

# AAiPS

## Newsletter

Vol. 16 Issue 4

October-December 2006



### AMERICAN ASSOCIATION OF INDIAN PHARMACEUTICAL SCIENTISTS

P.O. Box 7244  
Colonia, NJ 07067

#### HIGHLIGHTS IN THIS ISSUE

- Annual Meeting in San Antonio-Nov 1
- AAPS Election Results
- Upcoming Companies
- India News

#### PRESIDENT'S MESSAGE

I am sure, those of you who are planning to attend the Annual AAPS Meeting in San Antonio, Texas from October 31 to November 2 this year, have reserved your evening on Wednesday, November 1 for the GRAND ANNUAL AAiPS CELEBRATION. We have planned a fun-filled evening with Indian cuisine, Indian dance and music in addition to keynote speakers from India and USA. My only request to you all is to register in advance (at [www.aaps.org](http://www.aaps.org)) so that we can make adequate arrangements. AAiPS has strong following and great roots. We should all be proud of our membership in AAiPS and the parent organization (AAPS). Year 2006 can be considered "The year of taking account of AAiPS - where it has been for the last two decades and where it needs to go and grow". With this in mind, we had three strategic initiatives this year viz. Vision committee, Awards strategy committee, and Finance strategy committee. These three committees have worked diligently and have made considerable progress. This includes draft vision statements along with a proposed action plan for implementation. The awards system has been revised to meet current and future needs. The finance strategy of the AAiPS has been undergoing a revision to establish a sound financial management system. The details of these strategic initiatives will be covered in the coming newsletters. I take this opportunity to thank the three Strategy committee Chairs Dr. Vinod Shah, Dr. Suggy Chrai and Dr. Sampat Singhvi for their dedicated contribution. Contributions from many of you working on these committees are highly appreciated.

In addition, Dr. Hemant Joshi who has taken the responsibility as Editor of the newsletter also has worked hard to streamline the newsletter format, which is being further refined. I appreciate his efforts. On a similar note the key business of any organization depends on the activities, which are managed by the Program Committee. The efforts of Dr. Pramod Chemburkar who is the Chair of the Program Committee assisted by our secretary Dr. Punit Marathe are highly noteworthy.

We should continue to work hard on all fronts- bringing in new members and renewing the annual members and finding a way to serve our life members. The AAiPS website has become more accessible and informative for the members. In 2004, we had established the DC Metro chapter under the leadership of Dr. Mehul Mehta. The organization started the efforts to expand our horizon in reaching out to other regions. Our goal will be to expand the activities in this area by creating more chapters in other regions as long as some minimum requirements are met. Please let us know if you are interested in such efforts. I am very grateful to both new and old sponsors for their support for making 2006 a great year. Finally, I would thank the members of the hardworking and dedicated executive and working committees for their continued support viz. Navnit Shah, Dilip Wadgaonkar, Ramesh Raikar, Bala Srinivas, Barry Fox, Chuck Bass, Vijai Kumar, Hoshang Unvala,

Chandra Sahajwala, and Suresh Mallikarjun. 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 either by email at [MYELVIGI@hotmail.com](mailto:MYELVIGI@hotmail.com) or by telephone at 908-766-3453 with your suggestions and ideas.

### FROM THE EDITOR'S DESK

Dear Readers, Business environment is all about competition. It does not matter who starts the game, but the winner is the one who finishes the game first. In the new business environment of Team Matrix, as rightfully quoted by Vincent Lombardi, only cohesive teams work. Teamwork is not just the sum of individual efforts. In teamwork, one plus one is not two, but has to be more than two. Teamwork is all about efficiency and how to improve productivity. Till recently, the teams consisted of people within the company. But, with the new era of outsourcing, the team members could be from different companies. Communication skills are now essential for every scientist in addition to their scientific knowledge. With the emergence of China, India and South American countries, the team members could be from different countries too. In such a situation, the knowledge of different cultures is also vital for the success of a project.

Regards,

Hemant N. Joshi

[hemantnjoshi@gmail.com](mailto:hemantnjoshi@gmail.com)

### QUOTE OF THE MONTH

"Individual commitment to a group effort - that is what makes a team work." "People who work together will win, whether it be against complex football defenses, or the problems of modern society." - Vincent Lombardi: Winning coach of Super bowls I and II

### REGIONAL MEETING UPDATE

*Contribution by Dr. Bala Srinivas*

#### JULY 27, 2006 REGIONAL MEETING

Dr. Owen Richards, President of Quantic Regulatory Services, made a presentation entitled 'To Be or Not to Be', 'That is the Question' in relation to consultancy-at Mogul Restaurant in Morris Town, NJ. The meeting was well attended. Dr. Richards provided a brief description of the structure of one or more of the following list of skill sets: Laboratory (Micro/Chemistry), Validation (Process/Methods), Processing, Cleaning, Packaging/Labeling, Warehousing/Distribution, Regulatory filings, Compliance (cGMP), Quality Assurance, Clinical Development, Clinical Studies (GCPs), Pharmacovigilance, Leadership and Project Management.

Consultants are assigned, based on their skill sets, to review client's operations in depth and provide appropriate advice and remedial recommendations to the client. This may include mentoring. Quantic consultants do not get involved manually in the operations of the client company. There is a 'fire-wall' between consultants providing advice and recommendations and those assigned to independent auditing of the clients operation to avoid collusion between the two functions.

In the last few years several pharmaceutical companies have come under 'Court Consent Decrees'. Also many companies are seeking expert assistance to avoid coming to that stage. This has provided immense consultancy opportunities to individuals and small and large consultancy companies.

The assignments include prospective quality systems analysis and development, remediation of specific technical issues, auditing of sites, products, processes, drafting policies and procedures.

Dr. Richards warned the aspiring consultants on unpredictability and immense commitment needed in the field of consultancy. In his opinion it cannot be compared to a steady job with a reputable company and is best suited for those with sufficient financial security. The commitment required from consultants may cause loss of flexibility in personal life, will require travel and having to work weeks and months away from family.

AAiPS thanks Dr. Owen Richards for his excellent presentation.

### AAPS ELECTION RESULTS

The first regional meeting of the AAiPS Metro DC Chapter was held on June 10, 2006 at Mirch Masala Restaurant in Kentlands. About 30 members attended the meeting. This was the third such event hosted by the local chapter in little over a year. Mr. Kumar Barve, Majority Leader, MD State Government was the invited speaker.

Mr. Barve delivered a captivating talk, laced with humor, on how he came about to be in politics, his experiences with campaigning and getting bills passed and what the future holds for Indian-Americans in politics. He is the first elected representative of Indian origin in the US state legislative body. He is also a member of several committees. Notable amongst them are the Health and Government committee and the Joint Technology Oversight Committee. He has also served as the first Chairman of the Science and Technology sub-committee.

He was awarded the Legislator of the Year Award by the Montgomery County Maryland Medical Society in 1995, 1996 and 2000, making him an unprecedented three time awardee. In addition to his accomplishments in politics, he is the founder and CEO of Environmental Management Services in Maryland. His achievements were a source of pride and inspiration to all of us at the meeting including several youth who were also in attendance. The chairman of the chapter, Dr. Mehul Mehta welcomed him and presented him with a plaque on behalf of the chapter.

## PARTICIPATE IN AAPS ELECTIONS

AAPS election results are out. Congratulations to the following people who won the elections: Deepa Deshpande (Vice Chair, Biotechnology), Bhaskar Jasti (Secretary/Treasurer, Biotechnology), Raman Venkataramanan (Vice Chair, PPDM), and Prabhu Nambiar (Vice Chair, Regulatory Sciences).

## RECOGNITIONS

*Compiled by – Hemant Joshi*

AAiPS congratulates the following:

**Dr. Kamal Midha – New FIP President** for the 2006-2010 term. Dr. Midha is at present an adjunct professor in the College of Pharmacy and Nutrition and College of Medicine at the University of Saskatchewan, Saskatoon, SK. Dr. Midha is a recipient of the AAiPS outstanding achievement award.

**Mr. Praful Sheth –New FIP Vice President** Mr. Praful Sheth has been elected as the Vice President of FIP. Mr. Sheth is the immediate Past President of Indian Pharmaceutical Association and is still very active in IPA activities.

**Dr. Vinod Shah- New FIP Fellow**

The Council of the International Pharmaceutical Federation (FIP) convened at the 66th FIP Congress in Salvador, Bahia, Brazil on Saturday, 26th August to elect Dr. Kamal K. Midha as the new President of FIP.

Additionally, Dr. Vinod Shah was nominated as FIP fellow. Dr. Shah was the past President of AAPS and a recipient of the AAiPS outstanding achievement award

**Dr. Ajaz Hussain Receives IPS medal**

During the FIP congress 2006 in Brazil, Dr. Ajaz Hussain of Novartis was awarded the IPS medal. IPS medal recognizes outstanding contribution to pharmaceutical sciences or pharmaceutical practice. It is awarded to a pharmacist who has made unique contribution to the global pharmaceutical industry. Ajaz is the Global Head of Biopharmaceutical Development at Sandoz.

## UPCOMING COMPANY

*Compiled by Rajiv Sheel*

**Novavax, Inc., Malvern, PA.**

Dr. Rahul Singhvi was appointed President and CEO of Novavax in August, 2005. He took over at a time when the company was on shaky footing. Novavax was a specialty pharmaceutical company focused on women's health with a 100-person sales force promoting its FDA-approved Estrasorb®, a transdermal estrogen replacement therapy.

Since taking over in 2005, Dr. Singhvi has redirected resources to the company's long neglected Biologics group, enabling the transformation of Novavax into a cutting edge, particulate vaccine biotech company. Its Avian and Seasonal Flu vaccine

development programs offer the hope of true, practical solutions to pandemic and epidemic influenza concerns. More information on Novavax, can be found at [www.novavax.com](http://www.novavax.com). Dr. Singhvi joined Novavax in April, 2004 as Vice President, Pharmaceutical Development and Manufacturing Operations and was appointed Senior Vice President and Chief Operating Officer in April, 2005. Prior to joining Novavax, Dr. Singhvi spent 10 years with Merck & Co, his final position as Director of Vaccine and Sterile Operations in the Merck Manufacturing Division. He received his Bachelor of Technology from IIT, Kanpur, his MS and Ph.D. in Chemical Engineering from MIT and his MBA from the Wharton School.

## CONFERENCES

### AAiPS supports CHI conference

AiPS has provided support to a conference organized by Cambridge Healthtech Institute. The title of the conference is – “Drug Development in India – Planning and managing drug discovery & development activities”. The conference is scheduled for November 16-17, 2006 at Boston Park Plaza, Boston, MA. Please note that AAiPS members get 20% discount on registration. For more information, please visit: <http://www.healthtech.com/2006/pci/index.asp>.

### CpH India (Chemical & Pharma Ingredient) will debut alongside 2006 IPC

CMPi's new harma ingredients show, CPH India, will debut in December alongside the prestigious annual Indian Pharmaceutical Congress (IPC) and Pharma Expo at Bombay's Exhibition Center. Revised dates for CPH India are December 1-3, 2006.

## INDIA NEWS

### Suven-Lilly Collaboration

Suven Life Sciences Limited announced that it has signed an agreement with Eli Lilly and Company to collaborate on the pre-clinical research in the therapeutic area of central nervous system disorders.

### Mylan Takes Over Matrix

Mylan has agreed to spend \$736 million to acquire a controlling stake in Matrix, an Indian manufacturer of APIs and solid oral dosage forms. Matrix is the second largest API manufacturer when it comes to either the number of DMF's under development or developed

### India Topping Contract Research Business

With 15 prominent CRO's in the country, India's CRO business values at about \$100 -120 million and is growing at 20-25% per year. The second and third place was held by Italy (\$60-70m) and Spain (\$25-33m), respectively.

### India to overhaul drug price policy

India is planning to change its pharmaceutical price policy by setting up ceiling prices for about 250 drugs and is revising the list of drugs which can be included on the existing cost-based price control system. Under the proposed ceiling price-based plan, the weighted average price of three to five leading brands, will act as the ceiling price for the maximum retail price. The pharmaceutical industry is expected to meet India's Chemicals and Fertilizers Minister to discuss some of the proposals. The government may also consider exempting anticancer and antiretroviral drugs from the 15% customs duties applicable to medicines.

### DSM and Lupin enter into alliance on cephalosporins

DSM Anti-infectives India and Lupin have entered into an agreement to supply and market cephalosporins. Lupin expects to supply the active pharmaceutical ingredient for a range of products to DSM under the alliance. Both companies expect to strengthen their positions in this segment through enhanced utilization of existing resources and improved market access.

### Ranbaxy launches Italian operation

Ranbaxy Laboratories has set up a wholly owned subsidiary, Ranbaxy Italia, in Milan and expects to use the "organic" growth route to develop its presence there. In the past, the company has used acquisitions to jump-start operations in markets such as France. It plans to introduce generic medicines in Italy by early next year. Ranbaxy has now consolidated

its presence in the top five European pharmaceutical markets and is also present in 21 of the 25 EU countries. The \$16.5 billion Italian pharmaceutical market is the fourth largest in Europe after Germany, the UK and France.

### **Indian Pharmaceutical Congress conference to be held in December 2006**

The 58th Indian Pharmaceutical Congress to be held in Mumbai in December 2006 is going to showcase strengths of Indian pharmaceutical industry in the areas of human, material and intellectual resources.

### **OBITURARY**

It is with deep regret we report the loss of four leading scientists and educators of Pharmacy in the US:

**Dr. Arthur Mlodozeneic-** Until his death, he served as Vice President and CSO of PharmQuest Corporation in Mountain View and CSO for Conformia Software, Inc. in Redwood City. He worked in companies such as Upjohn, Hoffman La Roche and Merck in various capacities. He was also professor of Pharmaceutics at the University of California.

**Dr. Joseph R. Robinson-** Dr. Robinson received his Ph.D. from the University of Wisconsin-Madison in 1966. He became a professor at the UW-Madison in 1966 and retired from there in July 2005. He received numerous other prestigious awards. He was a founder of AAPS.

**Dr. Milo Gibaldi-** Dr. Gibaldi received his Ph.D. from Columbia University. He can be considered one of the fathers of Pharmacokinetics. He was one of the youngest Chairman of the Department of Pharmaceutics at State University of NY at Buffalo. He was a great teacher and mentor. He was also the Dean of School of Pharmacy at University of Washington in Seattle, and a contributory editor for AAPS News Magazine.

**Dr. Joe Schwartz-** Professor of Pharmaceutics at Philadelphia College of Pharmacy and Science passed away in September 2006 after prolonged illness. Dr. Schwartz was an authority on solid dosage forms and had received many awards including the AAiPS fellow award.

### **RESEARCH CITATIONS FROM INDIAN SCIENTISTS**

Controlled release by permeability alteration of cationic ammonio methacrylate copolymers using ionic interactions. H. Ravishankar, P. Patil, A. Samel, H. U. Petereit and R. Lizio, *Drug Dev Ind Pharm.* 2006, Jul; 32(6):709-18.  
[hema.ravishankar@degussa.com](mailto:hema.ravishankar@degussa.com)

A multiparticulate drug delivery system was studied in which the drug release of a model drug theophylline could be modulated by interactions of ammonio methacrylate polymer and anions. The system consisted of a EUDRAGIT NE coated anionic core, layered with drug and further layered with EUDRAGIT RS. The effects of different anions like chloride, succinate, citrate, and acetate as well as the thickness of the polymer layers on the in vitro drug release were studied. It was seen that succinate and acetate anions had permeability enhancing effects and citrate and chloride anions had permeability retarding effects on the polymer.

A sensitive in vivo model for quantifying interstitial convective transport of injected macromolecules and nanoparticles, Reddy, S.T., Berk, D.A., Jain, R.K., and Swartz, M.A. Institute of Bioengineering, Ecole Polytechnique Federale de Lausanne, Lausanne, Switzerland. *J Appl Physiol.* 2006 Oct; 101(4):1162-9.

Effective interstitial transport of particles is necessary for injected drug/diagnostic agents to reach the intended target; however, quantitative methods to estimate such transport parameters are lacking. Fluorescently labeled macromolecules and particles are co-infused with a reference solute at constant infusion pressure intra-dermally into the mouse tail tip, and their relative convection coefficients are determined from spatial and temporal interstitial concentration profiles. To demonstrate sensitivity and usefulness of this model, the effects of size, shape, and charge on interstitial convection were compared. Data showed that size exclusion (within a specific size range) dominates molecular convection, while mechanical hindrance slows larger molecules and nanoparticles; proteins convect slower than linear molecules of equal molecular weight, and negative surface charges increase convection through matrix repulsion.

Economic impact of workplace productivity losses due to allergic rhinitis compared with select medical conditions in the United States from an employer perspective. Lamb C.E., Ratner, P.H, Johnson, C. E., Ambegaonkar, A.J., Joshi, A.V., Day, D., Sampson, N., and Eng B., *Curr Med Res Opin.* 2006 Jun;22(6):1203-10. PCA Occupational Medicine, Salem, VA, USA.

The Work Productivity Short Inventory was used to assess the impact of a predefined group of health conditions on workplace productivity for the previous 12 months. A total of 8267 US employees at 47 employer locations volunteered to

participate in health/wellness screenings. Both absenteeism and presenteeism (lost productivity while at work) were recorded. Allergic rhinitis was the most prevalent of the selected conditions; 55% of employees reported experiencing allergic rhinitis symptoms for an average of 52.5 days, were absent 3.6 days per year due to the condition, and were unproductive 2.3 h per workday when experiencing symptoms. The mean total productivity (absenteeism + presenteeism) losses per employee per year were 593 US dollars for allergic rhinitis, 518 US dollars for high stress, 277 US dollars for migraine, 273 US dollars for depression, 269 US dollars for arthritis/rheumatism, 248 US dollars for anxiety disorder, 181 US dollars for respiratory infections, 105 US dollars for hypertension, 95 US dollars for diabetes, 85 US dollars for asthma, and 40 US dollars for coronary heart disease.

### AAiPS OFFICE BEARERS FOR 2006 -2008

**President :** *Mukund "Mike" Yelvigi*

**Vice President :** *Dilip Wadgaonkar*

**Secretary :** *Punit Marathe*

**Treasurer :** *Ramesh Raikar*

**Immediate Past President :** *Suggy Chrai*

**Past President :** *Sampat Singhvi*

**Members-at-large :** *Barry Fox, Vijai Kumar and Vinod Shah*

**Metro DC Chapter Chair :** *Mehul Mehta*

Various committees chairs are :

**Programming :** *Pramod Chemburkar*

**Newsletter :** *Hemant Joshi – Editor*

**Scientific :** *Navnit Shah*

**Sponsorship :** *Bala Srinivas*

**Membership :** *Dilip Wadgaonkar*

**Vision Committee :**

Chair - *Vinod Shah,*

Members - *Krip Borah, Praful Sheth (FIP-India), Ajit Singh (AAC, India), Atul Mehta, Suggy Chrai, Ben Issac, Paul Likhari*

**Finance Strategic Committee :**

Chair - *Suggy Chrai,*

Members - *Bala Srinivas, Andy Honeycheck, Dilip Parikh, Ramesh Raikar.*

**Awards Strategic Committee :**

Chair - *Sam Singhvi,*

Members - *Nemi Jain, Dev Wadke, Yatindra Joshi, Vijai Kumar, etc.*

### ADVERTISEMENT RATES

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

**One year ads (four issues only)-**

**\$1000 full page per year, \$500 half a page per year., \$250 quarter page per year**

**One time ads (one issue only)-**

**\$400 full page per issue, \$200 half a page per issue., \$100 quarter page per issue**

**No ad under a quarter page**

**Contact for advertisements :**

**Mukund 'Mike' Yelvigi, [myelvigi@hotmail.com](mailto:myelvigi@hotmail.com)**

or Hemant N. Joshi, Editor, AAiPS Newsletter, [hemantnjoshi@gmail.com](mailto:hemantnjoshi@gmail.com)

### AAiPS SPONSORS

AAiPS thanks the following sponsors for their support of this organization.

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### PEOPLE ON THE MOVE

Dr. Neelima Phadnis has joined KOS Pharma in Florida. She was earlier employed at Schering Plough, Memphis, TN.

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