Interview: Alan MacNeice – Executive Director & Site Leader, Jazz Pharmaceuticals, Ireland



As Jazz Pharmaceuticals' first directly-owned, managed and operated facility, this is a huge milestone for us. It is a crucial step in the creation of a global infrastructure to support our operations

16.09.2016

Tags: Ireland, Manufacturing, Jazz

Alan MacNeice, Executive Director and Site Leader at Jazz Pharmaceuticals, highlights the strategic importance of the Athlone site as the company's first purpose-built, directly owned, managed and operated manufacturing facility; the special design of the facility catering to Jazz Pharmaceuticals business model; the importance of their human resource (HR) activities and company culture; and the strengths of the broader Irish pharmaceutical landscape.

Jazz Pharmaceuticals' Athlone manufacturing facility in County Roscommon is its first purpose-built facility. Can you provide a strategic overview of this new facility?

As Jazz Pharmaceuticals' first directly-owned, managed and operated facility, this is a huge milestone for us. It is a crucial step in the creation of a global infrastructure to support our operations, giving us the ability to more closely oversee and control the process of bringing high-quality products to patients.

This was deemed necessary because of our identity as an international biopharmaceutical company with a focus on patients with unmet medical needs. Our mission is to improve patients' lives by identifying, developing and commercializing meaningful products, with a special emphasis on debilitating and life-threatening conditions. Often, our products are the only approved treatment for a particular condition, which means that we absolutely need to have a reliable supply chain and the strongest possible control over our manufacturing processes. Nobody loves your product more

than yourself, so bringing them in-house gives us a far greater degree of control, oversight and security than doing it secondhand through contract manufacturers.

This is a fully integrated manufacturing site, including standard facilities, packaging and warehousing, along with the usual support functions like quality assurance (QA), materials, engineering and management. Currently, we are manufacturing the oral solution, Xyrem® (sodium oxybate) for the treatment of narcolepsy. We also have some support activities for our clinical development portfolio.

I joined Jazz Pharmaceuticals in 2013, when the Company had decided that it needed greater control over certain elements of our supply chain for some critical products, which means we wanted to manufacture them in-house. Ireland had already been selected as the country and my first task was to identify a suitable location. Subsequently, I managed the design and construction of the facility, the ‘start-up’ and now I oversee its operations.

Why was Ireland, and specifically Athlone, selected as the site for such a significant facility for Jazz Pharmaceuticals?

[Featured_in]

Firstly, the company had then recently become an Irish company following its merger with Azur Pharma, so it was a sensible decision that would keep the organization structure simple.

More importantly, however, I honestly believe that Ireland is among the best locations in the world for pharmaceutical manufacturing. There is a long tradition and therefore robust track record of manufacturing excellence here, there is a significant talent pool from which we can draw, and Ireland has one of the most highly regarded Competent Authorities in the world, which works to our advantage. Ireland is not only diligently regulated but among the best-performing in the world when it comes to compliance and quality in the pharmaceutical manufacturing industry. Combine this legacy with the fact that it is very easy to do business in Ireland, because there is so much state agency support and it is easy to develop a collaborative relationship with them, and the choice of Ireland seems obvious.

Athlone itself also has a robust history of pharmaceutical manufacture and development. This was largely built through Elan Pharmaceuticals, which came here 40 years ago, and now there is a biopharma cluster here, with companies such as Jazz Pharmaceuticals, Alkermes, Alexion, Bioclin, PPD and Athlone Laboratories. This also meant that there was an existing talent pool available, which is another key criterion. There were a number of other advantages as well. We were able to

obtain a large site here, which gave us a lot of flexibility for long-term development regarding the sort of operations we could build on-site. The site was also owned by Roscommon County Council, which were amenable to working with a pharmaceutical company, so negotiations with them were efficient.

Our successful development in the past two to three years has proven that we made the right choice. We are among the fastest greenfield start-ups in Ireland, if not in the world, and we have delivered this facility with great value for money.

Jazz Pharmaceuticals' growth strategy has a strong emphasis on corporate development, for instance, most recently with Celator Pharmaceuticals in 2016 and before that, Gentium. As a manufacturing facility, how do you respond to these commercial developments?

Our growth strategy is centered on innovation and diversification, and we achieve this through a combination of in-house R&D and strategic corporate development, including acquisitions of and investments in meaningful and differentiated products. What is also unusual about Jazz Pharmaceuticals is that we have significant scientific and technological diversity within our product portfolio, for instance, with small molecules like Xyrem® (sodium oxybate), larger molecules like Erwinase® (asparaginase Erwinia chrysanthemi) and Defitelio® (defibrotide sodium), and peptides like Prialt® (zincontotide), which fall somewhere in between. We do not rely on just one scientific platform.

The paramount concern was to align our facility with the overall company strategy and business model. It became evident that to be a manufacturing support for the organization, we needed an agile team and facility that could operate across multiple technological and scientific platforms quickly and easily.

[related_story]

First, we conceived the site to be very flexible, based on a modular layout to allow us to add on multiple suites on a small scale. Then we did the same with the workforce: we profiled the kind of people we want to hire, which were people who have shown a propensity to learn beyond their initial education and a willingness to change, and ideally had experience of multiple technologies. We have nearly all pharmaceutical technologies represented within our relatively small team on-site. It was not just about whether they have experience in our current projects but the scope of their experience and whether they have other competencies. Now, we have people with experience in biotech, vaccines, medical devices, etc., so our workforce is very multifaceted.

Our guiding vision for this facility was to build a high-performing, knowledgeable and agile team, offering manufacturing solutions to the organization.

Was there a challenge to recruit for this facility as a relatively small company in Athlone, away from the traditional centers of Dublin and Cork?

One of the benefits of this location was the availability of talent around us due to the history of pharmaceutical manufacturing in this area. It is also an easy area to convince people to relocate to, particularly for those with more than five to ten years of experience who are more family-oriented. There is great quality of life here: it is less congested than Dublin and Cork, property prices are lower, and there are great education facilities for children.

As a smaller company, recruitment is actually easier, because we only need one person for each role. We do not need to find 40 or 50 experts in a specific area.

Company culture is critical to Jazz Pharmaceuticals. We profile the kind of people we want not just to fit our business model but also our work culture. The other piece of the puzzle is in retention, and we invest enormously in this. We want to fundamentally align our team to our overarching goals and ensure that they understand our values as a company. For instance, we have an annual group exercise to understand everyone’s work behaviors to reduce potential friction and increase efficiency. We then set behavioral ground rules to guide our working habits as a team. Only then do we begin planning execution and after that, we are very disciplined about executing our plan. It is not just a question of building a team, but maintaining it.

Going back to the point on the diligence of the Irish regulatory agency, with the Health Products Regulatory Authority (HPRA) having been described as one of the strictest pharma regulator in the world, would you consider that an asset or a burden?

The HPRA is undoubtedly a huge asset, not because they are just diligent, but because they are collaborative in exercising that diligence. As a former chairman of the International Society for Pharmaceutical Engineering, I have had experience with many other regulators, and it has highlighted to me the value of a collaborative National Competent Authority such as the HPRA.

> The HPRA is undoubtedly a huge asset, not because they are just diligent, but because they are collaborative in exercising that diligence

This facility is a great example. When we were beginning to design it, we realized there was insufficient documentation in the industry literature regarding some aspects of the facility. We then

requested a meeting with HPRA on these aspects, highlighting how we wanted to approach them but stating that, as there is very little documented guidance, we wanted to have a conversation about their expectations. This meeting was secured in a timely manner, and we received a collaborative and helpful response from them, which assisted in our design of the facility. We then had a follow up meeting with HPRA to receive more feedback before submission to the authorities for planning permission. As a result of these interactions by the time we did our first GMP inspection, we had already established a working relationship with HPRA. Our expectations were aligned and they had some understanding of our competence.

The ability to have this constructive and ongoing dialogue is a huge part of the Irish industry's success in compliance and quality assurance.

Part of the Irish pharmaceutical industry's success has been attributed to its collaborative spirit, or what David Keenan from Mallinckrodt called the 'pre-competitive space'. How will Jazz Pharmaceuticals position itself within this space?

While the success of our own operations naturally remains our top priority, collaboration and community fall very much within our own values. Our CEO, Bruce Cozadd, stressed this at the opening ceremony of this facility, when he said that we would be a "good neighbor". We have a part to play in supporting the broader community, from the simple things at a local level to our geographical neighbors in Athlone to the wider Irish pharmaceutical industry. For instance, we support IDA Ireland's efforts to encourage pharmaceutical foreign direct investment (FDI); they use us as an example of a successful recent pharmaceutical FDI start-up. We have also used the services of some of the support companies around, not just because they are our neighbors but because they do quality work. APC, a Dublin-based process research company, is a good example of this. Many of the companies involved in the design and construction of this facility were Irish. We see ourselves playing an active corporate citizenry role and supporting the existing professional networks. For instance, we recently hosted a cleaning validation expert group from BioPharmaChem Ireland. This level of collaboration benefits not only us but the wider industry, and I am proud to see Jazz Pharmaceuticals within that space.

See more interviews