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India accounts for 30.3 % (2,911) of 9619 Drug Master Files (DMFs) filed with the USA, which is the highest outside of the USA. India has been accredited with approximately 1187 CEPs, more than 950TGA, and 584 sites approved by USFDA. Despite a challenging intellectual property regime, pharmaceutical R&D activities are increasing in India. An average of 8-10% of the total revenue of the India domestic pharma market, i.e. US \$ 15 billon, is spent on R&D.

Zydus Cadilla has launched "Lipaglyn" (Chemical name is Sarogltazar), its original research being to treat Hypertrigycerdemia in Type-2 diabetes. Glenmark has several new chemical and biologics. Contract Research and Manufacturing Services (CRAMS) in India is estimated to reach US\$ 18 billion in 2018, up from US \$ 7.6–7.8 billion in 2013. The biopharma market is valued at US \$ 2.5 billion whereas India is expected to grab at least 20-25% of global market share in biosimilars in the next five years.

## **Cooperations with Japanese Companies**

India is also making inroads to new regulated markets like Japan. Several initiatives have been undertaken by industry for engaging with Japanese pharma companies, including contract manufacturing of advance intermediates for drugs under clinical development/about to be made commercial, marketing APIs to Japanese Generic and Innovation companies, providing quality intermediates to the Japanese innovator companies.

In summary, the last few years have reshaped and repositioned India in the realm of healthcare and pharmaceuticals, and the results have started to show in its high ranking position in the global pharmaceutical market.