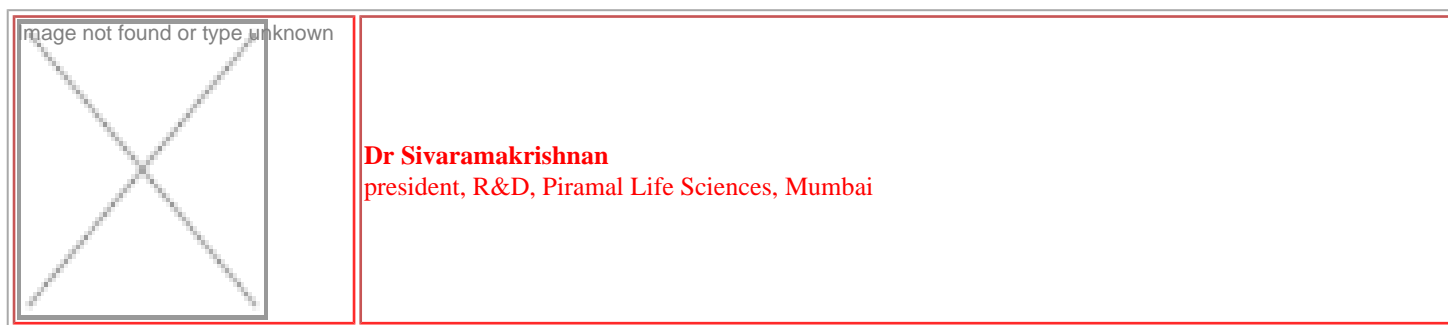


Making NCE a reality in India

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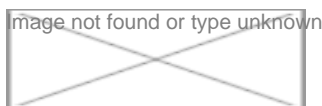


The life sciences industry in India is witnessing exciting times, with a paradigm shift in its image as a low-cost drug development destination to being a prospective drug discovery hub. As the industry waits with baited breath for the commercialization of India's first new chemical entity (NCE), scientists and researchers at Piramal Life Sciences, a research-driven organization of Piramal Healthcare focusing primarily on NCE research, are leaving no stone unturned to make this endeavor a reality.

Dr Sivaramakrishnan, president, R&D, Piramal Life Sciences, plays a proactive role in the company's drug discovery pursuits. "Drug discovery is not for the faint-hearted. It requires patience and long time commitment not just from the company but also from the scientists," he says.

At Piramal, his research interests extend from being a process chemist looking into APIs and contract research to looking into

drug discovery with medicinal chemistry along with other facets like biology and toxicology. “My focus extended to the domain of drug discovery. Working in this organization helped me in learning and experiencing how a new drug is discovered and developed subsequently. This has converted me into a big supporter of the product patent regime,” says Dr Sivaramakrishnan.



When he joined Piramal, the company had taken a call to work in three disease areas – oncology, inflammation and metabolic diseases. At that time, it had the best natural products collection and the team explored that for newer compounds. Today, the company has three compounds in clinics in oncology, three compounds in clinics in metabolic diseases and one compound in inflammation diseases. Piramal is also into discovering potent CDK inhibitors. Its lead chemical compound in oncology, a Cdk-4 inhibitor, has completed two phase I studies and is being tested in another phase I/II trial for multiple myeloma. “Our goal is to launch our lead product in oncology by 2013,” he adds. Trials for these compound are being conducted in India, the US, Canada, Australia and New Zealand.

Also, the Department of Biotechnology (DBT) and Piramal have begun phase II of their drug discovery public private partnership to find new drugs from 14,000 bioactive cultures discovered in a nationwide search of biodiverse habitats in collaboration with nine national institutes.

Dr Siva, as he is popularly known, is very passionate about this project. A total of 245,000 different microbes were collected and characterized at the national centers. Extracts from these microbes were screened for biological activities across four different therapeutic areas, namely cancer, diabetes, inflammation and infectious diseases.

Based on the results of these studies, the team identified more than 14,000 cultures that showed potent activities in the above disease conditions: 5000 extracts for anti-infective, 500 extracts for anti-cancer, 6000 for anti-diabetes and 2900 extracts with anti-inflammatory properties. All these cultures are in the process of classification and storage in a national repository created by the DBT at the National Center for Cell Science.

Dr Sivaramakrishnan has had an impressive career of more than 25 years in the industry. He has amassed a wealth of experience in process chemistry making international Drug Master File (DMF) dossier filings for regulated markets such as the US and Canada, has hands on experience in contract research and manufacturing services and in filing process patents of active pharmaceutical ingredients (APIs) and has also delved into medicinal chemistry and drug discovery work.

“I am part of a developing industry where, when I started my career, it was about doing what multinational companies asked for and now it is at a stage when the pharmaceutical industry in India is making its own drugs, patents and new processes,” he says.

Dr Sivaramkrishnan did his M Sc degree from St Xaviers College, Mumbai. After a three-year stint at Colour-Chem, he pursued a doctoral degree in synthetic organic chemistry from the University of New Brunswick, Canada. A post doctoral stint at the University of Pennsylvania, Philadelphia, followed where the first seeds of interest in development chemistry was sown within him.

Dr Sivaramakrsihnan returned to India in 1984 to join Searle India (now RPG Life Sciences) where he met his mentor Dr K Nagarajan. Dr Nagarajan, a reputed organic chemist, was then the director of research at the company. For four years, Dr Sivaramakrishnan worked in pharmaceuticals and agrochemicals before moving back to Canada to pursue his post doctoral in synthetic chemistry from the Universite de Montreal.

His desire to work in India brought him back to the country towards the end of 1991. He joined Bangalore Pharmaceutical and Research Laboratories (BPRL), then a young start-up. According to him, working at BPRL was his greatest learning experience. He had the opportunity to set up a research laboratory from scratch for both chemistry and pharmaceutical formulations. Together, they set up one of the best labs in Bangalore for API, pharmaceutical formulation and analytical research with pilot plants.

In 2000, the BPRL, rechristened as Recon in 1995, was hived off in two parts. The formulations part went to Zydus Cadila and the API business went to Hikal. Dr Sivaramakrishnan joined Hikal, where he continued his work on APIs and was involved in the filing of patents for one of the very large volume APIs, making dossiers for the US. He was also involved in setting up a plant that was later approved by the USFDA.

In 2003, Dr Sivaramakrishnan met Dr Somesh Sharma, MD, Piramal Life Sciences, and subsequently joined as its head of process research. Dr Sivaramakrishnan works closely with Piramal's collaborative projects with Eli Lilly and Merck. He is also

in the advisory committees of a few reputed colleges and government laboratories and is a recognized PhD guide for Mumbai and Mysore universities. Last year, he was admitted as a Fellow of the Royal Society Of Chemistry, UK.

Nayantara Som in Mumbai