Market Analysis:

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Toxicology and pharmacology are challenging areas in the clinical trial process. Although the results gained are vital for the safety of medicines and are required by regulatory bodies around the world, the processes involved, especially animal testing, remain controversial. Almost all of the work is outsourced and the major companies involved have come under considerable pressure from activist groups.

Companies vary from large multi-nationals, small or medium sized organizations, Biotechnology, Medical Device, Generics or Niche companies to Clinical Research Organizations (CROs). CROs are Global organizations, service providers that undertake outsourced clinical trials for pharma companies to help get a compound on to the market. Their work includes specialist Phase I services, Pharmacokinetics/ Pharmacodynamics and Phase II –IV Services.

Typically, large pharmaceutical companies are structured in a 3-tier arrangement. At the top and generally in the country of origin is the Holdings Company: comprising Board Members, Senior Management, Legal, Corporate Affairs and Public Relations. Next comes the R & D company, again most often in the country of origin and comprising: Bench R & D (Chemistry, Pharmacology, Toxicology, Kinetics) and Clinical R & D (Phases I, II, III and Regulatory). Finally, the Local Operating Company, often described as an 'Affiliate' and usually based in the country where the products are marketed, comprising: Marketing, Sales and Medical.

Medicines Development

Only 1 in every 5,000 products screened is approved as a new medicine and only 30% of approved and marketed drugs produce profits that cover their R & D costs. Around 40 new medicines are approved each year and the average cost of developing a single drug, from initial discovery to approval is estimated at more than £400M.

Most drugs fail to make it to market but still incur development costs. On average it takes more than 10 years to progress through 'Phases' from initial Discovery to product approval.

The experiments and trials are different in each Phase. Experiments from earlier Phases may continue even though a project has moved on to the next Phase. During each Phase, more is learned about the drug's properties and there are key milestones where a pharmaceutical company decides whether to continue or stop development.

Facts

- Global pharmaceutical sales in 2010 topped $911bn, which equated to a growth of 2.90%.
- In 2010, the FDA approved 88 new drugs and biologics.
- The research-based pharmaceutical industry is one of the few remaining leading high technology industries in Europe, amounting to 17% of EU business R&D investments, and about 3.5% of the total EU manufacturing value added
- The pharmaceutical industry invested more than 16% of total sales back into research and development.
- Approximately 633,100 individuals are employed within the pharmaceutical industry in Europe, including 113,400 in R&D facilities.
- On average, 17.0% of total health expenditure in Europe is currently spent on pharmaceuticals and other medical nondurables.
- Thanks to innovations in healthcare European citizens can expect to live up to 30 years longer than they did a century ago