doi: 10.4172/0975-0851.1000105

Joint Meeting

OMICS Group Conferences
Accelerating Scientific Discovery

2nd World Congress on Bioavailability & Bioequivalence: Pharmaceutical R & D Summit-2011

International Conference on Pharmaceutics & Novel Drug Delivery Systems

Compelling Reasons for Doing Bio Equivalence Studies in India

Mak Jawadekar

Director Research , Pfizer Inc, Connecticut, USA

- Emerging markets are no more an option, but a strategic imperative for global clinical research
- India is one of the fastest growing clinical research destination with a growth rate 2-1/2 times the overall market growth.
- As the world's third largest producer of drugs by volume, with drug research and development work force, india is a major player in the pharmaceutical industry.
- India has over 100 fda approved manufacturing units. India has filed the maximum number of andas in the us almost equivalent or more than the number of andas filed by us companies.
- Indias clinical research landscape is undergoing a glorious metamorphosis, aided by uniquely differentiating capabilities, a rapidly transforming health care market and an enabling environment i.e rapidly adopting itself to global standards.
- India's strength in formulation development, new drug delivery system and backed by excellent chemistry and bio analytical technics has brought down cost of bio equivalence studies dramatically and without compromising international standards
- India is rated as one of the most attractive destinations for clinical trials and bio equivalence studies by various surveys.
- India's capability in bio equivalence has evolved with exceptionally good knowledge, highly trained and skilled technical man power in bio analytical services including method development validation and sample processing with strict adherence to cfr part xi.
- Huge volunteer data base, experience & knowledgable ethics committee, new schedule y of the regulators enables compliance with global regulations.
- I had an opportunity to audit one of the leading ba/be centres in india namely, quest life sciences pvt.ltd
- This centre is audited and approved by usfda having 100 beds clinical facility and a good bio analytical laboratory, has filed over 30 andas in the us.
- They have a volunteer data base over 3000 subjects and in addition over 800 post menopausal women subjects.
- The company has even conducted bio equivalence studies on cancer patients.
- These studies have been filed in the us besides european regulatory requirements.
- They have faced innumerable audits from international clients, mainly from the us and europe.
- I was surprised to find that the cost of the ba/be studies in india is less than half of the study conducted in the us besides study schedules is one of the fastest as compared to many other centres outside india.
- Quest has made a couple of para iv filings.
- A slide show of one of the facilities is available on request.