

Interview: Dominic Carolan - CEO, National Institute for Bioprocessing Research & Training (NIBRT), Ireland



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FDI into Irish pharma has almost exclusively targeted in biologics production over the last few years, largely due to Ireland's skilled workforce of bioprocessing technicians. NIBRT director Dominic Carolan discusses how the institute supports the Irish biopharma industry through training and recruitment solutions, while pursuing research that may help to reduce the cost of manufacturing biologics.

From your perspective, how have you seen the industry change since you stepped down as chairman of PharmaChemical (now BioPharmaChem) Ireland in 2010?

Reflecting on the differences between then and now, the biggest change has been that the industry has experienced a resurgence of FDI in investment, particularly in the area of large molecule or biologics manufacturing. This investment has come from both old and new investors, with companies like Pfizer, Lilly and MSD that have existing facilities in Ireland expanding their capabilities in large molecule production, and new investors such as BMS, Alexion, Regeneron and Mallinckrodt establishing their first sites in the country, also in biologics or supporting biologics. With these investments in mind NIBRT has been looking at the skills need for the future along with IDA Ireland and BioPharmaChem, and we anticipate that the amount of people involved directly in manufacturing biologics in Ireland will nearly double over the next five years.

This expansion in biologics is very much a shift from the historic base of the Irish pharma sector, and one that many in the Irish pharma community put much effort into driving. Ireland's pharmaceutical manufacturing base was and still is predominantly focused in small molecule synthesis rather than large, and today employment in this area is relatively stable. There have been changes of course, driven by genericization following patent expiries, growing volumes and associated changes in efficiencies of scale, and of course developments in terms of manufacturing technologies and operational excellence; as such some small molecule facilities have closed, while others have actually been expanded, and in Pfizer's case one facility slated for closure has been able to stay open by achieving a dramatic improvement in performance.

All in all, biologics represent about 20 percent of the manufacturing value in Ireland at present, and this proportion will be growing steadily over the coming years.

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How has the investment logic to invest in Ireland changed over the years?

For decades Ireland has been seen as an English speaking gateway to Europe with a stable government and a very competitive, open, and transparent tax regime. There have been clear commitments that this will continue to be the status quo, and these incentives have and are still core to Ireland's ability to win large scale FDI investments in many industries, the pharmaceutical industry among them.

There are of course other highly significant considerations at play, and what we've seen recently is the availability of skilled professionals is at the very top of the agenda for the entire biopharmaceutical industry. A lot of countries offer competitive tax incentives, a lot want to attract FDI, but globally there is a dearth of skilled professionals to work in biopharmaceutical manufacturing at the global level. Through a broad based effort across Ireland, led by the IDA and NIBRT, we have successfully differentiated Ireland as the country with a significant, reliable, and high quality supply of professionals skilled in biopharmaceutical manufacturing. As such, Ireland is currently one of the few locations in the world that has as competitive of financial investment incentives as we have, along with the skills the industry is looking for, and this has certainly been a key factor in our ability to win the majority of the large biopharma investments that have been announced over the last few years.

Now NIBRT has a variety of functions; could you please give a brief overview of NIBRT's activities today?

NIBRT was set up by the government, and the main facility was built with EUR 60 million of investment funds from the IDA. We opened for business in 2011, and essentially do training for biologics manufacturing, not only for industry in Ireland but industry globally, about 25 percent of the training we do is for international audience.

Aside from training, we also do valuable research in state of the art technologies that are appropriate for the industry in the future. As we like to say, the facility we have here is a full scale working pilot plant for biologics manufacture, and its essentially a flight simulator for the bioprocessing industry where people can train in a risk free environment and get a strong knowledge of what the industry's like.

These two functions are our core mandate, and one that we've been growing since 2011. We've grown the numbers of people training 15 to 20 percent per annum. With the growth of the industry in Ireland, we anticipate that the growth in our training and education will grow in the future.

NIBRT was founded with the goal of being self-sufficient; how close have you come?

NIBRT was founded with the goal of becoming financially self-sufficient, and we nearly achieved that goal in 2015, covering 92 percent of our costs through our for-profit services in training and research.

Our training and some research services are all provided at profitable rates such that the profits can go into subventing our research costs. NIBRT was founded with the goal of becoming financially self-sufficient, and we nearly achieved that goal in 2015, covering 92 percent of our costs through our for-profit services in training and research.

However, over the next few years this number is likely to drop somewhat as we are actually seeking to significantly expand our research mandate. We're bringing in a new Chief Science Officer, Professor Michael Butler who was previously working at the University of Manitoba in Canada and will be arriving in September. We also aim to significantly increase the number of researchers we employ and research teams we manage. These research teams should become self-sufficient in terms of grant and industry funding within a few years, however for the mean time we will have the support of IDA Ireland to cover the temporary deficit.

Considering the research itself, our core strength where we have a very strong international reputation is in bio analytics. Professor Pauline Rudd is one of our principle investigators and she is a global leader in the study of glycosylation, with a fantastic reputation internationally; she is constantly traveling to different seminars, and is really a fantastic ambassador for NIBRT

internationally, along with Dr. John Bones.

A collaboration with Thermo Fisher Scientific was recently announced; how does this project fit into your research agenda and strategy?

If you take our starting point as bioanalytics and ask “where does research need to go in the future,” there is a clear focus towards improving bioprocessing efficiency and reducing costs. Process Analytical Technologies (PAT) play a key role in driving this change, and to develop new PATs you need to understand analytical techniques and how they function much better.

There are several companies working in this area including both Waters and Thermo Fisher Scientific. NIBRT has actually been a Waters center of excellence for a number of years, and we’ve recently signed a collaborative agreement with Thermo Fisher Scientific. Under this agreement we will be given access to some of their newest technologies to demonstrate and test different applications, and prepare detailed application notes in the process to develop a better understanding of the areas it can be applied for the industry. We get access to more powerful tools for research, and can figure out how to train people to integrate such technologies into manufacturing processes; Thermo Fisher Scientific will get a better understanding of how their customers might use the technology, and how to show them the advantages of using new technologies to better detail the complex structure of large molecules. We are also in the early stages of negotiating similar collaborations with other technology providers, so more announcements will likely soon be coming.

I’d also like to highlight that we have had strong support from the industry to direct a body of research that is focused on manufacturing technology, and are working to develop a structure and program to this end with other stakeholders including Science Foundation Ireland. The amazing thing is that so much of the industry at a global level wants to be a part of such a project; of the companies we’ve developed this program with so far roughly 25 percent do not have any manufacturing presence in Ireland and want to participate from an international base.

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Regarding your other core purpose; Ireland has a relatively small population, and the supply of human resources is in general limited. How has NIBRT ensured a significant supply of professionals with the right skills to the biopharma industry in Ireland?

It is one of our core purposes as an organization to enable recruitment, along with training, to as great of an extent as possible. With the number of tools and options that we have developed to

enable recruitment we haven't seen any real bottleneck for the companies that have are open to the full range of recruitment options that exist, and that NIBRT can help facilitate. Of course we are greatly aided by the fact that in general Ireland has a significant amount of university graduates, with some statistics showing that the adult Irish population has the highest proportion of university graduates of any country in the EU.

One of the bigger initiatives we have recently carried out was a government funded "springboard program" which essentially looked for graduates or unemployed/underemployed individuals and gave them conversion courses that gave them the skills needed to work in bioprocessing. 400 people went through this program last year, and based on our evaluations we estimate that up to 65 percent of this course's graduates have secured jobs in the biopharma sector; these are individuals who would never be able to get such jobs without the existence of a facility like NIBRT offering the types of training we do.

It was recently announced that NIBRT is working closely with BMS on a number of fronts to prepare for their first Irish facility to come online; could you give us an overview of the types of support NIBRT has provided BMS?

One of the widest scope collaborations we currently have underway is with BMS who are building their first Irish production facility in Cruiserath at present. Using BMS as an example, we have taken a number of steps to help them recruit new students.

First, we actually hosted a careers day just for BMS letting them use the facility and the atrium; they set up departmental stalls, and 22 BMS employees came, most flying in from the US, to run this event which was attended by 500 graduates.

Second, we run training not only for direct graduates, but also for indirect graduates from STEM disciplines other than biology or biotechnology; through cross training courses NIBRT is able to align the skills of these indirect graduates with the needs of the biopharma industry, and this greatly expands the pool of graduates that biopharma investors can recruit talent from.

Third, we have organized a "skills net" program to help meet their demand for bioanalytical scientists; as such, together with the department of social welfare, we identified 40 graduates who were either under-employed or unemployed who could be candidates for intensive training or "upskilling", and BMS selected 20 to have trained and then take on as interns, with the option to extend a full contract to them after three months.

Our vision is for NIBRT to be a strong supporter of the Irish pharma industry, and to become increasingly relevant for international companies through our services and research.

Fourth, we've also provided cross training for BMS employees that have worked in small molecule production, to help them transition into large molecule production.

Finally, while not associated with recruitment as much, we've also turned over one of our labs and some office space to BMS's Manufacturing Tech Support team, who will be doing the tech transfer from the US into the Cruiserath facility.

Looking forward, what are the main objectives you'd like to see NIBRT accomplish over the next few years?

Our vision is for NIBRT to be a strong supporter of the Irish pharma industry, and to become increasingly relevant for international companies through our services and research. Part of that would mean we'd like to see the proportion of our activity with international collaborators via research and training, which is currently at about 25 percent, increase substantially. In terms of research we will be increasing our efforts and investment substantially, and hope to double or triple the number of researchers we employ in five years, and commensurately increase our research output, while pursuing research that is scientifically excellent and relevant at a global level.

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