Interview: Gearóid McDermott – Site Director of Amneal Pharmaceuticals, Ireland



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Gearóid McDermott, director of Amneal Pharmaceuticals' first site in Ireland down in Cashel, Co. Tipperary, outlines the exciting progress they have made in the past 14 months, the strategic role of the site as Amneal's first manufacturing facility for inhalation products as Amneal enters the high-value generics space, and his ambition to build a sustainable business for Amneal Ireland.

This Amneal facility here in Cashel is Amneal Pharmaceuticals' first investment in Ireland. What have been the highlights of the past year?

It has definitely been a very exciting fourteen months or so for us here at this Amneal facility in Cashel. The overriding priority at the moment is on getting the facility ready for commercial production. This used to be a Johnson & Johnson production facility and it is absolutely fabulous, but it has been idle for about four years, so a lot of work has been required to get it up and running again. That alone is a massive undertaking.

In addition, we would like to build three separate production suites within this facility, with distinct equipment trains in different types of clean rooms, so those are three additional projects on the construction side. Then there is team-building and all the support processes and services that a manufacturing facility requires – obvious things like IT systems, wireless networks and videoconference facilities. When we first arrived, we did not even have office chairs to sit on. I had to bring along a kettle on our first day of work!

We are very proud of what we have achieved. We started with two employees in the beginning and now we have 54, along with many service contractors coming on site daily.

The goal is to get our first equipment train to make the first registration batches for inspection, firstly by the Health Products Regulatory Authority (HPRA), the Irish regulator, in Q1 2017, and the FDA a few months later. Hopefully we will have approval for our first product by the end of 2017, which means commercial production in 2018.

What is the significance of this facility for Amneal's global operations?

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Amneal is a highly diversified, global generics company, with products in the tablets, the oral doses, liquids, transdermals and OTC spaces. Now, we are looking to expand into high-value generics, which are products that are not as easily replicated. This Cashel facility is intended to be a highly strategic global facility to that effect. Specifically, Amneal is moving into the inhalation space and this facility will be looking to produce metered dose inhalers (MDIs) as well as dry powders inhalers (DPIs), which are products that Amneal has not manufactured before.

That said, that core business is expected to occupy only a third of this facility. We are looking to enter other areas, namely injectables. For injectables, we are retrofitting part of the building to have aseptic processing capacities in preparation for future products. Furthermore, an entire side of the building has been left vacant, and we have earmarked that space for biosimilars production. Construction on that is expected to begin in 2017, and it will ultimately manufacture products developed by our sister company, Adello Biologices, previously known as Therapeutic Proteins International (TPI).

Why has Amneal decided to expand into the inhalation space?

This is really a growing market within the industry. In addition to the big companies dominating the sector, there is a whole raft of smaller generic companies like Amneal breaking into the market, so there is definitely a lot of potential. As a result of Amneal's diversified product range, they have built a reputation as a single-source supplier, especially in the US, and consequently, have strong relationships with the large pharmacy chains. This network is something we can leverage on to market our inhalation products.

Despite being a generics company, innovation is very important to us and Amneal has very strong R&D activity in our New Jersey headquarters. This local facility is focused on reaching operational status at the moment but we will get more involved in R&D product development at the right time.

Products in this space are of high value because of the challenges associated with their manufacture. The technology behind DPIs is even more complex and more expensive, but we believe that this will be the growth driver in the future as they are increasingly seen as better solutions with higher efficacy and more consistent delivery. User error is very high for MDIs as up to 75 percent of patients get the timing wrong between the spraying and the inhaling. DPIs are pre-metered, the patient sucks in a disc so there is nowhere else for the powder to go, and there is the added advantage of it only expels the drug when there is sufficient breath flow, so patients always receive the right dose at the right time in the right location.

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Why makes Ireland the right location for such an important facility for Amneal?

It comes down to the vibrant and robust ecosystem here. There are so many clusters of expertise in the API, pharma, biopharma and medtech sectors and that is fantastic because it fosters talent development. The various associations do a stellar job of promoting the exchange of ideas and expertise, for instance, BioPharmaChemical Ireland (BPCI) would be a key player here. The National Institute of Bioprocessing Research and Training (NIBRT) is the flagship platform and a lot of sharing, both formal and informal, occurs through these channels. On a more personal level, you can simply pick up the phone and speak to a counterpart to glean their insights. Naturally, we do not share trade secrets or intellectual property, but people are always available to discuss conceptual problems or regulatory requirements. The downside of such rich pollination is that people move a lot within these clusters, but as long as the talent keeps circulating, it is probably a positive aspect.

We have found working with the HPRA to be excellent as well. We have had a number of preliminary meetings with them and they have proven to be very collaborative and helpful.

You moved from J&J to Amneal to set up this facility. What personally attracted you to Amneal?

It is a company of 4,000 people, which means that we are very close to the decision-makers. The company is owned by two brothers and they have personally visited this site, which is rare in Big Pharma. We do not have direct contact with them on a daily basis but we know that we would be able to get a quick response, often within 24 hours, if necessary. For capital projects like this, for instance, in a big pharma company, decision-making would take around 6 to 8 months of preparation and evaluation and bureaucracy. Here, we can get decisions for fairly substantial POs signed off on the same day.

Amneal’s strength as a generics player is in the diversity of its portfolio and their associated ability to be a single-source supplier to pharmacy chains, as I have alluded to. From a local site perspective, this is fantastic too because we have a variety of platforms and products here. As I outlined, we are planning to use this facility for inhalation products, injectibles and biosimilars. This means that if one product does not do as well as expected, the site will have other products to leverage.

Many smaller Irish communities would have seen plants come and go, and they are typically skeptical about new investments because they wonder how sustainable the job creation really is. Here, we think we are building something sustainable and long-lasting. We anticipate that by 2020, should our products reach the market successfully, we will be looking at around 200 to 250 new jobs here, which is fabulous. Right now we only have around 50, but getting a site ready for commercial production is typically a 2.5- to 3-year cycle. We are very optimistic we can leverage on the Amneal brand to reach these figures in a few years.

On a final note, what are your key priorities for Amneal in Cashel for the next few years?

Fundamentally, it is about growing the team here and building our competences. Products will come and go but if we have the talent and the competences here to adapt to new products, we would be able to keep reinventing ourselves and stay ahead of the game. We do not want to be a one-trick pony. We want to be proactive rather than reactive. As site leader here overseeing the conception and development of this facility, I want to build something that is sustaining and sustainable. The world is our oyster.

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