

AAiPS

Newsletter

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AMERICAN ASSOCIATION
OF INDIAN PHARMACEUTICAL SCIENTISTS
P.O. Box 7244
Colonia, NJ 07067



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PRESIDENT'S MESSAGE

Dear Members,

While I take this opportunity to wish all our members, sponsors and well wishers a Very Happy and Prosperous New Year, I also would like to welcome our new president and the executive committee for 2008-2009. I am very proud that over the last 20 years our association has grown into a very well established nationally and internationally recognized body representing pharmaceutical scientist of Indian origin. As I said at our annual meeting in San Diego, this is all possible because of your sustained interest in the organization as well as the great patronage of our growing number of sponsors. The executive committee members who worked hard last two years with me deserve all the credit for what the organization is today, they are

Punit Marathe, Sam Singhvi, Ramesh Raikar, Suggy Chrai, Barry Fox, Pramod Chemburkar, Pankaj Paranjpe, Dilip Wadgonkar, and Vijai Kumar.

In terms of new and exciting things, a notable mention is our redesigned Website at aaips.org coordinated by Pankaj Paranjpe. Please visit the site to know more about the association, its activities, and renew your membership on line. In the years to come we have many challenges to face and our next Executive committee is looking forward to working with you all.

Regards
Mike Yelvig
President

QUOTE OF THE QUARTER

“If your experiment needs statistics, then you ought to have done a better experiment.”

- Ernest Rutherford (1871- 1937) English physicist. Nobel prize for chemistry 1908.

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ANNUAL MEETING NOVEMBER 14, 2007 UPDATE

Vijai Kumar

The American Association of Indian Pharmaceutical Scientists (AAiPS) held their annual meeting dinner at the Marriott Hotel and Marina in San Diego, CA on Nov 14, 2007. This event coincides with the AAPS Annual Meeting and Exposition every year. The honorable chief guest for the evening was the visionary founder, CEO and chairperson of the Board of Directors of the Institute of OneWorld Health based in San Francisco, CA, Dr. Victoria Hale. The grand San Diego ballroom was packed with over 300 guests including members, supporters, sponsors, guests and volunteers who enjoyed networking over drinks and delicious hors d'oeuvres during reception, inspiring talk by the chief guest, and Indian dinner.



AAiPS Team with Dr. Hale

given to a faculty member from a recognized Indian Pharmacy education and research center. This award offers a grant, funded by AAiPS, of US \$4000 that covers participation at the AAPS Annual Meeting, usually held in North America and also provides opportunity for the faculty member to visit the research centers of pharmaceutical companies and educational institutions. The selection of the winner for this award is facilitated by Indian Pharmaceutical Association. The winner for 2007 was Prof. Javed Ali of Jamia Hamdard University, New Delhi, India. Dr. Ali was selected from an impressive list of candidates who applied. AAiPS plans to continue offering this award every year.



Dr. Sampat Singhvi presenting plaque to Dr. Ali

AAiPS President, Mukund Yelvigi kicked off the meeting by making a presentation to give an overview of the organization and highlighting its accomplishments in 2007. Following the introduction, chief guest, Dr. Victoria Hale gave a very inspiring speech describing the work of her Institute in bringing critical medicines to the world's poorest population. Her talk was interspersed with personal anecdotes and stories which made it very interactive and interesting. The talk was followed by an Award Ceremony where several deserving scientists received awards for their varied contribution to pharmaceutical sciences.

This year, AAiPS introduced a new award, Distinguished Educator and Researcher Award,

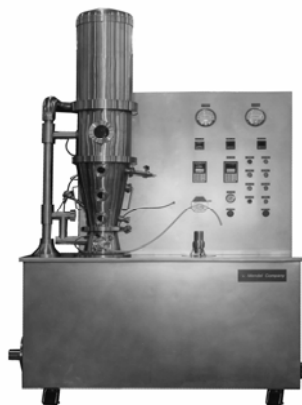


Mr. Yelvigi presenting plaque to Dr. Hale

Other awards given during this event included an Outstanding Achievement Award given to Dr. Anand Baichwal and three Distinguished Scientist Awards given to Dr. Robin Bogner, Dr. Sri Melethil, and Dr. Himadri Sen. Additionally, Graduate Student Scholarship of \$500 each was given to four deserving students from various schools in North America – Seema Betigiri and Rashmi Thakur of Rutgers University, Dabing Chen of University of Minnesota, and Jaspreet Vasir of University of Nebraska.



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PEOPLE ON THE MOVE

Dr. Jagdish Parasurampuria recently joined Palatin Technologies, Inc as VP of Product Development and Manufacturing. He can be reached at JParasurampuria@Palatin.com

Please send any “people on the move” announcements to Pankaj V Paranjpe at paranjpe@gmail.com for publication in the next newsletter.

PHARMA NEWS FROM INDIA

Compiled by Kinjal Gandhi and Anilkumar Gandhi (India)

Hepatoprotective Nimesulide developed by Lincoln Pharmaceutical

Nimesulide is a very potent anti-inflammatory and anti-pyretic which has captured 20 percent market

share in the NSAID segment in India. Almost all NSAIDs or pain killers due to their metabolic profile, have a complication on the liver. Nimesulide has some hepatotoxicity, which is identified by the medical profession. This is the reason for which it has been banned in several countries. Lincoln Pharmaceuticals (Ahmedabad, India) has launched hepatoprotective Nimesulide with the brand name of *Namsafe*. The novel formulation is a combination of Nimesulide with essential aminoacid methionine, the later reduces the toxicity of Nimesulide on the liver. The company has conducted four-multi centre clinical trial at various centers under the supervision of well known and renowned orthopedic surgeons and rheumatologists. One of the clinical trials has recently been conducted at Mumbai by well-known orthopedic surgeon Dr Prabhu. According to a press note from the company, the investigator has written in conclusion that the liver function test is normal with Namsafe. Other clinical trials have also shown

the same performance due to its innovative formulation. Namsafe is now awaiting patent rights.

ABLE: Indian biotech companies focusing more on export to Europe

Indian biotech companies are increasingly exploring the possibility of stepping up their business in the European countries, as per an assessment made by the Association of Biotechnology Led Enterprises (ABLE), the apex body of biotech companies in India. Companies such as Bharat Biotech, Shantha Biotechnics and Ocimum Biosolutions are the latest entrants into the European market. Bharat Biotech (Hyderabad, India) has entered into a licensing agreement with ThromboGenics (Belgium) to manufacture and commercialize THR-100, a novel of recombinant Staphylokinase, in developing countries. Ocimum Biosolutions has acquired the biotech division of MWG Biotech (Germany) and Oligo division Isogen Life Science (The Netherlands). The biotech export has registered a 47 per cent growth over the last fiscal year and it is expected to increase with the growth of bioservices, bioinformatics and biopharma. The association further stated that the Indian companies need to focus on research services, clinical trials, Bio-IT/data management, biogenerics and manufacturing, vaccines and molecular diagnostics, as these are the emerging areas in the Indian biotech sector. Indian companies are leveraging their strengths and must now focus on building critical mass in their core areas.

The Indian Pharmacopoeia 2007 published

The new edition of the Indian Pharmacopoeia entitled Indian Pharmacopoeia 2007 has been published. This is the fifth edition of the Indian Pharmacopoeia after Independence. The Indian Pharmacopoeia 2007 is presented in three volumes. Volume 1 contains the Notice, Preface, the structure of the IPC, Acknowledgements, Introduction, and the General Chapters. Volume 2 deals with the General Monographs on Drug Substances, Dosage Forms and Pharmaceutical Aids (A to M). Volume 3 contains Monographs on Drug Substances, Dosage Forms and Pharmaceutical Aids (N to Z) followed by Monographs on Vaccines and

Immunosera for Human use, Herbs and Herbal products, Blood and blood-related products, Biotechnology products and Veterinary products. The scope of the Pharmacopoeia has been extended to include products of biotechnology, indigenous herbs and herbal products, viral vaccines and additional antiretroviral drugs and formulations, inclusive of commonly used fixed-dose combinations. Standards for veterinary drugs and products that were published as a Supplement to the previous edition of the Indian Pharmacopoeia now form an integral part of this compendium. The Pharmacopoeial standards included in this publication adhere to the concept of harmonization with those used internationally, also keeping in view technological status for manufactures and analysis of different sectors of the industry, without compromising with the quality of the products. In addition to the past practices of requesting for comments, the contents of revised appendices and monographs have been publicized on the website of the Indian Pharmacopoeia Commission, for collecting comments from various institutions and organizations.

Argenta and Dr Reddy identify drug candidate for chronic respiratory diseases

Argenta Discovery, a respiratory drug discovery and development company, and Dr Reddy's Laboratories have announced a major milestone in their development program targeting a novel disease-modifying approach to treat the underlying cause of certain chronic respiratory diseases, including chronic obstructive pulmonary disease (COPD) and severe asthma. In a press release Argenta's Chief Executive Officer, Dr Christopher Ashton, said: "Just 18 months after signing the deal with Dr Reddy's, the team has already selected the first candidate drug to proceed into pre-clinical development". "We are very excited by the exceptional progress this program has made within such a short timeframe. With GMP material already manufactured we are on target to enter Phase I in mid-2008 and Phase II in 2009," he said. COPD is a leading cause of morbidity and mortality worldwide with an overall prevalence in adults over 40 years currently estimated at between 9 per cent and 10 per cent. Unlike many other major diseases, deaths due

to COPD are increasing and the World Health Organization (WHO) estimates by 2020 COPD will be the third leading cause of mortality and the fifth leading cause of morbidity in the world.

Some important patent news in brief:

Abacavir and Trizivir Patent Applications Withdrawn by GlaxoSmithKline

GlaxoSmithKline which was facing strong pre-grant opposition for its antiretroviral drugs Abacavir and Trizivir in India, from the Non-profit Government Organizations over the patentability yardstick under section 3(d) of the Patents Act, 1970, dropped the patent claims on the same.

Roche's Valganciclovir Patented in India

An Indian Patent No. 207232 was granted to Hoffman-La-Roche for antiviral drug Valganciclovir against the mail-box Application No. 959/MAS/1995 filed July 27, 1995 under section 5(2) of the Patents Act, 1970. Interestingly, the application claims its earliest priority dated July 28, 1994 (pre-1995) probably making Valganciclovir the first pre-1995 drug compound to be patented in India.

Suven receives patent on 'NCE'

Suven Life Sciences received Indian patent for New Chemical Entity (NCE) indigenously researched and developed. Patent was granted on substituted 3-aminoalkoxyindoles as 5-HT (Serotonin) receptors against the mail-box Application No. 883/MAS/2002 filed November 28, 2002. Suven has also made a corresponding US patent filing via PCT National Phase published.

Pharma patents increase in 2007

For Indian medicine companies engaged in basic pharmaceutical research, the year 2007 was a year of filing patent applications. Most of the filings came from companies engaged in chemical and biotechnology-based research of new medicine.

Source: *Express Pharma Pulse, Pharmabiz, The Economic Times, The Hindustan Times*

BOOK REVIEW

Pankaj V. Paranjpe

Science Business: The Promise, the Reality, and the Future of Biotech by Gary Pisano, Harvard Business School Press, November 2006

I would highly recommend this book to anyone who is interested in knowing more about how drug discovery and development works. Gary Pisano is currently Professor of Business Administration at Harvard Business School and has published extensively on product development and technology strategy among other areas. In Science Business, Pisano effectively dissects the biotechnology and pharmaceutical business and goes on to suggest multiple ways in which current productivity issues within the industry could be solved. Science Business was named the best biotech book in 2007 by Strategy+Business magazine.

CAREER CORNER: FROM BUFFALO TO BANGALORE

Karthik Ramani

*Associate Scientific Manager, Analytical and Formulations
Biocon Ltd, India*

Working in India- My Personal Experience

I was recently asked to pen my experiences working in India as there are many Indian pharmaceutical scientists in the US, eagerly waiting to know about individuals who have come back. While, I initially thought that it would be very easy to share my experiences, I did suffer from writer's block and was unable to weave my thoughts together. What would readers' expectations be? Would they be seeking serious feedback and information that would enable them to take a decision on their future prospects in India or would my account just serve as reading material for the subject of discussion amongst the Indian Diaspora over a cup of coffee or tea? Instead of putting together facts and statistics on the percentage growth of the Indian

pharmaceutical and biotechnology sectors and the business environment, I decided to write about the opportunities that were provided to me by the organization I joined and what I have been doing over the last two years. With the disclaimer that the outcome and experience could turn out to be different for each individual, depending on risk-taking capabilities, expectations and of course luck, here goes my story.

I returned to India in 2005, to take up a position at Biocon Limited, India's largest biotechnology company, immediately after graduating with a Ph.D. in Pharmaceutical Sciences from the University of Buffalo, State University of New York. I did have offers from a few companies in the US. Many of my friends (with the exception of few) and some of my family members thought I had gone crazy. Perhaps five years of lab work had somehow resulted in my brain getting rewired! Was I not moving away from a plethora of opportunities (and certainly, signing off on bonuses and salary in dollars!) in the land of dreams? How was this possible? Something was wrong somewhere.

It was indeed a huge decision on my part but I must confess that it came straight from the gut! (combination of some reasoning and lots of faith). Nevertheless, prior to my decision, I was keeping track of the biotechnology industry in India through various articles in newspaper and magazines. So, it was definitely not a decision that I took, immediately after waking up one fine morning. I decided to join Biocon, (after being interviewed by the then President and current Head, R&D during their visit to the US) even without visiting the campus! and I had "some idea" about the position I was about to take up (discussed over phone with my Manager). I am sure many of you are convinced that I am a lunatic to make career decisions like this and glad that you are not like me. Well...I should say that, among the few good decisions I have taken, the decision to return to India, probably ranks number one. It has indeed been a fabulous experience to be part of a wonderful organization and the rapidly developing Indian biotechnology industry. The learning curve has been steep, stimulating and immensely gratifying to say the least. The work environment is more or less like an

academic setting in a typical US university, although the objective and goals are different (true for industries in the US too).

Four months into my job, I was entrusted with two tasks; one was to scale up insulin formulations (soluble and suspension) in our new manufacturing facility (which had not yet been commissioned) in a time frame of three to four months and the second was to establish a formulation group capable of handling the development of protein injectables. Both the tasks were equally challenging in different ways.

The first task was quite nerve wrecking given the very aggressive time frame and my complete lack of experience in process development and large scale manufacturing of biologicals. Add to the above factors, the fact that the new facility did not even have a functional laboratory to carry out small scale trials. Quite a lot of time was spent mobilizing glass-ware to conduct experiments, finishing work, washing glass-ware in the evening and getting ready for the next day. While it was annoying at first, I soon started enjoying this routine and had great fun. With inputs from my managers and excellent contribution from one my colleague (who incidentally had also returned from US for her marriage and decided to stay back in India, yes we were a team of two crazy people!), the job was successfully executed in record time (sure, we did have several sleepless nights). This gave a lot of visibility and recognition in the organization in a very short span of time. This exercise also taught me few valuable lessons. One thing I realized is not to have preconceived ideas about one's job and not to be rigid in one's thinking. While it is important to have some expectations, one must be willing to learn and adapt quickly to meet requirements, even if the environment is not very conducive. Secondly, do not expect things to be given on a platter. This is especially important for people returning from US (apologies if I am offending anyone here, it is not my intention). This is based on my observations at the work place. There were few people (from the US) who joined along with me and were undoubtedly talented and brilliant. But they are no longer with the organization because of their unreasonable expectations and their unwillingness

to understand the system. The organization hiring you from the US definitely appreciates what you bring in terms of knowledge and valuable experience. However, every work place has its own set of systems and values and one needs to understand those fully before one can start thinking of suggesting and implementing changes. Try to establish your credibility and people will listen to you. While this might sound too obvious an advice, more often than not, people returning from abroad do not realize this and end up getting frustrated (and consequently frustrate people around!). My sincere request to anyone interested in returning to India is to be more pragmatic in expectations and give yourself sufficient time to settle down. Be fair to yourself. Now back to the story.

The second task was also equally challenging given that we had to start from scratch. While we had an outstanding mass spectrometry group for characterization, we did not have any other infrastructure for screening formulations. So the first few months were spent deciding on the kind of infrastructure needed to carrying out pre-formulation studies and equipments required. I had to prioritize the list of equipments (it is difficult to get the budget approved for procuring all the instruments needed at one go) that were to be purchased, wait for budget approval, contact local vendors (at least two) who were representing the parent companies more often than not, located in the US (and sometimes in Europe), get quotations and sometimes participate in negotiations This has been a terrific learning and humbling experience for me.

Another valuable lesson I learned (the hard way) during this process was to come to terms with the fact that very little technical support is available for many of the instruments (exceptions are always there) you purchase outside India and you will probably have to resolve problems faced by directly interacting with the manufacturer (present across different time zones). For those of us, who have taken equipment maintenance for granted, this will definitely be difficult and frustrating. But this can also be viewed as a learning experience wherein you get to know more about instrumentation aspects rather than just being an end user.

The second challenging aspect of establishing a group has been in getting the right people. Protein formulation is still a niche area in India (unlike the US). Given that our group handles projects on follow-on biologics and novel antibodies and is involved in conducting pre-formulation studies, formulation development, designing and conducting stability programs for pre-clinical and clinical phases, process development and large scale manufacturing of biologicals, it has been quite difficult finding candidates with the relevant background. Nonetheless, I have been quite lucky to find some talented people and currently, the group has six members (expected to expand further in the next few months).

I have tried to share some of my interesting experiences so far and hope that you will enjoy this article and become more adventurous in your career decisions. There is no dearth of exciting and challenging opportunities in India. Always be on the lookout for openings and be willing to experiment. And trust me, the fact that you get to work for a home-grown organization gives you enormous fulfillment (at least, definitely for me) at the end of the day. I sincerely hope to see many more of you in India, in the near future.

OUTSOURCING CLINICAL RESEARCH TO INDIA

Dr. Minal Mehta

Over the last 30 years, the biopharmaceutical industry has been successful in launching nearly 1,400 new chemical entities as human therapeutics. However, this has been at the cost of major investment of financial resources and time in the face of considerable risk of failure. Along with cost, time is a crucial factor for pharmaceutical companies involved in clinical research. Considering a fact that a patent lasts 20 years, starting from the instant the drug is discovered and approved, more than half the time is lapsed before the drug is finally marketed. With the increasing pressure on pharmaceutical and biotech companies to get their drugs successfully launched through clinical trials, and considering the expense involved,

it is not surprising that outsourcing to low cost economies like India has become a popular option.

India has penetrated the global multibillion dollar clinical research industry to emerge as an outsourcing hub scaling up to second destination of choice for outsourcing of clinical trials. According to a Confederation of Indian Industry (CII) study, clinical trials in India in 2002 generated \$70 million in revenues. It predicts that the revenues would grow anywhere between \$500 million and \$1 billion by 2010.

Multiple factors including demography, economy, infrastructure and government policies have ensured the gradual, sustained and progressive migration of the industry towards India. There are apparently 40 million asthmatic patients, about 34 million diabetics, 8-10 million people with HIV, 8 million epileptics, 3 million cancer patients, more than 2 million cardiac-related deaths, 1.5 million people with Alzheimer's disease; 15% of the population is hypertensive, and 1% suffers from schizophrenia. These typically coincide with therapeutic segments where global clinical research is focused, making India a potential patient pool. Pharma giants are also attracted to India due to the fact that the country offers nearly 700,000 specialty hospital beds, 221 medical colleges, over 600 ICH/GCP compliant sites and skilled English-speaking medical personnel. Availability of fundamentally trained manpower, facilitating contract research organizations and developing standards of infrastructure has also been the attracting features towards India. Simultaneously booming IT industry ensures relevant software accessibility and optimal data management required for swift conduct of the trials.

Quintiles Transnational, a leading global CRO with revenues touching \$2 billion, has completed 10 years in India in 2007. Quintiles India is growing at a rate of 25 percent over the global growth rate of 20 percent. In 10 years, it has emerged as the leading CRO in India. Inspired by the growth and success of Quintiles India, the other global CROs like PPD, ICON, PRA, Parexel, Kendle, PharmaNet, Omnicare, Chiltern, ClinTec and Covance too felt the urge to start their operations in

a country where economy is booming and has plenty of resources to do business in the CRO space. Most of these have set up only in last couple of years.

The Indian government is offering incentives to promote local pharmaceutical companies and attract foreign firms. For example, companies that conduct in-house R&D receive a tax exemption on all profits. India plans to create an independent drug regulatory authority similar to the US Food and Drug Administration to provide more rigorous and consistent drug regulation. Eventually, India hopes to establish a reciprocal agreement with the US so when one country approves a drug, the other will also approve it. In 2003, India removed several regulatory hurdles to performing clinical trials. Starting in January 2005, a change to Schedule Y of the Drugs and Cosmetics Act permits 'same phase' drug trials in India as in other countries and also permits phase 1 trials of foreign drugs. Till then, the law required that any foreign drug tested in India should be tested at a phase 'behind' what was already done elsewhere. Also in the same year India adopted more stringent patent processes resembling that in the US. Accordingly the amended Indian patent act in March 2005 covers not only process but also product patents which ensure assurance to international companies that data collected from their trials would not be utilized to make generic versions of the drug.

The incentives have coaxed more than one company to invest in India: GlaxoSmithKline conducted several trials in 2004, and Pfizer doubled its clinical research investment in India to roughly \$13 million, with plans to invest another \$30 million over the next five years. This may be a fraction of Pfizer's total global R&D of \$8 billion, but the interest indicates a growing optimism for this market. Likewise Johnson & Johnson and Eli Lilly are conducting eight studies in India. Sanofi-Aventis, Merck, Wyeth, Bristol-Myers Squibb and Roche also count among the list of companies conducting clinical research in India. Hence trials for standard drugs which would then have cost approximately over \$150 million are now projected to cost a whopping 60% less. The pace for drug trials in the country is so fast that the Clinical Data Interchange

Standards Consortium (CDISC), USA, a non-profit organization committed to the development of clinical research organizations' standards the world over, is looking at setting up its chapter in India. Additionally, The World Health Organization (WHO) expanded its clinical trial registry platform to include trial registers from India.

Though potential bureaucratic problems and ethical constraints due to curtailed regulations are some of the unresolved issues; India offers immense possibilities in advancing clinical trial research at a fraction of the cost.

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

One year (four issues only): \$1000 full page, \$500 half a page, \$250 quarter page

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Contact: Mukund Yelvigi, myelvigi@hotmail.com

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AAiPS WEBSITE

The newly redesigned website of AAiPS is now available at www.aaips.org. Please visit the website today and let us know your feedback. We will be continuously improving the website throughout the year. You can get in touch with Pankaj V. Paranjpe at paranjpe@gmail.com with your ideas on what else would you like to see on line and how to organize the information even better. Thank you.

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