AAiPS

Newsletter

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AMERICANASSOCIATION
OF INDIAN PHARMACEUTICAL SCIENTISTS
P.O. Box 189 Mount Freedom, NJ 07970

INSIDE THIS ISSUE

Newsletter Editor: Raghu Kasu
Co-Editor: Dinesh Nyavanandi
Editorial Board: Mike Yelvigi, Sampat Singhvi

PRESIDENT'S MESSAGE

Dear Members,

This has been another unusual year with a promising start after the vaccine rollout followed by current concerns around variants. And while we feel as though we are approaching the last lap, all of us really would like to see COVID in the rear view mirror.

As we did last year, so too this year we have stayed in touch virtually through Zoom and have remained busy. In light of the terrible COVID situation in India in April/May, AAiPS created a fundraising platform through GiveIndia to allow our members, friends & families to help our brothers and sisters back home.

Additionally, AAiPS has organized two regional meetings which were very well attended and generated good discussions. Our distinguished speakers were Dr. Banga from Mercer University (April 29) whose presentation was on *Advances in Transdermal Systems: Basics* and Dr. Murthy from University of Mississippi (June 24) who shared his perspectives on *Nose to Brain delivery of Drugs: Opportunities and Challenges.*

In keeping with past tradition, AAiPS will continue with the student Research awards. Dr. Saluja, chair of the Awards Committee has sent an announcement to various universities requesting student research abstracts – the deadline for abstract submissions is Aug 27.

For the upcoming Annual Meeting, the EC has been carefully monitoring the COVID variant situation and will soon make a decision on whether we will have an in-person meeting this year.

Stay tuned and please continue to remain healthy and safe!

Sincerely,

Rupa Doshi, Ph.D. President, AAiPS

QUOTE OF THE QUARTER

"The greater danger for most of us lies not in setting our aim too high and falling short; but in setting our aim too low, and achieving our mark."

-Michelangelo

AAiPS Quarterly Webinar-2021

Nose to Brain Delivery of Drugs
Opportunities and Challenges

Professor S. Narasimha Murthy
Dept of Pharmaceutics and Drug Delivery
University of Mississippi School of Pharmacy

Biography

Dr. S. Narasimha Murthy is the Professor of Pharmaceutics and Drug Delivery and Dr.Murthy is also CSO of the company Topical Products Testing LLC which provides contract services to Pharmaceutical companies in the field of topical product development, characterization and evaluation (www.topicalproductstesting.com). Dr.Murthy is also the Founder-Director of a non-profit research organization, Institute for Drug Delivery and Biomedical Research in Bangalore, India (www.IDBResearch.com).

Dr.Murthy's research is in the field of topical / transdermal delivery and intranasal drug delivery. His research programs are funded by NIH, USFDA and Pharmaceutical companies. He has published over 130 research papers and presented over 250 scientific posters in various national and international scientific meetings. He has authored two books and over fifteen book chapters.

Abstract

Targeting drugs to the CNS is a challenging task due to the blood brain and blood cerebrospinal barriers. The olfactory tissues in the nasal cavity offers a direct pathway to the brain. However, olfactory epithelial tissue is a significant barrier owing to the cellular organization, enzymes, and efflux transporters. Several strategies have been explored to overcome the olfactory mucosal barrier to exploit this pathway for drug delivery to the brain and CSF. Some of the approaches and case studies of delivering drugs to the brain via intranasal pathway will be presented in this webinar.

The meeting was held on June 24th, Dr. Murthy discussed various opportunities and challenges of nose to brain drug delivery. The discussion was also focused on its current and future perspectives. The meeting was well attended with lots of discussion on this topic.

Advances in Transdermal Delivery Systems

Professor Dr. Ajay K. Banga
Department of Pharmaceutical Science
Mercer University

Biography

Dr. Ajay K. Banga is Professor and Department Chair in the College of Pharmacy, Mercer University, in Atlanta, GA. He also holds an Endowed Chair in transdermal delivery systems, and serves as co-Director for the Center for Drug Delivery Research. He has mentored 40 Ph.D. students as their major advisor, served on over 60 dissertation advisory committees, and his laboratory has been funded by over 100 grants/contracts from pharmaceutical and cosmetic companies, and by federal funds. He has written three books, published 165 manuscripts, 12 book chapters, and made over 260 conference presentations with his students. He has given over 90 invited lectures and served as a referee for over 40 journals. He is a Fellow of the American Association of Pharmaceutical Scientists. Dr. Banga has a Ph.D. in pharmaceutical sciences from Rutgers University, NJ, and he has served as a consultant to over 25 companies.

Abstract

Moderately lipophilic drugs can passively diffuse into skin and can be formulated as dermatologicals or as transdermal patches. Hydrophilic molecules and macromolecules do not normally pass through the skin but can be delivered by enabling technologies like iontophoresis, sonophoresis, or skin microporation achieved by microneedles or by thermal or laser ablation. Rationale for selection of delivery technology was discussed, as well as intricacies of performing in vitro skin permeation testing. Recent advances with application of microfluidics, nanotechnology, and 3D printing to transdermal delivery, and efforts to increase drug quantity that can be delivered were discussed.

The webinar was hosted on April 29th, with main focus on "Microneedle dosage forms" and its recent advancement in transdermal drug delivery. It was an excellent presentation which was educational and very well received.

Note: The webinar update was depicted in previous issue (Volume 32; Issue 01)

AAPIS would like to thank its Diamond Level sponsor: IDEAL CURES

 https://www.idealcures.com/	Ideal Cures (IC) is one of India's leading manufacturer and exporter of pharmaceutical excipients and ready-to-use coating systems for solid oral dosage forms. IC provides tailor-made solutions and products for the pharmaceutical and allied industries, through a network of customers and partners across more than 40 countries around the world. Leveraging over three decades of coating experience, technical know-how and expertise Ideal Cures' provides precise, simplified solutions uniquely shaped to meet a customer's requirements. IC provides its customers with a complete range of coating products and excipients complemented by technical and regulatory services. IC's product portfolio includes **INSTACOAT®** ready-to-use film coating systems, **ECOPOL®** range of Pharma Acrylic Polymer's, **ECOCOOL®** brand of cooling compounds, **ESPHERES™** range of microcrystalline cellulose, silicon dioxide, calcium carbonate, tartaric acid spheres, new generation of sugar spheres and **INSTANUTE®** coating technology for nutraceuticals and dietary supplements.

Pharmaceutical News:

Pharma putting digital drug delivery at heart of plans: Survey

Almost 90% of pharmaceutical companies see smart inhalers and other digital drug delivery devices as very or extremely important to their future plans, according to a Molex survey.

Molex, which is active in the digital drug delivery space through its Phillips-Medisize division, polled 215 people working at biologic and small molecule companies of all sizes. The survey sought to gather views on "digital drug delivery," a term Molex used to cover smart inhalers, digital pills and other products that record and share data on the administration of pharmaceuticals.

The survey found 54% of respondents see digital drug delivery as extremely important to the plans of their companies, with a further 34% of people saying the technology is very important. Only 1% of the survey respondents said the technology is of no importance.

https://www.fiercepharma.com/

Novartis hits setback in bid to block Regeneron's Eylea prefilled syringe as dual lawsuits drag on

Novartis won't be able to block Regeneron's popular Eylea prefilled syringe any time soon after a regulatory setback. But the Lucentis maker isn't giving up on the patent fight that could shift the anti-VEGF competition between the two drugs.

The U.S. International Trade Commission (ITC) on Monday ended an investigation into a Novartis complaint that sought to ban imports of Eylea's prefilled syringe based on alleged patent infringement. The termination followed Novartis' request to withdraw the complaint a month ago—two weeks before a trial in front of an administrative law judge—after the company received an unfavorable opinion from agency staffers.

Instead of pursuing a case at the ITC, Novartis is now making its arguments in federal court. Novartis alleges infringement on the prefilled syringe patent in a lawsuit filed in federal court in New York, while Regeneron has an antitrust complaint against the Swiss pharma in that state.

Before Novartis' ITC retraction, reviewers at the agency's Office of Unfair Import Investigations sided with Regeneron, noting that Novartis' patent and related claims of infringing imports were invalid, according to a redacted document prepared before the hearing. The ITC originally opened the case last July.

Staffers recommended to delay any import ban on Eylea prefilled syringes even if Novartis eventually won the case; they raised concerns over public access to the drug as Regeneron switches its production to the vial format.

https://www.fiercepharma.com/

Is remote work here to stay for biopharma? Early indications point to yes

Covid-19 cases in the US have begun to ebb, following a nationwide vaccination campaign that has nearly 60% of American adults receiving at least one vaccine dose. And with more and more individuals being inoculated, the biopharma industry is openly

wondering how to bring its employees back to the office.

The early consensus among bigger companies indicates that some sort of new normal will take shape once the pandemic officially ends, with employees spending

time both at their offices and working remotely. How quickly that develops remains an open question, however.

Large swaths of the workforce want to continue at least some remote work as Covid-19 recedes in the US, according to a Harvard Business School poll released in March. Among the more than 1,500 full-time remote workers surveyed, 81% said they either don't want to go back to the office at all or would prefer a hybrid remote/in-person model.

And though some professionals noted that they missed meeting their colleagues face-to-face, 61% said they'd like to work 2-3 days per week from home. Only 18% responded they want to go back to the office full-time.

https://endpts.com/

Lonza Announces Manufacturing Expansions in Europe and the US with Nearly $1 Billion Investment

Swiss CDMO Lonza Group has announced plans to expand manufacturing at its sites in Visp, Switzerland and Portsmouth, New Hampshire in the US, committing $950 million to the projects. The almost $1 billion investment will specifically go towards expanding the company's mammalian drug substance manufacturing facilities at the sites.

The investment is projected to create 550 jobs across the two sites. Lonza says it's supported by a strong pipeline and underlines the company's continuing commitment to serving customers across modalities and scales.

According to the company, $715 million of the investment will go towards expanding Lonza's existing Visp facility where Lonza aims to increase large-scale biologics manufacturing capacity to meet customer demand in the contract manufacturing space. The rest will go to constructing a new next-generation facility in Portsmouth to support late-phase clinical and commercial development and manufacturing. Lonza expects the facility will be up and running in 2024 and has already begun recruitment to bring on more than 300 new employees.

https://xtalks.com/

Sanofi, GlaxoSmithKline, Boehringer accused of playing games, destroying emails related to lawsuit over contaminated Zantac

A recent court filing raises new questions about how major pharma companies like Sanofi, GlaxoSmithKline, and Boehringer Ingelheim have dealt with a lawsuit related to recalls of certain over-the-counter heartburn drugs due to the presence of a potentially cancer-causing substance found in them.

More than 70,000 people who took Sanofi's Zantac and other heartburn drugs containing ranitidine, which have been recalled over the past two years, have sued the manufacturers, including generic drugmakers, and other retailers and distributors as part of a consolidated suit before US District Court Judge Robin Rosenberg in Florida.

A recent court filing shows how the companies may have played games with the plaintiffs' lawyers and delayed access to key documents, in addition to possibly destroying emails.

https://www.bloomberg.com/

Alexion co-founder Stephen Squinto is back in the game as CEO, this time for a small gene therapy player

With his name already behind a rare disease success story in Alexion, Stephen Squinto was looking for a great story to drive him to jump back into the biotech game. He found that in a fledging non-viral gene therapy company, and now he's got a few backers on board as well.

Gennao Bio launched with a $40 million Series A co-led by OrbiMed and Logos Capital with participation by Surveyor Capital. The biotech, which is looking to use its cell-penetrating antibody platform to deliver nucleic acid "payloads" during into the nucleus, had to rush for its initial series — and had a name change along the way.

https://endpts.com/

Covid-19 roundup: Pfizer CEO Bourla to write book about vaccine arms race; Chinese mRNA shot set for PhIII trial in Mexico

Pfizer CEO Albert Bourla has inked a deal with Harper Business for a book to tell the "behind-the-scenes" story of the company's race to develop a vaccine. The book is titled "Moonshot: Inside Pfizer's Nine-Month Race to Make the Impossible Possible."

Bourla helped drive Pfizer's unprecedented race to an emergency use authorization in just nine months, a previously unheard-of pace for vaccine development. And since, he's worked to protect the intellectual property that undergirded that work.

The company announced that it generated $26 billion in 2021 revenue, which is more than $10 billion than initially expected. That's more money than any drug or vaccine has ever generated, and good for 30% of the company's total expected revenue in 2021. It's also more than double the expected cost of R&D in 2021.

https://essentials.news/

Biogen pushes in a fresh stack of chips and starts prepping a global R&D game plan after watching the cards turn on early thrombolytic data.

After patiently steering through a decade-long journey for its early-stage clinical work, a small Tokyo biotech has clinched a deal to out-license its lead thrombolytic agent to US heavyweight Biogen — which sees a potentially game-changing impact on the clot-busting field after taking a careful look at some upbeat Phase IIa data.

Three years after Biogen anted up $4 million to gain an option on the drug from TMS, the big US biotech is making a small bet to beef up its stroke portfolio. The BD team inked a deal to go ahead and grab rights to the drug for $18 million, with another $335 million in milestone cash on the table for a successful outcome.

Biogen execs say they were convinced that TMS-007 — a plasminogen activator out of Tokyo University — could go on to become the first

significant new thrombolytic agent to hit the market in 25 years.

https://endpts.com/

With backing from Bayer, a London firm will pitch its 'hospitals at home' concept for decentralized trials

Money is flying for companies promising to revolutionize the way clinical trials are conducted. Leaps by Bayer is the latest to get behind one of these players, leading a $200 million venture round for Huma Therapeutics and its digital "hospital at home" tech.

London-based Huma unveiled a $130 million Series C, which it will use to expand its digital platform in the US, Asia and the Middle East. As part of the round, the company can exercise another $70 million commitment later on.

https://rwr-news.com/

Sun Pharma announces settlement of patent litigation for Generic Revlimid® (lenalidomide) in US

"Sun Pharma" and its subsidiaries and/or associate companies) along with one of its wholly owned subsidiaries today announced that they have reached an agreement with Celgene Corporation (Celgene), a wholly-owned subsidiary of Bristol Myers Squibb, to resolve the patent litigation regarding submission of an Abbreviated New Drug Application (ANDA) for a generic version of Revlimid® (lenalidomide capsules) in the US.

Pursuant to the terms of the settlement, Celgene will grant Sun Pharma a license to Celgene's patents required to manufacture and sell (subject to USFDA approval) certain limited quantity of generic lenalidomide capsules in the US beginning on a confidential date that is sometime after March 2022. In addition, the license will also allow Sun Pharma to manufacture and sell an unlimited quantity of generic lenalidomide capsules in the US beginning January 31, 2026.

As a result of the settlement, all Hatch-Waxman litigation between Sun Pharma and Celgene, regarding the Revlimid® patents, will be dismissed. Additional details regarding the settlement are confidential. The agreement is subject to customary regulatory approvals.

https://www.business-standard.com/

US govt to invest $3.2bn to develop pills to treat Covid

The US is taking another medical moonshot to beat the pandemic, plowing in $3.2 billion to develop antiviral pills to treat Covid-19 infections. If all goes well, some of those pills might become available by the end of this year.

The new programme, coming on top of the $18 billion success story that resulted in effective vaccines in record time, will create platforms that will initially target coronaviruses, and then could be expanded to other viruses with pandemic potential – helping to better prepare the nation for future viral threats.

https://health.economictimes.indiatimes.com/

Venus remedies wins battle against French pharma firm to revoke Indian patent for intravenous paracetamol

In a historical breakthrough for the Pharmaceutical industry in the country, Venus Remedies Limited won a 10-year long legal battle that challenged patent claimed by French pharmaceutical firm SCR Pharmatop for producing the intravenous paracetamol. In a decision dated 4th June, 2021, the Indian Patent Office decided in favour of Venus Remedies and upheld its decision for revocation of the Indian patent on the grounds that the process lacked any inventive step that made it superior to other existing solutions.

Venus's opposition was intended to remove any Indian Patent hurdle in manufacturing of Intravenous Paracetamol solution in India. As intravenous paracetamol plays a critical role in managing inflammation and fever, hence the revocation of this patent is an encouraging development for the healthcare sector in the country reeling under the current pandemic.

https://www.livemint.com/

Indian pharma companies' sales to rise after resilience in FY21: Fitch

Indian pharmaceutical companies' sales will grow robustly in the financial year ending March 2022 (FY22) as sales normalise in categories affected by the pandemic in previous year. Most pharma companies reported resilient operating performance in FY21, benefitting from gradual stabilisation after 1Q FY21, geographical diversification and sales of pandemic-related drugs.

https://www.business-standard.com/

Lupin gets warning letter from USFDA for Somerset facility

Drug firm Lupin on Sunday said it has received a warning letter from the US health regulator for its Somerset facility in the US.

The United States Food and Drug Administration (USFDA) had inspected the company's Somerset, New Jersey, facility from September 10, 2020, to November 5, 2020, Lupin said in a regulatory filing.

"The company does not believe that the warning letter will have an impact on disruption of supplies or the existing revenues from operations of this facility," it added. Lupin is committed to addressing the concerns raised by the USFDA and will work with the FDA and the New Jersey district to resolve these issues at the earliest, the filing said.

https://www.bloomberg.com/

No plans to get into vaccine production as it requires separate manufacturing infra: Sun Pharma

Sun Pharma has no immediate plans to enter into vaccine production as getting into the vertical would require an altogether different manufacturing set-up, as per a top company official. The Mumbai-based company, which is strong in various generic therapeutic segments, is eyeing biosimilars to fuel its future growth.

"I think our preliminary assessment indicates that vaccines will require a dedicated manufacturing facility and it cannot be produced in a facility where

we are making multiple other products," Sun Pharmaceutical Industries Managing Director Dilip Shanghvi said in a call with analysts.

The billionaire industrialist noted that for getting into vaccine production, a completely new set of manufacturing infrastructure is required.

https://www.moneycontrol.com/news

Why big pharma had a responsibility to profit from the pandemic

The pharmaceutical company Pfizer expects to earn up to US$26 billion (£18 billion) this year from the sale of its COVID-19 vaccine. Profits for the first quarter of 2021 are apparently 44% higher than they were a year ago.

Similarly, Moderna expects to make US$18.4 billion (£13 billion), and record its first ever profit this year.

This has led some to ask whether it is right for these big drug companies to effectively profit from the pandemic - especially in light of commitments from competitors Johnson & Johnson and AstraZeneca to sell their vaccines on a non-profit basis.

https://theconversation.com/us

FDA denies emergency use nod for Covaxin in US

The US Food and Drug administration has denied approval for emergency use of Bharat Biotech's Covaxin, and has asked for additional data, biopharmaceutical Ocugen, the US partner of the Indian vaccine maker has said.

FDA recommended that Ocugen "pursue a Biologics Licence Application (BLA) submission instead of an EUA application" and "requested additional information and data". Ocugen anticipates that data from additional clinical trials will be needed to support the submission. "We were close to finalising our EUA application when we received (FDA's) recommendation to pursue a BLA path. While this will extend our timelines, we are committed to bringing Covaxin to the US," said Ocugen's Shankar Musunuri agencies.

https://health.economictimes.indiatimes.com/

Tris Pharma® Acquires Park Therapeutics

Tris Pharma, Inc., a specialty pharmaceutical company with a portfolio of approved products and a late-stage pipeline of product candidates for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) and related conditions, has acquired Park Therapeutics, a company developing a unique, first-in-class, investigational NCE for the treatment of pain which is Phase III-ready.

Studies have demonstrated the potential for the NCE to provide strong efficacy in nociceptive and neuropathic pain, while maintaining a highly differentiated safety profile results from its unique, first-in-class dual mechanism of action as a highly potent agonist of the nociceptin/orphanin FQ (NOP), DOP and MOP receptors and partial agonist of KOP receptors. The drug has been studied extensively in both Europe and the US in approximately 2,000 subjects in 27 clinical trials including 8 efficacy trials against both placebo and active comparators, such as Oxycontin, Nucynta, morphine and pregabalin. The NCE cebranopadol has been granted Fast Track status by the FDA and was initially developed by

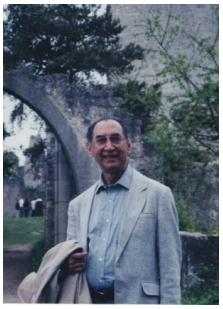
Grünenthal, a German company which specializes in pain. With the acquisition, Tris owns worldwide rights and all accompanying intellectual property for cebranopadol.

James Hackworth, Ph.D., co-founder and President of Park Therapeutics commented, "We have evaluated numerous NCEs, emerging technologies and different pathways in the pain space and we have never before seen such a potentially game-changing therapy. Cebranopadol's potential to deliver a superior safety profile and strong efficacy provide for an effective tool to address acute and chronic pain without the risks associated with traditional opioids".

Ketan Mehta, Founder and CEO of Tris Pharma added, "I have been pleasantly surprised to see the depth and breadth of data underscoring the superiority of treatment that this drug promises. We are fortunate to have this opportunity to acquire a late-stage asset and look forward to working with the FDA on its approval journey". He continued, "We are equally fortunate to have James join Tris' Leadership team as President of our Brand Division. In this capacity, James will lead our Commercial team, Corporate Development and Medical Team https://www.prnewswire.com/

OBITUARY

Dr. Kripanath (Krip):



It is with deep regret we inform you that Dr. Kripanath (Krip) Borah passed away on July 9, 2021 due to old age. He was 89 years old and has left behind wife two sons and grandchildren.

Krip was a renowned organic chemist and pharmaceutical scientist. He obtained his Ph.D. in Pharmaceutical Chemistry from Wurzburg University, Germany and served as head of R&D CIBA India.

He was instrumental starting production of Diosgenin steroids from plants in India. He immigrated to USA in 1976 and briefly worked at Boston College and William H Rorer in Pharmaceutical Development. He joined as Director or Organon USA in 1979 and retired from Organon in 1990. Later he served as Director of R&D at Enzon Biotech, G&W laboratories, Tomer Laboratories and PharmOps INC.

Krip took keen interest in Am.Assn of Pharmaceutical Scientists (AAPS) and Am.Asssn of Indian Pharmaceutical Scientists (AAiPS). He was elected President of AAiPS from---. He immensely contributed to pharmaceutical sciences in USA and India and has mentored many students and scientists. AAiPS Executive committee is very appreciative of his self-contribution to AAiPS and its scientists. He will be missed.

Charles A. Bass:

Charles “Chuck” Alan Bass, 61, passed away in the comfort of his beloved home in Wall Township on July 21, 2021. Chuck valiantly fought pancreatic cancer with grace and grit. Despite a devastating diagnosis, he remained as charismatic and upbeat as ever.He was a graduate of Wall High School and earned a bachelor's degree in physical chemistry at Rutgers University, New Brunswick. Chuck had a very impressive career in science and sales that spanned over four decades. He greatly enjoyed his long and successful career with Dow Chemical, which later transitioned into Dupont and then IFF. His most recent role was as Pharmaceutical Sr. Key Account Leader. He was extremely proud of his team and woke up every day ready to get to work.

He was a great supporter of AAiPS. The AAiPS Executive committee is very appreciative of his contributions to AAiPS and its scientists.

AAiPS Research Awards: 2021

The **American Association of Indian Pharmaceutical Scientists (AAiPS)** is pleased to announce the availability of **SIX** awards for the graduate students in Pharmaceutical Sciences. Applicants in pharmaceutical sciences should submit their research findings. Applications for consideration to the regulatory and clinical science should be focused on the drug regulation and practice and science in the clinical setting. ***FOUR*** awards will be given to the students of Indian heritage and ***TWO*** are open to all graduate students. The awards will be presented at the AAiPS Annual Meeting.

Criteria for submission:

Interested graduate students should submit no more than an 800 words summary of their research findings and up to two (2) images. The format should include Title, Author/s, Affiliation, Purpose, Methods, Results and Conclusion. Title, author/s and affiliation would not be counted towards 800 words.

At the end of your abstract, please include contact details (primary author's name, email and phone followed by major advisor's name, email and phone)

All applicants must present their research findings at the 2021 Annual meeting of the American Association of Pharmaceutical Scientists (AAPS). Abstract should have been accepted by AAPS.

Please include category on top of your abstract. You can apply to any one category from the five listed below. See the format below for writing your abstract.

Section:
Title:
Author's name:
Affiliation:
Purpose:
Methods:
Results:
Conclusion:
Contact details:

Categories to submit abstracts:

1. **Drug Delivery/Pharmaceutical Technologies:** All topics related to formulation, physical pharmacy, biotherapeutics, biotechnology, biosimilars, drug discovery and manufacturing/manufacturing Science and Engineering.
2. **Analysis and Pharmaceutical Quality:** All topics related to Dissolution Technologies, In Vivo-In Vitro Relationships/Correlations, Method Development and Validation, Electrophoresis, High-throughput Analysis, Hyphenated Methods—Small Molecule (e.g., GC-MC, LC-MS, etc.), PK Samples, Theoretical and Statistical Aspects of Method Validation.
3. **Pharmacokinetics, Pharmacodynamics, and Drug Metabolism:** All topics related to biopharmaceutics**,** bioavailability, First Pass Effects / Drug Absorption (Food Effects, Formulation Effects), Drug Interactions, PK and PK/PD Modeling, Tissue Distribution and Microdialysis, Toxicokinetics / Toxicology, Transporters.
4. **Clinical Pharmacology, Transitional Research and Biomarkers:** All topics related to clinical trials, pharmcoeconomics, pharmacotherapy, and therapeutic drug monitoring and transitional research.
5. **Regulatory Affairs:** All topics related to regulatory affairs like cGMP, CMC, regulations/guidance, ICH guidelines etc.

Please send your submissions by Friday, September, 4th. 2021 to:

Prof. Hardeep Saluja; Chair
Chair, AAiPS Research Awards Committee
Southwestern Oklahoma State University
College of Pharmacy, Weatherford, OK 73096
Email: hardeep.saluja@swosu.edu
Office: (580) 774-3727

LATEST TEXT BOOKS

Packaging Technology and Engineering: Pharmaceutical, Medical and Food Applications

Packaging uses and requirements have changed a lot in the past 150 or so years. A latest text book authored by DR. Monica Chuong, PH.D. entitled as "**Packaging Technology and Engineering: Pharmaceutical, Medical and Food Applications"** was published in 2020. This 544-page book is presented as four sections, eight chapters, plus Problems, Appendices, Glossary of Terms and Abbreviations.

DR. Monica Chuong, PH.D.
Professor of Pharmaceutical Science, Massachusetts College of Pharmacy and Health Science University

Section I Scientific and Technological Background to Materials.
Ch 1: Historical Perspective and Evolution
Ch 2: Chemical Engineering of Packaging Materials
Ch 3: Material Science and Chemistry
Ch 4: The Physics of Packaging Materials
Ch 5: Engineering of the Product: Design Formation and Machining.
Section II Application and Processing
Ch 6: Packaging for Various Applications
Ch 7: Food, Pharmaceutical and Medical Packaging
Section III Quality, Integrity and Traceability
Ch 8: Suppliers and Manufacturers of Packaging
Section IV Revision and Information
Problems: Questions, Calculations, Estimates and Dilemmas.

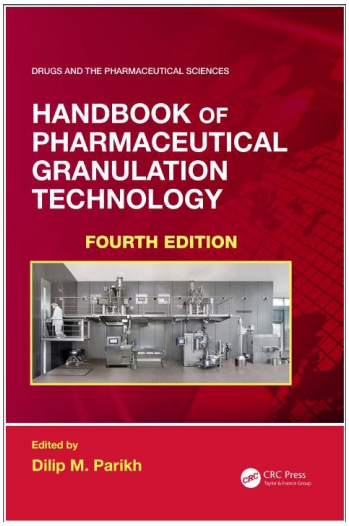
Author Bio: Monica Chuong, Professor of Pharmaceutical Sciences at the Massachusetts College of Pharmacy and Health Sciences (MCPHS) University, Boston, teaches Dosage Form I and II Labs, Pharmaceutics Lab I and II, Pharmaceutical Technology, Controlled Drug Delivery, Bioprocess Unit Operations, Introduction to Cosmetic and Personal Care Products, Unit Operations in Cosmetic and Food Sciences. She served as the Chair of American Association of Pharmaceutical Scientists (AAPS) Northeast Regional Discussion Group 2012, and will take the role as the Chair of AAPS Chemical and Biological Active Pharmaceutical Ingredient Manufacturing Technology Focus Group 2018. She is also a member of Society of Cosmetic Chemists.

LATEST TEXT BOOKS (Cont…)

Handbook of Pharmaceutical Granulation Technology

Edited by: Dilip M. Parikh
DPHARMA Group Inc., Ellicott City, MD USA

Dilip M. Parikh is a President and CEO of DPharma Group Inc. a Pharmaceutical Technology consulting organization. Previously, he was the Vice President with Synthon Pharmaceuticals Ltd., and Vice President and General Manager of Atlantic Pharmaceutical Services, Inc and was Manager of Process Technology with Niro Inc. His previous experience was with Sandoz (Canada), McNeil and Ortho Pharmaceutical in Canada and the US, and other pharmaceutical companies. Mr. Parikh has over 35 years of varied experience in the pharmaceutical industry ranging from product development, manufacturing, regulatory affairs, and operational management.



This fully revised edition of Handbook of Pharmaceutical Granulation Technology covers the rapid advances in the science of agglomeration, process control, process modelling, scale-up, emerging particle engineering technologies, along with current regulatory changes presented by some of the prominent scientist and subject matter experts around the globe. Learn from more than 50 global subject matter experts who share their years of experience in areas ranging from drug delivery and pharmaceutical technology to advances in nanotechnology. Every pharmaceutical scientist should own a copy of this fourth edition resource.

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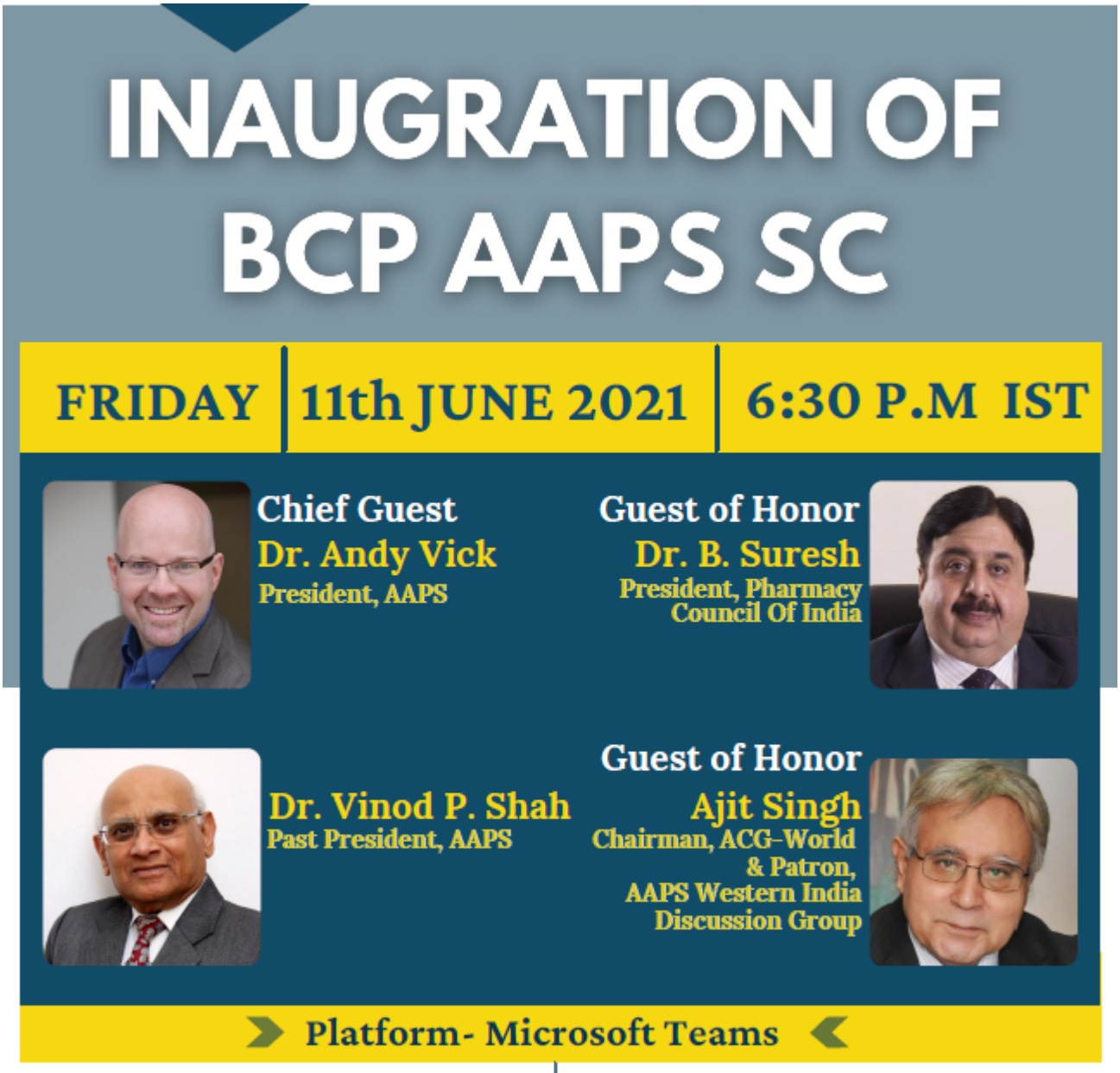
Dilip M. Parikh

AAPS STUDENT CHAPTER

AAPS STUDENT CHAPTER @ BOMBAY COLLEGE OF PHARMACY



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