

# AAiPS

## Newsletter

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### AMERICAN ASSOCIATION OF INDIAN PHARMACEUTICAL SCIENTISTS

P.O. Box 7244  
Colonia, NJ 07067

#### HIGHLIGHTS IN THIS ISSUE

- AAiPS Annual Meeting, Nashville, TN
- AAiPS Regional Meeting-NJ
- Constitution Finalized
- Katrina-Help Needed

#### FROM THE PRESIDENT'S DESK

I would like to thank the membership of AAiPS for matching the previous record attendance at the last regional meeting on May 5, 2005. At this meeting Sunil Kumar was elected President, Chief Executive Officer, and a member of the Board of Directors of International Specialty Products Inc. gave an excellent talk on "TRENDS IN SCIENCE & ENGINEERING TALENT RESOURCES." America's needs for scientists and engineers are growing much faster than the supply from American Universities. At the same time, the willingness of foreign Ph.D. graduates to come to the United States has decreased because of better job opportunities becoming available particularly in China and India. The presentation will show the data behind these trends and the possible solutions to this looming crisis. The meeting was attended by 77 members/guests, matching our previous record for May 5, 2005 meeting. For the last three years we have been able to attract members/guests to our regional meeting and the attendance has been steadily increasing. Thanks to the efforts of our management committee members for their hard work and dedication.

AAiPS has a strong following and great roots. We should all be proud of our membership for their involvement in this and the parent organization (AAPS). In addition, to continuing our great tradition of regional meetings in New Jersey, we have now added Metro DC Chapter. Our goal is to expand the activities in this area by creating more chapters in other regions as long as some minimum requirements are met.

We should continue to work hard on both bringing in new members and renewing the annual members and finding a way to keep the interest of our life members. We are proud to announce that we now have over one over one thousand names in our mailing list. This is up from 350 only four years ago. Of 1000 names 800 have complete mailing address and more than 400 now have email address. Our goal is to complete the email addresses which will help in better and fast communication with the membership. I would further expand the website for open discussion on these subjects and other subjects such as the expectations of the membership and how we can accomplish them.

Our next Annual Meeting will be held during the AAPS Annual Meeting being held in Dinner meeting is on, Wednesday, on November 9, 2005 in Nashville, TN. The meeting will start with a reception followed by dinner and presentations by several speakers. We have planned a very exciting program for this evening. Besides providing a nice Indian meal, we will have several well-known scientists and executives in the audience. The Guest of Honor for the Annual meeting which will be attended by 250 for this year will be Dr. Himadri Sen, President - Pharma Research & Regulatory Affairs, Lupin Research Park, Pune, India. and our Chief Guest will be James W. McGinity, Ph.D. of College of Pharmacy, The University of Texas at Austin, Austin, Texas. At the meeting we will offer scholarships to four worthy students Pooja Chandna, Rutgers Univ.; Sandeep Dhareshwar, Univ. of Kansas; Mudit Kakar, Univ. of Utah; and Fancy Thomas, Texas Tech Univ. and recognize three Fellow scientists for their accomplishment in the field of pharmaceutical science.

Finally, I would thank the very hardworking and dedicated executive and working committees for their continued support. The executive committee is also looking for 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 [schrai@att.net](mailto:schrai@att.net) or telephone 609 462 6845 with your suggestions, ideas etc.

*Suggy Chrai, Ph.D, M.B.*

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#### HIGHLIGHTS OF AAiPS REGIONAL MEETING NJ, AUG 11, 2005

##### Trends in Science and Engineering Talent Resources

*Review by: Hemant N. Joshi*

On August 11, 2005, Moghul Restaurant hall was bustling with about 80 enthusiasts who came to listen to Mr. Sunil Kumar, CEO and President of ISP, Inc. Moghul Restaurant had to add an extra table to make seating arrangements for people standing in the back.

As a typical businessman, Mr. Kumar did not want to waste this grand opportunity to promote his product line. His presentation was divided into two parts – ISP's technical competencies and Trends in science & engineering resources.

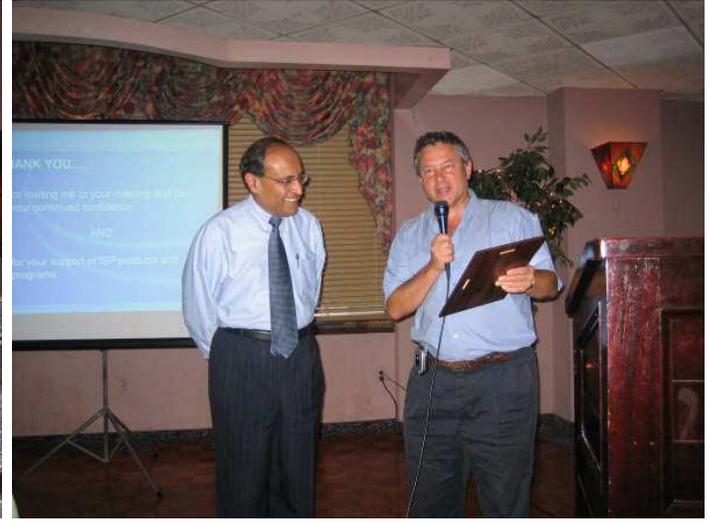
ISP is a major supplier for many solvents and pyrrolidone compounds. ISP provides pharmaceutical excipients and services, which are used in developing variety of formulations. ISP also provides personal care products and technologies.

Mr. Kumar transitioned to information on the high number of sales offices ISP has in many countries. Recently, ISP opened a sales office in Hyderabad, India. However, most of the manufacturing is conducted in the US

The major force behind the strong US economy is high level research and inventions in several areas such as transistors, fiber optics, lasers, medical technologies etc.



**Mr. Sunil Kumar, answering a question from the audience**



**Vice President Barry Fox thanks the Speaker Mr. Sunil Kumar, for an excellent presentation**

A US businessman also knows how to quickly convert an innovation into a marketable product. However, in the recent years, funding for research in physical sciences and engineering is flat except for the health sciences. If we consider inflation, the funding has actually decreased for many research areas. The ratio of federal funding for basic sciences to the GDP has decreased from 0.25% in 1970 to 0.16% in 2004. Mr. Kumar showed a direct correlation between the science enrollments and Federal funding. The most astonishing fact was the percent engineering degrees (% of total degrees) in China, Mexico, Japan and US were 40%, 27%, 20% and 5%, respectively. US, India and China produced approximately 60, 200 and 300 thousand graduates recently (source: NRC Science and Engineering Indicators, 2004). An article was published on 7/19/05 in Financial Times. It talked about the emergence of Asia as a global centre for science and technology. So far, the world looked at Asia as the area providing cheap labor. Due to shortage of highly skilled scientists at home, the US makes use of science and technology skills in Asia to increase their research productivity. More and more research centers are being opened in India and China.

When asked about the impact of this recent trend on the job market in the US, Mr. Kumar pointed that higher education is key to success. Audience had questions about the future of our kids. Mr. Kumar did not seem to be worried. American economy runs into trillions of dollars and should be able to weather the storm.

## INDIA NEWS

### *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 fertilisers 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-infective 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. With the government encouraging the use of generics to reduce healthcare costs, this segment is expected to grow rapidly. The

company also expects additional growth opportunities to stem from the expiry of some blockbuster drug patents by 2008-09.

#### PEOPLE ON THE MOVE...

*(If you know any changes in your career please contact us)*

Ajaz Hussain, Ph.D., has decided to leave the Office of Pharmaceutical Science (OPS) as its Deputy Director to join Sandoz as Vice President and Global Head for Biopharmaceutical Development. Many of you know Ajaz as the tireless champion of pharmaceutical product quality and a leader of numerous initiatives in FDA such as the "Pharmaceutical cGMP for the 21st Century - A Risk-Based Approach." He is also the architect of the CDER's Process Analytical Technologies efforts to establish a regulatory framework that will encourage the voluntary development and implementation of innovative approaches in pharmaceutical development, manufacturing, and quality assurance. Ajaz's breadth of scientific and regulatory knowledge will be irreplaceable as will his personal commitment to protecting the American Public. Please join me in wishing him the very best in his new career.

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

#### OBITUARY

We are sad to report that Dr. Sumer Dugar, formerly at G. D. Searle & Co, Chicago, IL and later at FDA (CDER) passed away on Oct 14, 2005 at Germantown, MD, after a prolonged illness. Condolences can be sent to 12231.Stonybolt Rd, Germantown, MD 20874

#### REVISIONS TO THE CONSTITUTION APPROVED

The draft of the revised constitution along with the summary of revisions/approval page titled "Revisions made to AAiPS Constitution – Revised March 2005". were sent to all life members and annual members of 2005 for their approval.

According to Article VIII, Amendment of the Constitution and the By-laws, Section 3:

*"Approval of two-thirds of the entire membership in good standing shall be required to amend the Constitution and the By-laws. No written response to a certified mail will be considered a positive response to the proposed amendments and changes. If more than one-third of the membership in good standing responds negatively in writing, then the proposed changes will not be adopted".*

According to the By-laws of the Constitution, Article I, Section 6:

*"Each annual member and life member who has been a member in good standing for at least six months shall be entitled to one vote. A new member shall be deemed to be a member in good standing from the date of payment of membership dues".*

I am pleased to announce that the revisions were approved with mast majority.

#### ANNUAL MEETING PRESENTATION ABSTRACTS

##### "Pharmaceutics at the Crossroads"

James W. McGinity, Ph.D.

The field of pharmaceutics has been broadened during the past decade to include several new disciplines. The major research focus of many academic institutions has changed from physical pharmacy, pharmaceutical technology and pharmacokinetics, to biotechnology and molecular biology. This changing paradigm in our Colleges of Pharmacy has attracted an increasing number of graduate students as faculty has become very competitive in obtaining grant support from the NIH. In the pharmaceutical industry, however, there remains a strong demand for well trained and educated Ph.D. scientists who have the skills and ability to characterize the physical and chemical properties of new chemical entities and then to design formulations for drug products that can then be manufactured on commercial scale high speed equipment. Through AAPS, academia is collaborating with colleagues in the industry and the FDA to address the future needs of the industry to ensure that future young scientists will have these necessary skills. These important issues will be the theme of my presentation this evening.

“DESTINATION INDIA”

Himadri Sen Ph.D.

India has moved up the value chain during the last 3 decades, since the process patent regime of 70's.

In the Generic space for regulated markets, API self dependence, followed by large number of DMF's and increasing number of Generic drug products submissions led by a few companies in the 90's, followed by increasing number of participants in the new millennium.

During this period, we have also seen a number of Drug Discovery candidates being licensed from a few companies since late 90's and some more companies are also well placed at this point of time.

In the Drug Delivery space, we have seen 2 major licensing deals, since late 90's to date, linked to milestone followed by royalty payment.

This is in view of the increasing R&D investments, committed since the last decade by large number of companies even up to 15% of sales. This investment although may appear meager as compared to MNC's in value terms, but is quite significant considering ADVANTAGE INDIA.

This advantage is being recognized more and more for its high skill and low cost in R&D including clinical, manufacturing and ancillary support services such as Excipients, Packaging components and Machinery. This is also evident from increasing number of strategic alliances in research and manufacturing.

In addition, the most important resource, our manpower need not be highlighted, as well spread across the globe.

Destination India is in the hands of Indians and what Indians make of it during its journey of shifting gear from Process to Product patent regime.

FROM THE EDITOR'S DESK

***Quote of the Month:***

**“Science without religion is lame, Religion without Science is blind”**

**Albert Einstein-The World as I see it.**

Dear Readers,

With Katrina and later with added fury of Rita hurricane- the news is overwhelming. While watching news at nights thoughts go in our minds as to what and how can we help those affected. My wife Meena is asking me “find out who is there in New Orlenes area especially any pharmacy students or faculty, and how are they doing? One person we know for sure is Dr. Burde Kamath, a pharmacy professor at Xavier University, but we have been unable to contact him. At AAiPS Executive committee meeting held on Sept 26 we discussed how AAiPS and its membership can help. One way our association can help is by individual members making some effort to help. We are asking through our readers; please spread the word, if any student or faculty member from the hurricane affected areas need help, then ask them to contact us (908-625-9512 or [MYELVIGI@HOTMAIL.Com](mailto:MYELVIGI@HOTMAIL.Com)). So that we can coordinate help efforts. And to all of you, if you would like provide shelter to some one, please contact us.

I am sure many of you will be at the Nashville AAPS and we look forward to seeing you there.

Regards

Mukund “Mike” Yelvigi

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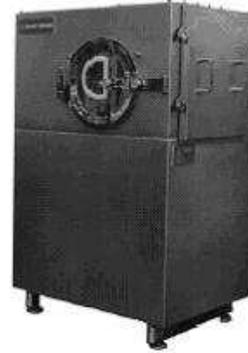
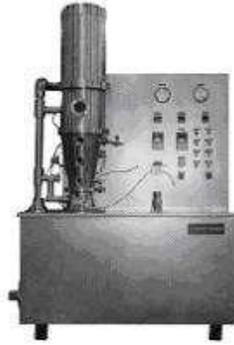
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