

# 'Stringent FDA requirements pose major challenges'

14 June 2015 | Features | By BioSpectrum Bureau

## 'Stringent FDA requirements pose major challenges'



Ingersoll Rand brings expertise to pharma and healthcare industry with sustainable solutions in the areas of HVAC and compressed air systems, tools, security technologies, and mobile or static refrigeration.

The HVAC for pharma market is growing at a CAGR of 8 percent, while the pharma HVAC market was around \$10 million for chillers and AHU (air handling unit) in 2014.

"The government has already unveiled 'Pharma Vision 2020' aimed at making India a global leader in end-to-end drug manufacturing, thereby making this sector highly lucrative for investments and growth," said Mr Sudarshan Ananth, territory VP & business head, HVAC & transport, India Climate Business Unit, Ingersoll Rand.

#### **Emerging trends**

India being the 3rd largest producer of pharma products and responsible for 8 percent of the world's production is a strategic market for HVAC products.

Indian pharmaceutical manufacturing facilities registered with US Food and Drug Administration (FDA) as on March 2014 was the highest at 523 for any country outside the US.

"There is a continuous capacity expansion needed to achieve high growth rates. We have seen a surge in the demand for AHU and chillers, with the pharma market now dominated by water-cooled and air-cooled screw chillers, with the former having a higher leverage due to better efficiency," Mr Ananth commented.

The Indian pharma industry is growing at a faster rate owing to large demand both in terms of import and export.

Pharma Industry is expected to touch \$55 billion by 2020 from the \$12 billion levels in 2013, and with 60-70% of revenues coming from the exports.

"Therefore, usually the last mile connectivity is a problem in pharma industry, as there is a need for refrigerated or conditioned transport for the drugs to the clinics or warehouses. It is imperative that organizations invest on technologies that are environment-friendly and sustainable, so as to address these issues more accurately and make distribution more efficient," Mr Ananth pointed.

#### India and international markets

According to Ingersoll, all major drug manufacturers in India use its chillers. "We have a strong presence in all the drug manufacturing states including Telangana, Himachal Pradesh and Maharashtra," he opined.

For Ingersoll, India is a key attractive market. "Other markets like Taiwan, Vietnam, Indonesia and Thailand are a growing market for us. We have a strong presence in all these markets. Our strategy of offering products that meets the local needs have helped us to grow well in these markets also," observed Mr Ananth.

#### **Hottest hurdles**

He pointed that there are a variety of healthcare challenges that are a barrier to better healthcare service and pharma solutions in India.

"The key challenge faced by the industry today is meeting the stringent FDA requirements on providing the proper environment which need controlled humidity," he revealed.

He further technically explained, "Many times, dehumidification is a costly process, and hence efficient heat recovery from the chillers are a big challenge. Controlling the complete system in an integral way from clean room door opening to chilled water management using single controls is a big challenge."

#### **Biggest opportunities**

Healthcare for all is a focus area for both central and state governments in India and other developed nations like the US. The HVAC industry has direct bearing on the growth of pharma and hospital sector.

"Hence, with the pharma sector poised to grow, especially with the state government providing appropriate infrastructure for growth, we feel there is a huge opportunity for HVAC players to look at newer playing fields," Mr Ananth emphasized.

Controlled air environment is necessary for temperature-controlled transportation of pharma products from source or manufacturing facility to storage or distribution centres, or within the manufacturing facility.

He also added that the localization push will necessitate a capacity expansion in the industry and in turn will help growing

usage of HVAC. "Identification of new export markets and opportunities for Indian companies in China will also lead to capacity expansion in the industry," expressed Mr Ananth.

Energy efficiency seems to be a key cost driver in the pharma and healthcare industry. Thus, HVAC companies are now offering a variety of HVAC technology solutions to increase energy efficiency.

### **Further expansion**

"We are expanding our business by offering VRF (Variable Refrigerant Flow) products in the hospitality, healthcare and commercial real estate segments, and launching energy efficient residential air conditioners with green refrigerants like R410a," Mr Ananth noted.

The company believes that its new wireless controller product is going to be a game-changer in the industry with hassle-free, reliable installations, and best-in-class technologies.