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June
2013

The Indian CRAMS Industry



The Indian Contract Research and Manufacturing Services (CRAMS) industry is estimated to be worth ~US\$6.6bn in CY2012. CRAMS industry has two main segments – Contract Manufacturing Services (CMS), which accounts for more than 60% of the industry; and Contract Research Services (CRS), which accounts for the rest. CMS is expected to dominate the industry in the foreseeable future. CARE Research expects the domestic CRAMS industry to grow at robust rate from CY2013-2017.

Huge export potential and changing disease pattern to boost industry growth

More drugs coming off patent to drive new research

Branded drugs worth ~US\$105bn in annual sales in US are expected to come off patent until CY2020. Of these, ~US\$92bn (~88%) worth drugs are expected to go off patent by CY2016. Due to many drugs going off-patent, the top-line growth of pharma companies is expected to come from generic drugs than from patented ones. Hence, pharma companies would be expected to enhance the allocation to R&D to increase the drug pipeline.

The costs of US pharmaceutical companies have increased due to several provisions of the Patient Protection and Affordable Healthcare Act coming into effect. This coupled with declining productivity, rising salary of scientists etc has led to steady rise in R&D expenditure. This is likely to increase the trend of outsourcing to CRAMS companies.

Rising cost for the pharmaceutical companies in US

Declining research productivity and stricter US FDA norms to boost CRA

R&D productivity of big pharmaceutical companies is on the decline mainly due to slowing down in discoveries of path-breaking medicines, increasing cost of research and constantly raising the bar by the US FDA. The US FDA has been taking more time in giving approvals by asking for additional clinical trials/studies, resulting in delays and higher costs. This has boosted the allocation to CRAMS companies for streamlining the drug research process.

Indian companies are increasingly being preferred due to their product mix catering to high-end research services, biologics and complex technology services. Also, India offers a significant pool of professionals in the area of drug development and research chemistry with large number of pharmacists and chemistry post graduates.

Increasing preference towards Indian companies

Challenges to Indian CRAMS Industry

Despite numerous growth potential CRAMS industry face multiple challenges. Regulation of drug manufacture and its processes and practices is carried out by the respective Food and Drug Administration Departments at the state level. Due to lack of a unified single Central authority, the enforcement of laws tends to vary from state to state. Such a regulatory framework is inconsistent with the long term goals of enforcing Good Manufacturing Practices (GMP). Moreover there is requirement of qualified medical professionals for research into diseases and sub-sectors such as bio-medicals. The XIIth Five Year Plan has mentioned the need to have qualified medical professionals for research into new diseases, cheaper drugs and emerging sub-sectors such as bio-medicals. The Planning Commission's Working Group on Drugs and Pharmaceuticals has proposed setting up of six new National Institutes of Pharmaceutical Education and Research to meet the growing demand.

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