Interview: Dr. Paul Downing – General Manager, Hovione, Ireland



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Dr. Paul Downing, General Manager of Hovione's manufacturing plant in Cork, outlines the successes of the past few years, his emphasis on staff development and training, the CDMO's advantages of agility and responsiveness, Ireland's value proposition for the pharma manufacturing industry, and his vision for the next few years.

Can you provide an overview of this Hovione facility in Cork?

For context, Hovione is a family-owned, independent Contract Development and Manufacturing Organization (CDMO). This plant is one of the oldest in the region and Hovione acquired it from Pfizer in 2009. Since then, we have made significant capacity and infrastructure investment and we are proud to be able to offer our clients a comprehensive range of equipment and services.

Currently, we have two API production buildings. The one in full operation has just in excess of 300m^3 reactor capacity, from 2.5m^3 to 16m^3, i.e. across the small to large spectrum. It caters for every material of construction: stainless steel, glass, and a range of conditions: high and low temperatures, high pressure, pyrophoric agents, chlorinated agents, etc. The second building, with 150m^3 of reactor capacity, is being planned for recommissioning.

Our newest facility is Building 10, which manufactures drug-product intermediates, typically active ingredients with a solvent and/or an excipient that requires a very specific particle size. This is where we spray-dry solid dispersion products. Most notably, this building houses the largest

commercial spray-dryer in the pharmaceutical industry! Particle engineering is actually one of Hovione's key selling points; we offer full support to a number of customers in terms of R&D, commercial development and supply chain.

We boast a fully-serviced tank farm, utilities and infrastructure. We also have a fully operational waste-water treatment plant, so nearly all of our waste is treated onsite.

Since I joined in 2014, as a local operation, we have doubled our output and increased the complexity of our operations significantly. We have also passed at least 20 regulatory and client audits. This expansion has also led us to create at least 40 new jobs here. In terms of the group, we are achieving – and even exceeding – our corporate targets, so overall I am very pleased with our performance.

What was the secret to this success?

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Crucially, as the company grows – Hovione itself has almost doubled in the last 5 years – we have to ensure that we stay loyal to our values. We are very good at what we do and we intend to stay at the top of our field.

Our values are about commitment to patients. We are very privileged to be able to work in this industry, where we make products that save lives. This is something we really emphasize to our staff: our products and drugs serve the world. For instance, we educate our staff on the therapeutic areas represented in this facility, bearing in mind confidentiality issues. We conduct safety and quality days, and also awareness sessions where we bring real patients on site to show our employees the true impact of what they are doing.

We also believe in engaging and empowering our staff. An organization like ours requires fast, high-quality decision-making. This means that we need to provide frameworks, structures and business processes that empower our staff to take the right decisions while keeping them accountable. This is completely different from having hierarchies, multiple layers of committees and presentations. In this way, we will differentiate ourselves locally with the diversity, agility and dynamism of our team.

Another key differentiator is that as a CDMO, we are not only audited constantly by regulatory authorities – the Irish Health Products Regulatory Authority (HPRA), the Americans with FDA and other international agencies – but also by our clients on due diligence, HSE, GMP or regular surveillance visits. We are therefore always audit-ready, which means we continuously invest in

and maintain this facility to the highest standards. For instance, since 1982, the Company has had 30 FDA inspections and have never received a warning letter, let alone failed one. That is an impressive record.

How do you attract talent to this site?

When we look for staff, we look for that personal commitment. As I said, it is all about mentality. From an operational perspective, the heart and soul of the facility is the people, so we need our people to align with the company vision. Currently, we have 175 people on site representing 17 different nationalities, with an average age profile of about 40. This is a young and dynamic site.

The most attractive thing about Hovione is that, because we have multiple clients and products, the product lifecycle is much faster than in other Companies. It is very fast-paced here, which means people can learn a lot very quickly. There are opportunities for people to work in many different disciplines and be exposed to different experiences.

We use our proximity to top academic institutes like University College Cork and Cork Institute of Technology to partner and bring in graduates either straight from university or those with initial levels of experience, on student placements, balanced of course with more experienced hires. We also make sure to have excellent training and development programs to give our employees opportunities for continuous personal and professional development.

Looking more broadly, we see that the pharmaceutical manufacturing industry globally is facing some new trends like continuous manufacturing. How do you see this site evolving against the industry's changing needs?

Continuous manufacturing is a very hot topic now and we see it becoming more mature in Ireland, especially as these trends are very US-led and US companies have executed significant Foreign Direct Investment into Ireland.

This site here per se will not be the most obvious fit as new technologies are typically tried and tested by the R&D functions, but it is very important that we keep abreast of these industry developments. There is a lot happening in Ireland on this, as a global manufacturing hub, so we do attend presentations and tap into local networks of expertise to keep up with the conversation.

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Hovione is investing in continuous manufacturing on two fronts. Two years ago we created a dedicated R&D team with the goal of bringing into the company the latest knowledge in the field

and applying them to solve problems for our customers. In March 2016, Hovione partnered with one of its customers to install a full-scale drug product continuous manufacturing facility on its New Jersey site.

Looking at the pharma industry through the lens of the innovator model, pharmaceutical companies manufacture the innovative products whilst on-patent, while the CMOs support or make generic versions when off-patent. However, increasingly, Big Pharma is restructuring to move to a more agile, responsive model. In Ireland, this has been taking place over the past decade.

This is where I think we are ahead of the curve as we are not trying to force-fit a big organisation into a smaller, more agile one. There are habits that will be very hard to break: all the layers of decision-making and committees. At Hovione, if something does not work, we simply fix it. We do not shift it up the management chain. In this respect, I think we are still a few years ahead of our contemporaries.

Ireland is considered a global manufacturing hub now. How would you describe Ireland's value proposition?

A few decades ago, quite a few countries decided to make the pharmaceutical industry an area of strategic national investment – Switzerland, Puerto Rico, Singapore, Ireland – offering similar incentives within the same time frame. The big players speculated in all markets. Ireland has established itself as a global manufacturing hub because of a number of strong advantages.

We can guarantee that we can provide products in safe operations and commit to delivering products on time, every time, at a competitive cost. This reliability and confidence extend to all aspects of the production chain: health and safety, environment, quality assurance (QA), GMP and sustainability.

There have been ups and downs in the industry, which is inevitable. But the long history of manufacturing here, extending along the value chain from corporate centers to facilities to even newer technology developments means that there is an industrial ecosystem that is deeply embedded here. For instance, so many of the industry players are based here that if a company wants to audit us, they can choose to either send someone in from HQ or from the Irish team who would already be familiar with the site and the sector here.

There is also a significant spirit of collaboration. Compared to other countries I have worked in, the industry here shares non-competitive knowledge much more openly, thanks to the platform that BioPharmaChem Ireland, the Irish pharma industry association, has created. I know that if I

encounter a problem, I can pick up the phone and call a colleague from a different facility and ask for help – *and vice versa.*

Finally, there are also very strong academic institutions here. You are never more than a couple of hours' away from an expert in the field.

Where do you see Hovione Ireland in the next few years?

I see huge potential for further growth. There will be increased competition locally and globally, which will enlarge our competitive space, but I trust in our ability to meet that challenge.

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