

The PDA Israel Chapter held its annual meeting on 16th December, 2007 at the David Intercontinental Hotel, Tel Aviv. The annual meeting has become something of a tradition among chapter members with many waiting eagerly for this professional and social get-together with colleagues from throughout the country.

The meeting opened with Raphy Bar, Chapter President, welcoming guests and was followed by Karin Baer, Treasurer since founding of the Chapter providing her annual report.

Thereafter proceedings moved over to the professional side with the first presentation given by Dr Yafit Stark, VP and Chief Clinical Officer, Teva Pharmaceuticals, providing a Roadmap of drug Development: From the Chemical to the Clinical. Dr Stark talked about what is on the critical path to successful development of New Molecular Entities and concluded that innovation in study design is critical to the success of clinical development. Innovation could include randomization techniques, selection of outcomes, statistical analyses and, in general traditional trial designs will be less applicable such that companies that cannot innovate will stagnate. Because of the vast development costs, studies have to be speeded up and efficiency increased including new initiatives to translate animal data into early human testing and phase 0 micro-dosing studies. Dr Stark pointed out that the way forward is the use of biomarkers and surrogate markers. In conclusion she emphasized that new biomedical science is being used in the pharmaceutical industry and companies planning innovative development need to be at the forefront of these technologies.

The second speaker of the evening, Professor Yoseph Caraco, Head of the Clinical Pharmacology Unit at Hadassah University Hospital, Jerusalem addressed the hot topic of "How similar are Biosimilars." Discussing the science behind biosimilars, Professor Caraco presented some interesting facts and problems that have occurred with biosimilars. His thought-provoking presentation left the audience wondering if biosimilars are really generic products at all, and just how similar a biotechnology "generic" really can be. He also raised concerns with issues such as leachables and extractibles where no less work is required in developing a biosimilar than for

the original, innovator product, and presented one case study where the work was insufficient with resulting product failure causing immunogenicity in patients.

After a cocktail reception and visits to the vendor exhibits, Dr Ilan Cohn, from the firm of attorneys Reinhold Cohn and Partners, talked about Patents and the Pharmaceutical Industry: Business Significance and Strategies. The concept of extending patents and the actual period during which an innovator benefits from the patent after registration of product was discussed. Dr Cohn also addressed the matter of generic companies filing patents for their methods of synthesis of known chemical entities.

The professional portion of the evening was closed out by Karen Ginsbury, who provided an update on Hot Quality and Regulatory Topics from PDA's Regulatory and Quality Affairs Committee. Karen described to delegates how the RAQC operates, with the ballot system and which topics were recently balloted: ICH Q10 comments, Monoclonal antibodies – EMEA guidance, Comments on batch release certificate for Investigational Medicinal Products (IMPS) as well as Viral Safety comments to EMEA. This was an opportunity for the Israel Chapter Members to learn about International PDA processes and how as members, they can be active in commenting on guidance in the making through their professional organization. Delegates were invited to indicate their particular areas of interest and to volunteer to participate in task forces in the making.

The meeting ended with a dinner and over 300 participants closed out another successful and active year of the Israel Chapter.