

AAiPS

Newsletter

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AMERICAN ASSOCIATION
OF INDIAN PHARMACEUTICAL SCIENTISTS

P.O. Box 7244
Colonia, NJ 07067

INSIDE THIS ISSUE

- *President's Message*
- *First Regional AAiPS/ NJPHAST Joint Meeting: April 18, 2018*
- *Second Regional Meeting: May 10, 2018*
- *Upcoming Events July 19, 2018, & Sept 13, 2018*
- *Pharmaceutical News from India*
- *Classified Column*
- *AAiPS Research Awards*
- *Sponsors*

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Editorial Board: Charchil Vejani, Mike Yelvigi

PRESIDENT'S MESSAGE

Dear Members,

Greetings and Best Wishes for Mother's Day and Father's Day.

Hope you all are enjoying the spring/summer of 2018. The last few months have been very eventful. In keeping with our goals to grow and increase diversity within AAiPS we have undertaken a few initiatives.

Firstly, we have announced the six 2018 Student awards to be given at the AAiPS annual meeting for presenting their research work at AAPS Annual meeting.

Secondly, we have initiated re-introduction of Young Educator award to be given in 2019. Please read about the details in the newsletter and watch for announcements on our website.

We had our first two successful regional meetings, and finally I want to invite you all to attend our third regional meeting scheduled for July 19th, at Crown of India.

The executive committee is looking for additional volunteers to help in several of AAiPS committees. I urge you to please come forward. Please feel free to contact me by email at vijai25@gmail.com with your suggestions and ideas.

Regards

Vijai Kumar

President

QUOTES:

“The reasonable man adapts himself to the world; the unreasonable one persists in trying to adapt the world to himself. Therefore, all progress depends on the unreasonable man.”- **GB Shaw**.

“An important scientific innovation rarely makes its way by gradually winning over and converting its opponents. What does happen is that its opponents gradually die out, and that the growing generation is familiarized with the ideas from the beginning.” —

Max Planck

REGIONAL MEETING UPDATE

NEW JERSEY- APRIL 12, 2018

The first regional meeting was held jointly with NJPhast (New Jersey Pharmaceutical Technology Association) on April 12, 2018 at the Hanover Marriott Hotel in Whippany, NJ. More than 70 persons attended across the industry.

Dr Martin Warman, of Warman Consultancy Services spoke on **“Pharmaceutical Control Strategy – what does it mean and how do we apply”**. The abstract of his speech is attached herewith.

In pharmaceutical manufacturing there is often confusion over the term control strategy. The view from an automation engineering perspective is often totally different than the view from a product quality/release view point, and often documents meant primarily to help the end user have to include definitions of the terms (for example ICH Q8 (R2)). Even within a specific usage of the term there is multiple perspectives, which can lead to further confusion and the need for clarification.

The purpose of this presentation is to give an over view of the world of control strategy, try to illustrate where some of the opposing viewpoints come from but also to do a deeper dive into the most common implementations of pharmaceutical control strategy, using the FDA complexity pyramid to help explain not only what pharmaceutical Control Strategy means, but more so how it can be differently applied (both even batch and continuous manufacturing) and also, to try and take a look into the future and suggest how pharmaceutical control will be impacted/changed by activities such as advanced manufacturing/Industry4.0.

SECOND AAiPS REGIONAL MEETING ON MAY 10, 2018

Dr. Lakshmi Raghavan, MS PhD Founder & President of Solaris Pharam. Inc was keynote speaker.



Dr. Raghavan who is an expert in the drug delivery area with special emphasis on Semi-Solid dosage forms discussed various QbD approaches in Semi-Solid Development. More than 50 persons attended for this talk across the industry.



He emphasized key critical parameters and concepts to be considered during the development phase, for Topical generics to make them bioequivalent to Reference Drug with minimum development cycle time.



Mr. Vijai Kumar President, presented the guest speaker Dr. Raghavan a recognition plaque.

AAiPS Upcoming Events-2018

Please mark your calendars for the upcoming AAiPS events in the Tristate area!

AAiPS Regional Meeting in New Jersey

Date: July 19, 2018

Time: 5:30 PM

Venue: Crown of India Restaurant.

Address: 660 Plainsboro Rd,
Plainsboro Township, NJ 08536

Topic: Innovations in Product Equivalence

Testing: Linking API and Formulation to their Biological Effect with Bioassays.

Speaker: Dr. Sid Bhoopathy Ph.D.

Dr Bhoopathy received his Bachelors in Pharmacy from Kakatiya University in 1996 and a PhD in pharmaceutical sciences from Virginia Commonwealth University in 2001. He is the Chief Operating Officer of Absorption Systems and in this capacity, directs the convergence of the commercial, technical, and scientific aspects of the company to execute its strategic and tactical growth plans.

AAiPS -TiE (The Indus Enterprize)

Joint Symposium in New Jersey

Date: September 13, 2018

Time: 5:30 PM

Speakers: 3 Renowned TiE speakers

Topic; Patient Centric Health Care Approaches, Telemedicine, Use of Artificial Intelligence etc.

Venue: TBA

AAiPS Gala Annual Dinner Meeting in Conjunction with AAPS Annual Meeting- Washington DC.

Date: November 6, 2018

Venue: TBA

**Guest of Honor: Ms. Vinita D. Gupta
Chief Executive Officer (CEO) of Lupin Limited.**

Ms. Vinita Gupta, CEO



Vinita Gupta is the CEO of Lupin Limited (Lupin) and the Chairperson, Lupin Inc., (LI) and its US subsidiary, Lupin Pharmaceutical Inc. (LPI).

A graduate in pharmacy from the University of Mumbai and an MBA from the Kellogg School of Management at Northwestern University, Vinita has not only been responsible for setting up Lupin's business in the U.S and Europe but has also been instrumental in formulating and executing strategy that has helped the company emerge as a global pharmaceutical powerhouse; amongst the most exciting growth stories in the pharmaceutical industry.

Vinita along with her brother Nilesh (Managing Director, Lupin Limited) were named Ernst & Young (EY) Entrepreneur of The Year 2015 and won the Forbes India Leadership Awards 2016 – Entrepreneur of the Year. She was also the winner of the inaugural EY, U.S. 2012 Family Business Award of Excellence and EY Entrepreneur Of The Year® 2012 award winner for the Health Services and Technology for Maryland and is regarded as amongst the most influential Indian Business Women globally. She was named by Forbes Asia in its Top 50 Power Business women listings for Asia Pacific regularly. Vinita also entered the Hall of Fame – Most Powerful Women in Business 2016 – Business Today and was recently named Outstanding Business Woman Leader of the Year - 11th CNBC India Business Leader Awards.

Pharmaceutical News:**Generics Approved in 2017 Led to \$8.8B in****Savings**

US FDA says that generic drugs approved in 2017 led to \$8.8 billion in cost savings during the calendar year, and \$11.8 billion in savings through February 2018. The estimate is based on pharmacy acquisition costs and does not reflect rebates, discounts or off-invoice adjustments, amounts to less than one-third of a percent of total US prescription drug spending in 2017 according to a recent IQVIA report, which put the figure at \$324.4 billion after discounts and rebates.

The total cost savings was determined by subtracting the average price post-ANDA approval from the baseline average price, multiplied by the quantity sold for the remainder of the year for each product.

In 2017, FDA's Office of Generic Drugs (OGD) approved a record 1,027 abbreviated new drug applications (ANDAs), 843 of which were fully approved.

Source: www.raps.org/news-and-articles/

Mylan and Biocon have first Pegfilgrastim in US

Mylan has received approval from the US Food and Drug Administration (FDA) for the first biosimilar of Amgen's Neulasta (pegfilgrastim) in the US, with the Fulphila(pegfilgrastim-jmdb) 6mg/ 0.6 ml injectable biosimilar co-developed with Biocon. Expected to be the first biosimilar pegfilgrastim available in US", Fulphila is set to be launched "in the coming weeks", Mylan anticipates with a "suite of patient services" to further support patients and caregivers with treatment.

Source: [Generic Bulletin, June 2018](#)

Amneal wraps up merger with Impax, creating Top 5 generic drug maker.

Bridgewater-based Amneal Pharmaceuticals LLC and Impax Laboratories Inc. have completed their merger. The deal creates the fifth-largest generic drug maker in the country, the new Amneal Pharmaceuticals Inc. said shares of Impax ceased trading on May 4, 2018, while the new company's AMRX shares began trading from May 7, 2018. The transaction was an all-stock deal, with each share of Impax common stock converted into the right to receive one share of Amneal Class A common stock

Source: www.roi-nj.com

Apotex and Strides to merge their Australia businesses to become the country's largest generics player

Apotex, the largest generics drug maker in Canada, has agreed to merge its Australian business with that of India's Strides Shasun. The combined operations are expected to create the largest generic drug maker in that country. Terms of the deal were not disclosed, but according to a public filing by Strides, the two have agreed to a share swap in which the Indian company will hold majority control. Strides said it will be earning accretive from year one

Source: Fierce-Pharma

Lupin appoints Nicholas Hart as head of specialty biz in US

Lupin has appointed Nicholas Hart as President of its Specialty business in US. Hart will lead the specialty strategic business unit in the US and will be responsible for its business growth strategy and organization.

Source: www.business-standard.com

MannKind and Cipla Enter an Exclusive Marketing and Distribution Agreement for Afrezza® in India.

MannKind Corporation, a company focused on the development and commercialization of inhaled therapeutic products for patients with diseases such as diabetes and pulmonary arterial hypertension, today announced an exclusive marketing and distribution agreement for Afrezza® in India with Cipla Ltd., a global pharmaceutical company.

Source: globenewswire.com

Sun Pharma's 2019 revenues to fall short on U.S. generics price pressure as manufacturing issues persist

Sun Pharma said pricing pressure in its generics market targeting the U.S. will likely lead to lower 2019 revenues as India's largest drug manufacturer continues to have regulatory issues with some manufacturing plants. The company said in its fourth-quarter and full-year 2018 report that it expects full-year 2019 revenues won't meet analysts' expectations due to poor generic sales and rising competition in the U.S. market, which accounts for about 35% of its total revenues. Earlier this year, another FDA inspection at the facility located in Gujarat, India, resulted in a Form 483 with three observations.

Source: [Fierce Pharma](#)

INDIAN PHARMACEUTICAL ASSOCIATION (IPA) UPDATES

Newly elected IPA office bearers

Dr. T.V. Narayan....President

Hon. General Secretary: Suresh Khannai

Hon. Treasurer: Dr. Hemant Mondkar

Editor-Pharma Times....Dr. Alka Mune

Editor-IJPS.....Dr. Divakar Goli

AAiPS Research Awards: 2018

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 annual AAiPS banquet in DC.

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 2018 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 categories from the five listed below. See the format below for writing your abstract.

<p>Section: Title: Authors name: Affiliation: Purpose: Methods: Results:</p> <p>Conclusion: Contact details:</p>

Categories to submit abstracts:

1. **Drug Delivery/Pharmaceutical Technologies:** All topics related to formulation, physical pharmacy, bio therapeutics, biotechnology, biosimilar, 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, 14th 2018 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

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 PHS 932: Advanced Physical Pharmacy II
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One year (four issues): \$1000 full page, \$500 half a page, \$250 quarter page

One time (one issue): \$400 full page, \$200 half a page, \$100 quarter page.

Contact: Mukund Yelvigi, myelvigi@hotmail.com

No advertisements under a quarter page

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