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Dear EPPIC members,

Happy New Year! It has been a year since we launched this newsletter. We had extensively covered the 2010 conference and also some of sessions in our first issue. In this issue we will be highlighting some of the sessions that we had at the second half of last year. We would like to encourage you to contribute to the newsletter in the upcoming year. Looking forward to working with you.

Praveena Raman, Elan Pharmaceuticals and
Darshana Patel
e-Newsletter editors

Careers: EPPIC Article and Survey

**Advancing the careers of life science
professionals of Indian origin**

EPPIC is conducting a survey to gather data on the career path of Life Science professionals of Indian origin in the United States. Through this survey EPPIC leadership is studying the successes and challenges faced by Indian Life Science professionals in academia and industry. The data will help EPPIC and similar organizations around the country to develop programs to support their membership and help them achieve success and satisfaction.

To help the leadership in this effort please participate in the survey: http://www.surveymonkey.com/s/EPPIC_Survey

The results of this survey will be published in Nature Biotech as a follow up to the first article that was published to introduce the survey.

Advancing the careers of life science professionals of Indian origin

Jagath R Junutula, Praveena Raman, Darshana Patel, Holly Butler & Anula Jayasuriya

Nature Biotechnology 28, 757-758 (2010)

Indian-American life scientists can advance their careers by networking, receiving help from mentors and pursuing collaborations in academia, industry and the nonprofit sector.

The full text of the article is posted on the EPPIC website.

http://www.eppicglobal.org/nbt0710-757_EPPIC.pdf

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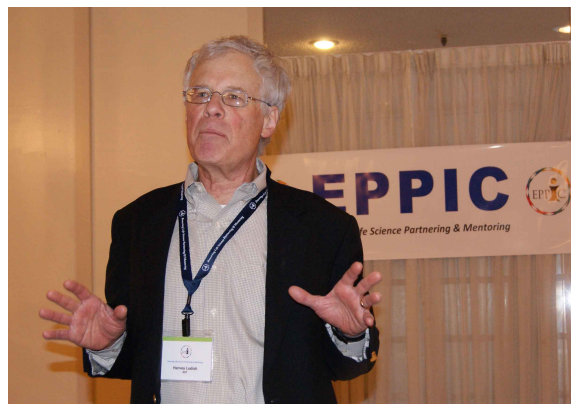
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The Biopharmaceutical Industry: A 50-years Journey by a Bioentrepreneur

by **Roopa Ramamoorthy and Naresh Sunakra**

The Biopharmaceutical Industry: A 50-years Journey by a Bioentrepreneur

sponsored by EPPIC on April 24th, 2010 at the Clarion hotel, San Francisco airport. The keynote speaker was Professor Harvey Lodish, professor of biology and of bioengineering at Massachusetts Institute of Technology and member of Whitehead Institute.



Prof Lodish gave us a glimpse into his career path. He started at Kenyon College in Ohio, and then went to Rockefeller University for his PhD. Here, he was room-mates with David Baltimore, a future Nobel Laureate. Professor Lodish then did postdoctoral work at MRC Cambridge with Francis Crick. He said his mother who did not really understand a research career, kept asking when he was going to Medical School. She only stopped when he received tenure at MIT. Dr. Lodish emphasized the importance of treating and managing people in the right way and that this can affect outcomes. He mentioned how he used to read his wife's textbooks on management psychology, while she was in business school. He feels that students should be encouraged to also explore other career options besides academic research, be it in industry, law or any other field. He was one of the early professors to recognize the importance of maternity leave for women grad students and postdocs. He said it was not only because he was a nice guy, but that enabled him to have very productive scientists in his lab. Early in his career a venture capitalist offered him \$5 Million to start a company. When he remained silent, they increased the offer to \$10 Million. This made Prof. Lodish realize his worth at that time. This led him and other professors at Harvard and MIT including Charles Cooney, ChoKyun Rha, Anthony Sinsky and George Whitesides to start a biotech consulting service. Later, he became a founding member of Genzyme along with these colleagues.

Dr. Jagath Reddy Junutula, president of EPPIC, shared the story of his long-term association with Professor Lodish, who had helped Dr. Junutula writing recommendation letters (in spite of not knowing Jagath personally, just based on his resume and publications). This helped Jagath establish himself as a scientist in the US and in a way, helped him become a good mentor himself. Dr. Shalabh Gupta and Pradeep Fernandes, the vice-presidents for the mentoring program introduced several members working behind the scenes to make this a success. They also welcomed input from the members to take this program in the right direction. There was an informal Q and A session at the end. This program also provided an opportunity for several old and new members of EPPIC to network.

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Compliance Oversight for offshore GMP Operations

By Ruchika Raval, President,
Global Biopharmaceutical Regulation

Compliance Oversight for offshore GMP Operations was held at Cabana Crown Plaza on Thursday June 3, 2010. The event started with a quick 15 min presentation from each speaker followed by a Q&A. The event lasted for two and half hours.

Mr. Ralph Napolitano started with how a firm could start off the procurement effort when the Contract Manufacture Organization (CMO) is overseas and how to use Quality Agreement to start a new relationship. Having Quality agreements specific for each site is important so that the sponsor is aware if the material or parts of it may be made at another site. The agreement should articulate in detail, the qualification of people on the project, the production areas that are within the scope the types of suppliers used, whether the sponsor wishes to know of change in suppliers. The agreement should also be a vehicle to align the quality system of the sponsor to that of the CMO.

So what would be the FDA commitments, whether the sponsor and CMO cosign the batch records or the CMO does that on their own or, whether the sponsor wants to know of deviations and scraped batches? When the CMO conducts the batch runs, there is no room to call some request out of scope of the agreement. This increases cost because the CMO can now cost out this additional request. Also add the details of the audits. How often and when will the sponsor be invited to the facility of the CMO in order to view the batch being made.

Dr. Maninder Hora emphasized the need for a detailed technical plan. Once the procurement is done and quality agreements are in place how does one actually transfer the production process to the CMO in a way that enables successful production runs at the CMO. He agreed that an agreement is a good to engage with the CMO. In addition Dr. Hora had Five "C" that the Sponsor should keep in mind for site selection, side by side planning and of the implementation which is the most important. He emphasized Capability, Capacity, Compliance, Cost and Customer Focus. He discussed each of these areas as it pertains to procuring a CMO in India and China. In his experience he found that the capability is in place and many firms have relocated US talent to India and China. The scientists there are extremely bright and are talented. The companies are eager to please and go the extra mile because they are eager to get and retain the business. India already makes 20% of the generics that are imported by US so there is a solid track record for small molecule. For Biologics Dr. Hora was guarded. While the scientific capability is still good, in his experience the equipment and execution capability was variable. The work culture in these regions is hierarchical and this does not allow for a frank discussion.

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Compliance Oversight for offshore GMP Operations

continued

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Stan Yakatan



Ms. Rochelle Young gave the FDA perspective. She informed the audience of the presence of FDA office in Mumbai and Delhi. Dr. Charles Ross is India Country Director FDA and Dr. Muralidhar Gavini is Assistant Director.

They both reside in India. The inspection resides at the Office of International Programs (OIP). She informed the audience that India is the fourth largest country to export Pharmaceuticals to US and so this country is one of the prime focus for FDA. She referenced the compliance tools that the agency uses. She was eager to inform the audience that one thing unique to foreign inspection is the up front preparation time and the total on site audit days. When a field inspector is in the US they are on site for up to 10 or 15 days to finish the inspection. On the other hand overseas whether it is UK, Germany, Israel or India and China she has a shorter time. Also the preparation time sometimes bleeds into the closing off of a previous audit.

She requested the audience to pass on to colleagues in India that anything that the company can do during walk-through that helps the inspector get an overview is very helpful. She informed the audience that the observations are in the same areas that she sees in the US. For example both places are struggling with areas such as inadequate batch records, process validation, data integrity, supply chain. She explained that some of the issues are cultural while others are derived from English as a second language. The specific example she gave was that 212CFR part 211 uses the phrase “the company shall”. This is not interpreted to be a mandate in India – the term “shall” seems to suggest to an Indian mind that it is an option and not a must. The cultural difference she found is that she is unable to interview and meet the operator and the people on the floor. Often the supervisors are present. She said she is more interested in meeting with the people that work on the floor and see if they know what is expected of them.



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Biotech and the Global Marketplace Opportunities in India

Biotech and the Global Marketplace Opportunities in India was jointly presented jointly by EPPIC, TiE, USIBC, BayBio and UC-Commercial Service on September 7, 2010 at the TiE conference room, Santa Clara.

India's biotechnology sector is estimated to be \$10 billion by 2015. The industry is expected to grow from present \$2.51 billion (FY 2008-2009) to \$5 billion by 2011. The Indian biotechnology sector, is one of the fastest growing knowledge-based sectors, and is expected to play a key role in shaping India's rapidly developing economy. Come learn about India's biotech market and latest trends, as well as, U.S. government resources that can help you find partners and tap into the biotech market in India.

Jeremy Leffler, COO of BayBio gave a Keynote Presentation followed by Ram K. Reddy, Founder, Chairman and CEO of Global Industry Analysts, Inc. Ram presented an elegant talk on "Emerging Trends in India's Life Sciences Sector - A Strategic Overview". Anurag P. Mairal, PhD, Associate Director, Stanford-India Biodesign; Executive Vice President, Orbees Medical gave a presentation on "Medical Devices in Asia: The New Frontier For Device Innovation and India's Role". Ms. Sathya Prabha, Commercial Specialist from U.S. Commercial Service office in Hyderabad, India briefed the services provided by US-Commercial service in India for pharma/biotech clients.

Power of Mentor-Mentee Relationship: Success Stories

By Darshana V. Nadkarni, Ph.D.

Executive Recruitment - Medical Device & BioTech

Jagath Reddy Junutula, Ph.D.

President, EPPIC GLOBAL & Senior Scientist, Genentech R&D.

The *Power of Mentor-Mentee Relationships: A Success Story* was jointly presented by EPPIC and IISc-AANA on September 25, 2010 at the TiE conference room in Santa Clara.

Mentoring is one of the key elements in breaking barriers and advancing careers as mentors can open doors, provide invaluable insights into cultural nuances, and provide feedback on presentation/communication effectiveness. Here we featured a 50 year success story of Prof. Appaji Rao on mentoring and building careers. Dr. Rao's 50 year long career in academia is centered around mentoring and helping guide his students in building successful careers, make right choices, and deal with many of life's dilemmas.

Dr. Appaji Rao shared his perspectives on mentoring and examples and lessons learned both as a mentee, when he was mentored and as a mentor when he helped groom his students into good students, successful

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Power of Mentor-Mentee Relationship: Success Stories

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professionals, and human beings with integrity. Dr. Rao was himself mentored by many people and he recognized and paid tribute to each one of them from his Chemistry teacher to his English teacher who wanted him to major in English literature to his parents who encouraged him to make a career in science. Dr. Rao then shared examples of his students who sought him out over the years for academic as well as personal challenges. Mentoring and coaching the students in science is the easy part, said Dr. Rao. It is the challenges posed by life, that are more complicated. He shared numerous examples of such challenges when his students came to him for guidance, including boy liking or not liking a girl to more serious issues. Dr. Rao stressed that chief qualities of a mentor are humility, patience, and most importantly being available to listen to mentee's issues.

Prof. Appaji Rao defined choice of his model mentor with following characteristics:

- Has a deep commitment to the welfare of students, colleagues
- Has a never give up attitude.
- Does not believe students are against him.
- Gives generously of his time and resources.
- Always supports his students even at risk to himself.
- Has confidence in himself and his usefulness.



A distinguished panel of experts then continued the dialog in the next round. Moderator, Yash Bhatnagar, Sr Manager, Applied Materials shared impressive statistics that in one study, employees who received mentoring were promoted five times more often than people who did not have mentors. The panel comprised of Dr. Ashok Kumar, Principal Scientist, ICOS Biologics; Dr. Usha Arunachalam, CEO, Applied Protein Sciences; Sunil Erraballi, President, India Rural Development Fund; Dr. Subba Rao Gunupudi, PhD, CEO, Dx-Sys, Inc.; Pradeep Fernandes, President, CellWorks; Dr. Ravi Kiron, PhD, Managing Director, Adjuvant Global Advisors; Dr. Surya Sankuratri, PhD, Director, Roche Pharmaceuticals. The panel continued the theme of what makes for a successful mentor-mentee relationships and panel members shared many of their personal stories. The forum was opened up to the audience for Q&A and led to an interactive dialog on the topic. During the break excellent snacks and tea were served and members got an opportunity for networking, renewing relationships, as well as building new relationships.

Baidya , an EPPIC Charter Member, made generous offer for EPPIC members/non-members to get 15% instant discount upon purchasing this book through EPPIC.

Please use "EPPIC" discount code to purchase this book at this link given below as EPPIC also gets additional 15% towards its funds. <http://www.ctuniv.org/affiliate.htm>

[Additional details about the book can be found at http://www.biopreneur.org](http://www.biopreneur.org)



Biopreneurs: The Molecular Millionaires is a robust, commercially-oriented readable book that should be read not only by specialists, but also by entrepreneurs who foresee Biotechnology as the business of tomorrow.

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