

# AAiPS

## Newsletter

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July - Sept 2009

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**Newsletter Editor:** *Uday Doshi*

**Assisted by,** *Rashmi Pai-Thakur, Mike Yelvigi*



**AMERICAN ASSOCIATION  
OF INDIAN PHARMACEUTICAL SCIENTISTS**

P.O. Box 7244

Colonia, NJ 07067

## PRESIDENT'S MESSAGE

Dear Friends

I would like to express my profound gratitude to the entire membership for giving me the opportunity to serve our organization. AAiPS has a strong following and great roots. We will continue to work hard on expanding and retaining our valuable members and finding a way to maintain the interest of our life members.

We are proud to announce that we will continue to offer the award initiated in 2007 to a pharmaceutical faculty member from a recognized Indian Pharmacy education and research center.

NJPhAST and The Indus Entrepreneurs (TiE) has initiated dialogue with AAiPS Executive Committee in working together on issues of mutual interest especially in holding a joint regional meeting in 2010.

Our goal is to compile an accurate list of e-mail addresses of all our members for effective communication. Please provide us with your preferred e-mail contacts. In fact, this will be our first newsletter to be mailed electronically – *“Green. That’s how we’d like the world to be”*.

Our next Annual Meeting will be held during the AAPS Annual Meeting on Wednesday, November 11, 2009 at Los Angeles, CA. Please register early for this exciting program to avoid disappointment.

Finally, I would like to thank the hardworking and dedicated executive committee for their continued support. I encourage all members to take an active role in this organization by attending our networking regional and annual meeting events, recruiting new members, organizing local chapters and providing ideas on how to improve the organization. Please feel free to contact me with any suggestions you have to make AAiPS stronger and more formidable.

Vijai (vjkumar@att.net)

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Meet our Chairman  
Shri Thanedar  
at the September  
regional meeting in NJ!

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## REGIONAL MEETING UPDATES

For the regional meeting on Jun 11, 2009, Dr Steve Hammond, PhD- Director/Team Leader Process Analytical Support Group, Pfizer Global Manufacturing, Pfizer Inc, Morris Plains, NJ discussed 'Advanced Control Systems to Improve Efficiency of Pharmaceutical Manufacturing Processes'.

On July 8, 2009, AAiPS along with the New Jersey Technology Council and TiE NJ-Philadelphia program jointly had a meeting to discuss 'Entrepreneurial Opportunities in Life Sciences'.

The Indus Entrepreneurs (TiE) was founded in 1992 in Silicon Valley by a group of successful entrepreneurs, corporate executives, and senior professionals. There are currently 12,000 members in 45 chapters across 10 countries. TiE's mission is fostering entrepreneurship globally through mentoring, networking, and education. Dedicated to the virtuous cycle of wealth creation and giving back to the community, TiE focuses on generating and nurturing the next generation of entrepreneurs. TiE, the nation's largest not-for-profit organization for entrepreneurs, has launched a New Jersey-

Philadelphia chapter. TiE NJ – Philadelphia. The aim of the above event held was to facilitate introduction, conversation, and exchange of ideas between entrepreneurs and investors in the Life Sciences industry.

The panelists discussed the following:

- Vision for the future for the life sciences industry and its impact on the next generation of products and services
- Opportunities in life sciences for entrepreneurial ventures
- Points of intersection between life sciences and healthcare IT
- Insights into raising funds particularly in this environment

The panel discussion was moderated by Raman Kapur, Chairman, Global Pharmaceutical Services and included the following panelists: Geeta Vemuri, PhD, Partner at Quaker Bio Ventures, Samir Patel, M.D., President, CEO & Co-founder of Ophotech Corporation. Joseph Fischer who has served as Lifeblood Medical, Inc's Chairman of the Board, President & CEO, Sundeep Bhan, President/CEO and Co-founder of Medsite Inc.



*From left to right: Vijai Kumar, Suggy Chrai, Ramesh Raikar, Uday Doshi ,*

*Steve Hammond, Mike Yelvigi, Barry Fox*

## PLAN ON ATTENDING OUR NEXT REGIONAL MEETING

TOPIC: **Growing a Pharma Services Company, the Azopharma Story**

SPEAKER: **Shri Thanedar, PhD**  
**Chairman, Azopharma Contract Pharma Services**  
**Chairman, Chemir Analytical Services Inc.**

AGENDA:

**SOCIAL HOUR** 5:30 PM  
**SEMINAR** 6:30 PM  
**DINNER** 7:30 PM

PLACE:

**Cinnamon Indian Restaurant,**  
**2920 Rt. 10 West, Powder Mill Plaza,**  
**Morris Plains, NJ.07950 Tel: (973) 734-0040**

DATE: **Thursday, September 10<sup>th</sup> 2009**

REGISTRATION:

**Before September 4 - Special rates for those registering and paying online: at [register@aaips.org](mailto:register@aaips.org)**  
**Members - \$30 and Nonmembers - \$35**

**After September 4 on site: Members- \$40 and Nonmembers- \$45 Students: \$20**

For more information, call: Punit Marathe (609)-818-7516 ([punit\\_marathe@yahoo.com](mailto:punit_marathe@yahoo.com)) Or  
Uday Doshi (973)-385-2057 ([udaydoshi@aol.com](mailto:udaydoshi@aol.com))

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## FAMOUS QUOTES

New ideas pass through three periods: It can't be done.

It probably can be done, but it's not worth doing.

I knew it was a good idea all along !

*-Arthur C. Clarke*

## NEWS ON INDIAN PHARMA

### **Sanofi-Aventis expanding clinical research activities in India**

Sanofi-Aventis, has decided to expand its clinical research activities in India with the help of its Indian subsidiary - Aventis Pharma Ltd. According to Sanofi-Aventis' sustainability report for the year 2008, the number of clinical trials conducted in India alone will be multiplied by seven by the year 2012. Currently, it is conducting 42 trials in India involving nearly 4,700 patients which is 45 per cent of the patient population enrolled in Sanofi-Aventis' clinical trials in developing countries. With India offering 10-year tax concessions on revenue to local companies making Research & Development (R&D) investments, a substantial increase in R&D activities of both multinational and domestic biopharmaceutical companies is inevitable. Analysts are projecting that total Clinical Research spending in India will increase by more than 30% annually through 2010.

### **NCRM partnered with Astec Inc for expanding research in hematopoietic stem cells, NK cells**

The Chennai based Indo-Japanese joint venture institute, NCRM (Nichi-In Centre for Regenerative Medicine) has entered into an agreement with Astec Inc, Fukuoka, Japan, the Developers of High-end Stem cell Processing & Expansion Systems and Devices. Both companies would jointly conduct research in the expansion of Hematopoietic stem cells and natural killer (NK) cells to enhance the benefits of immunotherapy for cancer. Also they agreed to work together to develop and standardize Devices for Zero Gravity Cell Culture to study the effects of Age-related Damages in space (open area) for future application in managing Treatment.

### **Kemwell collaborates with BI of Germany, invests Rs 25 billion for biopharma plant in Bangalore, India**

Kemwell Pvt Ltd, a leading formulations contract manufacturing and development services company, is investing around Rs 200-25 billion to set up an advanced biopharmaceutical manufacturing plant. The funding is from the company's internal accruals

and through a private equity partner. The company has entered into a in a strategic collaboration with Boehringer Ingelheim (BI), Germany. The facility set up will be at Nelamangala in the outskirts of Bangalore and is expected to be commissioned in two years. Under the collaboration agreement, the Bangalore-based Kemwell will support Boehringer Ingelheim's early clinical supply services ranging from full-service process development, manufacture, formulation and fill & finish at the cGMP manufacturing facility. It will have access to the German major's cell line development with the BI HEX technology platform, followed by a preferred access to the large-scale commercial production of its facilities in Europe.

### **Piramal Healthcare invests Rs 100 cr to expand business, sets up facilities in Ahmedabad, Chennai**

Piramal Healthcare Ltd which is one of the major players in contract research and manufacturing services (CRAMS) in the country has set up a facility in the special economic zone (SEZ) in Ahmedabad for formulations and another facility at Ennore, Chennai, for API manufacturing in order to initiate the business. The expansion will help the company to increase its client services and to grab the clients even at an early stage, said N Santhanam, chief operating officer, Piramal Healthcare. The Ahmedabad facility has its area spread of around five acres premises with 35 staff and the Ennore facility has almost occupied three acres adjoining its existing API manufacturing plant with 85 people.

### **Cadila Pharma to launch new biotech subsidiary, CPL Biologics Pvt Ltd**

The Ahmedabad-based Cadila Pharmaceuticals is all set to launch its biologic subsidiary, CPL Biologics Pvt Ltd, to carry out biotech research and manufacturing operations and contract research and manufacturing services. CPL Biologics is launched as the part of a joint venture (JV) between Cadila Pharmaceuticals and the US-based leading vaccine research company, Novavax, Inc. The new company will initially carry out the research and development projects for Novavax according to the JV signed in March, 2009. Cadila is also planning

to set up a biotechnology R&D and manufacturing facility in its current manufacturing facility at Dholka, Ahmedabad with an investment of Rs 20 billion. The joint venture will develop and commercialize Novavax's seasonal influenza virus-like-particle (VLP)-based vaccine candidate and Cadila's therapeutic vaccine candidates against cancer as well as its adjuvants, biogeneric and biological diagnostic products for the India. Novavax will also contribute technology to the joint venture for the development of several other VLP vaccine candidates against diseases of public health concern in that region, such as hepatitis E and Dengue fever.

#### **US FDA to start operations in India from August, to have 12 officials by 2010**

The regional office of US Food and Drug Administration in India is all set to commence its operations. The US drug regulatory body will have a total 12 experts in India by the beginning of next year to inspect and monitor the FDA approved facilities in India and to work with the Indian drug regulator on various issues. At present, six staff including Bruce Ross, country director, US FDA, one senior technical expert for medicines, two senior technical experts each for foods and medical devices has taken charge in India while two officials will join the office within by next month. Out of this, three drug inspectors would be working in Mumbai whereas two inspectors for medicines division will be joining at New Delhi in next year, informed Bruce Ross. The imports of medicines from India to US growing at a higher pace and the US FDA is trying to understand the Indian ecosystem and to work with the Indian regulator for better monitoring and control system. At present, 10.6 per cent of the total Indian exports to US comprises of medicines even as the rest of nearly 90 per cent is related to food sector. The imports of medicines from India was US\$ 1.38 billion in the year 2007-08, but growing at 39 per cent in dollar terms, which is higher than imports from many other countries. Out of the 6300 active drug master filings (DMFs) with the US FDA, almost 25 per cent equal to around 1700 are from Indian companies, said Ross.

#### **Glenmark acquires 7 pharmaceutical brands in Poland**

Drug maker Glenmark Pharmaceuticals has signed agreements with Iceland-based Actavis to acquire seven pharmaceutical brands in Poland. The acquisition would provide Glenmark its first access to the growing pharmaceutical market in Central and East Europe. "The Polish market (Central and East Europe) has good potential for branded generic products and Glenmark will now have the necessary front end and the product range to access and develop in this exciting market," company's managing director and CEO Glenn Saldanha said. The acquisition of the product portfolio of seven established brands was done through Glenmark Pharmaceuticals' Czech subsidiary Medicamenta that signed agreements with Actavis and Biovena, an affiliate of Actavis. The pharmaceutical market in Poland in 2007 was about \$7 billion and showed a growth of about 8% over the previous year.

#### **Sanofi-Aventis buys Shantha for Rs 3,740 cr**

France's biggest drug maker Sanofi-Aventis on Monday agreed to buy Shantha Biotechnics in a deal between Sanofi its French owners Merieux Alliance values the unlisted Indian company at Rs 374 billion, or about eight times its projected sales of Rs 44 billion for this fiscal. Merieux Alliance bought a 60% stake in Shantha Biotech in 2006 and subsequently increased it to about 80%. KI Varaprasad Reddy, who owns a 13.4% stake and is the founder of the Hyderabad-based company, will continue as managing director. The deal involves Sanofi's vaccine arm Sanofi Pasteur acquiring ShanH — which owns nearly 79% stake in Shantha Biotech, from Merieux Alliance. Shantha Biotech employs over 700 people and markets a range of vaccines in India and global markets. It also provides contract research and manufacturing services and has a wholly-owned subsidiary in the US. "Shantha's portfolio of new vaccines will complement Sanofi Pasteur's current vaccines, positioning the company to accelerate its growth in strategically important emerging markets," Sanofi-Aventis CEO Christopher A Viehbacher said. The new products under development at Shantha include a rotavirus vaccine, conjugated typhoid vaccine, and

a vaccine against the human papillomavirus which causes nearly all cases of cervical cancer.

### **Delhi High Court dismisses Bayer's plea for patent linkage**

In a landmark judgment, the Delhi High Court dismissed Bayer Corporation's Writ Petition to sanction the patent linkage system in India through a court direction. Holding that unpatented (generic) drugs are not spurious drugs, Justice Ravindra Bhat held that this petition was an attempt to tweak public policy. Patent linkage is a system in which the Drug Controller refuses to grant or delay a marketing approval to a generic drug manufacturer to manufacture and sell a drug if the drug is already patented. Patent linkage is known to be against public health interests as it will delay the entry of cheap, generic medicines into the market and keep medicines out of reach of those who need them. Bayer Corporation had filed a Writ Petition before the Delhi High Court against Union of India, the Drug Controller General of India and Cipla Ltd. seeking an order that the DCGI should consider the patent status of its drug, sofenib tosylate, before granting a marketing approval to any generic pharmaceutical company and refuse marketing approval to any generic company.

## **AWARDS**

The following awards will be presented at our next Annual Meeting to be held at Los Angeles, CA. We would like to invite our membership to send nominations for the two awards described below. Please send the nomination package by September 10, 2009 to Dr. Vijay Naringrekar, c/o AAiPS P.O. Box 7244 Colonia, NJ 07067.

### **Distinguished Scientist Award**

Recipient shall be individuals who have made significant and pioneering contributions particularly in the field of pharmaceutical sciences and technology and to the pharmaceutical and healthcare industry in general. Recipients may also be individuals who have made pioneering contributions through academic and professional excellence in the pharmaceutical and healthcare

fields.

Nominator must be a member of AAiPS. Nominee does not need to be a member. The nomination package should include:

- Letter of justification for nomination (maximum of 2 pages)
- Outline of significant achievement in pharmaceutical sciences
- CV
- One letter of recommendation

The award is a recognition plaque and will be presented during AAiPS Annual Meeting.

### **Outstanding Achievement Award**

Individuals for this award should meet the requirements for Distinguished Scientist Award, listed above and in addition, this award is given to individuals who have shown outstanding contribution in both quality and consistency over an extended period (more than 10 years) in any of the health care areas. Ideally, this individual is a member of AAiPS or who believes and supports AAiPS and its goals. This award is given to only US based individuals of Indian origin.

Nominator must be a member of AAiPS. Nominee does not need to be a member. Information package for this nomination is similar to the one above, except an additional recommendation letter is required.

The award includes a recognition plaque and will be presented at AAiPS Annual Meeting.

## **CALL FOR NOMINATION OF OFFICE BEARERS FOR YEARS 2010-2011**

In accordance with the constitution (see italicized material below), the Nominating Committee are seeking nominations from AAiPS membership for the following posts for the two years term starting January 2010:

President  
Vice-President  
Secretary  
Treasurer  
Chairman – METRO DC Chapter

*A three (3) member Nomination Committee shall be appointed by the President in consultation with the Executive Committee for starting the election process at least five months before the forthcoming Annual Meeting of the General Membership. The President, the Vice President, the Treasurer and the Secretary shall be elected by the entire membership of the Association. The President and the Vice President will serve for a term of two years. The Treasurer and the Secretary shall serve for a period of four years. The Officers of the Association, i.e. the President, the Vice President, the Secretary and the Treasurer should be members of the association in good standing. The President shall be an individual of Indian origin.*

Please send your nomination or intention to run for the office in writing by September 10, 2009 to Dr. Suggy Chrai Chair, Nominating Committee at AAiPS P.O. Box 7244 Colonia, NJ. 07067

### GRADUATE STUDENTS SCHOLARSHIPS

AAiPS has been awarding graduate student scholarships for those presenting their research work at the American Association of Pharmaceutical Scientists (AAPS) annual meeting. In 2009 the annual meeting will be held from November 8-12, in Los Angeles, CA, USA.

There are FOUR Research awards for graduate students in Pharmaceutical Sciences. Three awards are given to the students of Indian heritage and one is open to all graduate students.

Interested graduate students are required to submit a two page summary of their research findings. The format should include Title, Author, Affiliation, Objective, Methodologies, Results and Discussion. Please include your Telephone number, Fax and email address with their submission. We will

shortly announce the details of where and to whom these should be mailed.

### ADVERTISEMENT RATES

The rates of advertisement for the AAiPS newsletter are as follows:

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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### AAIPS Office Bearers for 2008-2009

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Vice President: Dr. Mohan Kabadi

Secretary: Dr. Punit Marathe

Treasurer: Ramesh Raikar

Immediate Past President: Mukund "Mike" Yelvigi

Past President: Dr. Suggy Chrai

Members-at-large: Dr. Pramod Chemburkar, Dr. Sampat Singhvi, Chuck Bass

Metro DC Chapter Chair: Dr. Mehul Mehta

Newsletter Editor: Dr. Uday Doshi, Assisted by Rashmi Pai-Thakur, Mike Yelvigi