tests after peripheral induction of formalin (50 μ l in the dorsal surface of hindpaw). Interestingly, our data point to a decreased nuclear accumulation of APE1 mRNA expression, changed its distribution in the inflamed group as compared to the sham group (i.e. reduced IL-6 expression) and alleviated pain, as assessed by measuring the paw edema. In support to our results, the study of Pacheco, 2017 reported that high-dopamine levels promote the stimulation of low affinity dopamine receptors including, DRD1, DRD2 and DRD4, inducing anti-inflammatory effect in microglia, while low dopamine levels selectively stimulate high-affinity dopamine receptors including, DRD3 and DRD5, triggering inflammation. In conclusion, inhibition of the Redox function by E3330 compound might constitute a novel approach for treating inflammatory pain through modulating the level of dopamine and the affinity of its D5R and D2R receptors inside spinal cord.

Audience Take Away Notes:

- This work highlights novel correlation between the multifunctional protein APE1/Ref-1 and pain signaling during inflammation, so the audience can consider this special correlation in future studies of pain mechanisms
- Yes, specially that focusing on an important concept that subcellular localization of key protein could be the major player under certain condition, rather than focusing on alterations in the expression level only
- In the field of pharmaceuticals, manipulation of Ref-1 activity is of high significance, as many scientists investigated this function in different models including cancers. Based on the clear involvement of such activity in cancer sensitization to chemo and radio therapies, group of researchers established company called Apexian pharmaceuticals that work specially on the investigation of the clinical efficiency of E3330 (APX3330) in different cancer types. Therefore, such chemical compound could be introduced to the market soon as anti-cancer drug, in parallel we can extrapolate our findings abstracted from rat models for pain condition to clinical studies on human in the future

Biography:

Amira Zaky studied Biochemistry at Alexandria University, Egypt and graduated in 1999. She then joined the research group of Prof. Ahmad Bassiouny at Department of Biochemistry, Faculty of Science-Alexandria University. She received her master degree in 2003. She Received her PhD degree in 2007 at the same institution, through sandwich program between Alexandria University and University of Texas Medical Branch (UTMB) in USA. In 2014 she promoted to assistant professor in the same department, then to full professor in 2020. Dr. Amira published 18 articles in SCI (E) journals. She was elected as African regional committee member in the international Brain Research Organization (IBRO-ARC) since 2016.



Eman A. Alam

Al-Azhar University, Egypt

Critical issues related to plant and pharmaceutical biotechnologies to achieve nations' development and welfare

In recent years, biotechnology has expanded too much in its scope, and applicability. Now biotechnology is well known for its great role in the field of medicine, and is also used in many other areas such as food and fuel. Via using plant and pharmaceutical biotechnologies, we can produce huge amounts of secondary metabolites by following different applicable methods. Applicable methods used for the enhancement of the in vitro production of secondary metabolites selection of source materials, Selection of superior cell lines, Optimization of culture conditions, Alteration of controls of secondary metabolism pathways, Elicitation (including physical, biological and chemical elicitation), Genetic transformation, Product release and adsorption. 8. Bioconversion, Root cultures, Cell culture or suspension culture, Cryopreservation, Production of differentiated tissues, (Micro) propagation, Precursor addition, Metabolic engineering, Bioreactors scaling up of production of secondary metabolites, Immobilization scaling up of secondary metabolites accumulation, Bio nanotechnology and other modern methods, used to improve the efficiency of these in vitro produced natural products. However, this field is very important and fruitful; there is a lack in developing countries regarding protection of IPR related to plant and pharmaceutical biotechnologies compared to developed countries. This study will also introduce some successful examples of protection of IPR related to plant and pharmaceutical biotechnologies in some developing and developed countries to be guided by them, to be improved in our country (Egypt) accordingly.

Objective of the study:

- Identification of biotechnology, types of biotechnologies, applicable methods used to improve the in vitro production of secondary metabolites, IBE in simplifying the education of green and pharmaceutical biotechnologies in schools and faculties, and also the impact of biotechnology in economy of nations
- Studying different legal means of protection of IPR in plant and pharmaceutical biotechnological fields
- 3- Comparative analysis of legal protection of IPR in plant and pharmaceutical biotechnological fields in both developed and developing countries
- Measuring the awareness regarding the legal protection of IPR in plant and pharmaceutical biotechnological fields in both developed and developing countries
- Plant and pharmaceutical biotechnological innovations during crises (e.g., COVID-19) and its impact on fighting diseases and establishing small and Medium Enterprises (SMEs) and governmental rules in this regard.
- Crimes of IPR in plant and pharmaceutical biotechnological fields in both developing and developed countries. This study is based on a hypothesis that: there is a difference between developed and developing countries (including Egypt) regarding the protection of IPR in plant and pharmaceutical biotechnological fields and studying this difference will lead us to improve the situation in Egypt. Comparative Studies of different legal means of IPR protection in plant and pharmaceutical biotechnological fields in both developing and developed countries will be done (Examples of Developing countries in this study are: Arab countries including; Arab Republic of Egypt, Tunisia and Kingdom of Saudi Arabia and others; African countries including; Nigeria and others; Asian countries including India and others. Meanwhile examples of Developed countries are: USA; European countries including France, Australia and others). Results indicated that, there is a difference between developed and developing countries in this regard and by studying these differences we can change the situation on land and awareness is an important factor in this issue

Biography:

Alam is a dedicated lecturer and a highly skilled researcher and Trainer, trained various science related subjects at undergraduate, postgraduate, doctoral and postdoctoral levels, with a special interest in phytochemistry, plant physiology (especially green and pharmaceutical biotechnology). Currently Dr. Alam is working on several plants' extracts which have proved significant effects and promising results in the treatment of colon and prostate cancer and as antioxidant, anti-inflammatory, antipyretic, diuretic, hepatoprotective, hepatocurative and antibacterial agents etc.,. She has got M.Sc. and Ph.D. theses in Plant Physiology, Production and improvement of secondary metabolites from wild medicinal plants using tissue culture techniques and biological evaluations of these secondary metabolites as in the treatment of many human dangerous diseases, this point is her first scientific interest. Additionally, Dr. Alam has submitted to 16 Patents related to new drugs extracted from plants and novel methods for the determination of flavonoids, anthraquinones/ and tannins in plants' extracts. Also, she has 45 Books in the area of medicinal plants and in the improvement of research skills of youth researchers and students, in addition to these she has also 36 Internationally Published Scientific Papers in this area of science. Dr. Alam is an enthusiastic, self-motivated, reliable, responsible and hard working person, also she is a mature team worker and adaptable to all challenging situations, able to work well both in a team environment as well as using her own initiative, able to work well under pressure and adhere to strict deadlines. She reviewed many international scientific books and scientific original articles (more than 250) for many international scientific publishers. She is the president of hundreds international scientific meetings and participated as keynote-speaker, resource person, organizer, moderator and chairperson in nearly about 1500 international scientific meetings and engaged in many international training programs as organizer and instructor in a collaborative work with many international scientific and training Organization in many countries in Europe, USA, Asia, Africa.

**Divya Sharma* & Priya Kumari**

Delhi Pharmaceutical Sciences and Research University, India

Development and in-vitro evaluation of κ -carrageenan bead for sustained delivery of repaglinide

Controlled drug delivery systems release drugs at a pre-set pace in order to maintain a constant drug concentration over a set period of time while minimizing side effects. Repaglinide is a low-dose drug that is administered immediately before a meal to lower blood glucose levels by releasing insulin from pancreas, which acts on the cells. Since repaglinide is totally passed by bile, it is a healthy substitute for diabetic patients along impaired kidney function. To retain therapeutic concentrations of repaglinide in blood plasma and reduce side effects such like hypoglycemia, kappa (κ)- carrageenan beads were used to establish a regulated and long-lasting drug delivery system. Drugs and enzymes, trapped using κ -carrageenan like a trapping medium. The Inotropic gelatin method is used to make micro beads. Optimized drug release formulation in vitro was tested in hydrochloric acid (0.1N) and phosphate buffer pH 7.4 using dissolution test apparatus. To learn drug release rate and process, in vitro data was fitted to zero and first order, Korsmeyer-Peppas and Higuchi models. Repaglinide adopted a method for controlling the release of microbead release control system, according to the Korsmeyer- Peppas model. This method eliminates the possibility of an alkaline microenvironment, which was previously created by using gastro-retentive drug delivery systems.

Audience Take Away Notes:

Researchers from the pharmaceutical sciences background will learn to formulate the sustained drug delivery system. Further, research could be performed on the evaluation and characterization of kappa carrageenan beads by Fourier Transform Infrared Spectroscopy (FTIR), X-ray diffraction (XRD) and Field Emission Scanning Electron Microscope (FESEM). The natural products incorporated hydrogel beads could be a part of novel drug delivery system as they would possess lower side effects, toxicity and environmental-friendly characteristics

Biography:

Divya Sharma has passed her M. Pharma from Kurukshetra University, Haryana, India. She has been awarded with a gold medal for having 1st Rank in her postgraduate programme. After that she joined Noida Institute of Engineering and Technology (Pharmacy Institute), Greater Noida, India for pursuing her career in academic field where she has been appointed as an Assistant Professor. She has published research, review paper, book chapter in the various multidisciplinary fields. She also had a patent that too related to the nano-formulation called phytosome. Right now, she is pursuing her PhD from Delhi Pharmaceutical Sciences and Research University, New Delhi, India

**Roberto Visentin**

University of Padova, Italy

Method for tailoring diabetes simulator for optimal in silico trial in target populations

Treatment of type 2 diabetes (T2D) involve a variety of medications, related to the stage of T2D progression. In silico trials can be helpful in this context, speeding up the drug development process and support treatment optimization. We recently proposed a T2D simulator (T2DS), consisting of a model of the glucose-insulin system and an in silico population describing glucose-insulin dynamics in T2D subjects. Both T2DS model and virtual population have been developed based on early-stage T2D data studied with sophisticated experimental techniques. This limits the T2DS domain of validity to this specific sub-population of T2D. Conversely, in order to provide the most suitable and effective testing platform, the T2DS should be equipped with an additional virtual cohort well reflecting the characteristics of the population object of study. In principle, this would require further complex experiments for each population under study, a time-demanding and expensive task. Alternatively, we propose a method for tuning the T2DS to any desired T2D target population, e.g. insulin-naïve (i.e., not experienced with insulin) patients, without the need to resort to complex and expensive clinical studies. To illustrate the method, we provide a case study aiming at extending the T2DS to insulin-naïve Caucasian individuals with T2D. First, the method consists on identifying the T2DS model on available literature data of the target population. The estimated parameters are then used as new reference for generating a new cohort of virtual subjects that are more representative of the Caucasian T2D population. Then, a model of basal insulin degludec (iDeg) is also incorporated into the T2DS in order to enable insulin therapy. The targeted T2DS is finally validated by simulating iDeg therapy initiation and comparing the simulated outcomes with the clinical ones. As result, we show that the simulated distributions of fasting plasma glucose and iDeg dose reproduce clinical data, meaning that the tuned T2DS is representative of Caucasian T2D subjects, and thus it can effectively support therapy optimization fir the target population. The methodology described here can be extended to other stages of T2D, allowing an extensive in silico testing phase of different treatments before human trials.

Audience Take Away Notes:

- Mathematical modeling and simulation can support drug development and testing
- It is important that a simulator well represents the pathophysiology of a particular population
- The rationale behind the proposed method is potentially applicable to other diseases

Biography

Roberto Visentin received the Doctoral degree in Bioengineering from University of Padova, Padova, Italy, in 2010, and the Ph.D. degree in Bioengineering from University of Padova, Padova, Italy, in 2016. He is currently an Assistant Professor at University of Padova. His current research interests include mathematical modeling, identification and simulation of physiological systems, with particular focus to glucose metabolism in healthy and diabetic subjects, and, more recently, to multiple myeloma cell treatment. On these topics, he published more than 20 papers in international peer-reviewed journals and tens of other contributions in conference abstracts and proceedings.

KEYNOTE FORUM

DAY 02

7TH EDITION OF GLOBAL CONFERENCE ON
**PHARMACEUTICS AND
NOVEL DRUG DELIVERY
SYSTEMS**

08-09 SEPT



Luis Jesus Villarreal-Gomez¹, Graciela Lizeth Perez-Gonzalez¹, Jose Manuel Cornejo-Bravo¹, Lucia Margarita Valenzuela-Salas¹, Edgar Ramiro Mendez-Sanchez¹, Ricardo Vera-Graziano², Alejandra Rocio Chavez Santoscoy³

¹University of Baja California, Valle de las Palmas Unit, Tijuana, Mexico

²Materials Research Institute, National Autonomous University of Mexico

³School of Engineering and Sciences, Mexico

Mucoadhesive systems for the fast delivery of drugs

The necessity of new systems for drug delivery in children and specific procedures is clearly needed, in the case of children the difficulty of the correct dose administration is a problem when the drug carrier is not easy to administrate by a non-specialized adult. Mucoadhesive electrospun fibrous systems are an interesting alternative for the treatment of pathologies in the oral cavity due to their capacity to release pharmaceutical drugs at a fast and sustained rate. Electrospun fibers have many characteristics that make them ideal drug carriers for local delivery. Mucoadhesives fibrous systems of poly (vinyl alcohol) and poly (vinyl pyrrolidone) loaded with propranolol and dexamethasone phosphate will be discussed for their potential application in the oral cavity. Physicochemical (SEM, FTIR, TGA, DSC) and biological (MTT assay) characterization will be described in order to present the morphology, chemical composition, and thermal behaviour of the fibrous mats, and cytotoxicity in fibroblast will be visualized, drug delivery rate, mucoadhesive and degradation rate will be also discussed. The evaluated mucoadhesive loaded fibers presented potential characteristics to be used in the oral cavity, where successfully tridimensional fibrous scaffolds were fabricated with an average fiber diameter of about 368 ± 161 nm, thermal stability higher than 250°C, fibers were degraded completely before 15 min and high mucoadhesive and biocompatibility in fibroblast were observed. All these results give potential characteristics to these systems and promote the continuing evaluation at higher levels such as in animals and clinical studies. Poly (vinyl pyrrolidone) loaded fibers with dexamethasone phosphate are proposed for endodontic procedures avoiding injection of the anti-inflammatory drug and poly (vinyl alcohol) loaded fibers with propranolol for the treatment of hemangiomas in children.

Audience Take Away Notes:

- Innovation on mucoadhesive systems
- Applications of electrospinning technique
- Innovation on drug delivery administrations

Biography:

Luis Jesus Villarreal-Gomez, studied Chemistry-Biology at the University of Sonora, Hermosillo, México and graduated in 2004. He then received his Ph.D. degree in 2013 at the University Autonomous of Baja California, Tijuana, México where he joined as a full research professor. Dr. Villarreal is founder and editor in chief of the Revista de Ciencias Tecnológicas (RECIT) (ISSN 2594-1925) and is editorial board member of several journals edited from MDPI, Hindawi, BenthamOpen, amongst others. Until now, he has published 34 papers and has reviewed more than 132 reviews. His research lines are biomaterials, tissue engineering, drug delivery systems, and biotechnology.



Axel H. Schonthal

University of Southern California, United States

Intranasal drug delivery: Perillyl Alcohol/NEO100 for glioblastoma leads the way

Malignancies located in the brain are difficult to treat, because most therapeutic agents are unable to enter the brain parenchyma from the circulation, due to the obstacle placed by the blood-brain barrier (BBB). Intranasal delivery of anticancer agent's holds potential as a more effective treatment approach, because direct nose-to-brain transport may circumvent the BBB, resulting in greater amount of therapeutic reaching the intracranial lesions. However, no intranasal anticancer agent has reached the market yet. We are studying perillyl alcohol (POH), a naturally occurring monoterpene related to limonene, and its pharmaceutical-grade, highly pure derivative NEO100 (NeOnc Technologies, Inc.), for purposes of intranasal delivery to cancer patients with brain-localized malignancies. In ongoing Phase 1/2 trials with recurrent malignant glioma patients, initial results are pointing to encouraging activity of intranasal POH and NEO100, along with high safety and maintained quality of life. These promising outcomes are supported by mechanistic studies of the molecular function of POH/NEO100, which revealed pleiotropic effects on key intracellular growth-regulatory pathways, including inhibition of Ras oncoprotein function, cell cycle arrest, aggravation of endoplasmic reticulum stress, and potent induction of apoptosis. In all, studies with POH/NEO100 lead the way toward clinical application of intranasal drug delivery as a well-tolerated and effective means to treat malignancies in the brain.

Audience Take Away Notes:

- Intranasal drug delivery has several advantages, but in the context of cancer therapy this concept has not yet been effectively applied; perillyl alcohol leads the way
- Perillyl alcohol is a natural compound that is not widely known — despite harboring a multitude of physicochemical properties that can be exploited for therapeutic purposes
- Awareness about perillyl alcohol might inspire other investigators to pursue related studies
- NEO100 is the first GMP version of perillyl alcohol undergoing clinical trials

Biography:

Axel H. Schonthal, PhD, is an Associate Professor in the Department of Molecular Microbiology and Immunology at the Keck School of Medicine of the University of Southern California (USC) in Los Angeles. He obtained his graduate degree at the University of Karlsruhe, Germany, followed by a postdoctoral stay at the University of California San Diego (UCSD) Cancer Center in La Jolla, California. He currently pursues the development of novel agents and novel delivery methods toward improved cancer therapy of brain-localized malignancies. As of 2022, he has authored about 200 scholarly articles and chapters, and has an H-Index of 50.

SPEAKERS

DAY 02

7TH EDITION OF GLOBAL CONFERENCE ON
**PHARMACEUTICS AND
NOVEL DRUG DELIVERY
SYSTEMS**

08-09 SEPT



Liberata Sportiello

University of Campania "L. Vanvitelli", Italy

Immune checkpoint inhibitors (ICIs) and immune-related adverse drug reactions: Focus on their neurotoxicity

Harnessing the power of the immune system to target cancer has been the aim of scientific research for over centuries. The irruption of immune checkpoint inhibitors (ICI) in 2011 has changed the therapeutic landscape of several tumors and, consequently, the prognosis of cancer patients. To survive, cancer cells must develop mechanisms to evade the immune response and the key role in the regulation of the immune response is given by the activation of T cells, in which stimulatory and inhibitory immune checkpoints are involved. Immune checkpoint inhibitors (ICI) are humanized monoclonal antibodies which block the interaction between the checkpoint receptors of inhibitory type (CTLA-4, PD-1, PDL-1) expressed on T cells and their ligands on antigen-presenting cells or tumor cells. Therefore, a cytotoxic T cell response can emerge and provide powerful antitumoral activity. To date, seven ICIs are available in the Europe, divided into three different groups, based on their target: anti-CTLA-4 (Ipilimumab), anti-PD-1 (Nivolumab, Pembrolizumab, and Cemiplimab) and anti-PDL-1 (Atezolimumab, Durvalumab and Avelumab). Due to ICIs mechanism of action is not tissue antigen-specific and not limited to the tumor microenvironment, the use of these drugs can produce a broad spectrum of toxicities, known as immune-related adverse events (irAEs). As reported in the literature, dermatologic, gastrointestinal and endocrine toxicities have been commonly described and they can occur in up to 65% of ICI-exposed patients, in addition to more severe toxicities affecting cardiac, pulmonary and neurological functions. Neurological immune-related adverse events (NirAEs) are rare, and affecting both the peripheral and central nervous systems, often requiring treatment discontinuation and sometimes with a significant deterioration of patients' quality of life. Evidence on neurological complications by ICIs is limited, most of which are brief safety reports from clinical trials or individual case reports, besides too few epidemiological data from meta-analysis of clinical trials and pharmacovigilance databases. Currently, the pathogenesis of these neurological complications is not completely understood, and this neurotoxicity remains one of the most ambiguous of all irAEs associated with ICI. As a result, the optimal management of NirAEs has not yet been established, even if several Scientific Societies have provided expert consensus-based recommendations regarding the treatment of neurotoxicity based upon its severity. In conclusion, IrAEs present a great challenge in modern oncology and innovation in the research of irAEs due to immunotherapy in the future probably could define sophisticated biomarkers to identify patients who are not only responsive to such therapies but also at higher risk of developing toxicity. These advances will support optimal care for all patients receiving ICIs.

Audience Take Away Notes:

- The audience will learn that, due to ICIs mechanism of action is not tissue antigen-specific and not limited to the tumor microenvironment, the use of these drugs can produce a broad spectrum of toxicities, known as immune-related adverse events (irAEs)
- The audience should be able to combine ICIs with other agents, or design new immunotherapies, to achieve broader and more durable efficacy as well as greater safety
- Given the different and new safety profile of ICIs compared with the conventional therapies, the oncologists need to be aware of their spectrum of toxicity, before prescribing ICIs to their patients
- Neurologic toxicities due to ICIs present some of the most diagnostically challenging and clinically diverse spectrum of irAEs. Given the lack of familiarity by many oncologists, this set of events produces a significant amount of anxiety and concern. Thus, multidisciplinary management by oncology and neurology is critical

Biography:

Liberata Sportiello studied Pharmaceutical Chemistry and Technologies at the Federico II University in Naples, Italy and graduated in 2006. She then specialized in Hospital Pharmacy in 2009. Successively, she joined the research group of Prof. Francesco Rossi before and Prof. Annalisa Capuano then, at the University of Campania L. Vanvitelli, in Naples, Italy. She received her PhD degree in Pharmacology in 2013 at the same institution. She has published more than 50 research articles in international scientific journals.

**Madhav Bhatia**

University of Otago, New Zealand

Hydrogen Sulfide: A stinky as and novel therapeutic target for inflammatory disease

Inflammation is a normal adaptive response to traumatic, infectious, post-ischemic, toxic or autoimmune injury. Uncontrolled inflammation, however, results in disease, and most of the diseases have been shown to have an inflammatory component. Identifying biological molecules that mediate inflammation, and strategies that could control inflammation, therefore, can lead to novel therapeutic approaches for several diseases. Hydrogen sulfide (H₂S), a toxic gas, has been known as an environmental and industrial pollutant for more than 300 years. In recent years, however, it has been shown to be produced in the human body. We have shown that H₂S, synthesized by the activity of cystathionine- γ -lyase (CSE), acts as a mediator of inflammation in different disease conditions. Based on the studies with experimental models of disease, which have been substantiated by recent clinical studies, we now have a good understanding of the contribution of H₂S to inflammation. Awareness of a new mediator of inflammation, which can be inhibited as a potential therapeutic approach for inflammatory disease, presents numerous opportunities. This is a new area of research with immense promise, both in terms of understanding the pathology of inflammation, and discovering new treatments for diseases which are major health problems.

Audience Take Away Notes:

- Inflammatory diseases represent major health problems, for which novel treatment opportunities are needed
- Hydrogen sulfide is a novel mediator of inflammation
- Hydrogen sulfide can act as a novel therapeutic target for inflammatory disease

Biography:

Madhav Bhatia heads the Inflammation Research Group in the Department of Pathology and Biomedical Science at the University of Otago, Christchurch. Research in his laboratory has shown hydrogen sulfide and substance P as mediators of inflammation and potential therapeutic targets for inflammatory diseases such as acute pancreatitis, sepsis, burn injuries, and joint inflammation. He has received numerous grants, has authored more than 190 contributions to the peer-reviewed literature, given several invited presentations in different countries and is on Editorial Boards of 46 journals. His publications have been cited more than 14000 times, and he has an “h”-index of 60.



Mihaela Ileana Ionescu

Iuliu Hatieganu University of Medicine and Pharmacy, Romania

The intrinsic antibiotic resistance of environmental bacterial species – A clue to understand the emerging of multi-drug resistant strains

The antibiotic resistance of bacterial strains evolves continuously. The nosocomial infections and the infections of immunocompromised patients put a lot of pressure on healthcare professionals. Very often the source of infection remains unclear but the hospital environment is the reservoir of the multi-drug resistant strains. There are many case reports of infections with otherwise non-pathogenic environmental species. The treatment of these infections is hampered by the emergence of multi-drug resistant strains. On the other hand, it is very difficult to treat infections with bacterial strains that exhibit intrinsic antibiotic resistance such as colistin. During an ongoing research project (PN-IIIP4-ID-PCCF-2016-0016, within PNCDI III) we are interested in the isolation and characterization of bacterial species isolated from some Romanian caves. The cave environment is unique and the contaminations with pollutants can be minimal in its deepest parts. We believe that a thorough analysis of the intrinsic resistance of bacterial strains inhabiting unpolluted environments where there is no antibiotic selection pressure will advance the understanding of nosocomial infections. From the point of view of healthcare professionals, there are some issues regarding the reports of antibiotic resistance. For the environmental species usually there are no interpretation standards. Also, for some antibiotics – notably polymyxin/colistin – there are many debates regarding the best laboratory tests recommended.

Audience Take Away Notes:

- The audience will have a general view of bacterial antibiotic resistance from two perspectives – the human infections and the environmental presence of bacterial strains with exhibit intrinsic antibiotic resistance
- Healthcare professionals have to rely on clinical standards to report the antibiotic resistance of the isolated from human infections. However, for some antibiotics and some environmental species, there are no interpretation data available. Our presentation highlighted some of these issues
- The source of infection in nosocomial infections is not easy to be established. Also, there are many case reports of infection with non-pathogenic bacterial strains that inhabit different environments
- The connection of the research studies with clinical issues is needed to manage infections with multi-drug resistant strains

Biography:

Ionescu studied General Medicine at the University of Medicine and Pharmacy Iuliu Hatieganu Cluj-Napoca, Romania and graduate as MD in 1994. She followed the residency program and received became specialist physician M.D. – speciality Laboratory Medicine in 2004. From 1994 until now she is a teacher at the Microbiology Department of the University of Medicine and Pharmacy Cluj-Napoca. She received her PhD degree in 2008 at the same institution. She follows a research internship at the Pasteur-Paris Institute, Laboratory of Structural Chemistry of Macromolecules supervised by Prof. Dr. Octavian Bârzu.



Ekaterina Pashkina

Research Institute of Fundamental and Clinical Immunology, Russia

A new approach based on glycyrrhizic acid for allergen delivery in allergen-specific therapy

The most effective method of treating allergic diseases is allergen-specific immunotherapy (SIT). To reduce the risk of side effects and improve delivery of allergens to the mucosa, various delivery systems such as liposomes, dendrimers, nanoparticles, etc. can be used. Today, there is a lot of data about delivery systems based on glycyrrhizic acid (GA) and its derivatives, but this delivery systems have not yet been used for allergen-specific therapy. At the same time, GA has been shown to have anti-inflammatory effects and is itself a potential treatment for allergic bronchial asthma and allergic rhinitis. GA can shift the balance towards Th1, increase the number of Treg cells, which means that in the future it is able to enhance the anti-allergic effect of SIT and reduce the risk of side effects. We have studied in our work the effect of the GA supramolecular complex and the allergen of house dust mite Der p 1 on the T lymphocytes and dendritic cells of patients with sensitization and doctor-diagnosed allergy to house dust mite allergen. It was found that the complex of GA and Der p1 increased the number of Treg cells in PBMCs compared to free Der p 1. Also, GA-Der p1 complex affect the inflammatory and Th2 cytokine production. The results of assessing the effect of the GA complex with Der p 1 on the phenotypic characteristics and cytokine production of cells from patients indicate a change in the Th1/Th2 balance towards the cellular immune response, an increase in the number of T-regulatory cells, which can enhance the efficiency of the Der p 1 peptide during AIT. The results of evaluating the effect of the GA complex with Der p 1 on the phenotypic and functional characteristics of immune cells indicate a change in the Th1/Th2 balance towards the cellular immune response and increase in the proportion of T-regulatory cells, which can increase the efficiency of the Der p1 peptide during SIT.

Biography:

Ekaterina Pashkina is a Senior Researcher in Laboratory of Clinical Immunopathology of Research Institute of Fundamental and Clinical immunology. She graduated from Novosibirsk State University with specialty in cytology and genetics. Since then, she has been working in the field of immunology and drug delivery. She received her PhD (Clinical immunology and allergology) in Research Institute of Fundamental and Clinical Immunology, in the field of «Immunomodulating properties of a complex of taftsin and cucurbit[7]uril». At present time, she also work as Adjunct lecturer (part time) in Novosibirsk State Medical University.

**Nikita Kale**

Oriental University, India

A novel drug delivery system: Fast dissolving film containing niosomes

FDF is also known as oral wafers which is a bunch of thin polymeric film which is now gaining widespread interest in the pharmaceutical industry. It is a novel formulation and is now accepted by various customers for supplying vitamins and self-care products specially. In the present day, it is approved for OTC medication for systemic delivery and under trials for prescription drugs. There are many benefits of FDFs such as rapid disintegration and dissolution of the drug, precise dose administration, patient compliance, safe and efficacious. Applications of FDFs include manage pain, allergies, sleep disorders and CNS disorders which require rapid absorption of incorporated drug, breath strips, delivery of vitamins and personal care products, topical application—mostly for analgesics and antimicrobial ingredients. Niosomes are microscopic lamellar structures formed by a mixture of cholesterol and single alkyl chain non-ionic surfactant following hydration in aqueous media. Niosomes are competent for both hydrophilic and hydrophobic APIs. The surfactant used in the manufacturing of niosomes is chemically stable, accurate in composition and having a low cost. Some benefits of niosomes are greater patient compliance, use for a variety of APIs, vesicles can be modified as per requirement, act as depot to release the drug steadily which allow controlled release, highly stable and osmotically active, target drug delivery. Niosomes were utilized to allow for sustained release of the drug, whereas the films were used to increase the drug's bioavailability via sublingual route.

Keywords- FDF, Niosomes, Targeted drug delivery.

Audience Take Away Notes:

- Audience will learn about the new technologies like fast dissolving film and niosome technology
- Various approaches and technology used in novel drug delivery system
- Rationale for selecting dosage form and which type drug can be used

Biography:

Nikita Kale studied Pharmaceutics at Modern Institute of Pharmaceutical Sciences, Indore, affiliated to RGPV University Bhopal and graduated as Master of Pharmaceutics in 2015. She then joined the Modern Institute of Pharmaceutical Sciences, Indore, India as Assistant Prof. She is pursuing PhD in Pharmacy from Oriental University, Indore. She obtained the position of an Associate Professor in 2021. She has published more than 5 research articles in SCI (E) journals. She has guided many UG & PG students for research work.

**Prateeti Chakraborty**

Bangabasi College, India

Catecholase activity, electrochemistry and magnetic behavior of an azido bridged dinuclear copper (II) complex of a phenol based “end-off” compartmental ligand

A dinuclear Cu(II) species $[\text{Cu}_2\text{L}_2(\text{H}_2\text{O})_2(\text{N}_3)](\text{NO}_3)_2$ (L = 2,6-bis(N-ethylpyrrolidine-iminomethyl)-4-methyl-phenolato) where two Cu centers are bridged by phenoxido and 1,1-azido bridges with Cu–Cu separation of 3 Å have been synthesized with the view to explore the role of azido bridge on catecholase activity and electrochemical property and the roles of both the bridging groups on magnetic coupling of two copper centers. The complex exhibits excellent catecholase activity in acetonitrile as well as in DMSO medium not only by oxidizing 3, 5-di-tert-butylcatechol (3, 5-DTBC) but also tetrachlorocatechol (TCC), a catechol which is very thorny to oxidize, under aerobic conditions and becomes the first example of its own kind. CV study reveals three quasi-reversible reductive couples which are tentatively assigned as $\text{Cu}_2 \text{II}$ to CuIICuI and CuICuI reduction followed by reduction of CuICuI complex to Cu^0Cu^0 species. Variable temperature magnetic study suggests the presence of an antiferromagnetic spin–exchange interaction between Cu (II) ions in the dimer via double bridge where the antiferromagnetic contribution of Phenoxido Bridge predominates over the ferromagnetic interaction of Azido Bridge.

Audience Take Away Notes:

- By explaining magnetic and catalytic behavior present in the complexes audience will be able to learn the role of azido group in magnetic coupling and catecholase activity
- The audience will learn the synthetic methodology of above mentioned coordination complexes
- This research will help to understand the competitive antiferromagnetic behavior of phenoxido and azido bridge
- The simple synthetic strategy will help researchers to develop such coordination complexes in no time

Biography:

Prateeti Chakraborty studied Chemistry at Bethune College affiliated to University of Calcutta and graduated in 2007. She then did her master's from the same university in the year of 2009. After completing her post graduate study she joined the research group of Prof. Das at University of Calcutta and received her PhD degree in 2015. After 1 years of postdoctoral research in the same lab on Zn Chemistry, Catalysis she Joined Sharda University, Greater Noida as an Assistant Professor. Presently, she is working as an Assistant Professor in Chemistry at Bangabasi College. She has published 4 book chapters with an International Publisher and more than 35 research articles in journals of International repute.



Mia Karam

American University of Beirut, Lebanon

Novel connective tissue growth factor (CTGF)-loaded alginate and alginate sulfate/polycaprolactone nanoparticles with promising wound healing activity

Diabetes is a metabolic disorder characterized by hyperglycemia and affecting more than 460 million people worldwide. Uncontrolled diabetes can lead to secondary complications such as non-healing diabetic foot ulcers (DFUs) due to ischemia and peripheral neuropathy. Non-healing DFUs can worsen to gangrenes and may require partial or complete amputations, burdening the healthcare system with billions of dollars annually. DFUs are caused, in part, by the deficiency in growth factors (GFs) implicated in keratinocytes and fibroblasts proliferation, migration, and extracellular matrix deposition. The deficiency in GFs such as connective tissue growth factor (CTGF) and insulin-like growth factor (IGF-I) disrupts and delays efficient and complete wound healing. Herein, we report the development of novel double emulsion alginate (Alg) and alginate sulfate (AlgSulf2.0)/polycaprolactone (PCL) nanoparticles (NPs) for the controlled delivery of heparin-binding GFs, CTGF and IGF-I, to promote accelerated wound healing. The NPs physicochemical properties, GFs encapsulation efficiency and release profiles, cytocompatibility, and wound healing activity were assessed in immortalized human keratinocytes (HaCaT) and primary human skin fibroblasts (HSF). The synthesized NPs had a spherical morphology with an average hydrodynamic size of 214.46 ± 26.94 nm, a polydispersity index of 0.099 ± 0.054 , and an average surface charge of -16.86 ± 5.52 mV. Both Alg and AlgSulf2.0/PCL NPs showed high encapsulation efficiency of IGF-I (99.74 % vs 99.62 %) with a low burst release (11.99 % vs 7.93 %) and a slow sustained release over 35 days in vitro (91.6 ± 9.89 % vs 75.57 ± 11.77 %). Moreover, treatment of HaCaT cells with Alg/PCL and AlgSulf2.0/PCL NPs did not show any toxicity when used at concentrations ≥ 50 $\mu\text{g/ml}$ for 72 h, as evidenced by MTT assay. Finally, we found that HaCaT and HSF cells treated with Alg and AlgSulf2.0/PCL NPs loaded with 5 $\mu\text{g/ml}$ CTGF respectively, induced rapid wound closure due to cell proliferation and migration. Double-emulsion polymeric NPs based on Alg or AlgSulf2.0 are promising novel drug delivery systems for the safe and controlled delivery of heparin-binding GFs. They can efficiently promote accelerated diabetic wound healing in human skin cells and fibroblasts and can be further applied for the delivery of other heparin-binding GFs for the treatment of various diseases.

Audience Take Away Notes:

- This presentation will introduce the audience to new drug delivery systems investigated in research
- Researchers in the fields of biomedical engineering, nanotechnology, drug delivery, and wound healing will be able to build on this research for future research collaborations
- Interested presenters may want to invest in our new wound healing strategy
- Researchers will learn the technique for synthesizing the nanoparticles and may use them for the delivery of other drugs in different applications

Biography:

Mia Karam is a fourth-year biomedical engineering PhD student at the American University of Beirut, Lebanon. She received a bachelor's degree in life and earth sciences from the Faculty of Sciences at the Lebanese University and a master's degree in molecular and cellular biology and in cancer studies from the Doctoral School of Science and Technology at the Lebanese University, Lebanon. Her thesis work focuses on the use of polymeric nanoparticles as drug delivery systems for wound healing and cardiovascular applications.



Rakhi Mishra

Dr. D.P. Rastogi Central Research Institute of Homoeopathy, India

Monograph on *Butea monosperma* (Palas): An important plant for Lac cultivation

Butea monosperma (Family Fabaceae) popularly known as 'dhak' or 'palas', commonly known as 'Flame of forest' is an important plant and is extensively utilized for lac cultivation. Lac cultivation plays an important role in the tribal economy. *B. monosperma* is found in countries like India, Bangladesh, Nepal, Pakistan, Sri Lanka, Myanmar, Thailand, Laos, Cambodia, Vietnam, Malaysia, and western Indonesia. The major insect pest of *B. monosperma* is lac insect (*Kerria lacca*) which feeds on the sap of the tree but yields beneficial product, lac resin which is very useful to the mankind and also became the source material for versatile resin (shellac) and lac dye and wax. *B. monosperma* being principal lac hosts tree is the single largest producer of rangeeni lac from India due to its abundance in the nature, and high tolerance to hot climatic conditions. Lac cultivation on *B. monosperma* is, therefore, an important tool for self-employment and the economic growth of poor and backward tribal section. The objective of the present work was to prepare a *B. monosperma* monograph for pharmacopoeial standards. Present study reveals the LOD (2.85%), Total Ash (5.43%), Alcohol extractive values (13.26%), Water extractive values (29.15%), Total solids (3.32%), Wt/ml (0.92g) and Alcohol content (53%). High Performance Thin Layer Chromatography (HPTLC) analysis of chloroform extract of *B. monosperma* was performed by using toluene: ethyl acetate (9:1, v/v) as mobile phase. In HPTLC analysis various spots was observed under UV light 254nm and UV 366nm, confirms presence of active constituents. The present physicochemical, phytochemical and HPTLC data are to be considered as monograph of pharmacopoeial standards for aforesaid drug and may open the wide area of research on plant *B. monosperma* bio-chemistry.

Audience Take Away Notes:

- Audience will come to know the uses of *Butea monosperma* plant in cultivation. How *Butea monosperma* plant parts can be utilized for further research growth in health and agriculture sector. Present research gives an alternate option of not using chemical based toxic pesticide during cultivation hence, prevent use of pesticide in cultivation and hence create good impact on the health of people and children and environment surroundings
- From present scenario Audience got the idea of latest research done on this medicinal plant and analytical technique used to prepare monograph which can be further utilized for the study of other plants too
- Yes, it gives one of the best natural solutions of increasing cultivation naturally
- Increase Lac cultivation
- Resist the uses of highly toxic pesticides in cultivation.
- Good for environment

Biography:

Rakhi Mishra, PhD. chemistry, MSc. Chemistry, BSc. Chemistry (hons), Graduated from Amity University, Noida India and graduated as MSc. Chemistry in 2015. She then joined Jubilant Chemsys limited (Research and Development centre), Noida India in Analytical Chemistry Department. After two years of research work period she then joined research group of Dr. Binit Dwivedi, Drug standardization Department, DDPR CRI (H), Ministry of AYUSH, and Government of India. She is working in Drug Standardization Department from last five years. She has published one book and more than 22 research articles in SCI (E) journals and in international/national conferences abstract books souvenirs.

**Adam Sikora**

Nicolaus Copernicus University, Poland

Future needs for inhaled drug delivery

Asthma and COPD are among the most common chronic non-communicable diseases. Many different environmental and individual factors are involved in their development. The main goals of treatment are to prevent symptoms of the disease, reduce the risk of exacerbations, and improve the patient's health. A common group of drugs used in the control of asthma and COPD are bronchodilator drugs. An example is formoterol, which as a long-acting selective β_2 -adrenoceptor antagonist, has a bronchodilating effect in patients with reversible airway obstruction. The aim of the study was to verify the correctness of operation of the commercially available DPI inhalers in the field of dry powder aerosolization containing formoterol fumarate. Comparative analyses of the two inhalers were performed using a Next Generation Impactor (NGI). For this purpose, formoterol fumarate in the form of inhalation powder in gelatin capsules was used. The quantification of the drug deposited on each impactor stage was determined by high performance liquid chromatography. The particle size distribution at various flow rates was determined and the extent of drug delivery to the lungs was estimated indirectly by determining the percentage of FPF showing the greatest therapeutic effect during inhalation. On the basis of the presented research results, it can be suggested that there is great difference in aerolization effect depending the utilized inhaler. The main reasons for the differences in the performance of the tested inhalers may be differences in the structure and properties of these medical devices. Although all capsule inhalers may look similar to the patient, even the smallest differences in their structure may affect aerolization and the method of drug delivery to the lungs. Therefore, it is crucial, that the inhaler should be selected individually for each patient, taking into account the patient's age and inhalation possibilities. The studies were financed by a grant from the National Centre of Research and Development, Poland, LIDER Program, No: LIDER/52/0276/L-12/20/NCBR/2021

Audience Take Away Notes:

- The audience will observe that selection of DPI is crucial to effective pharmacotherapy using respiratory drugs
- This research could expand other faculty research or teaching
- Yes, the topic will improve provide new information to assist in a design problem

Biography:

Adam Sikora, PhD, studied Pharmacy at Nicolaus Copernicus in Toruń, Collegium Medicum in Bydgoszcz, Poland and graduated as MS in 2014. Then he has joined the research group of Prof. Michał Marszał at Medicinal Chemistry. He received his PhD degree in 2019 at the same institution. He is focused on stereoselective syntheses, pharmaceutical analytics and respiratory medicines, including studies of API aerolization.

**Prerna Sharma**

Guru Gobind Singh College of Pharmacy, India

Characteristic features of essential oil composition in selected genus of *Ocimum sanctum*

The main aim of this research is to provide a literature of the *Ocimum* plant, to know the significance of the *Ocimum* species carried out by pharmacognostical study and experimental design for GC-MS. *Ocimum* genus are very important for their therapeutic potentials. Among the most important aromatic herbs for its enormous medicinal properties. An extreme Attention has been put on those literature reports wherein the utilization of Tulsi and their pharmacognostical study has been done by performing morphological and microscopic leaf and experimental design by using essential oil by GC-MS instrumentation method. The utilization of these characteristics would be important for the drug discovery scientist to develop a specific formulation of the crude drug, which will be a magical therapeutic agent in the future, with the many advantageous. GC-MS chromatogram of the *Ocimum sanctum*, *Ocimum canum* and *Ocimum gratissimum* oil showed major peaks and has been identified after comparison of the mass spectra with NIST library, indicating the presence of three phytocomponents. From the results GC-MS study suggested that anethole which is well reported antimicrobial compound is more in *O. canum* (2.66%) in comparison to *O. sanctum* (1.28%) but absent in *O. Gratissimum*. The results indicated that the antimicrobial activity is more in *O. canum* due to presence high amount of anethole in comparison to *O. Gratissimum*, and *O. Sanctum*. The GC-MS study suggested that anethole which is well reported antimicrobial compound is more in *O. canum* (2.66%) in comparison to *O. sanctum* (1.28%) but absent in *O. Gratissimum*. The result revealed that *O. canum* has a microscopic character of that can be identified by the characteristic GC MS analysis of extracts, to distinguish between different species of the *ocimum* plant.

Biography:

Prerna Sharma is currently working as a assistant professor in Guru Gobind Singh College of Pharmacy, Yamunanagar. She is 9.7 years teaching experience as assistant professor and Training & Placement Officer and She is selected as panel expert for AICTE STTP Programme. Her field of specialization is Pharmacognosy and She has completed his master in Pharmaceutical sciences (2012) honor with gold medalist / appreciation in RITS ,Sirsa, India and recently she is pursuing his PhD from the Uttarakhand Technical University, Dehradun, India, Her field of expertise is standardization of herbal plants/ herbal formulation. Her research area includes pharmacognostical & phytochemical investigation of Indian medicinal plants; she has 30 research/review publication national/international journals of repute to her credit, 40 Copyrights, 2 Patents and deligated more than 30 National/international conferences /workshops. She is honored with young research scientist award by SPER and TIPA in Thailand .She is also president in SPER women forum and life member of professional bodies like association of pharmaceutical teachers of India (APTI).



Merita Kucuku

Freelance consultant, Albania

Vaccines against rotavirus, data based on a study for safety and efficacy

Vaccines and vaccination are important for the prevention of infectious diseases. In the history of vaccination, we have savings of lives of people of different ages from children aged 0 days and the very old people. The vaccine against rotavirus before using the rotavirus vaccines the situation in the USA was: 4 or 5 children had symptomatic rotavirus gastroenteritis, 1 in 7 required a clinic or emergency department visit, 1 in 70 was hospitalized, 1 in 200000 would die from this disease, within the first 5 years of life, The cost of the situation was estimated: 410000 physician visits - 205÷272 000 emergency department visit and 55- 70000 hospitalizations was estimated to be approximately \$ 1 billion. Approximately 20- 60 deaths per year among children aged < 5 years. The situation in developing countries related to rotavirus gastroenteritis continues to be a major cause of severe childhood morbidity, approximately half a million deaths per year among children aged < 5 years. Of the estimated 8.795 million deaths in children younger than 5 years worldwide in 2008, infectious diseases caused 68% (5.970 million), with the largest percentages due to pneumonia (18%, 1.575 million, uncertainty range [UR] 1.046 million-1.874 million), diarrhea (15%, 1.336 million, 0.822 million-2.004 million), and malaria (8%, 0.732 million, 0.601 million-0.851 million). 41% (3.575 million) of deaths occurred in neonates, and the most important single causes were preterm birth complications (12%, 1.033 million, UR 0.717 million-1.216 million), birth asphyxia (9%, 0.814 million, 0.563 million-0.997 million), sepsis (6%, 0.521 million, 0.356 million-0.735 million), and pneumonia (4%, 0.386 million, 0.264 million-0.545 million). 49% (4.294 million) of child deaths occurred in five countries: India, Nigeria, the Democratic Republic of the Congo, Pakistan, and China. Rotavirus disease burden globally and in India. Children < 5 years old are risked from rotavirus infectious. According to Rao, TS et al. Vaccine, 2014 1 in 260 children die and in all world 453.0000 deaths, 2, 5 million hospitalizations which means 1 in 58 children and 24 million outpatient visit 1 in 5 children. The situation in India: The risk is 1 in 256 die and a total of 99,000 deaths. 1 in 31-59 hospitalization and in total are 456,000-884,000 deaths. 1 in 13 children outpatients visit and in total 12 million outpatients visit according to Rao, TS et al. Vaccine, 2014. Route of rotavirus infectious transmission. The transmission of rotavirus infectious is fecal-oral route, through close person to person contact and through fomites. The vaccines used against rotavirus infectious. Rotavac (a G9,P reassortant) licensed in India. Efficacy vs. severe RV gastroenteritis by serotype.

Biography

Merita Kucuku studied Master degree: "Chemical Analysis and Determination of the structure by Instrumental Analysis" and Master theses: "Validation and optimization of the determination method of merthiolate in the vaccine by spectrophotometer by means of Factorial Design "Studied Ph. D: "Study and chemical-analytical evaluation of some vaccines used in Albania". More than 10 years of experience in the field of safety and efficacy and regulatory issues of vaccines, Head of National Regulatory Authority of Vaccines & Immunobiological Products in Albania, and experience as Head of Control Laboratory of medicines in the National Agency for Medicines & Medical Devices (NAMMD). Trained in international agencies and organizations for: Safety, efficacy, AEFI and quality control of vaccines, and GMP. Quality Control/ Quality assurance of laboratories (ISO 17025). Environmental issues as: Environmental Impact Assessment (EIA) and Strategic Environmental, Assessment (SEA), "Strategies for chemicals management", (Pharmaceutical waste management). Training for instrumental analysis as GC, GC- MS. Basic toxicology. National expert on the identification of populations at risk and gender dimensions under MIAproject,UNDP. Expert in the project: "Strengthening of capacities for chemical management in Albania", arranged from UNITAR.

**Shiv Kumar**

Maharaja Ranjit Singh Punjab Technical University, India

Formulation and evaluation of tablet containing different variety of native starches

Starch is known to be one of the most abundant carbohydrate molecules found in tropical roots and tubers, grains, and cereals. Various botanical sources of starch, including maize, potato, corn, wheat, etc., have been used as a staple food for millions of people for centuries. There is a good source of starches in these tropical plants, and are underutilized but can be utilized as excipients in pharmaceutical preparations. In industry, starch is often used in the manufacture of tablets and other solid dosage forms. In addition to being used in tablets as a binder, it can also act as a disintegrant. The pharmaceutical industry generally utilizes starch obtained from maize and potato. Starch pastes are routinely prepared at a concentration of 5-20% during tablet manufacture. At concentrations between 5 and 15%, starch is useful as a disintegrant in many tablet formulations. In this study, native starches were tested for their disintegrant potential in paracetamol tablet formulations. Using the wet granulation method, paracetamol tablets were prepared with different variety of native starches. Based on the compendial specifications, the physical, chemical, disintegrant properties, and dissolution profiles of the isolated starches were measured and evaluated. Different variety of native starches were white, off-white, and pinkish in color, odorless, and fine in texture, with a polyhedral, oval, and irregular shape, resulting in passable to poor flowability and compatibility with the drug. All starches possess satisfactory values of different parameters such as amylose content (< 28.66), solubility (< 25.38), swelling power (< 26.86), and water absorption capacity (< 103.51). Furthermore, all tablets with different starches showed acceptable average tablet weight, hardness ($\approx 4\text{kg}$), friability ($< 1\%$), and disintegration time ($< 15\text{ min}$). The tablets passed the dissolution test for immediate release tablets ($\geq 70\%$ release in 45 min). All native starches passed the physicochemical tests for starch and the quality control tests for acetaminophen (paracetamol) tablets. Therefore, they are suitable for use as economical and alternative sources of starch in pharmaceuticals. The major finding of this work is among all the native starches, one bean starch showed the properties as that of super disintegrant with a faster drug dissolution profile as compared to all other tested starches and marketed tablets.

Audience Take Away Notes:

- They will know the utilization of waste and unused portions of the vegetable, fruits, crops, etc
- They can know the use of the waste product as an excipient
- Yes, they will use this knowledge to expand and solve the research problem
- It will ease production and reduce the cost of the product

Biography:

Shiv Kumar pursuing a Ph.D. in Pharmaceutical Sciences under the supervision of Dr. Amit Bhatia (Associate Professor) at the Department of Pharmaceutical Sciences and Technology, Maharaja Ranjit Singh Punjab Technical University, Bathinda, Punjab and graduated as M. Pharmacy in 2019. He has joined a university as an Assistant Professor in India and has an experience of more than one year in the field of research.



Khagga Bhavyasri
Osmania University, India

Aryl Amine content determination in different Indian brands of hair dyes by analytical techniques

Paraphenylenediamine (PPD) is a chemical substance that is used in hair dye because it is a permanent dye that gives a natural look, and the dyed hair can also be shampooed or permed without losing its colour. PPD containing hair dyes have been associated with cancer and mutagenicity. Apart from that, PPD has potential toxicity which includes acute toxicity such as allergic contact dermatitis and sub-acute toxicity. The European Union Cosmetic Directive allows a maximum concentration of 6% PPD in hair dyes, while the Bureau of Indian Standards has set a maximum permissible limit of 30% and not less than 3% PPD after dilution of the powder form and a maximum of 4% and not less than 1.2% after dilution of the oxidation liquid type. A simple rapid, precise and accurate method has been developed to determine the concentration of para-phenylenediamine in different marketed hair dyes by UV-Visible Spectrophotometer and RP-HPLC. The PPD analysis was performed using NaOH solution as Diluent at 246 nm. The methods were linear in the concentration range from 0-15 μ g/ml. All the validation parameters were performed according to ICH (Q2)R1 guidelines and all the parameters were found to be within the limits. Analysis of PPD in different brands of hair dyes was performed and all the brands contain PPD within the limits. Hence the developed method can be used for routine analysis of para-phenylenediamine in hair dyes.

Audience Take Away Notes:

- PPD is harmful if it's not within the limits and it causes many allergic reactions
- A simple method has been developed to determine PPD in hair dyes by UV-Spectrophotometer and RP-HPLC
- To choose a good hair dye for regular use

Biography:

K.Bhavyasri has 12 yrs of research work and academics experience in the field of pharmaceutical analysis. Presently working as Associate Professor and Head, Dept of Pharmaceutical Analysis in RBVRR Women's college of Pharmacy which is Affiliated to Osmania University, Hyderabad, India. Done PhD from JNTU Hyderabad, India, M.Pharm from Osmania University Campus. Total 110 International Publications are there and 20 conferences attended cum presented.

**Maimuna Fatima**

G. Pulla Reddy College of Pharmacy, India

Formulation and optimization of self-micro emulsifying drug delivery system (SMEDDS) of Clopidogrel Bisulfate by using D-Optimal mixture design.

The present work aims to develop self-micro emulsifying drug delivery system (SMEDDS) to improve in-vitro dissolution of Clopidogrel Bisulfate an Anti-platelet agent, belonging to BCS class II. Initially, solubility studies were performed to identify the solvents showing highest solubility of API. Then ternary phase diagrams were plotted for selected components of oil, Smix and water to identify the area of micro-emulsion existence. By using D-optimal mixture design liquid SMEDDS were optimized using three independent variables: Oil phase X1 (Oleic acid), Surfactant X2 (Tween 80) and Co-surfactant X3 (PEG 600). Two dependent variables selected were R1: Self emulsification time (sec), R2: Percentage drug release within 90min. FTIR studies confirmed that the drug and excipients were compatible. The liquid SMEDDS were evaluated for thermodynamic stability studies, visual observation, robustness to dilution, drug content, self-emulsification time, dispersibility test and drug release. Stability study was performed at 40°C/75% RH. Contour plots and Response surface plots indicated that with the increase in oil ratio (X1) there is increase in Self emulsification time and decreased percent drug release. For these formulations predicted vs. Actual responses showed correlation of 0.963 for self-emulsification time, 0.9177 for %drug release in 90 minutes. Optimized formulation OPF1 Oil (20.25ml), surfactant (39.74ml) and co-surfactant (40ml) obtained from the design (with criteria <40 sec for Self-emulsification time and >85% release in 90 min.) showed self-emulsification time of 33.87 seconds, 101.41±0.21 %drug release in 90min., particle size of 528.6nm and PDI of 0.560, from which it can be inferred that micro range emulsion has been formulated and the particle size possess large interfacial surface area for drug absorption. The surface morphology of optimized formulation (OPF1) was examined by SEM and was found to be smooth. Zeta potential is useful in knowing the surface charge of the particle which determine its stability. Zeta potential can be either positive or negative, stable formulations may possess +30 to -30 mV charge. The formulation OPF1 showed a Zeta potential of -15.9 mV. Optimized formulation (OPF1) showed best results in terms of self-emulsification time (85% in 45 min) and was stable for 1 month. The results demonstrated potential of SMEDDS as a means of improving solubility, dissolution and hence the bioavailability.

Audience Take Away Notes:

Formulating Novel drug delivery system i.e., SMEDDS to enhance solubility and bioavailability of the poorly soluble drug when compared to conventional oral dosage forms with the aid of lipids, surfactants and co-surfactants

Biography:

Maimuna Fatima received her Bachelor of Pharmacy Degree from G. Pulla Reddy College of Pharmacy, Hyderabad, India in 2019. She is currently pursuing her Master's degree in Pharmaceutics with the same institution, she is presently working on a project related to Lipid-based formulation i.e., Nanostructured Lipid Carriers under the guidance of Dr. K. Latha in partial fulfilment of the award of the degree of Master of Pharmacy. She has attended various National (ATMOS 2022, DRPI 2022, DISSO India 2022, APP INDO-US Conference, TRIM 2022, and many more) and International Conferences (ICOPS 2022-IIUM, CRS 2021,2022) and received an award as the best presenter at 2 National Conferences. She has published a Research Article and a book Chapter, few more Research and Review articles are under review by various Scopus Indexed Journals. Her research interest includes Nano drug delivery systems, Lipid-based formulations, Computer aided DDS, AI & Robotics in Pharma.

**Bhupendra G. Prajapati**

Ganpat University, India

Self microemulsifying systems based topical lipstick of antifungal agent

Self-emulsifying system-based lipstick may prove to have potential of enhancing the moisturizing characteristics and deliver the hydrophobic drug antifungal drugs for the treatment of lip fungal infections. In this study, the self-emulsifying (SEDDs) mixture of Ketoconazole was obtained using Isopropyl myristate (Oil), Tween 80 (surfactant), and combination of Transcutol P and PEG 400 as co-surfactant. The medicinal lipstick was developed from the SEDDs by using waxes such as bees wax, carnauba wax, and lanolin along with cow ghee and castor oil. The lipstick formulations were assessed on the basis of physicochemical features, such as pH, spreadability, softening point, breaking point, content uniformity, and in vitro drug release. Furthermore, several discriminating tests were performed to evaluate the medicinal potential by performing tests such as skin irritation, ageing stability, and antifungal study. The optimized formulation showed exceptional results in physicochemical analysis and ~88% release of drug in 12 hours. The formulations displayed adequate stability for the period of 2 weeks at various conditions such as room temperature and refrigeration (2°C to 8°C) with no signs of irritation in the skin irritation study. The zone of inhibition produced by lipstick formulation was significantly higher as compared to reference standard (Ketoconazole in ethanol) which shows high antifungal activity. It was concluded from the outcomes that SEDDs based lipstick formulation showed a lot of promise as topical antifungal treatment option for lip fungal infections.

Biography:

Bhupendra works as a Professor in the Department of Pharmaceutics, Shree S.K.Patel College of Pharmaceutical Education and Research, Ganpat University, Gujarat, India. He is an alumnus of Hemchandracharya North Gujarat University, Patan (Doctorate), and M.S.University, of Baroda (B.Pharm and M.Pharm). He has 20 years of experience in academic/research/industry (17+2). He is the recipient of the Carrier Award for Young Teacher by AICTE, New Delhi in 2013, Distinguished Associate Professor in TechNExt India 2017 by CSI, Mumbai, and President award of Staff Excellence in Research (2019) and Capacity Building (2020) by Ganpat University for the consecutive years 2021 and 2022 respectively. He claims in his name more than seventy national and international publications. He fetched grants for Research Projects, Staff Development Programs, Seminars, Conferences, and Travel Grants from National and State Government agencies. He is closely associated with the industry as an advising and research mentor in formulation development projects/problem-solving. His two patents were published and Three applications were submitted to the Indian Patent Office in the field of NDDS. He has delivered more than 50 expert talks and was invited to scientific sessions at several national and international conferences, seminars and workshops. He supervised 7 Ph.D. and 48 PG research scholars (6 Ph.D. and 2 PG pursuing) in the field of Lipid base formulations, Nano/Mircoparticulate Drug Delivery, Bioavailability Enhancement, and Modified release formulations. In the last three-year 7 Prizes were secured by his PG and Ph.D. research scholars at national and international conferences. He is presently the editor of three international books, 1 topic editor and, 1 section editor. He contributed 4 book chapters, 16 accepted, 5 submitted, and 12 in the compilation phase. He is an active life member of IPA, APTI, and CRSIC. His current research focus is in the field of lipid- based drug delivery and nanotech formulations



Aysu Yurdasiper
Ege University, Turkey

Development and characterization of salbutamol sulfate dry powder inhaler formulations for asthma management

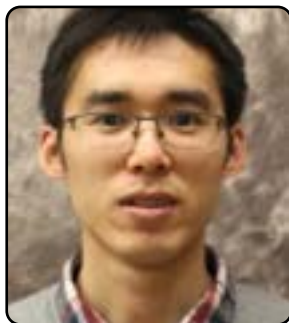
Asthma is a chronic disease that causes inflammation of the airways and makes it difficult to breathe. The best way to manage asthma is to avoid triggers, take medication to prevent symptoms, and control asthma attacks. The inhalation route is frequently used to administer drugs for the management of respiratory diseases such as asthma. Pulmonary drug delivery systems are a fast-response system because they can deliver adequate and necessary doses of drugs to the lungs with minimal systemic side effects while avoiding the first-pass effects of the liver and targeting the drug directly to the lung. Dry powder inhalers (DPI) contain drugs as inhalable powder. It has advantages such as increasing physicochemical stability, extended-release profile, and direct delivery of the drug to the site of action in the lungs. They do not require dissolution of the drug as in nebulizers, and unlike metered dose inhalers, DPIs have no propellants, so the dispersion of the powder is dependent on the patient's inhalation. Salbutamol sulfate (SS) is a β_2 -agonist used as a bronchodilator in chronic obstructive pulmonary diseases like asthma. By preparing DPI formulations, the short half-life of SS can be extended and the problems associated with systemic toxicity can be overcome. Also, pulmonary administration provides an alternative route of administration to avoid hepatic metabolism of SS and the local effect can be enhanced by direct targeting the lungs. DPI formulations containing SS were prepared with chitosan, trehalose and leucine combination by using a spray dryer. Following the formulation of the drug, resultant powders were determined via scanning electron microscopy (SEM), differential scanning calorimetry (DSC), thermogravimetric analysis (TGA), dynamic light scattering particle size analysis, and surface charge analysis. The in vitro aerosol dispersion performance and drug dissolution behaviour was evaluated using a next-generation impactor (NGI) (using an Aerolizer at 100 L/min flow rate.) and the NGI dissolution cup, respectively. A high-performance liquid chromatography method was used for measuring the drug content. Morphologies of the spray dried microparticles were exhibited by SEM and the particles have an irregular, corrugated surface. The optimized formulation mean volume diameter (Dv_{50}) and zeta potential were $3.91 \pm 0.18 \mu\text{m}$ and 11.28 ± 0.47 respectively. The fine particle fractions from chitosan-based formulations (48.13 ± 2.26) were significantly higher ($p < 0.001$) than those of formulations without chitosan (41.07 ± 1.35). The DPI formulation has satisfactory deposition in the airways. The mass median aerodynamic diameters (MMAD) were around $3 \mu\text{m}$ for all formulations. Chitosan-based DPI prolonged drug residence time in the lung (7 hours) and maintained a relatively high drug concentration (72.34%) for a longer time. These results supported that chitosan-loaded DPI containing SS for treatment of asthma exhibits prolonged drug retention at the targeted site. This optimized formulation might represent a plausible delivery vehicle for targeting the treatment of asthma via enhancing the therapeutic efficacy of SS and could be a promising candidate for the treatment of asthma.

Audience Take Away Notes:

- This work will present novel formulation design for the development of dry powder inhalers
- The formulation development scientist as well as research scholars will be able to gain knowledge about approaches that can be utilized for the formation of dry powder inhaler formulations
- It will be explained which parameters should be considered in the new formulation design
- Yes, this research will help the faculty teach their students about the detailed concept of the dry powder inhaler formulations and will familiarize the researchers and teachers to the dry powder inhalers while also learning formulation strategies
- This work could provide practical solutions to problems associated with the formulation concept
- It provides learning approaches to overcome the limitation faced in the development of dry powder inhaler formulations using novel carriers and excipients
- Preparation, formulation and characterization of dry powder inhalers containing salbutamol sulfate which is employed in the treatment of asthma
- This conference can enable to provide new multidisciplinary studies and new collaborations with the audience

Biography:

Aysu Yurdasiper obtained her BSc and MSc degree in Faculty of Pharmacy from Ege University, Izmir, Turkey and respectively, followed by a Ph. D degree from Department of Pharmaceutical Technology, Ege University, studying on Nano gel delivery system invitro- in vivo studies on dermal drug delivery. Her work is focused on dry powder inhalers, dermal delivery (topical, transdermal drug systems), controlled release formulations (nanoparticles, micro particles) for drug delivery and Nano medicine in pulmonary delivery. She is Editor in chief in American Journal of Drug Delivery and Therapeutics also Editor and on the Editorial Board of several International Journals. She has filed a National patent on dry powder inhaler formulation and she is a member of Turkish Pharmaceutical Technology Scientists' Association (TUFTAD), Turkish Pharmacists' Association (TEB), Controlled Release Society (CRS) and American Association of Pharmaceutical Scientists (AAPS). She has been working as an Assistant Professor in Department of Pharmaceutical Technology, Ege University. Her current research interest focus on development of novel Nano medicine including polymers and in vitro-in vivo evaluation for treatment of respiratory diseases.

**Fanfei Meng**

Purdue University, United States

An immunoactive polymer mediates nucleic acids delivery for cancer immunotherapy

Since the success of immune checkpoint blockade and chimeric antigen receptor T cell therapy, over a dozen immunotherapies have been approved in the past few years, and thousands of immunotherapeutics are currently in development pipeline. However, immunotherapy benefits only a small fraction of cancer patients with identified tumor antigens and/or well-accessible tumors. New therapeutic strategies are needed to improve the efficacy of immunotherapeutics in broader patient populations with hard-to-reach, unidentified tumors. An approach gaining interest in the immuno-oncology community is to treat locatable and accessible tumors locally and stimulate antitumor immunity in situ to exert systemic effects against distant tumors. To develop an effective local immunotherapy, we have produced a polyethyleneimine derivative (2E'), which activates immune cells and co-delivers Paclitaxel (PTX), a hydrophobic immunogenic cell death inducer, and PD-L1 siRNA (siPD-L1) or cyclic dinucleotide (CDN), immunomodulatory nucleic acids or nucleotides. The immunoactive polymeric assembly 2E'/PTX/siPD-L1 was developed and characterized by transmission electron microscopy. The cytotoxicity, cellular uptake, PD-L1 silencing, and immunostimulatory effects of 2E'/PTX/siPD-L1 were tested on immune cell (bone marrow-derived dendritic cells) and murine cancer cells (CT26 colorectal carcinoma). The antitumor effects of intratumorally injected 2E'/PTX/siPD-L1 and 2E'/PTX/CDN were evaluated in female Balb/c mice bearing CT26 tumor. Surviving tumor-free mice were re-challenged with live cells on the contralateral side to test if systemic antitumor immunity was established. We show that a single local administration of 2E'/PTX/siPD-L1 or 2E'/PTX/CDN induces strong antitumor immunity, resulting in immediate regression of large established tumors, tumor-free survival, and the resistance to tumor rechallenge in a CT26 tumor model. This study supports that effective in-situ induction of antitumor immunity can lead to systemic protection from distant and recurrent diseases. 2E'/PTX/siPD-L1 and 2E'/PTX/CDN complexes are promising delivery systems for local cancer immunotherapy.

Audience Take Away Notes:

- A new immunoactive complex was developed for cancer immunotherapy
- Effective in-situ induction of antitumor immunity can lead to systemic protection from distant and recurrent diseases
- This study explores the untapped utility of NPs as a way of increasing the potential of chemotherapy to induce immunogenic cell death for cancer immunotherapy
- This research investigates the role of carriers in cancer immunotherapy

Biography:

Meng is a postdoctoral associate at Purdue University, working with Prof. Yoon Yeo in the Department of Industrial and Physical Pharmacy. His research interests are developing nucleic acid-based formulations to stimulate the immune system to fight cancer and prevent infectious diseases. His currently research focus on designing new drug delivery systems for macromolecules such as proteins and nucleic acids delivery for cancer immunotherapy and vaccine development.

POSTERS

DAY 02

**7TH EDITION OF GLOBAL CONFERENCE ON
PHARMACEUTICS AND
NOVEL DRUG DELIVERY
SYSTEMS**

08-09 SEPT

**Keerti Maheshwari**

Delhi Pharmaceutical Sciences Research and University, India

Formulation, development and evaluation of chronotherapeutic drug delivery system for the treatment of Nocturnal Asthma

Nocturnal asthma mainly known as night time asthma, it is mainly occur during sleep. The mechanism of this related to the circadian rhythms that may influence mediators and inflammatory cells, cholinergic tone and hormonal changes. Chronotherapeutics is defined as a treatment system where the in vivo drug availability has been timed in accordance to cyclic rhythms of drug related biological phenomena to create maximum benefit minimizing harm. Salbutamol Sulphate used drug for the relief from several respiratory system associated problems such as asthma, bronchitis, apnoea, and other respiratory tract infection. Salbutamol Sulphate may be useful in the treatment of nocturnal asthma. This study is to especially design and evaluate for the Pulsatile drug dosage delivery system and oral site-specific containing Salbutamol Sulphate, which is knowingly targeted the colon in pH time dependent and to regulate the drug deliver level with the circadian rhythm of nocturnal asthma. In this study, we mainly focus on have attempted to develop chrono pharmaceutical approach using a novel drug dosage form and microsphere dosage form, that drug taken during night with a programmed start of drug deliver early in morning time, that could prevent sharp increment in the effective time of asthmatic attacks during the morning time, and time where the asthmatic attack chances are larger. The subsequent idea to design a novel to treat with the high potential benefits by the drug dosage novel drug delivery system. Based on the concept that at the pH of colon various polymers release the drug due to their solubility at specified pH, a designed pH time dependent activity pulsatile novel drug delivery dosage system. The main specific objective of this research is to treat the nocturnal symptoms of the asthma by the drug delivery system of salbutamol sulphate by the exploring the feasibility of time and pH time dependent activity colon specific, of the chronotherapeutic drug delivery system. A satisfactory conclusion was made to develop new chronotherapeutic microsphere formulation using polymers chitosan and Eudragit S100 and evaluated for In vitro characterization studies. Here are some highlights of my research work that help researchers in their nocturnal asthma novel drug delivery system: Chitosan microsphere novel drug delivery system in chronotherapeutic system and pulsatile drug dosage delivery system, Circadian rhythms of GIT physiology and other related diseases including metagenomic sequencing, Study of Pharmacokinetic and pharmacodynamic study of drug administration.

Biography:

Keerti Maheshwari has done M. pharma in pharmacology from Jayoti Vidyapeeth women's university, Jaipur in 2017-19, B.pharma from Jayoti Vidyapeeth women's university, Jaipur in 2013-17. After that Joined as a Junior technical officer in National institute of pharmaceutical education and research, Raebareli in 2019-2021. After that joined as a JRF in Centre for precision medicine and pharmacy in Delhi pharmaceutical sciences and research university, New delhi.

**Ibrahim A. Alsarra**

King Saud University, Saudi Arabia

Self-nanoemulsifying drug delivery system (SNEDDS) of apremilast: In-vitro evaluation and pharmacokinetic studies

Psoriatic arthritis is an autoimmune disease of the joints; it can lead to persistent inflammation, joint damage and disability. Apremilast (APR) was the first FDA approved oral anti-psoriatic arthritis drug. It APR immediate release tablets Otezla® have 20-33% bioavailability compared to APR absolute bioavailability 73%. APR-SNEDDS were formulated to enhance APR's solubility, dissolution and oral bioavailability. The assay of drug was carried out using a validated HPLC method. The standard plot obtained linearity in the concentration range of (0.1 to 100 µg/ml) with $R^2 = 0.9991$. Using Lauraglycol-FCC as the oil phase, de-ionized water as the aqueous phase, tween-80 as the surfactant and transcitol-HP as the cosurfactant, nine APR-SNEDDS were developed namely (F1-F9) by spontaneous emulsification method. Various thermodynamic tests were carried out on APR-SNEDDS. Stable SNEDDS were characterized then subjected to in-vitro drug release studies via dialysis membrane. The optimum formulation was F9 which showed the maximum in-vitro drug release (94.9%) over 24h was furtherly investigated in in-vivo studies. F9 was composed of 15% oil, 60% Smix, and 25% water had the lowest droplet size (17.505 ± 0.247 nm), low PDI (0.147 ± 0.014), low ZP (-13.35 mV), highest %T (99.15 ± 0.131) and optimum increases in the relative bioavailability (703.66%) compared to APR suspension (100%) over 24h. These findings represented APR-SNEDDS as a possible alternative delivery system for APR and for future studies to evaluate the major factors that influence the encapsulation efficiency and stability of APR. Moreover, the application of APR-SNEDDS for oral delivery, efficacy and safety assessments.

Audience Take Away Notes:

- Introduce self-nanoemulsifying method as a possible alternative delivery system
- Apply different formulation techniques using self-nanoemulsifying drug delivery system
- To create and optimize SNEDDS of APR to increase its solubility and dissolution rate which sequentially will upgrade the extent of the oral bioavailability and therapeutic efficacy of the drug
- Explain various thermodynamic stability tests and it were applied on the formulated self-nanoemulsifying drug delivery system

Biography:

Ibrahim A. Alsarra received his Bachelor of Pharmacy (B.S.), in 1996 from College of Pharmacy, King Saud University, Kingdom of Saudi Arabia and his Doctor of Philosophy (Ph.D.) in Pharmaceutical Biotechnology and Drug Formulation Development, Division of Pharmaceutical Sciences, School of Pharmacy, University of Missouri-Kansas City, Missouri, USA. He joined King Saud University in 2002 and is currently the Assistant Secretary for Research and Scientific Affairs, Arab Pharmacists Union as well as the Deputy Director for Research and Technical Affairs, Centre of Excellence in Biotechnology Research; the only biotechnology center in Saudi Arabia, King Saud University.



Essa Abdullah Aldulaym

Imam Abdulrahman Bin Faisal University, Saudi Arabia

Antibiotic and phytoconstituent combination loaded gastric floating microsphere for the effective eradication of Helicobacter Pylori infection: Formulation, physicochemical and microbiological assessment

The present investigation aimed to develop an antibiotic and a phytoconstituent combination loaded gastric floating microsphere for the effective eradication of Helicobacter pylori infection by the synergistic effects of the loaded drugs. The microsphere formulations were prepared by quasi-emulsion method, and then the prepared formulations were assessed for various parameters including in vitro drug release study and in vitro anti H. pylori activity. The production yield, drug content, and entrapment efficiency of the microspheres were increased on increasing the polymer and the drugs amounts. All microspheres were exhibited prolonged in vitro floating time (12 h), and controlled in-vitro drug release (for 24 hours). The surface morphology imaging study revealed that the microsphere was spherical in shape and has a porous surface with interconnecting channels. DSC study demonstrated the absence of drug-drug and drug-polymer interactions. The in vitro MIC results showed that the anti H. pylori activity of the microsphere containing both drugs was showing synergistic and more prolonged effect than the microsphere containing single drugs. Thus, it could be concluded that the loading of two synergistic drugs in a gastric floating microsphere could be an excellent option to effectively eradicate H. pylori infection and the pharmacokinetic and pharmacodynamic assessments of our microsphere formulation can be expected to provide a rewarding outcome.

Audience Take Away Notes:

- The use of novel drug delivery system in combination treatment of H.pylori.
- The application of the microsphere drug delivery system as novel drug delivery system in improving the drug stability and bioavailability.
- The new applications of the novel drug delivery system in Research and development of new drugs.
- The Novelty of the research by combining to different medications (phytoconstituents with antibiotics) and increase eradication of H.pylori infections.
- The ability of increase residence time of the anti-h.pylori drugs leads to improve medication adherence.

Biography:

Essa Aldulaym, Clinical pharmacy student, Imam Abdulrahman Bin Faisal University, Entrepreneur of EdTech platform, Part-time Project manager of Founders2Founders company.

**Joanna Chałupka**

Nicolaus Copernicus University, Poland

The effect of commercially available DPIs on respiratory drug aerosolization

FP (fluticasone propionate) is a synthetic fluorinated cortisol derivative with a strong anti-inflammatory effect. In inhaled form, it is used to treat asthma, and less frequently, to treat COPD. Typically the DPI inhaler used for administering dose of drug is provided in the standard medicine package. The use of a non-genuine inhaler to administer the medication into the respiratory track creates a risk of incorrect aerosolization of the dry powder containing FP. The aim of this study was to verify the correctness of action of the various commercially available inhalers in terms of dry powder aerosolization containing FP. To that reason, the analyses with the use of NGI were performed. The conducted research allowed determining the Aerodynamic Particle Size Distribution (APSD), Fine Particle Fraction (FPF) and Fine Particle Mass (FPM). The quantitative determinations were made on the basis of the HPLC analytical method. The dry powder fractions distributed on the new generation impactor were collected using methanol. The samples were centrifuged and then filtered with a syringe filter into the chromatography vials. The FP content was quantified at each impactor level. The APSD plot was constructed and the FPF was calculated using the definite integral ranging from 1 to 5 μm . The conducted research has proven that various commercially available inhalers should not be used interchangeably. Moreover, the research showed that FPF decreases with the decrease in air flow velocity, which may have an impact on the therapeutic effect of the inhaled drug in people with low respiratory efficiency. The studies were financed by a grant from the National Centre of Research and Development, Poland, LIDER Program, No: LIDER/52/0276/L-12/20/NCBR/2021.

Audience Take Away Notes:

- The audience will observe that selection of DPI is crucial to effective pharmacotherapy using respiratory drugs
- This research could expand other faculty research or teaching
- Yes, the topic will improve provide new information to assist in a design problem

Biography:

Joanna Chałupka, studied Pharmacy at Nicolaus Copernicus in Toruń, Collegium Medicum in Bydgoszcz, Poland and graduated as MS in 2022. In 2021 she has joined the research group of Prof. Michał Marszałł at Medicinal Chemistry at the same organization. She is focused on stereoselective syntheses, pharmaceutical analytics and respiratory medicines, including studies of API aerolization.

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