

## **ISPE INDIA AFFILIATE – YPEP WORKSHOP WELCOMHOTEL VADODARA, 21<sup>st</sup> JANUARY 2012**

ISPE India Affiliate organised a one-day workshop on 21<sup>st</sup> January 2012 at WelcomHotel Vadodara, Gujarat. The Chief Guest for this workshop was Dr. Hemant Koshia, Commissioner, FDA, Gujarat. He complimented ISPE for organising such a very useful training programme in Vadodara for the first time in Gujarat. He also requested ISPE to conduct many more such programmes in other parts of the country including Gujarat. The special invitees for this workshop were Dr. A Ramakishan, Asst Drugs Controller, CDSCO, Ahmedabad and Dr. Bharat Patel, Joint Commissioner, FDA – Testing Lab, Vadodara.

The workshop started with an opening session by Mr. Gopal Nair, Vice-Chairman, ISPE India gave a brief on ISPE, its membership benefits, chapters and affiliates. Eminent Speakers like Mr. S.G. Belapure, President Zydus Cadila delivered information on ICH Q8. Mr. R R Tuljapurkar, Sr. Vice President – Quality, Zydus Cadila spoke on CAPA and Root Cause Analysis. Mr. Kapil Bhargava, Former Dy. Drugs Controller, CDSCO presented the topic ICH Q10. Dr. Dushyant Patel, President and CEO, Astral Pharmaceutical Industries spoke on Management Reviews. Mr. R.Raghunandan, Former Vice President -Quality (South Asia), GSK presented the topic ICH Q9 and Mr. Vijay Kshirsagar, Executive Vice President, Unichem Laboratories Ltd. gave an overview on Validation – New US FDA Guidelines. The Workshop was concluded with an hour long questions and answers session.

The Workshop witnessed 109 participants, a mix of Junior and Middle management professionals from API, Regulatory, Manufacturing unit and many other supporting units. Numerous requests were received by the participants to open a Chapter in Baroda and to conduct such training programmes in future as well.