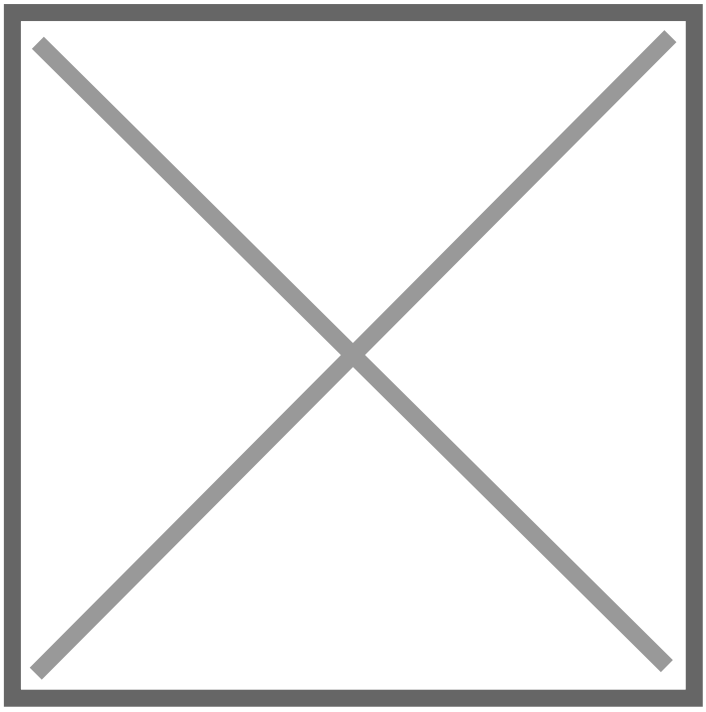
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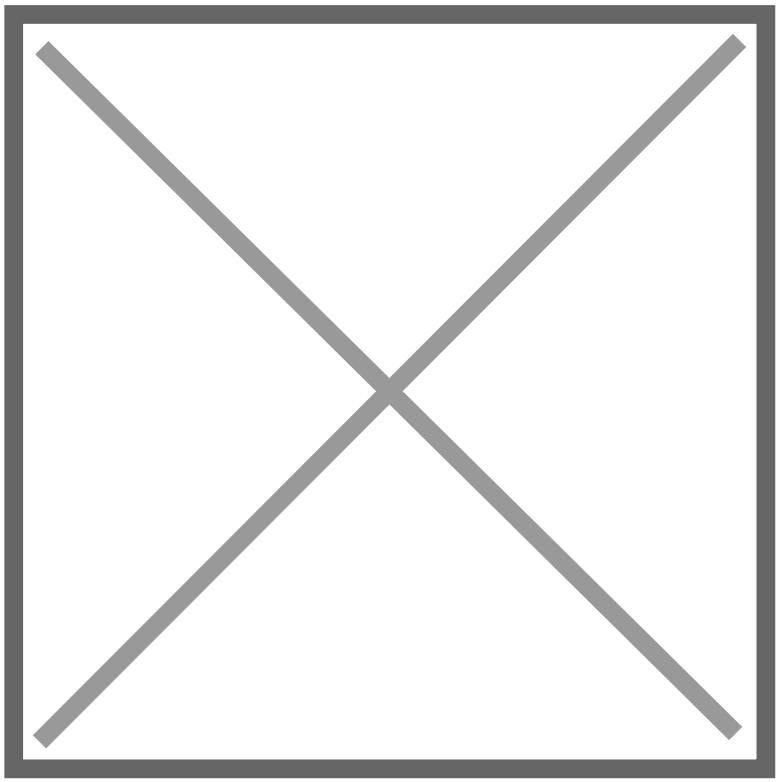
Clinical trials

Clinical trials essentially involve testing a new medicine in select categories of people and are among the most time-consuming components (it may take as many as seven to nine years) in a new drug's lab-to-market journey. They consist of three phases prior to drug approval. The purpose of phase 1 is to determine how the drug acts in humans, including identifying possible side effects. If results from phase 1 trials are positive, the drug is tested in a larger group of patients to determine how it affects a specific disease and what its short-term side effects may be. Phase 2 studies focus on comparing the new treatment with the current treatment or placebo. These continue to test drug safety and are larger than phase 1 studies. In phase 3 clinical trials, the drug is further studied for safety and efficacy in a much larger group of patients. If phase 3 results are successful, a new drug application is submitted and reviewed by the FDA. Phase 4 clinical trials are conducted after a drug has been FDA approved. These studies continue to evaluate a drug's long-term effects.

With increasing pressures on R&D cost containment across the global pharmaceutical industry, there is an increased focus on reducing the cost of clinical development, which accounts for two-thirds of the development costs. This is in addition to the pressure of accelerating the pace of the entire process of drug development. These challenges have led to a paradigm shift in the approach of major pharmaceutical companies.

"According to a recent study (Tufts Center for Study of Drug Development), the process of drug discovery and development takes 14.2 years (average) and costs $802 million. Clinical trials are the most significant direct costs related to drug discovery and development. The cost attached is about $282 million and takes about seven years to complete. These place significant strains on a company's resources and management time and hence significant amounts of these activities are being outsourced," said Dr Nirupa Bareja, group head (HR), Biocon India.

Outsourcing has become the mantra of the industry and contract research has evolved into a huge market. India is in a unique position to tap this new business opportunity because of three factorsÃ¢â?¬â?¢a large pool of qualified English speaking professionals, India's traditional strength in the pharma business and the cost-effectiveness of the study here.



At present the CRO segment in India mainly consists of contract research, contract manufacturing and clinical trials. The Indian market has companies doing clinical research and trials for the molecules developed in-house (captive CRO) like Eli Lilly. And there are organizations doing contract research and trials for other companies (independent CRO) like Quintiles Spectral, SIRO Clinpharm and Syngene. Aurigene, Shantha Biotechnics and Chembiotech. Syngene International, a Biocon Group company, set up in 1994 was India's first integrated CRO in the area of drug discovery. It is presently serving over a dozen pharmaceutical R&D units in Europe and the US.

"Contract research is very innovative, capital intensive, involving lots of R&D. Further, the field is not process but product-driven and cannot be operated on a large scale," said Dr Swaminathan Subramaniam, COO, Aurigene Discovery Technologies Ltd, a Boston-based drug discovery organization, with research facilities in Bangalore.

Contract manufacturing has become a big industry as India offers a strong manufacturing base at competitive costs, supported by a well-developed engineering base and an abundance of scientific talent. Eli Lilly, Bharat Biotech and Shreya Biotech are some of the important contract manufacturing companies.

Besides contract research and manufacturing, India is also emerging as a global hub for clinical trials. "India is being projected to grow in this field on account of adequate patient population having a wide spectrum of diseases, from common to the rarest, qualified medical professionals, good communication network and IT capabilities," said VV Raghavan, managing director, Lotus labs, an independent Bangalore-based contract research organization. "Clinical trial is a very data and quality-intensive work and may involve high percentage of travel. The scope of any error is very limited and involves high degree of ethics both personal and professional," commented Rajiv Gulati, managing director and chairman, Eli Lilly and Company (India) Pvt Ltd.

Quintiles, Specialty Ranbaxy, Siro Clinpharm, Eli Lilly, Clingene International (a subsidiary of the Biocon India Group), Lotus labs, Clintec International, Pfizer, Novo Nordisk, Lambda Therapeutic Labs, Novartis, etc. are some of the companies conducting clinical trials in India.

Goldmine for students

The Contract Research Organization (CRO) market has great potential and offers tremendous career opportunities. "The Indian CRO market is currently growing at 20 percent per annum and has excellent growth opportunities," said VV Raghavan of Lotus Labs. "Market trends indicate that the CRO market is going to experience rapid growth in the coming years and will become an indispensable part of the drug development process. The CRO industry is a major employer of medical and scientific staff and hence the demand for qualified personnel is on the increase. The potential is huge and the opportunities exist at every level," commented Nirupa Bareja of Biocon. "The potential is for real, the opportunity could be as big as 150 crore in year 2007-08," said Rajiv Gulati of Eli Lilly. "As on date, clinical research is still a sunrise industry in India and contributes just 0.7 percent to the global clinical research industry but this scenario is soon expected to change. India is tipped to be one of the major hot spots for clinical research in the coming decade. Analysts estimate that by the year 2010 India would contribute 20 percent to the global clinical research industry revenues," said Shamiq Hussain, general manager, Clintec (India) International, a Europe-based CRO. This optimism is bound to translate into a huge job market for the students.

"At Biocon India in addition to the technical competency, we look for a scientific analytical temperament in an individual. They must also be result-oriented, team players with good interpersonal skills, innovative, performance-driven, leadership-oriented, creative out-of-the-box thinkers and passionate about the job," commented Nirupa Bareja, group head HR, Biocon India.

In most of the companies, the standard procedure of selection is that resumes are received as a result of advertisements and walk-ins, which are screened and candidates further short-listed for an interview. "From a selection perspective, we follow a well-defined process. Based on the annual manpower planning, the recruitment is planned division-wise and the review of this is done on a quarterly basis. The short-listed candidates are interviewed both at Biocon and at various campuses. The interviews include both written tests (technical and aptitude) and personal interviewing," said Nirupa Bareja of Biocon.

She added, "From a qualifications perspective, we look for post doctorates, doctorates, medical doctors, post graduates in the fields of organic chemistry, molecular biology, microbiology, biotechnology, pathology, biochemistry, pharmacology, etc. depending on the job profile. At Biocon India in addition to the technical competency, we look for a scientific analytical temperament (as a mandatory quality) in an individual. They must also be result-oriented, team players with good interpersonal skills, innovative, performance-driven, leadership-oriented, creative out-of-the-box thinkers and passionate about the job."

This sentiment is echoed by most of the company heads. "We look for candidates having flexible thinking, a confident attitude and an aptitude for learning about other fields besides their core area," said Dr Swaminathan of Aurigene. "We look for aspiring candidates who have a desire to learn and grow in this field" commented VV Raghavan of Lotus labs. "In the contract industry, the people should be highly skilled and versatile to take up different projects and execute them at low cost in order to be competitive and effective," was the opinion of Raman Akella, head administration, Shantha Biotechnics, Hyderabad.

Recruiting by way of referrals, headhunters, advertisements, CVs received electronically and by mail is the norm. But many companies also go to premier institutes like NCL Pune, IITs, and IISc to recruit. At the entry level prior experience is not always sought, though is sometimes preferred.

The manpower requirements for each project could vary and range from two people to a hundred people per project. "The manpower need is typically dependent on the extent and the nature of outsourcing which is done to the CRO and is also dependent on the phase of the clinical trial work undertaken," observed Rajiv Gulati of Eli Lilly.

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In any CRO, the job categories depend on the nature of the contract service undertaken. Scientists in the field of synthetic organic chemistry, molecular biology and bioinformatics are required at Biocon. Aurigene looks for screening pharmacologists, chemical researchers and experts in the field of genomics, computational biology and bioinformatics when the project is in the initial stage of drug discovery. A few job categories at Shantha Biotechnics include fermentation, purification/process analysts (technical), quality assurance, registration/documentation personnel (regulatory), plant and process, quality assurance, operations personnel (management) and medical advisors. In a company conducting clinical trials, the job categories could be

multifaceted like coordinator, monitor, clinical investigator, research associate, clinical research physician, analytical chemists trial materials manager, project manager, medical writers, data managers, documentation personnel, lab technicians, and statisticians.

In this segment, growth prospects are excellent and are performance related. The salaries are very attractive and much above the average salaries in the medical sector or pharma industry. Employees are given every opportunity to excel, challenge boundaries, and go beyond expectations with sky being the limit. In the CRO sector on an average the men to women ratio is about 4:1.

Rolly Dureha