

# Specialist expertise for fluorine-based APIs

**Jeffery Hinkle and Ashis Mukherjee of Navin Fluorine International Limited (NFIL) describe how this India-headquartered company has recently entered the contract research, development and manufacturing service sector offering fluorine-based capabilities for new chemical intermediates and APIs. The company recently commissioned a cGMP pilot plant and has also acquired UK-based Manchester Organics.**

In May of this year, Navin Fluorine International Limited (NFIL) acquired a controlling stake in UK-based chemical research company, Manchester Organics Limited to enhance its position as a speciality fluorochemicals business. The company says the acquisition consolidates its position in the contract research and custom manufacturing services (CRAMS) sector by strengthening its small-scale development and pilot/kilo-level capability. In recent years NFIL has been investing in building a strong research-driven business model including CRAMS out of its Surat and Dewas sites in India.

NFIL has a turnover of about \$100 million and is headquartered in Mumbai, India. The company is traded on the Indian National Stock Exchange (NSE) and Bombay Stock Exchange (BSE), and is a part of the Arvind Mafatlal Group. NFIL is more than 40 years old and has extensive expertise in fluorine chemistry. It has invested heavily in growing its business beyond its core area of speciality fluoro intermediates for life sciences with a state-of-the-art R&D centre opened in 2008, followed by the commissioning of a new pilot plant in 2009, and completion of a brand new multi-product/process plant for manufacturing in July 2010 in Surat.

## Growth in fluorochemicals and CRAMS

"NFIL was originally founded in 1967 to enter the fluorochemicals market for speciality chemicals from refrigerants to agriculture," explains Dr Jeff Hinkle, global head of business development, CRAMS.

"Initially the focus was primarily product-based and to back-integrate these all the way to fluorspar to build one of largest integrated fluorochemical complexes in India. However, the more recent expansion into the CRAMS space was determined to fill a niche for contract research and manufacturing services for highly potent fluorinated compounds for pharmaceutical and agricultural areas, and also now for the electronics and electrochemicals markets. The use of fluorine in designing effective molecules is well-known and growing worldwide, particularly because fluorine's halogen electronegativity, without the steric bulk of chlorine or bromine, enables the replacement of hydrogen by fluorine to change electrochemical interactions without adversely impacting steric binding.

"Growth has been sustained at a good pace, and is expected to continue at an even

better pace with the acquisition of Manchester Organics, the opening of the Dewas cGMP facilities in India, and traction with our CRAMS business.

The Dewas facilities were originally built to manufacture a few NFIL

fluorochemical products, but all non-cGMP activities were consolidated into the company's Surat location by 2009 and the site was freed and re-designated as the NFIL cGMP site catering primarily to pharmaceutical companies. Construction of the cGMP facilities started in 2010 and were completed in April 2011, with the official dedication on May 6, 2011.

"We have already had numerous enquiries from companies needing Phase 1-3 cGMP materials, and a potential to produce a fluorinated generic API for a third party that plans to market the product in India," says Hinkle. "The facility can be audited by clients at their convenience, and offers flexibility and multi-product handling capabilities, along with a good team of chemists and engineers. The facility is under the leadership of NFIL's quality control and assurance team."

## Synergies for new processes

So what was the thinking behind the acquisition of Manchester Organics? According to Dr Ashis Mukherjee, president, CRO and chief technology officer of NFIL, previously had good working relationships with the principals at Manchester Organics, helping the company when it was unable to complete larger-scale requirements for its clients:

"Leading up to and since the acquisition, we have found synergies in Manchester Organics' ability to help with development of newer processes on small scales, and then transferring that to India for the larger scale for more economic production," he says. "The objective is to help the client with a seamless transition from gram- to ton-scale needs, and also to enhance the fluorination capabilities of both sites. The combination gives Manchester Organics' clients access to lower-cost, larger-scale manufacturing and cGMP possibilities, and also gives NFIL's clients a Western laboratory for R&D activities



**NFIL has expanded its activities through acquisition and through the opening of a new cGMP pilot plant at its Dewas, India facility (pictured above).**

and interactions potentially in closer proximity, as well as access to a large number of catalogued chemicals available from the UK. Overall, it helps with our global approach."

### Approaches to solving challenges

To solve a challenge for a client, NFIL can approach the project in two different ways, one being an FTE (full time equivalent) basis, where a dedicated team from one to five or more chemists solves a synthetic challenge, improves a process, or provides dedicated resources to meet the requirements. The other approach is FFS (fee for service), where NFIL evaluates the chemistry, determines the best synthetic approach, estimates the raw material requirements, and provides a quotation to the client.

"From either type of project, we would provide regular, generally weekly, project updates by conference call, and deliver to the milestones required," says Hinkle. "With our new Manchester Organics combination, we can say yes to more projects managing the capabilities, capacities and expertise between the locations. Our scale-up expertise and both non-cGMP and cGMP infrastructure can be quoted similarly, and are now available to take up projects emerging out of NFIL contract research activities, as well as Manchester Organics' client needs.

"Certainly, one of our most basic differentiators is the fact that we are back-integrated into the production of our own sulfuric acid, and HF from fluorspar. We have well-diversified and secured global sourcing for fluorspar that is not dependent on any one country or source. With the growing infrastructure, size and financial support of the company, we believe we can offer extremely responsive and economical service and support to our clients. In addition, we have staff with more than 30 years' experience handling hazardous fluorination chemistry safely and efficiently," he adds.

"Although fluorination chemistry is one of our biggest niches as the largest HF producer in India and globally the largest BF<sub>3</sub> producer, we have successfully leveraged that into an extensive portfolio of fluorinating agents, chemistries and intermediates, and we now have considerable expertise beyond fluorination.

"As you might imagine, complicated projects involve many steps with numerous chemistry expertises required either before or after the fluorination step. We can strategise to conduct the fluorination step where the chemistry makes the most sense, and provide the best efficiency and economy. Based on success with clients, we have moved to projects that don't even involve any

fluorination – in fact, we are one of India's largest consumers of bromine and chlorine as well. Aromatic and heterocyclic chemistries are also among our strongest areas.

"We believe NFIL is unique in many ways: NFIL has more than 40 years of experience in fluorination and related areas of manufacturing; is one of the largest in its area of expertise, but is not restricted only to fluorination chemistry; has a willingness to grow through partnerships; has a global mindset and business approach while bringing the advantages of being located in a cost-effective country for service and manufacturing; and provides an opportunity for our clients as a key strategic partner and collaborator.

"As a result of this, in spite of the challenging economy, NFIL has been growing and continuing to invest for the future and for the long run," Hinkle concludes.

### Further information

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## Meet Jeff Hinkle and Ashis Mukherjee of NFIL



**Dr Jeffery Hinkle**



**Dr Ashis Mukherjee**

Dr Jeffery Hinkle is global head of business development for the CRAMS division of Navin Fluorine International Ltd. His responsibilities include marketing and business development for NFIL's contract research services, custom synthesis capabilities, and contract manufacturing (both cGMP and non-GMP), with a current focus on the USA and Europe. Dr Hinkle assumed his current position in 2009 following a successful tenure as senior director in the Research Planning and Integration (RPI) group of Merck Research Laboratories in Rahway, New Jersey, USA, where he was responsible for the creation and optimisation of global basic- and preclinical-development strategic sourcing/partnering efforts, for development of a partner-

relationship management system, and for serving as Merck's partner relationship executive for several strategic external partners.

Dr Hinkle has more than 20 years of experience in business development, business management, technical leadership, and business process optimisation, including international business and marketing development positions of increasing responsibility with Degussa (now Evonik Industries), as well as his experience at Merck Research Laboratories. He is a graduate of Ursinus College in Collegeville, Pennsylvania, USA, with a Bachelor of Science Degree in Chemistry, and holds a PhD in Organic Chemistry from Princeton University and an

MBA with a dual major in Marketing and International Business from the Rutgers University School of Business.

Dr Ashis Mukherjee is head of R&D, CRAMS at NFIL. In 1994, he returned to India from completing postgraduate research at The Rockefeller University in the USA to begin a career with Ranbaxy, initially working in drug discovery. He later had responsibility for the company's full R&D programme in several therapeutic areas. Following Ranbaxy, he became one of the key founders of Chembiotech, one of the first contract research organisations based in Calcutta, India. He later entered the CRAMS sector with a move to Shasun Chemicals and Drugs Limited, followed by a period at PI Industries Limited where he was chief technology officer and president of the company's Fine Chemical Division. Following PI Industries, he joined NFIL as the company's president, CRO and chief technology officer. Dr Mukherjee holds a BS in Chemistry from the University of Delhi; an MS in Chemistry and an MTech in Chemical Analysis from the Indian Institute of Technology; and a PhD in Organic Chemistry from the State University of New York, which was followed by his postgraduate research.