

Best of both worlds

Being based in India is no bar to competing in the US, according to **Piramal Pharma Solutions**

Piramal Pharma Solutions (PPS) comprises three main businesses: API Services, Formulation Services and Generics. It is one of four main business units within Piramal Healthcare, which is itself the larger of the two component parts of Piramal Enterprises, a giant Indian company with a market capitalisation of about \$2.5 billion

The other main businesses within Piramal Healthcare are: an India-based over-the-counter drugs unit; Decision Resources Group, a US-based healthcare analytics provider; Piramal Critical Care (PCC), also US-based and in inhalation anaesthetics; and, a former Bayer diagnostics business in Germany. PCC was headed for four years by Vivek Sharma, who took over PPS in 2014 and is now seeking to drive further growth.

Sharma, who has a background in operations and was formerly managing director of the Boston-based private equity firm PHC Partners, describes PPS as “an end-to-end solution provider”, centred on its core capabilities in chemistry, supplemented by others that have come through acquisition in Europe, Canada and the US over the past decade.

What ‘end-to-end’ means is that in the development of APIs and formulations, PPS goes the whole way from drug discovery, where it offers medicinal chemistry and select biology services for pre-clinical research through Phase I-III development and ultimately on to commercial-scale manufacture and life-cycle management as a drug nears the end of its patent life.

The latter, Sharma remarks, is increasingly of interest to Big Pharma companies. “We are truly global in every way.” The company has US and European assets but can also bring the cost advantages of larger-scale manufacturing in India to the biotechs as well as Big Pharma companies.

Until recently, Piramal’s only North American presence in APIs had been through a Canadian site near Toronto, which offers GMP development and manufacturing of low volume, high value APIs. Earlier this year, though, it acquired its first US site, the former Coldstream Laboratories in Kentucky, which brought commercial-scale sterile injectable manufacturing into its global palette.

The Toronto site came to Piramal in 2005 along with some other former Avecia sites, which also included Grangemouth, UK, a site now largely dedicated to ADC conjugation; a third has since closed. A former Pfizer site at Morpeth, UK, was acquired in 2010 and carries out formulation development and commercial manufacture of both APIs and formulations.

Bulk manufacture of APIs and formulations takes place at sites in India. The flagship site at Digwal, near Hyderabad, makes GMP APIs. Ennore, near Chennai, makes key and registered



Piramal’s site near Toronto is mainly early phase development



starting materials to ‘pseudo-GMP’ standards, while others at Ahmedabad and Pithanpur, in the West and North of India respectively, carry out formulation at development and commercial scale respectively.

“Customers can get the best of both worlds – Western standards and Indian costs,” says Dr Ramesh Subramanian, who joined PPS in January as VP of strategic marketing. “For instance, we could do the first two to four steps of a project Ennore, then move it Canada. There are several projects that have followed this path already.”

Subramanian says that PPS focuses on customer mix and product mix. “Biotech companies, who may have only one molecule, typically seek proximity to the supplier, so they are a big target segment for our Canadian site. Big Pharma companies are likelier to be more comfortable with India as a location, as they work on multiple projects, with cost being a driver for them, assuming, of course, that you are reliable and can deliver.”

In terms of product mix, the company differentiates itself by the chemistries it offers. For instance, the Canadian site has performed some very challenging chemistries – in one recent example it was able to perform a very difficult chemistry that eluded others, leading to a \$1 million+ opportunity.

PPS continues to invest in innovation and differentiating offerings. Via Ennore, it also offers relatively unusual ozonolysis capabilities. Biocatalysis is a more general capability. PPS also seeks to incorporate the concept of Green Chemistry into all that it does. Recently, it invested in some Advanced Flow Reactor systems by Corning to integrate flow chemistry into its mix.

“Quality by Design is big for us and will become more and more important,” Subramanian says. The company has now appointed a head of QbD, in India, with the aim of looking at every process holistically. “People want not only robust processes but also to be able to identify scalability problems early.”

Sharma stresses three more ‘soft’ USPs: quality – PPS’s track record on inspections is very solid,

with no observations of any kind during the three FDA audits it has seen in the last few months; regulatory capabilities, which it sees as a key asset in getting customers’ products to market; and, customer-sensitivity.

“We are very open and nimble in our approach,” he says. “I do not think, as the CEO, that I am above all that – we all, as a team, get involved in ensuring that customers get the right level of attention.”

PPS is also looking at other business areas outside pharma where its core competencies of chemistry, regulatory knowledge and scale-up expertise could assist clients. Flavours and fragrances, plus agro, are two such potential areas and PPS is in discussion with a major flavours and fragrances house on development projects.

The pharma industry’s definition of what is ‘core’ is constantly shifting, Subramanian notes. For example, in the past, biology discovery was never outsourced, now CROs have major expertise in it. As this process plays out, Piramal will continue to look for more capabilities, with high potency APIs – which it currently lacks – and expanding fill-finish capacity high on the list. “If we could add these to ADCs it would be a very nice capability set,” he says.

In past press conferences at CPhI, PPS has been bullish about its aim of becoming a top five player in contract manufacturing of APIs. It is nowhere near that goal yet, Sharma admits, “but we do have aspirations to being a major player”. Organic growth clearly cannot achieve that alone and further acquisitions will be a major part of the mix. “We are aggressively looking for opportunities. We are agnostic as to the location, but it has to add the right value.”

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