

## Heralding growth

*Many try to become jacks of all trades and ultimately end up becoming master of none. But Calyx Chemicals and Pharmaceuticals with its strong focus has already become a leading global supplier of anti-TB drugs. And they aim to make their mark in the anti-malarial, anti-hypertensive and anti-infective segments too. **Suja Nair** reports*

Calyx Chemicals and Pharmaceuticals has come a long way since its inception in 1979. As an extension of finished dosage company Alma Laboratories, the company is today a US FDA, WHO (Geneva), European Directorate for the Quality of Medicines (EDQM) approved, ISO 9001 and 14001 certified manufacturer of intermediates and Active Pharmaceutical Ingredients [APIs] with an excellent custom synthesis capabilities. Calyx is headquartered in Mumbai, with its manufacturing and R&D facilities on the outskirts of the city.



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- **Smitesh Shah**  
Chairman and Managing Director  
Calyx

The company started with world class flask technology with five 20 litre flasks and today have their presence in multiple locations with huge multiple reactors of world standards. It has grown from being a three member team to staff strength of 580 people, of which almost one third are in R&D with a minimum master's degree and PhDs. **According to Smitesh Shah, Chairman and Managing Director, Calyx, "As a company we have more than 50 Confidential Disclosure Agreements (CDAs) signed and are actively working with 25 of them on live projects, from gram to ton quantities. Out of the top ten innovator companies, we work with at least four on an active basis world-wide. We currently service leading drug discovery companies around the world with their requirements for contract manufacturing, custom synthesis and collaborative R&D that include Full Time Equivalent (FTE) as well as Fee-For-Service (FFS) and bioanalytical services."** The multipurpose manufacturing plants have capabilities to produce from grams to tons in compliance with current Good Manufacturing Practice (cGMP), United States Food and Drugs Association (US FDA), World Health Organization (WHO), European Directorate for the Quality of Medicines (EDQM), ISO 9001:2000, ISO 14000:2004, HIS and Certificate Of Suitability (COS) norms, while their global footprint includes marketing and sales offices in US, Japan and sourcing office in China.

## From yesterday to today



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- **Prashant Ogale**  
Vice President-Projects  
Calyx

Till 1990 Calyx concentrated on a number of products, but then decided to master one product. **In APIs Calyx deals in the anti TB, anti diabetes, anti malarial, macrolides, anti hypertensive, anti depressants, anti psychotic segment, etc., and on Contract Research and Manufacturing Services (CRAMS) side they deal with multiple chemistries. Calyx is among the top three API manufacturers in the selected products that they are in.** It started concentrating on anti-TB drugs and by 1995-96 had become the global leader in anti-TB drug Pyrazinamide. **Today, Calyx has captured almost over 50 percent of the world market in this product.** Since Calyx is already approved for the WHO TB programme, they feel

that they would become the natural candidate for WHO aided funds for the anti-malarial in a year. It is also among the top four companies in the Erythromycin range of products. With their capacity and productivity improvements they hope to go one level up.

Year 2000 saw Calyx having a strong hold on the domestic market and venturing into international markets. In 2001 Calyx started its CRAMS business and started working with both generic and innovator companies. Calyx was among the few Indian pharma companies to be a part of a New Drug Application [NDA] in 2003 and also went through an FDA inspection of its manufacturing site at Tarapur, near Mumbai, which has seven production suites, which cater from kilo to tons level.

All seven plants have the latest facilities and standards to fulfill growing customer demands. Thus, along with the new ones the old facilities too continue to operate. **Apart from the new state-of-the-art R&D facility in Dombivli, Calyx has added more feathers to its cap with two new manufacturing facilities at Tarapur plant with a kilo lab and a multi ton cGMP intermediate plant along with Hydrogenation facility.**

#### **Positioning for tomorrow**

**Calyx plans to close 2008 with revenues of around Rs 150 crore and targeting about 30 to 50 percent growth in the next two years from CRAMS related services, and remaining from APIs and intermediates. The company would like to exceed this because they have the delivery mechanism in place, have customer acceptance and believe that they have the best team in the country coupled with good reputation to support since the last 28 years. Calyx offers a range of APIs, chemical intermediates and building blocks to pharmaceuticals, biotech, chemical and drug discovery companies.**

#### **No compromise on quality**

**At Calyx the most stringent quality control procedures are followed in its facilities so that its products are safe and efficacious and suitable to exceed world class standards and fulfill their demands. Shah contends that, "The USP of our company is that we believe in values such as excellence, integrity, transparency and honesty and above all collaboration and in teamwork. Our passion is chemistry."**

Prashant Ogale, Vice President-Projects, Calyx, adds, "Our gram level lab, which is equipped with world standard equipment like Nuclear Magnetic Resonance (NMR), analytical support, high pressure liquid chromatograph (HPLCs) etc are already in operation. We are ready to take on the FTE business from Europe, USA and rest of the world with a bang at the gram scale. All the molecules are also developed so that when we start at gram level, we can then move on to kilo level."

As there is no room for compromise on quality, similarly, safety of the people working at Calyx is also of top priority. Shah says, "We have safety team 24X7 at our plants. At Tarapur we have more than one lakh accident free man hours, with safety standards that are very high due to very elaborate monitoring systems and accident analysis system."

## R&D focus

Research in pharma-ceutical industry is not just about new chemical entities (NCEs) and new drugs. It is also about what unique services of products a company can offer. Calyx aims at innovation in R&D and excellence in various processes and that is what differentiates Calyx from its competitors. The company is fully focused on developing its R&D facility as per the international standards and for that matter it has set up a state-of-the-art research facility in Dombivali, which is in the last phase of development. This lab will further enhance and expand Calyx's current capacity to provide global clients a seamless range of services from cutting-edge R&D to large scale manufacturing and analytical development. Shah opines, "At Calyx we believe in continuous productivity improvement and in offering a service that is cost effective, speedy and quality based."

**The R&D centre has seven synthetic and four analytical labs.** These labs are built with international markets in mind, with scientists working round the clock. Post expansion, the facility will house 350 scientists, with process labs, cGMP kilo labs, analytical labs, along with cGMP pilot plant facility to ensure enhanced productivity for CRAMS.

The amount they are spending on the R&D shows their dedication towards developing their company. Showing the example of Calyx's investment in these facilities Ogale says, "One of the most important machines at the R&D facility of Calyx is 400 MHz NMR. It goes in to the nucleus of the molecule to find out the exact composition and then it synthesizes further beyond that, to identify what is happening inside." Giving details, Madhu Gautam, Assistant General Manager, Calyx, says that very few Indian companies have invested Rs 2 crores on a 400 MHz NMR.

Dr Bansi Lal, President R&D, Calyx, has more than 50 patents to his name, says, "We have defined a model for training any new person at Calyx. This person is kept under training for initial period of six months. In Calyx, we have the best software's available to keep us upto date. We also have information group consisting of PhD and MSc. If something happens, it comes on the radar and is transmitted. Safety is very important part for us."

## Expansion on cards

With three sites on the outskirts of Mumbai, Calyx is in full swing to expand from its current size. It has two sites in Dombivali, of which the R&D centre is nearing completion. **The main manufacturing site at Tarapur, is five times the current size of its R&D centre, which is going to be the main focus of their expansion plans. The 100 crores expansion plan is slated to start by end 2008.** Gathering money for expansion had been a Herculean task, but with strong banks to support them, it became possible. Revealing funding details Shah states, "We would go to the private equity route and in three years time we believe we would come up with our own solution." He added that all of his banks have been extremely supportive and co-operative in building this infrastructure.

## Pollution control

At any given point of time safety of environment has always been a top priority. Calyx as a company has always stood by the ground to deal with the problem of environmental pollution. **Calyx is a member of central effluent treatment plant as well as Bombay waste management.** At Calyx, all gas vents are scrubbed so that all the harmful pollutants are removed and only then vented into the

atmosphere. Dealing with problems of water pollution concerning smaller plants where the load is less, they adopt pentone process where all the pollutants are chemically killed and then are later discharged to the central effluent treatment plant. Whereas in Tarapur, as the load is far bigger, they have a big effluent treatment plant with primary, secondary and tertiary treatment done. Later, once that is done it is sent to the central effluent treatment plant for further processing. As far as solid wastes are concerned, they are sent to Bombay waste management that deals with solids based disposals.

### **Road blocks**

It is not easy in this competitive field to keep up with the rapidly changing world, to bring up an organization to a recognizable position, a lot of perseverance and dedication is required. Calyx also had to face the test of time through which it had come out successfully.

Reflecting on the past, Shah says, "It has been a difficult task to build up a team but Calyx can today boast of a robust team with high knowledge power. Of all, the most demanding task was to make people and customers believe that Calyx can come up with a state-of-the-art facility." Besides a growing customer base, **Calyx has received validation of this success with the recent Indian Drug Manufacturers' Association's (IDMA's) Quality Excellence Award 2007.** As Vice-Chairman of Pharmaceutical Export Promotion Council (pharmexcil) Shah is adept at balancing his roles. Revealing his work philosophies he says, "As an organization we need to bring ourselves in such a position that through us the industry at large is also benefited. We believe in being present everywhere virtually, rather than physically, at a given point of time and deliver to the fullest. One thing we at Calyx had always believed in is speed to deliver and do what ever is necessary to facilitate the needs of our customer."