

Roger Viney, Global Head of Generic Sales, Hovione

I interviewed Hovione's Global Head of Generic Sales Roger Viney at the recent CPhI Worldwide; my aim being to find out what makes the company stand out from the crowd. Roger explained how Hovione's 50 years of serving the pharmaceutical industry has forged a company with, in his words: "a unique culture and offering".

Elizabeth Valero, Editor.



ABOVE: Spray drying building, Cork plant.
LEFT: Roger Viney.

Tell me a bit about your background and how you came to be working for Hovione?

After completing my Ph.D., I worked as a technical manager in the performance polymer industry. I soon realised that it was the business side that motivated me and for the past 12 years I have had an international career working in the fine chemical industry, where I have held positions in sales, key account management, marketing and business management. For the last seven years, I have been focused on the pharmaceutical market. I wanted to work for the best company in my area, so I came to Hovione.

Can you describe the Hovione ethos?

We are totally obsessive about providing our customers with the best products and services. Everyone in the company, from production operators to the finance director, can tell you our *raison d'être* (reason for existence) is 'to collaborate with our customers to make great medicines'. The company has a very strong set of values. We are very principled in our approach, which drives our quality and safety culture, we are always searching for innovative solutions to problems and we deliver on the commitments we make to our customers.

How is Hovione performing in this difficult business climate?

We are doing very well; last year our sales grew by 14%. There was strong demand for all our products and services. Our generics API sales are very robust, driven by growth in Asia and in particular Japan. Our custom manufacturing business has a very strong pipeline of projects both in the area of API synthesis and particle engineering. We are also seeing a great deal of interest in our integrated inhalation drug product development services.

Tell me more about Hovione's generic contrast media expansion in China and the benefits for customers. Our customers asked us to provide them with the security of

buying API from a supplier they really trust, but at a price that gives them a competitive edge. So, in 2008 Hovione bought 75% of x-ray contrast media manufacturer Hisyn and formed a joint venture based in Taizhou, China. Hovione has been manufacturing contrast agents since the 1990s at its site in Portugal and this investment was the latest step in our strategy to be the leading generic manufacturer of contrast agent API. Hovione already has over 25 years of manufacturing experience in China, so we were able to seamlessly integrate Hisyn into the Hovione group. Today, Hisyn's main products are the x-ray contrast agents iohexol and iopamidol.

Contrast media are administered intravenously in large volumes, therefore quality is of the utmost importance. Hisyn operates to the same high quality and compliance standards that have made Hovione an industry standard in these areas. Manufacture of contrast agents is a complicated process and control of impurity profile and endotoxin levels are critical. Hisyn supplies the rapidly growing local market and is exporting API to the most demanding markets in the world. Hisyn boasts an enviable record in developing its product range. Over the last year, the x-ray contrast agent iodixanol has been commercialised. We have recently also started to offer the MRI contrast agent gadopentetate dimeglumine.

What differentiates Hovione from competitors with regards to its custom synthesis of APIs?

We offer a wide range of chemistry capabilities, but we believe that offering chemistry alone is not sufficient. Hovione has positioned itself to manage the lifecycle of an API according to our customers' needs. We are able to do this by virtue of our assets and our methodologies. We have assets in the US, Europe and China, which allow us to site our customers projects where they feel most comfortable and where the cost of goods matches their expectations. Our quality systems are the same across all manufacturing assets and we are experts in transferring production between sites as the needs of our customers dictate.

Even more important is our approach of Excellence in Development and Manufacturing. This represents our structured and integrated use of methodologies such as Quality by Design, Britest, Lean Manufacturing and Six Sigma to improve chemical processes at all stages of the API lifecycle. This allows Hovione to make process development fast and reproducible, anticipating problems in scale-up. We are able to maintain full but flexible cGMP compliance during all the development steps. Finally, Hovione can provide continuous improvements in manufacturing costs, quality and HSE throughout the lifetime of the API.

What new technologies does Hovione have to offer in particle engineering?

As a result of Hovione's background in manufacturing corticosteroids for inhalation, we were very aware of the limitations of jet milling to produce the correct particle size distributions for inhaled APIs. Jet milling is a high-energy, size-reduction technology and it can produce material with a significant amorphous content, which in turn can influence the stability of the finished formulation. Jet milling is an inefficient process that can lead to reproducibility problems and creates the potential for metal contamination from the milling machine.

We have developed a novel and proprietary process based on combining homogeneous fluidization with drying. This is a relatively low energy technique that gives consistent crystal shape and size within the inhalation target range of 1-5mm. After particle size reduction the powder is isolated by specialized drying. This process offers efficient drying conditions that only expose the product to mild temperatures for a very short time. The resulting API has a reproducible and narrow PSD and a stable 100% crystalline form. The process is flexible and can produce a particle size distribution exactly matched to specific formulation requirements.

We have used this technology successfully for our generics APIs like fluticasone propionate, and we are also offering this



ABOVE LEFT: Bottom of drying chamber.
ABOVE: Manufacturing in cleanroom.
BELOW: Cleanroom glove box.

technology as a part of our custom manufacturing portfolio for new compounds.

You must be very proud of Hovione's part in the launch of Inavir — can you tell me about it?

Yes, we are very proud of this achievement as it is the culmination of 15 years of work at Hovione. Inavir is a drug for the treatment of influenza that has just been launched in Japan. It is an inhalation powder delivered by the TwinCaps inhaler, which was designed by Hovione and licensed to Daiichi Sankyo and Biota Holding Ltd.

TwinCaps is a beautifully simple pre-filled device that patients find very easy to understand and to use. Its design allows both young and old patients with limited lung capacity to easily inhale the full dose. Its simplicity allows for a low production cost and the device is disposable after one use, which is important for communicable diseases. Hovione is continuing its development of dry powder inhalers and has just patented a product named X-Caps. This device is based on the same design principles as TwinCaps, but is capsule-based and can be re-used.

What does the future look like for Hovione?

I think it looks very exciting. We are a privately-owned company with a long term view. We will develop to meet the ever-changing needs of our customers. However, we believe that quality, compliance and technical excellence will always be the foundations of successful business relationships in the pharmaceutical industry.

Hovione will continue to look for the interfaces where our competencies can be brought together to supply differentiated products and services that solve our customers' most difficult problems. In the future we will be expanding our capabilities into sterile processing. I expect we will also be in a position to offer more formulated generic products rather than just APIs.

Web links:

Particle Design Services:
www.hovione.com/particle/services.asp

Innovation and Expertise in Inhalation Technologies:
www.hovione.com/inhalation/innovation.asp



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