

## **Seminar on Drug Regulatory Affairs**

A seminar was conducted on Drug Regulatory Affairs on 4<sup>th</sup> December 2010, in Thorale Bajirao Peshwe Sabhagruh. Welcome and introduction was done by Dr. P. M. Kelkar, Director Dr. V. N. Bedekar Institute of mgmt. Studies, Thane. In his introduction he explained the importance of the course for Pharma industry.

Inaugural speech was given by Dr. Vijay Bedekar, Chairman VPM. In his speech he talked about the importance of the skill-oriented programs and how the course will be useful for the carrier of students.

Dr. Albinus D'Sa Deputy Country Director, USFDA India Office, (US Embassy), New Delhi, was the chief guest for the conference. He had specially come from New Delhi for the seminar. He briefed the delegates about the FDA regulations and appreciated the management for introducing such courses which is the requirement of the market.

Dr. Muralidhar Gavin, Senior Assistant Country Director, USFDA The American Centre (US Consulate General), Mumbai, was invited as Keynote speaker. He briefed in details about the requirements of US government regarding FDA regulations, how permissions are granted for export etc. Dr. S. R. Sharma, Jt. Commissioner FDA, Konkan Division, Regulatory Affairs compliance in India was the next speaker who enlightened the delegates about the FDA regulations.

After the Lunch break three more speakers gave their talks. Dr. Anant Prabhu, Pharma Consultant, spoke about the regulatory affairs requirements in manufacturing, MS Sangita Sardesai, Manager, Global Quality Audits, Sanofi-Aventis gave overview of Regulatory requirements for API and Formulations. While the third speaker Dr. Milind Joshi, President, Global Regulatory management, J. B. Chemicals and Pharmaceuticals Ltd. Mumbai presented his views on International Regulatory Harmonization.

The session was followed by Question Answers where there was a good interaction among the audience and the panelists. Dr, Siddhan, StrategicBusiness Advisor to Board Arch Pharmaceuticals proposed the vote of thanks. The seminar was very useful for the participants.



