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Contract research and manufacturing services (crams)-present status in India

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Contract research and manufacturing services (CRAMS) is one of the fastest growing segments in the pharmaceutical and biotechnology industry. The pharmaceutical market uses outsourcing services from providers in the form of contract research organizations (CROs) and contract manufacturing organizations (CMOs). Increasing costs of R&D, coupled with low productivity and poor bottom lines, have forced major pharmaceutical companies worldwide to outsource part of their research and manufacturing activities to low-cost countries like INDIA. India soffers significant cost advantages over mature manufacturing hubs in Europe and North America. India has already emerged as one of the leading cost-competitive and quality manufacturing hubs for many global players including big pharma companies. Moreover, the current economic crisis along with the continuous pricing pressure and pro-generic agenda are driving Pharma companies to leverage the strengths of Indian pharma manufacturers. The present study describes role of CRAMS, benefits & risks, present status in INDIA.

Biography

Goundla Thejo Ganesh Reddy is a student of JSS College of Pharmacy, JSS University, Ooty, Tamil Nadu, India. He has completed his B Pharm from JSS College of Pharmacy, Mysore during the year 2012. Presently he is pursuing M Pharm in Pharmaceutical Quality Assurance in JSS College of Pharmacy,Ooty. He has presented posters at national level and has attended various National and International Conferences. His current areas of interest are Quality Assurance, Regulatory Affairs, Quality Management Systems, analytical method development of novel drugs.

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Drug filing and approval in USA & Europe

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This topic aims at overviewing the drug filing and different aspects of obtaining US FDA & EMA approval for a drug in order to get a Marketing Authorization in United States of America & Europe and their effective role in improving the standards laid down by them. Drug approval is a process by which new / generic drug is approved so that it can be marketed. All new / generic drug products must be approved by the respective regulatory agency governing the intended market before the products can be introduced into the market. Drug approval standards in the US & Europe are considered by many to be the most demanding in the world. By law, all new drugs must first be shown to be safe and effective before they can be approved by the Food and Drug Administration (FDA) for marketing. United States Food and Drugs Administration (USFDA) is the regulatory agency which is responsible for safety regulation of the food and drug products in US. European Medicines Agency (EMA) is the regulatory agency/ decentralized body which is responsible for safety regulation of the food and drug products in Europe. Drug approval process in USFDA involves submitting of an Investigational New Drug (IND), followed by submission of New Drug Application. The applications are reviewed and agency officials examine the drug's safety and efficacy data and the drug is approved. EU establishes 4 different drug approval process

1) Centralized Procedure

2) Decentralized Procedure

3) National Procedure

4) Mutual Recognition Procedure

Biography

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