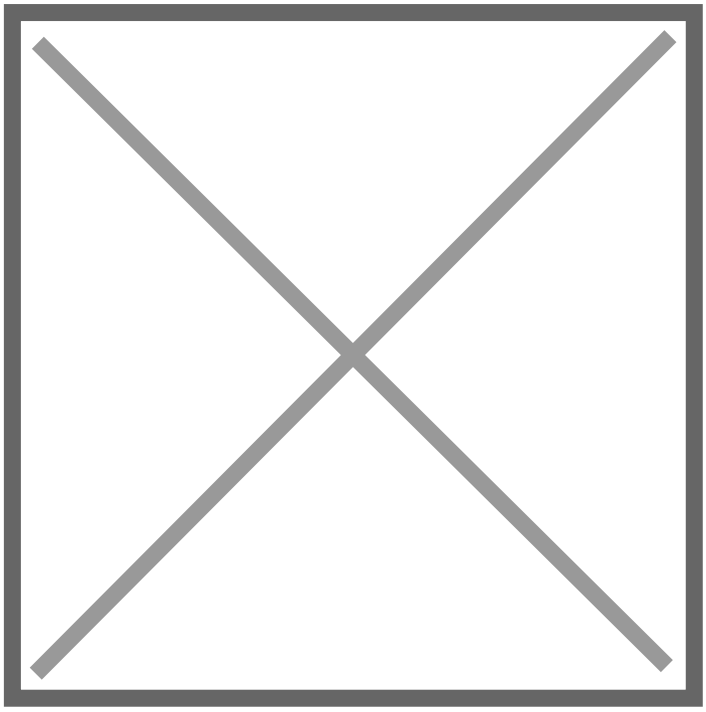
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Asia a global manufacturing hub

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Asia a global manufacturing hub

The Asia Pacific region has long served as a hub for low-cost manufacturing. With over 80 FDA approved manufacturing plants, India is only next to the US in terms of FDA approved facilities.

Asia is, no doubt, a major center for manufacturng chemical based pharmaceuticals. It is a favored destination for contract manufacturing. But the biopharma manufacturing is small. According to a recent report published by HighTech Business Decisions, "Biopharmaceutical Contract Manufacturing: Best Practices Pricing Study 2006", between 2002 and 2006, the size of the biopharmaceutical contract manufacturing market is expected to double, reaching more than $2 billion in 2006, with revenues rising in tandem with contractors' new capacity coming online. To keep up with the increasing demand, which could reach a total level of one million liters of tank space required for contract manufacturing services, contractors are building, acquiring, and expanding capacity while making better use of existing capacity.

Sandra Fox, president, HighTech Business Decisions, stated, "We spoke with 30 directors of biomanufacturing at pharmaceutical and biotechnology companies worldwide, and 16 biopharmaceutical contract manufacturers to document prices paid and prices charged in the industry. Of the total biopharma contract manufacturing market, only a small percentage of work will be conducted in Asian countries. Although small today, this percentage is expected to grow as pricing pressures in biotechnology markets increase and companies seek access to Asian markets. To meet this need, new mammalian cell culture facilities are being built in Asia and experienced biomanufacturing contractors are establishing operations in Asian regions."

India and South Korea are emerging as the hot spots for biopharma contract manufacturing. Indian companies like Biocon, Bharat Biotech, Biological E, Serum Institute and Shantha Biotech have world-class facilities for biopharmaceutical contract manufacturing. Earlier there was some reluctance to contract to Asian biopharma manufacturers because of concerns of IP and regulatory compliance. But now some of the Asian countries are changing and becoming very competitive in biopharma manufacturing.

According to Ernst & Young, Indian firms are expanding and scaling up manufacturing capacities to become global players. Companies like Biocon, Dr Reddy's Laboratories and Panacea Biotec are preparing generic versions of biotech drugs. In China too the case is similar.

US FDA history

Achieving GMP stamp approval from the US Food and Drug Administration (US FDA) is considered toughest in terms of its standards and efficiency. In 1963, the US FDA introduced GMP. It discovered contaminated large volume intravenous fluids

manufactured by Abbott and McGaw Laboratories, which led to GMP revision in 1976. The 1976 revision remains unchanged until 2005. US FDA also ensures equivalence of Generic Drugs.

The global pharmaceutical industry is an estimated $500 billion in 2005 divided into patented drugs, generic (off patent), prescription drugs and over-the-counter medicine. The industry is growing at seven percent to eight percent per annum. The US continues to be the leader while India's share is less than two percent of the global pharma market. An estimated 70 percent sales are made in the US and Europe. Since June 30, 2004, the State Food and Drug Administration (SFDA) has been closing down manufacturers that do not meet the new GMP standards.

The Indian pharmaceutical industry ranks fourth in terms of volume and 13th in terms of value in the global pharma industry. China is the world's ninth drug market, and in 2008, it will become the eighth largest market.

Manufacturing size

The pharmaceutical manufacturing market is worth about $50 billion, out of which roughly 30 percent or $15 billion is outsourced. Active Pharmaceutical Ingredients (API) or bulk drugs outsourced market is worth $10 billion. One can classify API into three segments: branded prescription drugs, over-the-counter drugs and generic prescription drugs. With drugs worth over $50 billion going off patent in the next five years, the generic market will be the key driver of the global API market. It is expected that the overall outsourcing market will be about $30 billion by 2010.

Currently India supplies API to about 50 countries worldwide. The demand for Indian APIs will increase year-by-year due to its quality and cost advantage. Indian manufacturers produced worth $1.5-$2 billion API in 2005. 70 percent of the total API manufactured is exported.

Indian pharma tops

The pharmaceutical manufacturing sector in India has come a long way in complying with the good manufacturing practice (GMP) set by World Health Organization (WHO) in 1968. July 2005 marks the beginning of new chapter in the Indian pharma industry. The GMP as per the Schedule M of the Drugs & Cosmetic Act became mandatory. Today, India has more than 800 GMP compliant manufacturing plants. There are more than 5,000 small manufacturing plants facing closure due to lack of expertise and capability.

Today, Indian pharma companies have upgraded or building plants, which are not only GMP compliant but approved from international drug authorities. Many mid to large-sized ones have achieved GMP approval of highly regulated markets such as the US, Europe, Australia, Latin America and Canada. The most stringent, US FDA approval is distributed between large and midsize companies.

India triumphs in having maximum number of US FDA approved plants after the US. India has 70 to 75 US FDA approved plants and all comply with WHO GMP. Out of this more than 50 percent are API manufacturing plants. Andhra Pradesh ranks first in having the most US FDA approved plants followed by Gujarat. Most of the plants got approvals without
Form 483.

The story does not end there. The number of US FDA approved pharma manufacturing plants is expected to increase by at least 30 percent in 2007, according to a study conducted by the BioSpectrum Advisory Services (BSAS). BSAS is a unit of BioSpectrum magazine. The large portion of the increase will be shared by mid size pharma companies. Most of the companies are upgrading and building new facilities as per US FDA standards. Apart from Andhra Pradesh and Gujarat, Himachal Pradesh is the next favored state for setting manufacturing plants.

India comes fifth in terms of API manufacturing. It has established itself as low cost and high quality API production country. With product patent regime in second year and more than $80 billion generic expected to go off patent in two to three years, India is well positioned to capture the outsourcing opportunity. The US DMF filing has increased exponentially since 2003. Out of 4835 Type II active DMFs till Dec 05, India's share is 16 percent or 656. We expect DMFs filing for other countries to increase simultaneously along with the US.

The ANDAs filing increased constantly from the year 2003 to 2005. We expect the trend to continue further. The ANDA filing is dominated by big pharma ones while midsize are too expected to increase the filing.

BSAS research indicates an average of two DMFs and two ANDA filing per month with US FDA by most of the midsize ones, while big ones are expected to file more. Companies will also increase the filing to less regulated markets.

In spite of having large number of US FDA plants and many others who are gearing up for inspection, there are a number of small companies who are yet to comply with GMP. Today, when GMP has become benchmark of quality, the smaller companies need to upgrade in order to survive and compete.

The increasing number of US FDA plants will give Indian pharma an opportunity to tap the regulated (high and less) markets. On one side, Indian pharma companies are upgrading their facilities to meet the stringent US FDA stamp; we also see increase in patent filings and R&D investment.

US FDA approved facilities comparison

The number of US FDA approved facilities in India at the end of March 2006 stood between 71 and 75. India comes second in US FDA approved plants after the US. India has more than 800 WHO GMP compliant manufacturing facilities.

US FDA facility growth in India

BSAS expects India will have 30 percent more US FDA approved facility by the end of 2007 compared to March 2006. Most of the future US FDA approvals will be for midsize pharma companies.