Interview: James Byrne – VP Site, Ipsen Manufacturing Ireland

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James Byrne, VP Site for Ipsen Manufacturing Ireland, discusses the strategic importance of the Ireland site as the sole provider of peptides for products generating over 50 percent of Ipsen's global revenues; his strategy for attracting and retaining the best talent; and his thoughts on the impact of new manufacturing trends on Ipsen Manufacturing Ireland.

Can you provide an overview of the strategic significance of this manufacturing facility for Ipsen's global operations?

The Ipsen Group operates in 115 countries, with seven industrial sites and three major R&D centers located in China, France, Ireland, the United Kingdom and the United States.

The Dublin site, opened in 1989, is the Group's center for the production and development of peptide active pharmaceutical ingredients (APIs). The site currently produces the APIs for both Somatuline® (lanreotide) and Decapeptyl® (triptorelin). As well as peptide API production and development, Ipsen in Dublin also has responsibility for the development of small molecule APIs and analytical development.

This is thus one of Ipsen's key manufacturing facilities globally. Sales from these two products amounted to over EUR 700 million in 2015, which is over half of Ipsen's global revenues of EUR 1.4 billion in 2015. That is very significant and this places the onus on us to ensure that our manufacturing process is reliable and the facility is very robust.

Furthermore, sales of Somatuline® have been growing rapidly: more than 30 percent in 2015 and close to 40 percent in H1 2016. This places a significant strain on our manufacturing – but it is a very nice challenge to have! To respond, we have had to ramp up production significantly by adding shifts and recruiting extra people to improve our productivity significantly and create additional capacity in the short term.

At the same time – and in anticipation of future growth – we are currently investing a significant amount to expand the facility. This involves a number of capital projects, which are in different phases of design, construction and qualification. We are looking to both add capacity and improve existing technology. For instance, we have increased the level of automation significantly. Being a sole-source producer, we try as much as possible to minimize all risks that can impact our manufacturing. This site currently has one of the best risk rating from FM Global, which means we are a highly protected site and all of our designs consider risk minimization and mitigation very closely.

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Finally, we have a large Chemical Development Group on site employing over 25 people. They not only support commercial manufacturing but also work on developing new peptides and small molecules. The Development group work closely with our Research colleagues; Ipsen's research facilities are based in global research clusters like Cambridge in the US, Oxford in the UK, and Les Ulis in France. From a commercial manufacturing point of view, it is great to have this expertise on site because even though we have been manufacturing these peptide APIs for the past 25 years, it is very helpful to draw on the deep expertise of our Development colleagues. The Development group on site are currently working on several peptides at various stages of Clinical Development and we hope they will be successful in the clinic and go into production in the next few years on-site.

You mentioned that recruitment is a challenge, and other manufacturing facilities have discussed this gap in supply and demand. How is Ipsen responding to this?

One of the top challenges for us in the past couple of years has been recruiting and retaining talent. We have done very well so far through dedicated and focused effort. There is still a gap in supply and demand especially in key areas like Quality and Process Engineering. Being located in West Dublin, we are part of a rapidly expanding Bio Pharma cluster, so it can be easy sometimes for people to move to different companies since they do not even have to relocate! Fortunately it works both ways and overall, being part of a cluster has huge benefits for Ipsen in terms of

expertise and knowhow.

Fundamentally, we want to not only be the best but also make Ipsen a great place to work. For us, this means being focused on developing people: giving them opportunities for development, empowering them, and creating the right culture and environment. We are a flat organization, which means that we give our staff a lot of responsibility. As a mid-sized pharmaceutical company, we are also more flexible and able to provide our people with a large variety of work and opportunities. There is a lot of internal career mobility: for instance, someone in production can move to quality assurance (QA) or quality control (QC), and then perhaps on to our Development group.

With just over a hundred people, we are also small enough to know everyone and as a company, we support and organize numerous social and team events throughout the year.

We invest significantly in training at all levels of the organization: professional, management and leadership, partnering with organizations like the Irish Management Institute (IMI). Our manufacturing process is complex and we really value the expertise of our employees so we really believe in investing in keeping them.

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Even if we are focused on excellence in delivery, results and key performance indicators, we have been adopting a more holistic approach to focus now more than ever on people and people development.

There are many new trends and ‘hot topics’ in the manufacturing industry, most notably with the discussion on continuous manufacturing and 3-D printing. How is Ipsen Ireland responding to this?

Peptide manufacturing definitely lends itself to some of these new technology developments. Our chemical Development group has started to look at continuous manufacturing for our Peptide manufacturing process; last year, for instance, they invested in some new equipment to explore this avenue. Based on early results, we can definitely see more opportunities for peptide manufacturing using this approach.

One of the big challenges for our manufacturing is the handling of Potent Compounds. Our products tend to be very potent – for instance, Triptorelin (for our Decapeptyl® product) has an occupational exposure limit (OEL) of 50 nanograms/m^3. This means we need very specialized containment equipment to safely handle the API. In the last number of years, we have invested significantly in

our manufacturing and laboratories areas to ensure the safe handling of our products using only engineering controls.

Automation aims to upgrade existing technology where necessary. We have just completed a review of all our Manufacturing Information systems and are just finalizing a roadmap for the next couple of years to help transform our Manufacturing Information systems. As part of this project, we also discussed the use of 3D printing onsite as our Development Colleagues in France are already using 3D printers to develop new injection devices for our key products, which could be of great value for our patients. Maybe in the future we will find uses for 3D printing in our facility here as well.

Another aspect where technology can really help us with is in terms of compliance and investigation, critically in ensuring that we collect and maintain all the necessary data and records. In many cases, this is not only required for compliance but also invaluable for investigations and process improvement.

As a company, we are focusing on the effective use of technology to complement our work and bring additional value. There has been a push to digitalize as much as possible and I do think in some cases we need to question this impulse. For instance at this facility, we use a lot of visual management, which is very interactive and hands-on. This could be digitized but we would lose a lot of the human interaction in that case.

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What is your vision for Ipsen Ireland in the upcoming few years?

Globally, Ipsen is going through a huge transformation to reach its long-term vision of being one of the top-10 pharmaceutical companies by 2020 in terms of growth rate and profitability. Our Technical Operations division, of which we are a part, has launched a transformation program, ‘Enterprise Excellence’, to help us achieve our ambition of best in class.

As part of Technical Operations, we have set ourselves some ambitious targets to achieve: zero lost time accidents, 100 percent staff engagement, zero waste, 100 percent ‘right first time’ and 100 percent customer satisfaction.

At Ipsen Manufacturing Ireland Ltd., several years prior to the launch of ‘Enterprise Excellence’, we had started our transformation with the introduction of ‘operational excellence’, which focused on the training of a small population of people in the tools and implementation of projects to achieve improvements. Enterprise Excellence, on the other hand, is dedicated to improvement as an organization through the change in mindsets and behaviors.

I am in my tenth year at Ipsen and during that period, we have more than doubled our production output. This site has really been transformed in terms of the facilities, equipment and automation through significant capital investment. Furthermore, during that time, we have also transformed the culture – continuous improvement, collaboration, staff engagement and empowerment as well as a strong customer focus are all now more prevalent and important than ever before.

In terms of transformation, we have already enjoyed a lot of success, improving yields by over 30 percent through continuous improvement, increasing ‘right first time’ by over 100 percent and achieving ‘best in class’ safety performance.

For the next few years, I want to continue to grow our business here. With so much expertise and a track record of excellence, I think this site is a great selling point for both Ipsen and Ireland itself. In terms of production, we look forward to meeting the challenge of increased sales of Somatuline®. In the longer term, we are also excited about the prospect of manufacturing onsite the new peptides that are currently in development.

The way we will achieve this is very simple: by constantly striving to be the best.

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