AAiPS

Newsletter

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

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NJ 07970

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Newsletter Editor: Raghu Kasu
Editorial Board, Mike Yelvigi, Sampat Singhvi

PRESIDENT'S MESSAGE

Dear Members,

COVID 19 continues to impact us in ways that we had not anticipated at the beginning of this outbreak –with members likely to work from home and maintain social distancing through the end of the year.

The AAiPS executive committee stays connected through regular teleconferences and has decided that, in light of the current situation, AAiPS will not conduct any in-person events including regional and annual meetings through 2020.

In the last newsletter I had mentioned that in this new normal it is even more important to remain connected through groups like AAiPS. In addition to our AAiPS website and LinkedIn, we have recently started a WhatsApp group to facilitate communication with our membership.

Our goal for 2020 is to continue scientific exchange and strengthen our network and to that effect AAiPS and Indian Pharmaceutical Machine Manufacturers Association (IPMMA) have signed a joint three-year MoU to foster a stronger relationship between our two organizations. In addition, AAiPS is planning a virtual regional meeting in late August and details will be forthcoming. I hope that you will all be able to join us for this meeting.

In the meanwhile, please stay safe and healthy!

Sincerely,

Rupa Doshi, Ph.D.
President, AAiPS

QUOTE OF THE QUARTER

The value of a man should be seen in what he gives and not in what he is able to receive." – **Albert Einstein**

"Take up one idea. Make that one idea your life -- think of it, dream of it, live on that idea. Let the brain, muscles, nerves, every part of your body be full of that idea, and just leave every other idea alone. This is the way to success." -- **Swami Vivekananda**

Virtual Meeting Update:

AAiPS
American Association of Indian Pharmaceutical Scientists

Covid 19 Vaccines - Pharma Challenges, Technology, Players & Status.

Presenter: Vijai Kumar

AAiPS Web Meeting, August 27th, 7 PM EST.

Zoom Call details will be provided by Aug 20

Abstract

Never before has the entire pharmaceutical industry focused so quickly and collaboratively on one virus and one disease. As you know the return to normalcy hinges on vaccines — and, more specifically, pharma's ability to meet an extraordinary timeline. The industry is being asked to develop, test, scale-up, manufacture and distribute billions of vaccine doses — in a matter of months. This presentation will discuss the challenges, technology, players and current status to-date. Can pharma industry safely fast-track a process that can normally take a decade? For vaccines, and drugs in general, the road from research to commercialization is often mired with complications, setbacks and unknowns. Does the global industry have the manufacturing capacity to hit the billion dose mark?

About the speaker:

Vijai Kumar is a Senior Associate in the Compliance Practice at Lachman Consultants who assists clients with Quality Assurance and Regulatory compliance. He provides leadership and subject matter expertise, develops manufacturing strategies; resolves complex development, manufacturing and compliance issues. He has extensive experience in the development and manufacture of solid oral dosage forms, liquids, topicals, and small volume parenterals, including high-potency compounds. In addition, he has experience in biopharmaceuticals and biologics. He is the holder of nine patents and the author of a number of scientific peer-reviewed publications, author of a Chapter on Validation of Aseptic Processes in "Aseptic Pharmaceutical Manufacturing II" and on Dissolution in "Remington's The Science and Practice of Pharmacy"21st. & 22nd. edition.

Currently, President Operations, RK Pharma Inc, Pearl River, New York and he also serves as an active Adjunct Professor at Long Island University-

AAiPS and IPMMA Collaboration MOU.

AAiPS achieves a new milestone this year as it establishes a collaboration with the Indian Pharma Machinery Manufactures Association (**IPMMA**). Both associations have a common goal to promote science and technology.

An MOU was signed to foster sharing of information and promote growth and understanding between the two associations. The signing of this MOU will facilitate scientific exchange and provide opportunities for members of the associations to attend each other's annual and regional meetings in order to foster networking.

A link to access the IPMMA website will appear on the AAiPS website and likewise IPMMA will also provide a link to the AAiPS website on their platform.

We at AAiPS look forward to a long-term Association with IPMMA benefitting members of both organizations.

Pharmaceutical News:

Piramal sells 20% stake in pharma business to US-based Carlyle for Rs 3,700 crore

In one of the largest private equity deals in the Indian pharmaceutical sector, the US-based Carlyle has picked up a 20% stake in Piramal Enterprises subsidiary Piramal Pharma for US$490 million or nearly Rs 3,700 crore.

The transaction values Piramal's pharma business at an enterprise value (EV) of US$2,775 million, with an upside component of up to US$360 million depending on the company's FY21 performance. The final amount of equity investment will depend on the net debt, exchange rate and performance against the pre-agreed conditions at the time of closing of the deal, expected to close in 2020, said Ajay Piramal, Chairman Piramal Group.

https://www.fiercepharma.com/

Dr. Reddy's Laboratories Completes the Acquisition of Select Business Divisions of Wockhardt.

Dr. Reddy's Laboratories Ltd announces that it has completed the acquisition of select divisions of Wockhardt Limited's ("Wockhardt") branded generics business in India and a few other international territories of Nepal, Sri Lanka, Bhutan and Maldives.

The business comprises of a portfolio of 62 brands in multiple therapy areas such as Respiratory, Neurology, VMS, Dermatology, Gastroenterology, Pain and Vaccines, which would transfer to Dr. Reddy's along with related sales and marketing teams; and the manufacturing plant located in Baddi, Himachal Pradesh with all plant employees (together the 'Business Undertaking').

Dr. Reddy's signed a Business Transfer Agreement ('BTA') with Wockhardt, to acquire the above-referred business undertaking for an upfront consideration of Rs.1,850 Crores.

In view of the COVID-19 pandemic and the consequent government restrictions, there has been a reduction in the revenue from the sales of the products forming part of the Business Undertaking during March & April, 2020. Subsequently, through an amendment to the BTA, Dr. Reddy's and Wockhardt have agreed that the deal consideration shall now be upto Rs. 1,850 Crores, to be paid.

G V Prasad, Co-Chairman and Managing Director of Dr. Reddy's said, "This deal is in line with our strategic focus on India and has paved a path for accelerated growth and leadership in the domestic market. We believe that the acquired portfolio offers a good growth potential for us.

https://www.businesswire.com/

Former Indivior CEO pleads guilty in federal Suboxone probe a day after stepping down from post

Federal prosecutors have hounded opioid maker Indivior for years over its marketing of Suboxone Film as a safe painkiller despite addiction risks. After snaring more than $2 billion in settlement money from Indivior's former parent company, the feds now have a former Indivior CEO fessing up in the Former Indivior chief Shaun Thaxter pleaded guilty to scheming to secure Medicaid formulary coverage in Massachusetts for opioid Suboxone Film through misleading information about the drug's dangers to children, the U.S. Department of Justice said in a release.

Lupin shuts down Indian plant after 18 workers test positive for COVID-19.

India's pharmaceutical manufacturing industry is no stranger to the novel coronavirus after multiple waves of infections have temporarily shut down operations at a number of drugmakers' sites. Now, a Lupin site that produces generic asthma and diabetes meds to the U.S. is going into lockdown.

Lupin has shut down an Indian manufacturing plant in western Gujarat state after 18 workers tested positive for COVID-19, two government officials told Reuters.

The affected plant is one of 11 Lupin operates at its Ankleshwar site, which sprawls across 40 acres and employs 984 workers. All 18 workers who tested positive worked at a single plant, and new infections haven't yet been found at any of Lupin's other facilities, an official told Reuters.

Additional workers who came into contact with the infected employees are being tested for the coronavirus.

Lupin, the third largest pharma in the U.S. by total prescriptions, is the latest Indian manufacturer to go on lockdown due to a COVID-19 scare.

Lessons from China: Agency execs discuss impact of COVID-19 pandemic lockdown and its aftermath on pharma.

The COVID-19 pandemic placed China in the spotlight, not only because it had the first cases of the disease but because it had some of the earliest reopenings. It’s an unenviable position, but one that can give insight into the impact on the pharma industry across issues such as digital engagement, healthcare access and communications.

WPP Health's Claire Gillis, international CEO, and Yi Han, executive vice president of WG Market Access, have had front-row seats to COVID-19 in China. Gillis travels frequently to China for WPP, while Han splits his time between Shanghai and the U.S. Both worked throughout the pandemic with pharma clients and agency teams in China, and more recently have tackled reopening issues.

The two spoke to Fierce Pharma about what they’ve learned and how the pharma industry will permanently change—and in some ways already has—because of the COVID-19 pandemic.

Both agreed the most immediate and lasting impact is the shift to digital engagement across the industry, from pharma sales reps to healthcare appointments to patient communications.

“When the pandemic first broke, the pharma industry in China reacted very quickly. Companies transitioned to ‘digital’ operating models almost immediately. This undoubtedly helped in terms of problem solving as the pandemic evolved,” Gillis said.

Pharma field teams moved quickly to engage digitally with physicians. Data and technology were deployed more quickly and more creatively, for instance in the switch from B2B to B2B2C communication and service delivery models “virtually overnight,” she said. Often risk-averse pharma and healthcare companies suddenly became innovators and began to act and react more like established online platforms, similar to those in banking and e-commerce.

https://www.fiercepharma.com/

Roche Pharma India expands partnership with Cipla for key oncology medicines

Drug firm Roche Pharma India said it has expanded its partnership with domestic pharma major Cipla to further improve access to its key oncology medicines in India.

Roche Pharma India has signed a "distribution agreement with Cipla to expand the scope of the partnership to include, marketing and distribution of its trademark oncology drugs - trastuzumab (Herclon), bevacizumab (Avastin) and rituximab (Ristova) in India," the company said in a statement.

The two companies had previously entered into a similar agreement in February 2018 for promotion and distribution of tocilizumab (Actemra) and other products, it added.

"We have been working as a partner with Cipla for some of our products... We hope to extend the same support to patients in India through this new agreement.

https://economictimes.indiatimes.com/

Mylan and Pfizer roll out tricolor branding for their giant generics combo, Viatris

Mylan and Pfizer's Upjohn unit unveiled new branding for the to-be-combined company, dubbed Viatris, on Thursday with a tri-color scheme that plays off the Latin meaning of the new company's name.

The reveal comes as the companies await Federal Trade Commission approval for their merger—now expected in the second half of this year—and a week after Mylan's shareholders gave the deal their blessing.

Also part of the new image? A focus on shareholders, Viatris Chairman Robert Coury said after that vote.

The logo's three swatches in blue, yellow and purple are meant to represent three paths—the literal Latin meaning of the Viatris name. The colors stand for access, leadership and partnership, the companies said in a release, and surround a globe symbol designed to "illustrate the company's core purpose of empowering people worldwide to live healthier at every stage of life."

https://www.fiercepharma.com/

Glenmark to Commence New Phase 3 Clinical Trial on Combination of Two Anti-viral Drugs Favipiravir and Umifenovir in Hospitalized Patients of Moderate COVID-19 in India

Glenmark Pharmaceuticals, a global pharmaceutical company, announced a new randomized, open-label study to test the combined efficacy of two antiviral drugs Favipiravir and Umifenovir as a potential COVID-19 treatment strategy.

Favipiravir is an oral antiviral drug approved in Japan since 2014. It has a unique mechanism of action by which it inhibits viral replication: Umifenovir is another oral antiviral drug licensed for treatment and prophylaxis of influenza A and B infections in Russia and China. Umifenovir impedes the viral attachment to cells and acts as a viral entry inhibitor. Additionally it exhibits modulatory effects on the immune system and induces interferon-production. Hence combined use of Favipiravir and Umifenovir acting on different mechanisms offers a comprehensive antiviral cover on pre-entry and post-entry life-cycle of the SARS-CoV-2 virus. Both antivirals inhibited virus infection in vitro and have shown efficacy in COVID-19 clinical trials. The current Glenmark study will examine whether early administration of this combination, both acting by

different mechanisms, enhances antiviral efficacy on COVID-19 patients.

The new combination clinical trial will be called FAITH – (FA vipiravir plus Um I fenovir (efficacy & safety) T rial in Indian H ospital setting). 158 hospitalized patients of moderate COVID-19 infection will be enrolled in the combination study and randomized in two groups: one group receiving Favipiravir and Umifenovir (with standard supportive care); and one group receiving Favipiravir along with standard supportive care. Patients in the arm receiving the drug will receive Faviprivir 1800mg bid and Umifenovir 800 mg bid on Day 1. Thereafter patients would receive Faviprivir 800mg bid and Unifenovir 800mg bid for the remaining course of the treatment. Duration of treatment will be 14 days and patients will be discharged after clinical cure and two consecutive negative tests for COVID-19 based on RT-PCR.

https://www.prnewswire.com/in/news-releases/

FDA looks to resume domestic inspections.

Months after halting most inspections amid the coronavirus disease (COVID-19) pandemic, the US Food and Drug Administration (FDA) said it plans to resume on-site domestic inspections beginning the week of 20 July 2020.

As a safety measure, FDA will pre-announce all inspections, save for retail tobacco inspections, for the foreseeable future.

The announcement comes nearly two months after the agency said it will implement a phased approach to

raps.org/news-and-articles

AAiPS Students Awards Sponsors:

- Dr Bharat Oza and Mr. Vijai Kumar: In recognition and memory of Dr Heddi Bhargava (for sponsoring for 4 years, 2019-2022)
- Dr Bharat Oza: To honor Dr. Krip Borah (for sponsoring for 4 years, 2019-2022)
- **Sannova Analytical Inc:** In recognition and memory of Dr Hanumant Rao (for sponsoring for 4 years, 2020-2023) [Paid for Year 2020]
- Dr. Mahendra Dedhiya (LIU): (for sponsoring for 4 years, 2020-2023)

AAiPS Research Awards: 2020

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 results will be declared in the first week of October and the winners will be contacted via email.

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 2020 Annual meeting of the American Association of Pharmaceutical Scientists (AAPS). Abstract should have been accepted by AAPS to be considered for the AAiPS graduate awards.

➢ 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:
Authors 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, Toxicokinetic / Toxicology, Transporters.

4. Clinical Pharmacology, Transitional Research and Biomarkers: All topics related to clinical trials, pharmco economics, 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, 2020 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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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
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