BioSpect
the business of Bi
24 years of leveraging the business of Bio
www.biospectrumindia.co

Top 20: Drug development facilitator

12 August 2014 | Features | By BioSpectrum Bureau

Top 20: Drug development facilitator



top-20-logoHaving initiated its operations in 2005, Fortis Clinical Research Ltd (FCRL) is a leading full service Indian CRO providing clinical research services to pharmaceutical, biotechnology and device companies across the globe. The company's comprehensive drug development services deliver expert quality and cost effective solutions for end to end management of clinical trials. Its huge infrastructural capacity consists of a state-of-the-art facility spread over 19,000 sq. ft., and four floors of the Sunflag Hospital and Research Centre in Faridabad (in the National Capital Region).

Within a short duration, FCRL has been able to garner major projects. Despite a slow market, the company was able to retain its growth, though marginal. During the FY 2013-14, the company recorded a revenue of Rs 350 crore as compared to Rs 344.40 crore in the FY 2012-13.

FCRL has 90 full time professionals with expertise in medicine, pharmacology, pharmacy, pharmaceutics, bioanalytics, nutrition, and statistics. Fortis has crossed more than 300 BA/BE studies since its inception in 2005 till date. The infrastructure consists of a 78-bed ward, two-bed ICU, phlebotomy stations, pharmacy, bioanalytical labs with LCMS and HPLC machines.

The company boasts of a rich bank of healthy volunteers drawn from the local community in Faridabad and NCR, and is currently conducting bioequivalence studies with generic products and clinical studies (phase 1 to IV) using healthy volunteers and patients at investigator sites as its main service offering. It has also conducted a number of BE studies in young, healthy female volunteers and post-menopausal female volunteers.

Its central laboratory was India's first to get ISO 15189:2007 NABL and CAP accreditation. Fortis has an experience of over 550 clinical trials in over 35 therapeutic segments. It has a 24-hour dedicated sample archiving facility, dedicated clinical research service department and real time web-based online reporting systems. The company claims to extend its services to about eight million patients annually. The FCRL team excels in end-to-end management across all clinical and pharmacovigilance studies.

The company has been approved and audited by regulatory agencies across the globe. These include the approval to conduct BA/BE studies by the DCGI (India). Audits were also done by AFSSAPS (France) in February 2008, ANVISA (Brazil) in March 2006, August 2007 and August 2009. The USFDA has also successfully audited the company in July 2010. Successful inspection of a Bioequivalence study and Quality Management System of FCRL by AGES PharmMed.