

# Interview with Dr David Mitchell, Managing Director, Novartis Ringaskiddy Ltd

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*Dr. Mitchell, what attracted you to join Novartis after a decades-long career at AstraZeneca?*

If you had told me a year ago that I would leave the company I'd worked for 27 years and move to Ireland, I would never have believed you! However, moving here has been a very positive, rewarding experience. Novartis is a really exceptional company.

Novartis has a strategy of largely insourcing the manufacture of active ingredients, particularly active ingredients for products that are still protected by patent. Companies who have outsourced this process to countries such as China and India have experienced difficulties due to differing quality standards when compared to a European level. In contrast, Novartis has generally maintained local operations and profited from maintaining local standards.

Another appealing aspect of working in Ireland is experiencing at first-hand how integrated the industry is in this country. There is a supportive government, and we enjoy the close proximity of many other major international pharma companies. The collaboration that arises from operating so close to other companies has personally been a pleasant surprise.

The quality of employee readily available in Ireland is also very appealing. With over 50% of the pharma industry workforce holding a third level qualification it comes as no surprise that there are strong links between the education system and the industry. The Irish Universities and higher education colleges play a key role in educating young people for a career in the pharma sector.

***When you first arrived here, what was your vision for further development of the site?***

As someone in a leadership role, an early task is to assess the performance of the company, and ascertain whether or not a change of direction is needed or whether we must simply build on existing success. Thankfully, the situation was more a case of the latter and it is certainly a case of evolution rather than revolution.

Our site in Ringaskiddy, Cork is strongly positioned to pick up a constant stream of new products from the Novartis's development pipeline. We are increasingly focusing on smaller volume, more potent drugs rather than high volume products. We also benefit from some specialist manufacturing technologies, for example we have a very large-scale chromatography capability.

***Why do you believe Ireland is able to attract continued investment, despite a weakened economic environment?***

There are many compelling reasons but from my perspective three in particular stand out.

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Firstly, access to a well-educated workforce as referenced previously. The second reason is Ireland's reputation for quality. Internationally, Ireland has a great reputation for quality; there hasn't been a single FDA warning letter sent to this country in over a decade.

And finally, Ireland is an attractive country to do business in with a competitive taxation regime.

***What is your most pressing challenge today?***

Operational excellence and staff competence, give us a competitive edge as an organization. However, there is still a knock-on effect from the boom years or "Celtic Tiger" years experienced by the Irish economy. Labor costs remain quite high in Ireland, even compared to the UK. My most pressing challenge, therefore, is to ensure that manufacturing practices are lean and there is a focus on increasing productivity through technical improvements and through eliminating non-value added work.

We have great new potential medicines in our pipeline and a strong commercial product range. We are well positioned to accommodate the new products that will be coming through development.

One way Ireland can better differentiate itself is to move up the value chain and continue to invest in the biopharmaceutical sector, and look for ways to attract further foreign direct investment in this sector.

***Is this industry lagging behind, in terms of operational excellence?***

Compared to more established industries, particularly those that have had to drive quality and innovation up whilst at the same time drive costs down I would say we are behind but catching up fast. This industry has always had a high regard for quality but historically was not subject to strong pricing pressures. Of course this has changed due to the combination of financial pressures on Western healthcare budgets with generally ageing populations, huge un-met medical need in the developing world, fewer new medicines making it to markets and a looming patent expiry cliff threatening to decimate innovator Pharma company's sources of income.

Employing Lean Six Sigma techniques to drive Operational Excellence has been a relatively new endeavor for the industry. In my opinion there is much we can learn from other industries, such as fast moving, perishable goods or the automotive industry. We should look to implementing a similar supply chain management approach. Lean Six Sigma techniques are best applied when one is in an expanding industry that wishes to reduce wastage. It was not really designed as a cost-cutting exercise. Essentially, we are looking to do more with less, and reduce the overall cost of medicines.

***What is the nature of the link between drug discovery and manufacturing? Do manufacturing realities limit the creativity of research?***

At Novartis, we do not limit our drug discovery ambitions by thinking about manufacturing constraints. It is medical need that drives our research and development.

***What can be done to reduce risk in the development process?***

The industry is littered with examples of facilities being built while a product is in phase III of development, and the product never reaching the market.

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Building flexible multi-product facilities is one way of hedging the risk. This is also another reason third party producers have become more popular, as it can be more cost effective or quicker in these instances to utilize their assets within the supply chain.

Novartis believes in having a strong hold on its intellectual property, which is one of the reasons we have chosen not to pursue this route. We also believe in maintaining our focus on R&D so that we are constantly enriching our pipeline.

***Is the company fully utilizing its production capacity, or will we see consolidation down the line?***

In Ireland our manufacturing assets are highly utilized and it is more likely that we will continue to increase our manufacturing capacity. In 2013 we will see investments to increase our capability to make launch products.

***Do you think Ireland will continue to be a preferred destination for investment for this industry?***

I believe we will continue to see investment, Ireland is well placed geographically in relation to Europe and the US, and as we spoke of earlier, there is a competitive tax regime and operating incentives to take into consideration when choosing to invest here.

Operating costs may be lower elsewhere, but geographically, politically, and in terms of workplace standards and workforce competence, Ireland is still an excellent place to do business and to house global operations.

The Pharma industry generates over 50% of Ireland's global exports, so as an industry, it is a governmental priority.

***Where will you take this site of the next 5 years?***

*Making Quality Medicines Right First Time, Every Time* will be our primary focus. Getting the elements of Quality, Safety and process reliability right sets an excellent foundation for further development. In our industry it is important to have quality beyond mere compliance; we must operate significantly beyond the minimum standards of regulators. That is a clear direction we are taking with this site.

The next component is making sure we are well positioned to support our pipeline. Our capabilities must compliment the new products we want to bring to the market, and as mentioned, we are in a good position for this.

Finally Operational excellence is important to ensure the quality and reliability of our processes and that we can drive up our productivity and ensure cost competitive manufacture.

***What motivates you to come to work every morning?***

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At heart, I truly enjoy manufacturing and the creation process. I enjoy knowing that I'm involved in bringing treatments to patients and helping to improve people's health. We spend a third of our lives at work, so it's important that you enjoy what you do. The nature of our business, with bringing help to people who need it, is a big motivation; especially when we get feedback from patients whose lives have been turned around by our medicines. This for me is a big motivator.

***Do you have a final message for your peers and our readers?***

Since I've come to Ireland, I've been inspired by the level of energy and support for the industry I've encountered. Ireland is an excellent place to do business for our sector, and there is a fantastic resource of homegrown, talented people here that will offer our industry more opportunities for growth.

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