

AAiPS

Newsletter

Vol. 15 Issue 2

April- June 2005



AMERICAN ASSOCIATION OF INDIAN PHARMACEUTICAL SCIENTISTS

P.O. Box 7244
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HIGHLIGHTS IN THIS ISSUE

- TATA to enter Pharma R&D business
- President's, Message
- NJ Meeting – Aug 11, 2005
- AAiPS constitution revision
- Elections for Office Bearers

FROM THE PRESIDENT'S DESK

I would like to thank the membership of AAiPS for the record attendance at the last regional meeting on May 5, 2005. At this meeting Prof. Ravi Kane from Rensselaer Polytechnic Institute gave an excellent talk on "The Design of Nanoscale Therapeutics and Nanostructured Materials." The meeting was attended by 77 members/guests, surpassing our previous record of 76 for the June 26, 2003 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. On that day, in addition to the technical talk, we had a presentation by Dr. Thankam Mathew introducing her fifth book titled "Benefits of Herbs and Spices in Food".

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 and one full meeting at the AAPS annual meeting, my goal will be to expand one of our regional meeting.

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. My goal will be to bring a little more energy and structure to the membership committee and make the AAiPS website more accessible and informative for the members. In addition, to find, study and provide more benefits to the member of AAiPS. 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.

The organization started the efforts to expand our horizon in reaching out to other regions such as mid-west, west, south, etc. 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.

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 last meeting which was attended by 250 people was Honorable Kumar P. Barve, Majority Leader, Maryland House of Delegates and the Chief Guest was Veerappan S. Subramanian, Ph.D, President and CEO Kali Labs, Inc. Our Guest of Honor for this year will be Dr. Himadri Sen, President - Pharma Research & Regulatory Affairs, Lupin Research Park, Pune, India. We are in the process of selecting the Chief Guest. At the meeting we offer scholarships to worthy students and recognize 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 or telephone 609 462 6845 with your suggestions, ideas etc.

Suggy Chrai, Ph.D, M.B.

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HIGHLIGHTS OF AAiPS MAY NEW JERSEY REGIONAL MEETING

Our Second Regional Dinner Meeting of 2005 was held in Moghul Restaurant in Morristown, NJ on May 5, 2005

Prof. Ravi Kane from Rensselaer Polytechnic Institute gave an excellent talk on “The Design of Nanoscale Therapeutics and Nanostructured Materials.”

Nanotechnology is an up coming field with many applications in drug design as well as drug delivery systems. Interfacing nanoscale materials with bioactive molecules is important for the design of therapeutics, sensors, and functional composites. Dr. Kale’s talk described the efforts of his group to design potent nanoscale therapeutics and novel nanostructured materials.

His group is designing potent inhibitors of anthrax toxin. .Since the major symptoms and death from anthrax are due primarily to the action of anthrax toxin; the toxin is a prime target for therapeutic intervention. He also discussed characterization of polyvalent inhibitors and how they can neutralize anthrax toxin *in vivo*.

His group at RPI is also investigating the structure and function of biological molecules immobilized onto other types of nanoscale scaffolds, such as carbon nanotubes. , They have found that the nanoscale environment can also influence protein function. . Incorporating enzymes on carbon nanotubes has opened up opportunities for making novel biomaterials with applications ranging from biosensors to self-cleaning surfaces. Functionalization with biomolecules also provides a method for controlling the assembly of nonmaterial.

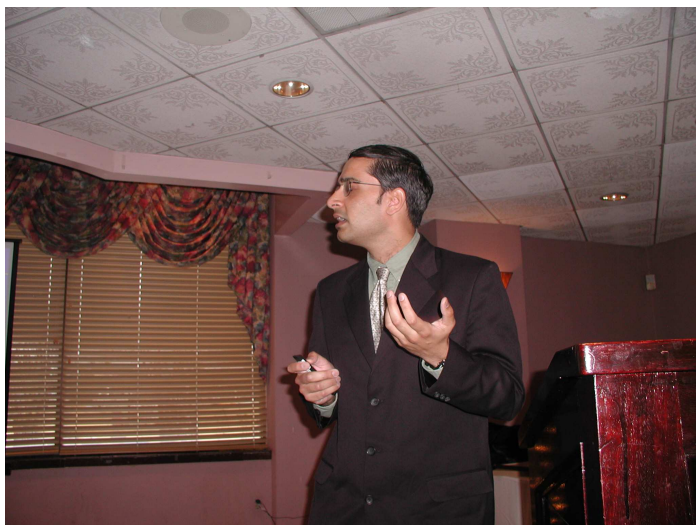
The Seminar was very well attended by representatives from the NY/ NJ /CN / PA area. The regional dinner meetings provide an excellent opportunity for members to get together in an in-formal session, and network with the local peers. The food served by Moghul was very well appreciated, and the meeting was a great success.



Dr Suggy Chrai, President AAiPS, Mr. Barry Fox Chair, Sponsorship Committee and Dr. Dilip Wadgaonkar, Chair Program Committee discussing the record attendance at the last regional meeting



Vice President Barry Fox thanks the Speaker Dr. Ravi Kane for an excellent presentation



Prof. Ravi Kane from Rensselaer Polytechnic making his presentation



Dr. Thankam Mathew introducing her fifth book titled "Benefits of Herbs and Spices in Food" to the AAiPS members at the regional meeting

AAPS-MANUFACTURING, ENGINEERING AND QUALITY (MEQ) FOCUS GROUP LAUNCHED

Call for Members

A new Focus Group (MEQ) has been created in AAPS. The scope of the MEQ Focus Group is to concentrate on the development of manufacturing, engineering, and quality assurance aspects of pharmaceutical operations. Activities will encompass, but are not limited, to the following topics:

- Manufacturing/packaging system designs
- Equipment system design
- Plant design and engineering requirements
- Manufacturing batch records
- Personnel training and maintenance of SOP systems
- cGMP compliance in the manufacturing/packaging areas
- Qualification and validation approaches and the changing scenarios with respect to quality by design, PAT, and quality system approach
- Quality assurance practices including change control systems, investigational reports, expiry date, specifications/product Recall practices/QA audit procedures and vendor certification programmers
- Technology transfers for API/drug products

- Supply chain issues/Inventory control and warehouse management

The MEQ focus group would be allied (aligned?) with the PT Section; however, members from other sections such as Biotec, RS, PDD, and PDDM, would also benefit by joining this group. The organizational goal is to provide a platform where AAPS members can learn, discuss, exchange ideas, and conduct seminars/workshops on the above areas.

If you have an interest in being a member of this focus group, please contact the following with your name, telephone number and email address.

Mukund "Mike" Yelvigi

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THIRD NJ REGIONAL MEETING TO BE HELD ON AUGUST 4TH, 2005

Abstract:

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."

Speaker:

Sunil Kumar

Sunil Kumar was elected President, Chief Executive Officer, and a member of the Board of Directors of International Specialty Products Inc. (ISP) on June 22, 1999. ISP (year 2004 sales of \$1.2B and net income of \$61MM) was a NYSE listed manufacturer of specialty chemicals until February 2003 when it was taken private. ISP chemicals are used in cosmetics, pharmaceuticals, food, and several industrial uses. Prior to coming to ISP, Mr. Kumar was President and Chief Executive Officer of GAF Materials Corporation (\$1.8B sales), which is the world's largest manufacturer of roofing products for residential and commercial buildings. A native of New Delhi, India, Mr. Kumar holds a Bachelor of Technology in Mechanical Engineering from the Indian Institute of Technology, Madras and an MBA from University of Louisiana. He is married and has three children.

INDIA NEWS

A program titled "Global GLP Workshop" will be offered in Bangalore, India during August 18-20, 2005. Details are provided at www.avitabio.com

Positions Available in India

For various positions in Indian Pharmaceutical companies, please contact Mr. Ramesh Patil at MRCIIN@YAHOO.COM

Tata and ex-Ranbaxians to form R&D company in India.

India's diversified Tata group and former executives of Ranbaxy Laboratories led by Dr Rashmi Barbhैया are to set up a new drug discovery and pharmaceutical development services company, Advinus Therapeutics.

Dr Barbhैया will take charge as CEO and managing director of Advinus, and both he and another senior ex-Ranbaxy hand, Sanjiv Kaul, who is currently with Chrys Capital, are expected to hold minority stakes in the new company. The facility, which will be headed by Dr Nuggehally Srinivas, formerly of Dr Reddy's Laboratories, will provide services for drug development. Its activities will include process and analytical chemistry, formulation development, metabolism, pharmacokinetics and clinical pharmacology and toxicology.

It is significant that the Tata group, which is reportedly expected to invest about Rs1 billion in the new venture, is making a comeback into the pharmaceutical business. Some years ago it had divested the group's pharmaceutical business, Merind, to Wockhardt, while Rallis disposed of its Pharma division to Shreya Life Sciences in 2001.

PEOPLE ON THE MOVE...

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

Dr. Vinod Shah after 30 years of dedicated service at the Food and Drug Administration has retired from the service.

Dr. Shah is an active founder member of AAiPS and is actively involved in AAPS activities.

AAiPS Constitution and Bylaws Being Revised

The Executive Committee (EC) is pleased to announce that the Constitution and the By-Laws of AAiPS have been modified to increase the span of the Association and facilitate the formation of Chapters. Several other minor changes have also been made. This is the second time the Constitution and the By-Laws have been changed since the inception of the Association. All members of the Association will get a separate mailing, with the new Constitution and changes identified, for ratification. The EC urges all members to please review and provide feedback on this important piece to the EC.

AAiPS Upcoming Annual Election of Office Bearers

The nomination process and the elections of office bearers for 2006 will take place this summer. A special note will go out in separate mailing soliciting names for nomination of various office bearers for the year 2006 and beyond. The open positions include: President, Vice-President, Secretary, and Treasurer.

FROM THE EDITOR'S DESK

Dear Readers: We look forward to enhancing the contents of this newsletter to bring you more informative new items. If you have any articles of general interest to our readers, please send them to me at MYELVIGI@HOTMAIL.com. Also if you have any questions to be answered, do not hesitate to send them. We will try to answer.

Have a nice and safe summer

Mukund Yelvigi

GUEST EDITORIAL

(The views presented in this column are solely that of the author(s) and not that of AAiPS and its executive committee)

Quality of pharmaceutical products is the responsibility of pharmaceutical industry and those who are involved in manufacturing and supplying the goods. We are developing products for human consumption and mainly for the people who are suffering from some disease. Patient should at least have one less headache to worry about quality of medicine he/she is consuming. The recent cases of recalls of pharmaceutical products are certainly not comforting. Management principles are in abundance and the one most applicable is the triangle of cost, time and quality. It is believed that one gets only best of 2 out of these 3. We try to balance out all three as a best solution. Quality in pharmaceutical product is a very complex phenomenon. A correct assay value, appropriate dissolution profile, desired content uniformity and satisfactory stability of the pharmaceutical dosage form do not mean best quality. It is the rate and extent of absorption from the dosage form which determines the bioavailability. Due to lack of in vitro – in vivo correlation ship for most of the products, high inter-subject and intra-subject variability's in the clinical data, and many a times, a lack of correlation between the plasma profile and the pharmacological effect, the quality of pharmaceutical product is hard to ascertain. Once we start looking into the clinical data in patients, we have to consider the pathophysiological changes taking place due to disease state and many drug-drug interactions. In spite of these complications, we must follow rules of quality set forth by FDA. That is a minimum requirement. The new PAT initiatives ask us to build quality in the pharmaceutical products. As a pharmaceutical scientist, it is our duty to develop and manufacture quality products. Recently a pharmaceutical company is being discussed at length for recall of all of its products and mind-boggling slack in quality. It takes many years to build reputation and it takes no time to ruin the reputation. We need to take this very seriously and must discuss the issue at length. AAiPS would welcome letters/opinions on this topic from the readers. We would like to receive suggestions to avoid this in the future. AAiPS as an organization of pharmaceutical scientist- highly recommend that all scientists practice highest standards of quality and ethics in whatever discipline they are involved - Hemant Joshi

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