BioSpectrum the business of Bio & Health Sciences

â€œWe'll have 120 scientists by year endâ€?

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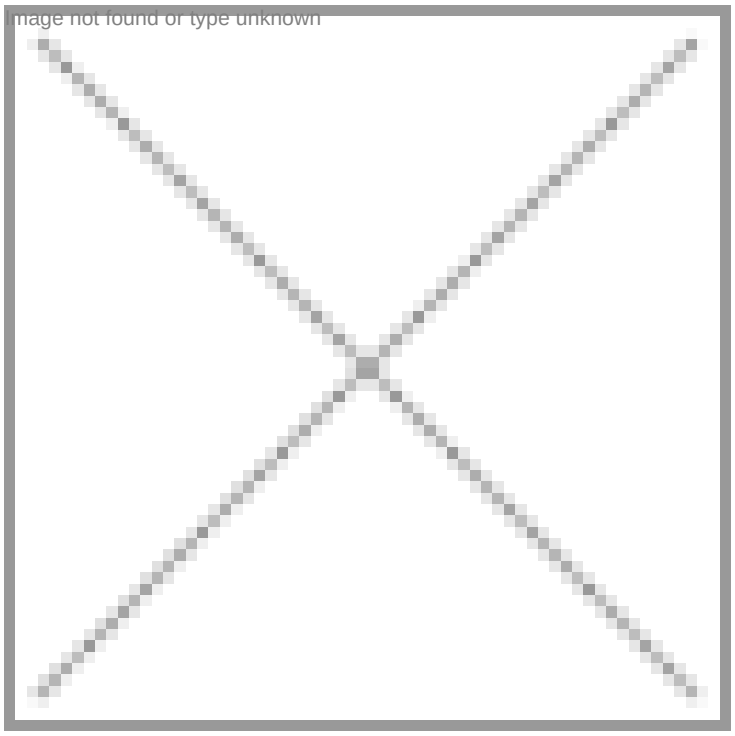

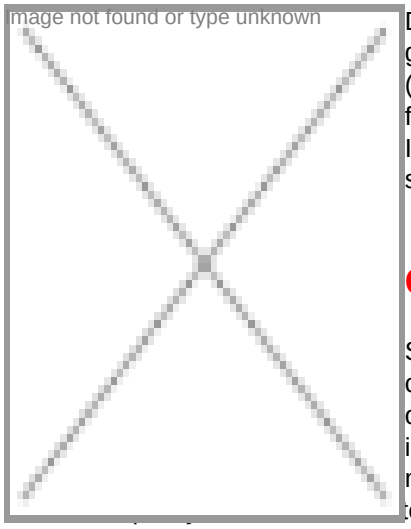

Dr Sudhir Nambiar, head of Pharma Development Center, AstraZeneca has nurtured the growth of the center that was set up in 2007 with an initial investment of Rs 67.44 crore ($15 million). This is AstraZeneca's fourth product research and development (PR&D) facility and the only one outside Europe, the other three facilities are in UK and in Sweden. In an interview with BioSpectrum, Dr Nambiar shares his plans for the center and the strategy he has chalked out to align the facility in India with the company's overall global

Q What are the major activities carried out at the AstraZeneca's Pharmaceutical

Safe, efficient and scalable processes for developing drug candidates are allotted to this center by the Global Project Management Group. The candidate drugs originate from any of the AZ discovery sites could be in the areas of neuroscience, pain, gastrointestinal, infection, respiratory and oncology. We optimize processes keeping green principles in mind. We develop analytical methodology to monitor the progress of reactions and to tes and finished products.

A solid state group of the company studies the crystallization processes in detail while developing the right polymorphs. The process engineering group ensures the safety and scalability of the processes. We have a strong process safety group that ensures the safety of processes that are scaled up. Other notable departments include the QA and the project management group. We also recruit accomplished scientists who do not want to be burdened with significant administrative responsibilities

on the science ladder so that they can focus on improving the scientific quality of projects.

Q How important is India for AstraZeneca as far as pharma R&D is concerned?

Pharmaceutical Development facility is a strategic arm of the Global Pharmaceutical Development function of AstraZeneca. We have a vision of developing processes from the discovery stage to the launch stage just like the other global PD groups. In fact, we are currently growing unlike other groups and hope to meet our budgeted target of 120 scientists by the year end.

Q What is the role of the center and is there any specific disease focus?

The Drug Discovery program at Bangalore is focused on finding a cure for TB. The PD Bangalore group will develop processes to any candidate drug (CD) emerging from the Drug Discovery Center, since these are received through the Global Project Management system just like any other CD from a European/ US Center. In fact, we are currently working on developing a suitable process for the first CD discovered in Bangalore.

Q What have been some of the achievements of this particular center since its inception?

The center has delivered an increasing number of global projects each year since 2007. It has demonstrated that it can develop innovative, safe, efficient, and globally-competitive processes to candidate drugs. It has proved that it can do this relatively inexpensively when compared to the European Centers. The contribution has been significant, so that a decision has been made to expand the facilities in Bangalore.

Q Why was India chosen in the first place, considering that it is known more for its development than discovery capabilities?

We develop processes toward new chemical entities (NCEs). This is different from developing processes to generic molecules. However, India was chosen due to its large talent pool of development chemists. It takes approximately a year to train chemists to develop processes toward NCEs.

Q What is the contribution of this facility in AstraZeneca's overall India R&D program?

The PD facility is a world-class center where cutting-edge science is performed. It gives an opportunity for Indian scientists to work on global projects in their own backyard. Along with the equally-sized and independent discovery group that is focused on finding a cure for TB, it reflects AstraZeneca's substantial R&D investment in India.

Q How will you align the overall activities in this facility with the existing global PR&D programs?

Since we get projects through the global PM group the work we do is no different from the work done by the other sites in Europe. The candidate drugs developed by PD, Bangalore are sent to Europe for formulation, safety, toxicology and finally clinical studies. We work in a truly global fashion in that we interact closely with our counterparts in Europe. While export/import of best practice is a continuous process.

Q Can you share about the current pipeline of candidates discovered by the company?

We are currently developing processes towards molecules from all areas including neuroscience, oncology, respiratory and infection. Since we started our activities relatively late compared to Europe, most of our molecules are in phase I and phase II stages of clinical trials.

Q What have been the overall investments for this facility? How many scientists have been recruited for this center?

The center was started with an initial investment of Rs 67.44 crore ($15 million). Right from inception the total investment of the company would be around Rs 89.92 crore ($20 million). The center is equipped with state-of-the-art equipments such as NMRs, LCMS, LCMSMS, XRPD, RC1, DSC, TGA, parallel synthesizers, and catalyst screening kits. Currently, we employ around 100 scientists who are a mixture of process chemists, analytical chemists, process engineers, process safety assessors, scale up personnel, QA and project managers.

An expansion to accommodate additional personnel is currently on for which AstraZeneca has invested additional Rs 8.99 crore ($2 million).

Q AstraZeneca is going through a major restructuring process in India, will this have an impact on its R&D programs?

Currently, our recruitment is continuing as planned. At this time, we believe that the restructuring program will not adversely

impact Indian operations.

Q Are there any plans for any collaborations with other research centers/institutes in India?

AstraZeneca supports research in a premier research institution in India. We provide scholarships to students at an Indian educational institution. We conduct open houses every year where we invite local students and teachers to visit our premises and understand the research being conducted. We host summer trainees from various Indian universities as well as from other global universities like Cambridge in the UK. We also train fresh science and engineering graduates in important aspects of process safety and release them to Indian industry thereby showing our commitment to improving process safety standards in India.

Q Apart from India, will we be seeing similar centers in other emerging nations?

AstraZeneca has a small scale center in China. At this point of time, there is no concrete plans for setting up centers in other emerging nations.

Q As far as drug discovery is concerned, where do you see India in the coming decade?

I predict that drug discovery activities in India will increase. I am very hopeful of a NCE coming from India.

Q What is the future plan to take this center to the next level of growth?

Currently, we are focusing on the early stage of projects and we are in a learning phase especially with late phase process development. As we progress, we expect to develop processes that will hopefully help to launch a new molecule in the market in future. While we have established a strong tradition of project delivery at relatively lower cost, we cannot rest on our laurels and need to continue our growth pace.

Nayantara Som in Mumbai