

Annual Report

Promoting world-class
biopharma investment
in Ireland

2016



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The NIBRT building.



2016 Annual Report

Promoting world-class biopharma investment in Ireland

Who we are

- ▶ NIBRT is a world-class institute, based in Dublin, Ireland whose mission is to deliver training and research solutions for the global biopharmaceutical manufacturing industry
- ▶ NIBRT partners with industry to support international best practice in all aspects of biologics manufacturing
- ▶ Opened in 2011, NIBRT's research and training building (6,500m²) features state-of-the-art pilot scale manufacturing facilities
- ▶ Established with IDA Ireland, NIBRT partners with all higher education institutes to provide training and research infrastructure facilitates not previously available in Ireland

What we do

- ▶ Train and educate over 4,000 people annually to work in all areas of biopharma manufacturing
- ▶ Collaborate with industry on scientific research to drive biopharma innovation
- ▶ Support major biopharma investment in Ireland
- ▶ Provide a test bed for new technologies and processes

NIBRT's vision

- ▶ Become a global leader in biopharmaceutical manufacturing research education and training
- ▶ Build out our research and development scale, capability and critical mass to establish NIBRT as a globally recognised centre for industry applied research and process development
- ▶ Be the hub for bioprocessing manufacturing research in Ireland and internationally
- ▶ Continue to support the growth and development of the biopharmaceutical industry in Ireland



NIBRT pilot plant.

1 Message from NIBRT CEO



NIBRT has had an outstanding year in 2016, a year in which all aspects of our business grew, Training, Research, Contract Research, and where Prof Michael Butler, a global leader in mammalian cell culture, joined us as Chief Scientific Officer from the University of Manitoba.

2016 was an exceptionally busy year for NIBRT. We progressed all aspects of the business, in particular the demand for in-house bioprocessing training for company employees was very strong. This reflects the robust state and growth of the industry globally and in particular the growth in Ireland. We extended our Open Course offerings and had a very significant growth in uptake, reflecting the quality of, and need for, these courses. Intake for Springboard courses was down in 2016 over 2015, reflecting the funding support from government and the reduction in unemployment. With the huge need for additional skills and personnel for the industry (8,400 for the biopharma manufacturing sector up to 2020 as identified in the DJEI Future Skills Needs report), continuation of a Springboard like programme is one of the solutions needed to ensure a strong supply of skilled personnel to meet industry needs.

Research activity, particularly on bioanalytical characterisation, continued to grow and a collaboration with Thermo Fisher was secured by Dr Jonathan Bones, involving their latest mass spectroscopy equipment. NIBRT was approached by industry and academic stakeholders early in 2016 to consider putting together a Research Centre bid in response to the SFI open call in late 2015.

Having identified there was strong support for a submission, NIBRT worked with the research community and industry to structure the proposal. It was submitted to SFI in November; the bid, led by Prof Michael Butler, has a research programme supported by researchers from seven Universities, three Research Institutes, and funding support from 27 Biopharma companies. We believe it is a compelling programme and look forward to a positive outcome expected in April 2017.

A number of new laboratories were completed to support new research teams and testbeds. In September we were delighted to announce the NIBRT-GE Single Use Technology Centre of Excellence to be established in the facility. It is expected that equipment will be installed in early 2017 and open for business in quarter 2. We are also delighted to be hosting the BMS Manufacturing Sciences and Technology team in one of our laboratories as well as the start-up company Valitacell.

My appreciation goes to all the NIBRT staff who continue to deliver great performance as we continue to grow the business.

Dominic Carolan
CEO, NIBRT

2 Message from NIBRT Chairman



2016 continued to be another strong year for the biopharma sector internationally. Annual sales of biopharmaceuticals are now over \$200 billion globally, and industry revenue continues to grow at a rate of approximately 15% annually. The NIBRT Board was delighted to see the continued expansion of the industry here in Ireland with investments from Shire, GE, MSD, APC, Grifols and others.

NIBRT's role is crucial to supporting this investment by ensuring a supply of a suitably skilled workforce. Indeed, the Expert Group on Future Skills Needs (EGFSN) report on the Future Skills Needs of the Biopharma Industry in Ireland forecast 8,400 new biopharma jobs by 2020. NIBRT are currently working with BiopharmaChemical Ireland and other stakeholders to ensure the effective implementation of this report.

Overall, 2016 was another excellent year for NIBRT with some notable highlights including:

- ▶ The Appointment of Prof Mike Butler as NIBRT Chief Scientific Officer
- ▶ The partnership with GE Healthcare to establish a single use centre of excellence in NIBRT
- ▶ The submission of a compelling and ambitious application to establish the Bio-Logic Research Centre
- ▶ Delivering over 18,500 days of training to 4,000 trainees from Industry, Academia and jobseekers
- ▶ The promotion of the exciting opportunities within biopharma via events such as CareerZoo, Biopharma Ambition and MIT Hackathon

- ▶ The further development of the NIBRT building to facilitate the ongoing expansion of all activities.

While the sector is growing well, there is now increasing diversification in the product pipeline with advances in innovative biotherapeutics such as cell therapy, gene therapy, combination products, precision medicines. In parallel, the nature of biopharma manufacturing processes are constantly evolving with novel technologies such as continuous bioprocessing, process intensification, single use systems, novel bioanalytics etc. To maintain and build on Ireland's success requires a constant effort from all stakeholders to further develop our value proposition, and the NIBRT Board is committed to prepare for the exciting opportunities ahead

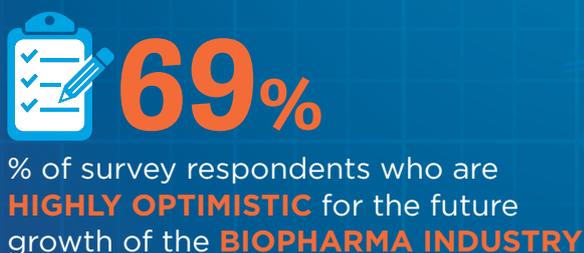
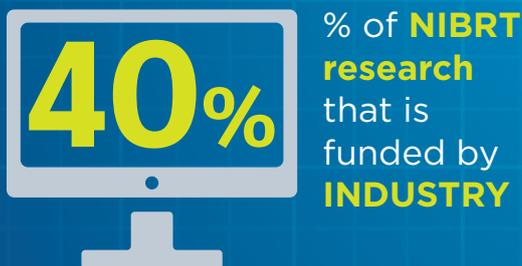
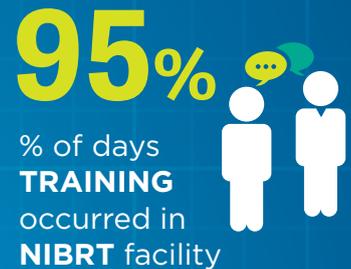
On behalf of the NIBRT Board I would like to thank Minister Mitchell-O'Connor and all her team at Department of Jobs, Enterprise and Innovation for their continued support of NIBRT. Finally, sincere thanks to NIBRT staff and to my fellow Board members for their commitment in ensuring the ongoing success of NIBRT.

Brendan O'Callaghan,
Chairman, NIBRT

3 2016 NIBRT by the numbers



% of NIBRT's costs that are covered by income NIBRT generates



4 Growth of the Biopharma Industry



10 years and over €10 billion of investment

2016 continued to be another strong year for the biopharma sector internationally. Annual sales of biopharmaceuticals are now over \$200 billion globally, and industry revenue continues to grow at a rate of approximately 15% annually. An increasing number and percentage of pharmaceuticals entering the market are biopharmaceuticals, with about 40% of Big Pharma and overall pharmaceutical R&D pipelines now involving biopharmaceuticals².

Building on a long history in pharmaceutical manufacturing Ireland has now won more than €10 billion in the past 10 years in biotech investment, and is now one of the world's top locations for biopharma. This success continued

in 2016 with a number of new investments announced including significant projects from GE, Shire and Grifols.

In April, 2016 **Shire** announced that it plans to expand its global biotechnology manufacturing capacity over the next four years by investing US\$400 million in Piercetown, Co. Meath to meet the rapidly growing demand for its rare disease treatments. A new, state of the art biologics manufacturing campus will be constructed, leading to the creation of approximately 400 permanent jobs on a 120 acre site. The facility will employ flexible production strategies enabling Shire to supply both clinical and commercial scale products.



May 2016: Minister Mitchell-O'Connor, TD with participants at NIBRT Careers in Biopharma Event.

2. R.A. Rader, BIOPHARMA: Biopharmaceutical Products in the U.S. and European Markets: U.S. Approvals, 2002-present

The roles at Shire's new campus will consist of highly skilled, full time jobs in the areas of R&D, operations, technical staff, engineering and construction. Construction of the new site is scheduled to begin in mid-2016 with the site expected to be operational by mid-2019.

In March, 2016 Grifols announced an additional \$85 million in its biologics plant at Grange Castle, Co Dublin. Grifols said it was bringing forward plans for the construction of a purification plant for the protein albumin to cater for rising demand. Construction will begin towards the end of this year, with the plant expected to be operation-ready in early 2020.

In an exciting development in September, 2016 GE announced a €150 million investment in a new biopharmaceutical manufacturing campus at Loughbeg, Ringaskiddy, Co. Cork. GE BioPark Cork, will feature Europe's first KUBio™, prefabricated, off-the-shelf bio-manufacturing facilities, owned and run by GE customers, and will serve as focal point for further investment in next-generation biopharmaceutical manufacturing in Ireland. The BioPark is expected to be home to more than 500 new jobs when fully operational; 400 with biopharma companies and a further 100 employed directly by GE.

These announcements complement the recent investments from BMS, Alexion, Lilly, Regeneron, Sanofi Genzyme, West Pharma, BioMarin and others which has seen the biologics sector creating 6,000 new jobs and significant secondary employment in construction and other services. Ireland has now established one of the largest concentrations of biopharma manufacturing capacity globally. However, the challenges of biopharma manufacturing were illustrated when it was reported in November 2016 that Pfizer had cancelled plans to invest into the expansion of the Grange Castle site.

The majority of this investment is focused on mammalian cell production of monoclonal antibodies but there is now increasing diversification in the product pipeline with advances in innovative biotherapeutics such as cell therapy, gene therapy, combination products, precision medicines. In parallel, the nature of biopharma manufacturing processes are constantly evolving with novel technologies such as continuous bioprocessing, process intensification, single use systems, novel bioanalytics etc. To maintain and build on Ireland's success requires a constant effort from all stakeholders to further develop our value proposition, and NIBRT is delighted to play a key role in preparing the talented workforce and driving biopharma manufacturing research for the exciting opportunities ahead.

Killian O'Driscoll,
NIBRT Director of Projects



2016 BIOPHARMA ANNOUNCEMENTS INCLUDE



SEPTEMBER 2016:

GE to invest **€150 million** in biopharmaceutical manufacturing campus in Cork, Ireland, and establish **ADVANCED MANUFACTURING TRAINING** centre at **NIBRT**



APRIL 2016:

Shire to expand biotechnology manufacturing capacity in Ireland



MARCH 2016:

IDA welcomes **\$85m Grifols Biologics Investment**, which boosts Ireland's Biologics Cluster



FEBRUARY 2016:

Pharma giant **MSD** to create **200 jobs** across three counties



FEBRUARY 2016:

APC Ltd announces **100 jobs** and opens new research facility in Dublin

5 Case study: GE Healthcare



In Sept 2016, GE announced plans to invest €150 million in a biopharmaceutical manufacturing campus in Cork, Ireland, and to establish an advanced manufacturing training centre at NIBRT

GE BioPark Cork will feature Europe's first KUBio™, prefabricated, off-the-shelf bio-manufacturing facilities, owned and run by GE customers, and will serve as focal point for further investment in next-generation biopharmaceutical manufacturing in Ireland. The BioPark will be a GE-managed campus including four fully-equipped KUBio factories owned by independent biopharma companies manufacturing proprietary medicines, with GE running centralised shared utilities and site services.

Patient demand for innovative medicines is driving rapid global growth of the biopharmaceutical industry, resulting in significant need for more production capacity. GE's KUBio enables pharmaceutical companies to quickly deploy new biologics manufacturing capacity and bring medicines to market faster. KUBios increase manufacturing flexibility and are between 25% and 50% more cost-effective to build than comparable traditional facilities. Carbon dioxide emissions can be reduced by 75% and water and energy use by approximately 80%. Build time can be shortened to 18 months from the usual three years.

GE BioPark Cork is expected to be home to more than 500 new jobs when fully operational; 400 with biopharma companies and a further 100 employed directly by GE. The construction phase, subject to planning approvals, is expected to begin by mid- 2017 and create up to 800 construction jobs.



Sept 2016: Barry Heavey (IDA), David Radspinner (GE), Minister Mary Mitchell O'Connor TD, Dominic Carolan (NIBRT) and Martin Shanahan (IDA) at the GE-NIBRT announcement.

To further develop biopharma manufacturing skills and expertise in Ireland, GE and NIBRT also announced their plan to create a NIBRT-GE Single-use Centre of Excellence at NIBRT's Dublin facility. NIBRT expects to train up to 1,500 bioprocessing professionals annually on next-generation biologic manufacturing technologies. These exceptional technologies for biopharma manufacturing will be used in GE BioPark Cork's manufacturing facilities.

“ Pharma companies world-wide are racing to respond to patient needs with new life-changing biological medicines and GE is investing in technology and service solutions, as well as industry skills and expertise, to enable them to make and get their products to market more quickly. We are delighted to be investing once again in Ireland, where we have ourselves a long history of manufacturing our own medical imaging products. **”**

Kieran Murphy CEO,
GE Healthcare Life Sciences,
GE Healthcare 

6 NIBRT Research and Innovation



Message from Prof Mike Butler, NIBRT Chief Scientific Officer

NIBRT research provides access to leading scientists in world class facilities to address key issues in manufacture of innovative biologic medicines.

The research programme at NIBRT is at a period of growth with several initiatives and development plans for a pipeline of future activity. Following my appointment as Chief Scientific Officer in September 2016 we made rapid plans to submit a full application in November for a Bio-Logic Research Centre in line with the call for proposals by Science Foundation Ireland (SFI). The application is structured with basic platform projects underpinning a series of five industrially-related targeted spokes in the areas of cell engineering, enabling analytics and next generation biomanufacturing. The initiative has attracted support from 27 biopharma and related companies who will provide >30% of the €41 million running costs of the programme. This will support a large research network for bioprocessing centred at NIBRT and including participation from all the Irish universities and three national institutes. Apart from the beneficial advancement in technology for efficient biopharmaceutical production, a significant goal of the Centre will be an expansion of the pool of talented highly qualified personnel required to sustain biopharma in Ireland. A decision on the outcome of our application is expected from SFI in April 2017.

Present research at NIBRT continues strongly in the areas of bioanalytics, which includes a unique world-class facility for glycoprotein structural analysis. This is complemented by our programme in bioinformatics and a newly furnished cell technology laboratory that will enable future efforts in upstream processing in the development of mammalian cell bioprocesses.

Finally, I would like to thank all NIBRT research team for such a strong performance last year in maintaining a high level of relevant research. Also, thanks are due to the Bio-Logic co-applicants and NIBRT research office staff for their continued efforts in developing a strong Research Centre application.

Prof Mike Butler
NIBRT CSO



BIO-LOGIC RESEARCH CENTRE

- 1** LEAD APPLICANT
- 10** CO-APPLICANTS
- 21** FUNDED INVESTIGATORS
- 27** BIOPHARMA AND RELATED COMPANIES
- 74** COLLABORATORS
- 6** IRISH UNIVERSITIES
- 3** NATIONAL INSTITUTES
- €40.9M** TOTAL PROGRAM COST
- €4.6M** INDUSTRY CASH
- 80** PHD GRADUATES
- 55** POST-DOCTORAL RESEARCHERS



Sept 2016: NIBRT Thermo Fisher Scientific Collaboration – Kick off Meeting.

Bioanalytical Characterisation

In June 2016, Thermo Fisher Scientific, and Dr Jonathan Bones, NIBRT announced a scientific collaboration focused on the development of analytical solutions for the characterisation of complex biopharmaceuticals. This collaboration will see NIBRT develop workflows on the Thermo Scientific biomolecule column range with its associated consumable portfolio in conjunction with sophisticated Thermo Scientific liquid chromatography systems and advanced Thermo Scientific Orbitrap high resolution mass spectrometers.

“Analytical characterisation of biopharmaceuticals remains a challenge for scientists and requires cutting edge chromatography solutions and mass spectrometry detection,” said Jakob Gudbrand, president of chromatography and analytical technologies at Thermo Fisher. “NIBRT is an independent centre of excellence with collaborations across the major biopharmaceutical companies in the industry. This allows them to provide valuable insights to improve the technology, simplify analysis, generate informative characterisation data and understand these complex molecules - ultimately enabling scientists to move from sample to knowledge quickly and efficiently.”

NIBRT’s workflows and methods will be uploaded to the Thermo Scientific AppsLab library, a unique cloud-based applications compendium that enables scientists across the globe to access and download these total analytical solutions directly to their instruments enabling them to simplify their analysis, generate highly informative characterisation data faster and understand their complex molecules better.

Bioinformatics and Data Analytics

Dr. Colin Clarke’s team specialises in the application of multivariate statistics and machine learning algorithms for the analysis of complex CHO cell datasets. In 2016 Dr Clarke was awarded an **SFI Career Development Award (CDA)** in furtherance of his career progression towards an independent research leader. In this project, which will be initiated in 2017, Dr. Clarke aims to study translational regulation events correlated with variation in CHO cell productivity during cell line development to enhance biopharmaceutical production.

Glycan Analytics

Dr. Radka Fahey and Prof. Pauline Rudd were successful awarded an SFI Fixed Spokes Award collaborating with Prof. Douwe van Sinderen (Principal Investigator at the APC Microbiome Institute) to carry out method development and analysis of human milk oligosaccharides.

“The training with NIBRT has equipped me with the crucial skills and knowhow to be successful in my new job. I have to say that enrolling with NIBRT really was the making of my career.”

 **Mark McGrath,**
Process Scientist



2016 RESEARCH BY THE NUMBERS



TOTAL RESEARCH INCOME FROM INDUSTRY 2011-2016

€5.4 million

Research Excellence

NIBRT Researchers have been awarded the following awards in 2016:

- ▶ **Dr. Jonathan Bones** - included on **The Medicine Maker Power List 2016**³ of the top 100 most influential scientists in the field of biopharmaceutical development, manufacturing and analysis
- ▶ **Prof. Pauline Rudd** - listed in **The Analytical Scientist 2016 Power List** of the Top 50 most influential women in the analytical sciences⁴
- ▶ **Dr. Simone Albrecht** - won the best poster prize at the 13th Symposium on the Practical Applications of Mass Spectrometry in the Biotechnology Industry in San Diego (Sept 2016)
- ▶ **Dr. Amy Farrell** - awarded a CASSS Mass Spec Student Travel Grant to attend and present at the 13th Symposium on the Practical Applications of Mass Spectrometry in the Biotechnology Industry in San Diego (Sept 2016)
- ▶ **Mr. Josh Smith** - won the Ginzo Shimadzu Best Poster Award at the 31st International Symposium in Chromatography Conference in Cork (Aug/Sept 2016)
- ▶ **Ms. Anne Trappe** - recipient of Student Fellowship to deliver an oral presentation at CHI 16th Annual PepTalk, San Diego (Jan 2017).

40% 

of NIBRT RESEARCH is directly funded by INDUSTRY

28

PEER REVIEWED PUBLICATIONS IN 2016



NIBRT Researchers have presented their research at

18 NATIONAL AND 30 INTERNATIONAL SYMPOSIA IN 2016

“ We have a fantastic relationship with NIBRT and really that is a facility and a capability, not only for the pharma industry, but for Ireland, in general, in terms of attracting new industries here. They're doing a fantastic job. **”**



Noel Heaney, General Manager,
BMS Biologics Cruiserath

3. <https://themedicinemaker.com/power-list/2016/>

4. <https://theanalyticalscientist.com/power-list/2016/>

7 MIT Hacking Medicine



Ireland's first world renowned Massachusetts Institute of Technology (MIT) 'Hacking Medicine' event took place in September, seeking to uncover treatment outcomes for patients. Over 100 participants took part in the Hackathon organised in partnership with NIBRT, BPCI, IPHA and DCU Alpha.

3R, a post-stroke recovery and rehabilitation platform which through a user-friendly remote device application that guides, assists and monitors the rehabilitation of stroke victims in their own homes, beat off strong competition from eight other teams to claim the top spot. The nine teams, were supported by 37 mentors from a variety of sectors including biopharma, health, technology, software and others, and worked throughout the weekend to develop solutions to provide patients with better treatment outcomes as well as specific areas such as better drug logistics and waste management, more effective doctor-patient interaction and a better overall patient experience.

The judging panel for the event included John Pugh, Accenture Digital UK & Ireland Innovation Lead for Life Sciences, Kieran Daly, CTO and Co-Founder at Health Beacon, Audrey McDonnell, CEO and Founder of Vanguard Health and Gerald Kierans, Director of Technical Services at Pfizer Pharmaceuticals.

Other project ideas included:

- ▶ Safe-Hands, a smart hand sanitising system which took second place overall in the competition; and
- ▶ Sun, Sea & Surgery, a pan European bed shortage solution which took third place

Commenting on the event, Matt Moran, Director of BioPharmaChem Ireland added; "The biopharma industry in Ireland is all about innovation, with over 25,000 talented people within the industry in Ireland, delivering innovative solutions to patients both here and globally. We are delighted to have MIT Hacking Medicine with us on this event to demonstrate innovation in this sector at its best, with the ultimate goal to improve patients' lives."



3R the winning team at the MIT Hacking Medicine event with Matt Moran (BPCI).

8 Contract Research



September 2016: Matt Moran (BPCI), Dominic Carolan (NIBRT), Minister Mary Mitchell O'Connor TD, Leisha Daly (Janssen) at launch of Biopharma Ambition.

2016 was a highly successful year for NIBRT Contract Research with project activity increasing by over 50%.

The contract research group provides a range of analytical services to support Clients with the physiochemical characterisation requirements of ICH-Q6B and Q5E including protein and peptide analysis, glycosylation and oligosaccharide analysis and protein aggregation analysis.

In 2016 the contract research group worked with numerous multinationals biopharmaceutical companies and biotech start-ups, providing best in class analytical data to support process optimisation and the characterisation of new clinical candidates.

“ The work of the National Institute for Bioprocess Research and Training (NIBRT) has been critical in this context and it's no surprise that many pharmaceutical/chemical companies locating in Ireland cite it as a key determinant in their choice of a location for investment. NIBRT is an invaluable resource for the sector and epitomises the collaborative spirit that is so vital to it. I was, therefore, especially delighted to see NIBRT receive recognition for its innovative work at the Irish Pharma Awards in October 2016, where it received awards for Pharma Education and Training and for Partnership Alliance of the Year. ”



Mary Mitchell O'Connor,
Minister for Jobs, Enterprise and Innovation



Left to right Patrice Knightly, Patrick Jennings, Brian Morrissey, Jo Withers, Caitriona Walsh, Alan Moran.

Levicept



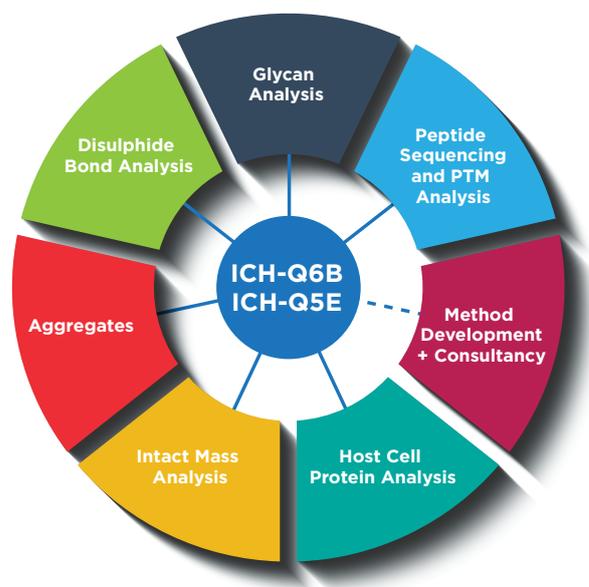
NIBRT Contract Research has enabled Levicept to access a wide range of

analytical services delivered through the provision of top specification analytical instrumentation. In addition to providing protein and glycan analytical services their ability to develop new methods to meet our specific needs enables us to quickly resolve our analytical queries in timely and cost effective manner. Working with NIBRT Contract Research has enabled us to gain a greater understanding of our clinical candidate.



Dr. Simon Westbrook CEO
Levicept

The launch of the Host Cell Protein analysis platform originally developed in the laboratory of Dr. Jonathan Bones⁵ has proved very popular among clients. This platform which enables the identification and quantification of Host Cell Proteins provides a powerful orthogonal alternative to the traditional immunoassay based platforms.



Analytical platforms provided by NIBRT Contract Research.

5. Farrell, A., Mittermayr, S., Morrissey, B., McLoughlin, N., Iglesias, N.N., Marison, I.W., Bones, J. Quantitative Host Cell Protein Analysis Using Two Dimensional Data Independent LC-MSE, **Analytical Chemistry**, 87(18), p.9186-9193, 2015.

9 Expert Group on Future Skills Needs

8,400 new biopharma jobs by 2020

The availability of people with the right skills and talent to work in biopharma will be critical to the continued growth of the industry and for Ireland to maintain its position as a key hub for biopharma manufacturing. In this context, NIBRT was delighted to work with a broad range of stakeholders from Industry, Government and Academia to develop a new report by the Expert Group on Future Skills Needs (EGFSN) on the *Future Skills Needs of the Biopharma Industry in Ireland*⁶. The objective of the study is to review the supply of, and demand for, skills for the biopharma industry in Ireland up to 2020.

The report which was published in August 2016 highlights the important contribution to the Irish economy in terms of employment and manufacturing exports from the biopharma sector. There is an ongoing need to ensure that we anticipate the changing skills requirements of the sector and ensure that there is a close alignment between industry's needs and the skills being taught in the education and training system.

The report highlighted that 8,400 new biopharma jobs will arise in the period up to 2020.

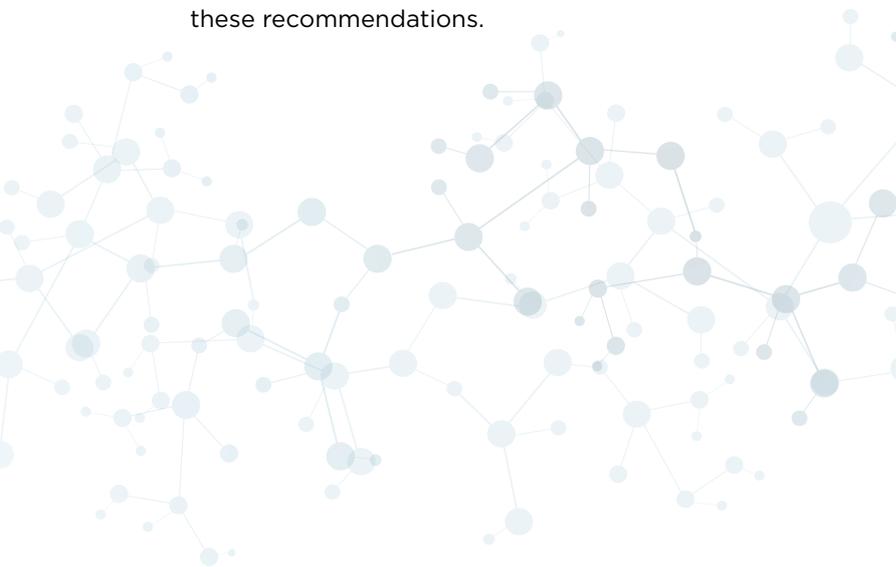


June 2016: Launch of Expert Group on Future Skills Needs of the Biopharma Industry in Ireland with Ministers Mitchell-O'Connor and Halligan with representatives from BMS, BPCI, EGFSN, IDA and NIBRT.

6. <http://www.skillsireland.ie/Publications/2016/Biopharma-Skills-Report-FINAL-WEB-VERSION.pdf>

These will be a diverse range of roles requiring specific scientific, engineering and technical skills across National Framework of Qualifications (NFQ) levels 6-10. As well as technical skills, soft skills including communications, team-working, problem solving and environmental health and safety are essential.

The Expert Group produced a set of recommendations which serve as an Action Plan for addressing the skills needs of the sector up to 2020. NIBRT is pleased to be working with BioPharmaChemical Ireland and other stakeholders in the successful implementation of these recommendations.



My NIBRT experience was transformative. As an industry professional with 10 years of experience in

biopharma, NIBRT offered a training course that I had never seen in the field previously. Expertly balanced in theory and practice, the course centered on hands-on practicals that mirrored what trainees could expect in real-life manufacturing facilities. The result was highly-engaged, knowledgeable individuals with new-found confidence through learning by doing. I would recommend NIBRT's course offerings having personally experienced the positive effect it had on my career.



Anne Marie Molloy,
NIBRT Student



RECOMMENDATIONS TO ADDRESS BIOPHARMA SKILLS DEMAND 2020

1. Raising Awareness of Careers within the Biopharma Industry
2. Ensuring alignment of skills provision with the needs of the industry
3. Improving the work readiness of graduates
4. Attracting, developing and retaining talent
5. Investing in the Continuing Professional Development of the Workforce
6. Maximising available programmes to consolidate skills supply

10 NIBRT Training and Education

In addition to training industry directly, NIBRT works closely with the Higher Education Institutes to ensure there is a strong supply of graduates in Ireland with the skills required for the biopharma and related sectors.

Industry Training

2016 was a very busy and productive year for NIBRT training. We were pleased to deliver over 18,500 learning days to 4,000 trainees. Key clients include Abbvie, AB Sciex, Allergan, Amgen, Amneal, Bioclin, BioMarin, Bioreliance, Bristol Myers Squibb, CAI, Compliance Group, Eirgen, Eli Lilly and Co., Janssen Biologics, Merck Sharp Dohme (MSD), Mylan, Pfizer, Regeneron, Roche, Sanofi Genzyme, Sartorius Stedim Biotech, Shire, Thermo FisherScientific, 3M.

Skilled Graduates

In 2016, NIBRT partnered with 12 Higher Education Institutes to deliver practical, experiential training to their students including University College Dublin, Dublin City University, Institute of Technology Sligo, Trinity College Dublin, Dundalk Institute of Technology, Dublin Institute of technology, Cork Institute of technology, Institute of Technology Tallaght, Galway Mayo Institute of Technology, National University of Ireland Galway, University of Limerick and Limerick Institute of Technology.



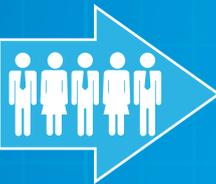
Commissioning Agents International (CAI) training at NIBRT.

2016 TRAINING BY THE NUMBERS



DELIVERED TO
4,000
TRAINEES

18,500
TRAINING DAYS



Over
400
JOBSEEKERS
receiving **FREE**
training programmes

TRAINING
DELIVERED ON

95%

OF AVAILABLE DAYS



I believe all aspects of the course helped me in securing my current role. The practical training,

lectures, CV and interview workshops were all excellent and gave me the confidence to do well in my interviews. I would 100% recommend this course to all, especially recent graduates who find they lack the required industry experience.



Edel Tierney,
Laboratory Technician



SPRINGBOARD
Building our future

Jobseekers

In 2016, NIBRT partnered with six Higher Education Institutes to provide free training programmes to over 400 jobseekers under the Springboard+ programme. On average, 65% of NIBRT trainees secure employment after participating in these very popular courses which are designed to meet the needs of the fast growing biopharma industry.

International Clients

International clients who travelled to NIBRT to access the state-of-the-art pilot plant facilities included a global training programme with AbbVie for Key Opinion Leaders and Health Care Practitioners, 3M, Sartorius Stedim Biotech, Thermo Fisher Scientific, Bioreliance, AB Sciex, C Technologies, Mylan, TR Pharm and Janssen Biologics.

NIBRT were also pleased to progress discussions with Philadelphia University and Thomas Jefferson University regarding a joint training initiative.

New Industry Masterclasses

In 2016 NIBRT partnered with Engineers Ireland to deliver a new program on “A Practical Introduction to Commissioning & Qualification” which offered industrial practitioners in the validation space the opportunity to engage with subject matter experts and to discuss case studies, best practices. Theory sessions were complimented with direct hands-on practical sessions using state-of-the-art bioprocessing equipment located in the NIBRT production training facility.

Suppliers

NIBRT partnered with several vendors to install new equipment in the NIBRT facility including the GE Single Use Centre of Excellence, Fannin Healthcare, Pall Corporation, Merck Millipore and Beckman Coulter.

11 Events and Conferences

In 2016, NIBRT hosted over 44 events with over 2,000 attendees. Some notable events included:

In February and October 2016, NIBRT hosted the Biocluster zone at CareerZoo, Ireland's foremost careers events for professionals and innovative employers. Over 20,000 people attended both events at the National Convention Centre which included exhibitors from BMS, Regeneron, Alexion, Amgen, MSD, PPD, Janssen Biologics, Sanofi Genzyme.

NIBRT was delighted to partner with Informa to see the return of the leading industry conference Bioproduction 2016 to CityWest, Dublin in October 2016. Featuring over 400 attendees BioProduction provides a unique platform for the key biologic manufacturers from across the globe.

Working closely with BMS, the "Career Open Day for BMS" was held on in Nov 2016 with over 400 attendees.

35 journalists from 22 countries attended the global NIBRT-AbbVie event "Managing Complexity: the new biologics landscape", in September 2016.

Amgen Biotech Experience provided secondary school science teachers with a unique opportunity to explore real-world applications of high-end science in form of a biopharmaceutical production plant.



Attendees at the Careers in BMS event, November 2016.

12 Biopharma Ambition



In association with BiopharmaChemical Ireland (BPCI) and the Irish Pharmaceutical Healthcare Association (IPHA), NIBRT organised the inaugural Biopharma Ambition conference on Sept 21st and 22nd 2016. The conference brought together senior international leaders from organisations such as AbbVie, GSK, Amgen, Lilly, BMS, Sanofi Genzyme, Mallinckrodt, BioMarin, FDA, MIT, MSD, Pfizer, Bayer, Janssen, Roche. Ministers Mary Mitchell O'Connor and Simon Harris addressed over 300 delegates in attendance. The plenary session featured world leading industry experts from the pharmaceutical industry, which is worth over €30 billion in exports and has the potential to add 8,000 jobs over the next three years in Ireland and has the potential to double its size in Northern Ireland by generating revenues of £1.6 billion per annum by 2020. In order to meet this ambition and realise the future full potential of the industry across the island of Ireland, North and South, the BioPharma Ambition Conference called for:

- ▶ **AN EMPHASIS ON TALENT:** invest in education and create a sustainable basis to fund excellence in STEM education particularly at university level in Northern Ireland and Ireland
- ▶ **GROWTH IN COMPETITIVENESS:** focus on the fundamentals of a competitive business environment to facilitate the long term investment decisions made for bioprocessing
- ▶ **GROWTH IN HEALTH INNOVATION:** ensure health services are capable of evaluating and bringing innovative medicines to patients quickly, by promoting more clinical trials and greater investment in IT and key specialists.



Minister Simon Harris, TD speaking at Biopharma Ambition, Dublin Castle, Sept 2016.

“ The course provided me with what I was missing and what employers were looking for which that was practical experience in a state-of-the-art Biopharmaceutical manufacturing pilot plant. ”



Judy Conmey,
NPI Biotechnician

13 2016 Awards

NIBRT was delighted to be recognised with the following awards in 2016:

Irish Pharma Awards, which acknowledge and celebrate the most original and innovative individuals and companies in the Irish Pharma sector.

- ▶ 2016 Pharma Education & Training Award
- ▶ 2016 Partnership Alliance of the Year with Bristol Myers Squibb
- ▶ Bioprocess International 2016 Awards nominee for best collaboration
- ▶ Dr. Jonathan Bones - included on The Medicine Maker Power List 2016 of the top 100 most influential scientists in the field of biopharmaceutical development, manufacturing and analysis
- ▶ Prof. Pauline Rudd - listed in The Analytical Scientist 2016 Power List of the Top 50 most influential women in the analytical sciences



W I N N E R



W I N N E R



14 2016 Trends in Biopharma Survey

NIBRT was pleased to publish the results of its “2016 Trends in Biopharma Survey”. The survey assesses the key trends in biopharma pipelines, manufacturing technologies and staff development. 69% are highly optimistic for the future growth of the biopharma industry. While development of talent is seen as a key threat to the future growth of the sector, with practical based training programmes seen as the most effective methods of staff development. Key findings include:



38% of respondents were from the biopharma manufacturing sector.
45% of respondents have greater than 10 years experience in the sector.



Overall, **69%** of respondents are highly optimistic for the future growth of the biopharma sector.



There is a strong consensus that monoclonal antibodies (mAb) are the dominant therapy for the immediate future. However, product pipelines will diversify in a 5-10 year period with products such as cell and gene therapies becoming increasingly important. A key challenge will be establishing cost effective manufacturing solutions for these newer therapies. Two thirds of respondents agreed that biosimilars would have a major impact on the market.



With respect to biopharma manufacturing, **67%** identified cell line development and optimisation as the highest priority area for further innovation.

73% indicated Single Use Technologies (SUT) as the technology which would have the most beneficial impact over the next five years. However, extractable and leachables (**65%**) and lack of standardisation (**58%**) of SUT remain key concerns.

While many saw high potential in continuous manufacturing, the process development of these technologies is a major challenge for **63%** of respondents.



Recruitment and development of talent is seen as a key threat to the future growth of the sector.

In particular, **57%** of respondents are having a high degree of difficulty in recruiting Bioprocess Engineers. Hands-on practical training, either on-the-job or in training pilot plant environment, are seen as the most effective methods of staff development.



Overall access to skilled staff, manufacturing models for new therapies and cost issues were included as the main challenges to the growth of the sector. Key opportunities identified included cell therapies, gene therapies, biosimilars and standardised platform based, cost effective manufacturing solutions.





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