



National Institute for
Bioprocessing Research
and Training

Annual Report 2020



**Promoting world-class
biopharma investment
in Ireland**

Thank you to all NIBRT Staff who contributed to a successful 2020

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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 training and research.
- ▶ Established with IDA Ireland and opened in 2011, NIBRT partners with Higher Education Institutes to provide training and research infrastructure facilitates not previously available in Ireland.
- ▶ NIBRT's research and training building (6,500m²) features state-of-the-art pilot scale biopharma manufacturing facilities.

What we do

- ▶ Train and educate over 4,700 people annually to work in all areas of biopharma manufacturing
- ▶ Collaborate with industry on scientific research to drive innovation in biopharma manufacturing
- ▶ 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 and internationally





Message from NIBRT Chairman

In an unprecedented year, NIBRT staff demonstrated commendable resilience to deliver innovative solutions for our clients. The Institute plays a key role in supporting the growth of the sector at home and beyond and is now developing a particular focus on helping clients prepare for the rapid growth in advanced therapeutics.



Reflecting on 2020, the Board would like to thank all staff for adhering to pandemic guidelines, adapting quickly to working from home, staying focused and keeping each other and our client staff safe through the year. I would like to acknowledge and thank the NIBRT team for their many successes during the year, including:

- ▶ Supporting the growth of the biopharma sector by delivering over 31,000 days of learning while adhering to strict Covid-19 preventative measures.
- ▶ The commercial launch and success of the NIBRT Online Academy.
- ▶ Welcoming the Guangzhou Bioprocessing Research and Training Academy in China as the third member of our Global Partner Programme joining our partners in Philadelphia and Sydney.
- ▶ The further development of NIBRT research and the organisation's leadership position in the Cell and Gene Therapy Forum.
- ▶ Strongly contributing to the Covid-19 national response.
- ▶ Their success at winning three awards at the Irish Pharma Awards

I would also like to mention the leadership of NIBRT CEO Dominic Carolan who retired in May 2020 and welcome Darrin Morrissey as the new CEO. In particular, I would like to thank my Board colleagues and IDA Ireland for their continued support of the Institute. NIBRT's success is built on partnerships with stakeholders from across Industry, Academia and Government. In this context we welcome the newly created Department for Further and Higher Education, Research, Innovation and Science.

Despite the many challenges imposed by Covid-19, the outlook for the global biopharma industry is for continued strong growth. Global sales of biopharmaceuticals are now over \$300 billion, with a compound annual growth rate of 12%.

The biopharmaceutical market is now $\geq 30\%$ of the world's total pharmaceutical market including $>40\%$ of pharmaceuticals in development now being biopharmaceuticals.

In parallel, the Irish biopharma industry rose to the challenge of the pandemic demonstrating its resilience in global supply chains. New foreign direct investment from Pfizer, MSD, Regeneron and others and the growth of the indigenous sector were welcomed throughout the year.

Notwithstanding these successes considerable challenges remain. As a partner in global supply chains the Irish sector is subject to macro-economic and political developments. The success of the Irish biopharma sector and NIBRT has been well noted by other jurisdictions who are now making significant investments in rival biopharma research and training infrastructure. The ability to efficiently manufacture highly complex advanced therapeutics in a cost-effective manner will be a key determinant of Irish biopharma's future success.

As we look forward to 2021 the Board will be focusing on NIBRT's performance in continuing to support the development of the biopharma sector. Specific areas of focus will include the scaling of NIBRT research activity via national and international collaborations, the development of capability in the manufacture of advanced therapeutics and the continued expansion of our training. Over many decades Ireland has built a biopharma sector with a global reputation. We look forward to continuing to partner with our stakeholders and to developing new collaborations in further enhancing this hard-earned reputation.

Brendan O'Callaghan

*SVP, Global Head of Biologics Platform, Sanofi.
NIBRT Chairman.*



NIBRT Board 2020

- ▶ **Brendan O’Callaghan (Chair)**
SVP and Global Head Biologics Platform, Sanofi
- ▶ **Dr Robert Baffi**
President of Global Manufacturing and Technical Operations, BioMarin
- ▶ **Prof Andrew Bowie**
Prof of Innate Immunology and Associate Dean of Research at Trinity College Dublin
- ▶ **Gerry Collins**
Global Platform Leader Parenterals at Janssen
- ▶ **Tommy Fanning**
Head of Biopharmaceuticals and Food, IDA Ireland
- ▶ **Prof Orla Feely**
Vice President for Research, Innovation & Impact (VPRII), UCD
- ▶ **Dr Tom Kelly**
Divisional Manager Cleantech, Electronics and Life Sciences, Enterprise Ireland
- ▶ **Prof Anita Maguire**
Vice President for Research & Innovation, Director A.B.C.R.F., UCC
- ▶ **Brendan McCormack**
President of IT Sligo
- ▶ **Darrin Morrissey**
CEO NIBRT
- ▶ **Tom Murray**
Director at Friel Stafford
- ▶ **Julie O’Neill**
Non-Executive Director



...an important element of our ecosystem is NIBRT. Through IDA Ireland, the Government invested in NIBRT which has transformed Ireland’s capacity to support biopharmaceutical training and innovation.



→ **Leo Varadkar TD, Tánaiste and Minister for Enterprise, Trade and Employment**

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Message from NIBRT CEO

It is an understatement to say that the Covid-19 pandemic made 2020 the most challenging and utterly unprecedented year imaginable. NIBRT started the year having had a highly exceptional 2019 and we had been projecting a record revenue year in 2020.



Covid-19 resulted in the closure of the NIBRT facility during the first wave of the pandemic in March and April, but on June 8th, following considerable hard work and significant changes to the running of the facility and to our business delivery model, we were able to reopen the NIBRT facility for training and research business. From then, in spite of all of the challenging headwinds, NIBRT had a remarkably successful year.

In line with IDA Ireland's success in attracting new biopharmaceutical investments to Ireland as well as continued expansions across the sector, the demand for NIBRT's training and education services held up very well. In 2020,

- ▶ We adapted our face-to-face training programmes towards a blended online/in-person approach and delivered training to 4,000 people from multiple companies across over 30,000 learning days.
- ▶ We moved to online delivery of our education modules and partnered with ten Irish higher education institutes to deliver teaching to postgraduate and undergrad students.
- ▶ We delivered training to 700 students the Springboard+ programme, which is and will continue to be central plank of the Government's post Covid recovery strategy.
- ▶ In January 2020, we launched the NIBRT Online Academy (NOA) offering a completely new service of remote training delivery to customers at precisely the time it was most needed by our customers. NOA has had an incredible first year of business, selling nearly 6,000 licences to users in Ireland and around the world; more than double what was originally projected.

In March 2020, in-person training of international customers and international visits to NIBRT, after an initial strong start, ground to a halt due to Covid. However, this decline in 'traditional' training was more than offset by a various excellent developments on the international front. As well as NOA enabling NIBRT training to be offered remotely to global clients, NIBRT also:

- ▶ Continued to develop and expand its global training partnership with Jefferson Institute of Bioprocessing in Philadelphia, USA.
- ▶ Launched a new global training partnership with the Guangzhou Bioprocessing Research and Training Academy in Guangdong Province, China.
- ▶ Signed a new deal to deliver training to Takeda Biopharmaceutical Manufacturing staff around the world in the coming years.

On the research front, the NIBRT research team overcame the challenges of Covid-19 shutdown to deliver highly impactful collaborative research projects with biopharma industry players; including Agilent, Allergan, BMS, Janssen, Siemens and Thermo Fisher, to name but a few. The Contract Services research team continued to deliver high-quality and well-regarded development and analytical services to industry. In response to the pandemic, NIBRT Research launched a series of Vaccine Manufacturing Online Seminars which were attended by a wide audience of stakeholders. And, we were delighted to welcome Dr Steven Ferguson as our seventh NIBRT Research Principal Investigator in a joint appointment partnership with UCD.

In terms of future growth areas, 2020 was a massive year for NIBRT. In the autumn, following extensive preparatory work and the submission of a comprehensive business plan, NIBRT received approval from the board of the IDA for an investment to expand our Foster's Avenue facility to incorporate Cell and Gene Therapy (CGT) capabilities. CGT represents the next wave of biopharma manufacturing growth and the newly-expanded facility, which we expect open in 2022, will enable NIBRT to expand its training and research services into this new area.

Lastly, 2020 was an exciting year for me personally as I joined NIBRT as CEO in June. Of course, this was right in the middle of the pandemic, so onboarding into my new role was not without its challenges.

I want to acknowledge the help and guidance that I received from the previous CEO Dominic Carolan during my initial transition period. Also, I would like to thank the NIBRT Chairperson Brendan O'Callaghan, the members of the NIBRT board and all NIBRT staff for welcoming me onboard and supporting in my first half-year in the role.

I look forward to another successful year for NIBRT in 2021, and hopefully with good health for all our staff, partners, vendors and clients.

Darrin Morrissey
NIBRT CEO.





2020 NIBRT by the numbers

4,000



Number of
trainees in **2020**

31,856



Number of **training**
days delivered

775

Number of



students trained
in **2020**

45.5%

% of **NIBRT**
research that is
funded by Industry



35



Number of
peer reviewed
publications

51



Number of
conference
presentations

0



Number of events,
conferences held in
NIBRT

€8.5
million



Value of equipment
donations in
2015-2019

0

Lost time
accidents



86

Number of
employees
working at NIBRT

50:50



Gender balance
at **NIBRT**



16

Number of
nationalities
working at NIBRT



The Biopharma Industry in Ireland – 2020

In a year of unprecedented challenges, the Irish biopharma sector showed strong resilience and continued growth. With a strong collaborative effort, the sector is well positioned to lead the post Covid-19 economic recovery with a number of exciting but challenging opportunities.



Economic Impact

The importance of the lifesciences sector (Pharmaceutical, Biotechnology, Medical Devices and Diagnostics) as a robust cornerstone of the Irish economy is well documented. The sector has grown rapidly from modest beginnings in the 1960s to reach global significance and in 2019 accounted for 32% of Ireland's GDP (€140.6 billion in exports).

Despite the many challenges in 2020, the biopharmaceutical manufacturing sector continued to see strong foreign direct investment across the regions, including:

- ▶ Pfizer to create 300 jobs in Dublin, Kildare and Cork
- ▶ MSD announces 240 new jobs with expansion at Dunboyne
- ▶ Allergan marks opening of new €160m biologics facility in Westport with 63 new jobs
- ▶ Regeneron Announces 400 new jobs in Limerick
- ▶ Gilead Sciences to create 140 jobs at Irish operations in Dublin and Cork

Of particular note was the first significant gene therapy manufacturing investment, with MeiraGTX's announcement of a major expansion in Shannon for plasmid production and viral vector manufacturing.

Biopharma activity in Ireland now comprises a diverse complex range of operations built on a platform of advanced manufacturing.



The EU Pharmaceutical Sector¹

800,000
direct jobs

€37 billion
contributed to research investment (2019)

€110 billion
trade surplus

Each year more than
60 new medicines
authorised at EU Level

1. https://ec.europa.eu/health/human-use/strategy_en

This has enabled growth in related activities such as global business services, clinical trial management, contract manufacturing and supply chain management. It also supports a vigorous indigenous sub-supply network, many of whom have developed as international market leaders in their own right.

It was also encouraging to see the continuing strengthening of the research and development community with companies like Avectas, Priothera, Onk Therapeutics making strong progress. A key highlight was the acquisition of Prof Luke O'Neill's Inflazome by Roche for €380m. While Irish life sciences investor Fountain Healthcare Partners also closed its third fund, having raised €125 million.

The extraordinary patient impact of gene therapies on patients was highlighted by reports of Irish haemophilia B patients being “functionally cured” after a clinical trial with a single dose of a new gene therapy (an AAV based gene therapy, UniQure's etranacogene dezaparvovec).

Impact of Covid-19

The sudden and unprecedented nature of the Covid-19 pandemic created very significant challenges throughout the year. Biopharma manufacturing activities were recognised as an essential service and demonstrated their resilience by continuing uninterrupted distribution to the global supply chains.

Those companies which were developing large scale capital projects faced particular challenges, but by working closely with leading construction and engineering companies disruption was kept to a minimum. For example, Wuxi Biologics went to site in Dundalk in February 2019, with foundations starting in March 2019 and first steel erected in May 2019. By the end of 2020, this 47,000m² “factory of the future” had successfully managed the Covid disruptions and was at 85% construction complete. While in Shannon, construction of a 14,000 m² development comprising three separate buildings, two of which have been committed to MeiraGTx continued apace. By year end clean rooms were ready for qualification and the second building was ready for handover to MeriaGTx.

The pandemic also provided new opportunities for the sector, for example with Beckman Coulter announcing recruitment for its facility in Tulla, Co. Clare for manufacturing of an antibody test for Covid-19. Regeneron's expansion in Limerick assisted its sister plant in US to develop capacity for its Covid antibody treatments. ICON's role in managing the clinical trial for the Pfizer BioNTech vaccine is also of particular note. With the Pfizer Grange Castle facility also performing quality control on this ground-breaking vaccine.

2. https://www.idaireland.com/newsroom/publications/ida_pharma



The Irish Biopharmaceutical Sector¹

Ireland is the **3rd** largest exporter of pharmaceuticals globally

€80 billion of annual exports

85+ pharmaceutical companies in Ireland
50 FDA approved

All the **TOP 10** global pharmaceutical companies located in Ireland

5 of the world's 15 top-selling pharmaceuticals manufactured in Ireland

Circa €2 billion invested in biopharma R&D by IDA client companies

NIBRT 2020

As reported in this Annual Report, 2020 was a year of strong performance for NIBRT with highlights including:

- ▶ Supporting the growth of the biopharma sector by delivering over 31,000 days of learning while adhering to strict Covid-19 preventative measures
- ▶ The commercial launch and success of the NIBRT Online Academy
- ▶ The further expansion of the NIBRT Global Partner Programmes with the opening of a facility in Guangzhou, China.
- ▶ Further growth of NIBRT research collaborations and research teams with a particular focus on CGT.
- ▶ This performance was reflected in NIBRT winning three awards at the Irish Pharma Awards

The NIBRT team was especially pleased to make a number of contributions to the national Covid-19 response including:

- ▶ Working with a broad coalition of partners to manufacture lysis buffer for the PCR test.
- ▶ Providing a range of free Covid-19 related lessons on the NIBRT Online Academy.
- ▶ Hosting a series of free vaccine manufacturing webinars.

Biopharma Manufacturing Challenges

Despite the success of the industry in Ireland to date, there are a number of key challenges in the years ahead:

Strong growth and capacity issues: The global sales of biopharmaceuticals are now over \$300billion, with a 12% CAGR³. The biopharmaceutical market is now in excess of 30% of the world's total pharmaceutical market and more than 40% of pharmaceuticals in development are biopharmaceuticals.

The requirement for global supply of multiple of Covid-19 vaccines will put increased pressure on manufacturing capacity and contract development and manufacturing (CDMO) operations will scale accordingly. Increased demand for biosimilars and biobetters will put further demands on manufacturing capacity.

More complex and diverse therapies: Monoclonal antibodies produced via mammalian expression systems will remain the dominant therapeutic modality⁴. However, the range and complexity of therapies will diversify considerably including multi-specific antibodies, antibody conjugates, antibody fragments, nucleic acids etc.

In particular, cell and gene therapies have shown strong clinical performance which will pose very considerable process development and manufacturing challenges to scale the production of these therapies.

Advanced manufacturing⁵: To remain competitive there is continued demand for new efficiencies, improved quality, and cost reductions in manufacturing processes. Key trends, many of which rely on vendor innovation, include:

- ▶ More flexible, modular multi-product, facilities
- ▶ Further adoption of single-use systems at clinical scales and commercial scales
- ▶ Steady increase in expression titres and purification yields, with incremental improvements in host cell lines, culture media, expression systems, vectors, promoters etc
- ▶ Continuous processing, including upstream perfusion and downstream chromatography
- ▶ Implementation of Industry 4.0 / digitalisation technologies with a particular focus on automation, robotics, big data analytics

Workforce development challenges: The World Economic Forum estimates that by 2022 the core skills required to perform most roles will change by 42%, which in turn will require everyone to have an extra 101 days of learning per person⁶. In NIBRT's annual survey 46% of respondents indicate the biggest challenge to the growth of sector is staffing and technical skills⁷.

3. CPhI Annual Industry Report 2019: Mammalian Biomanufacturing Industry Overview

4. Biopharma Benchmarks, Gary Walsh, Nature Biotech, Vol 36, Dec 2018

5. Seventeenth Annual Report and Survey of Biopharmaceutical Manufacturing Capacity and Production, BioPlan and Associates

6. World Economic Forum 2019: Towards a Reskilling Revolution

7. 2017–2019 Trends in Biopharma Manufacturing Survey, NIBRT and The Medicine Maker



With the right collaboration between industry and Government, such as the NIBRT example, we can catch these new waves of biopharmaceutical innovation while sustaining the significant progress we have made in capturing investments over the past five decades.



→ **An Tánaiste, Simon Coveney, TD**

Opportunities for Ireland

To address these challenges and to further develop the biopharma sector in Ireland, NIBRT recommends five calls to action:

- ▶ A continued focus on **workforce development** with a long-term strategy to develop appropriate solutions across all levels and demographics. Initiatives such as Springboard+ and Generation Apprenticeship are to be further encouraged.
- ▶ A focus on building **biopharma manufacturing research** of scale. In this regard, NIBRT welcomes the new EU Pharmaceutical Strategy⁸ and its focus “on investment in research, development and manufacturing of new medicines”.
- ▶ A focus on realising Ireland’s potential in **cell and gene therapy**, including how the development of skills, new production sites, and designated research and therapy areas could help foster innovation, create jobs and draw investments.

- ▶ A focus on growing the existing biopharmaceutical manufacturing base through the application of advanced manufacturing, including leveraging **Industry 4.0**, digital transformation technologies.
- ▶ Further **promotion** and marketing of Ireland’s biopharma value proposition to a global audience, including initiatives such as the NIBRT Global Partner Programme.

Impactful collaborations between Industry-Government-Academia are seen as the most effective mechanism to ensure timely implementation of these actions and ultimately to ensure that Ireland can continue to build on the success of its biopharma manufacturing sector.

Killian O’Driscoll

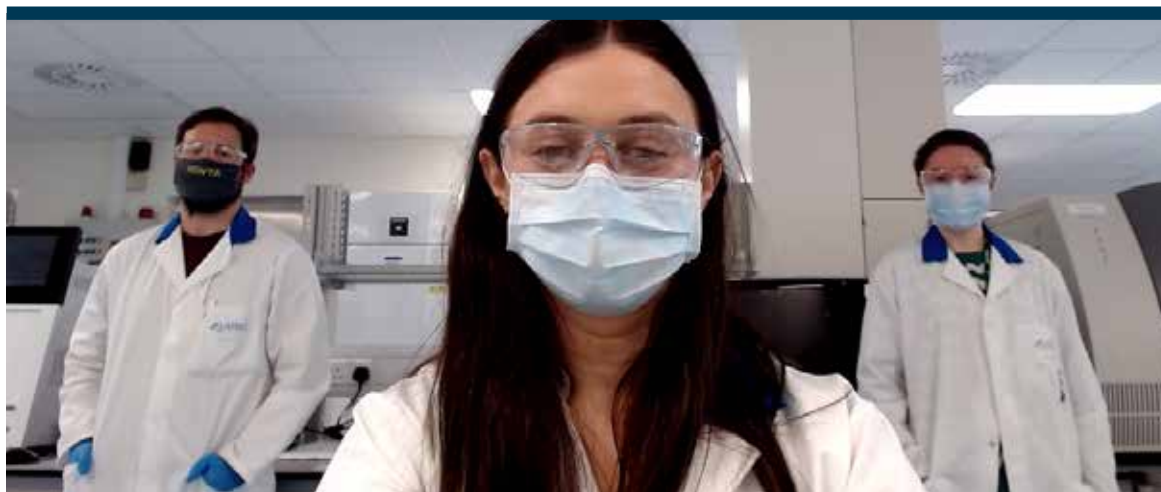
NIBRT Director of Projects

8. https://ec.europa.eu/health/human-use/strategy_en

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NIBRT's Covid-19 Response

In March 2020, the NIBRT facility was closed and staff worked from home in line with Government guidelines to curb the spread of the SARS-CoV-2 vaccine.



NIBRT trainers delivering training via video conferencing to a delegation from Saudi Arabia

Led by our Environment, Health and Safety team strict social distancing protocols and safety procedures were implemented and we were pleased to re-open the facility in June for essential work.

The NIBRT training team adapted to new ways of working with a greater dependency on remote delivery of content for clients who could not travel to the facility. Any essential practical sessions were safely delivered at NIBRT at reduced capacity and with full adherence with robust physical distancing and hygiene requirements. Our research teams maintained strict safety practices with reduced occupancy in the labs during the period. To date, there have been no reports of Covid-19 amongst our staff or associated with the NIBRT facility.

The NIBRT team was especially pleased to make a number of contributions to the national Covid-19 response including:

- ▶ Working with a broad coalition of partners, as part of the Covid-19 Alliance, to manufacture lysis buffer for the PCR test.
- ▶ Providing a range of free Covid-19 related lessons on the NIBRT Online Academy.
- ▶ Hosting a series of free vaccine manufacturing webinars.

- ▶ Donation of PPE, equipment and consumables to local hospitals.
- ▶ Continuing to deliver our training programmes to industry to support their uninterrupted manufacturing of biopharmaceuticals

The NIBRT Team also looks forward to contributing to the post Covid-19 recovery. Our training team has developed new courses and curricula focused on vaccine manufacturing and related areas which will be rolled out in 2021.

From a research perspective, a notable feature of many of the Covid-19 vaccines in development is the level of novel and advanced technologies being deployed and adopted for the first time. Within the first wave of new Covid-19 vaccines are the two recently-approved mRNA-based vaccines, while a number of the yet-to-be-licensed vaccine candidates are incorporating other innovative viral vector and novel recombinant protein technologies. NIBRT research teams look forward to contributing their expertise to ensure the efficient manufacturing at scale of these vital vaccines.



NIBRT Research and Innovation

NIBRT performs leading edge research, in collaboration with industry and academic partners, that advances biopharmaceutical manufacturing, supports and advances the biopharmaceutical industry in Ireland and the world, and increases the pool of highly trained doctoral and postdoctoral level scientists.



In 2020, despite the challenges of global pandemic, NIBRT Research continued to make significant contributions in its core research areas. These contributions included advanced analytical methods for process monitoring, novel methods for AAV vector characterization, glycan characterization and glycoproteomics methods, innovative single cell RNA sequencing, hydrolysates for cell culture supplementation, and new approaches to drug product stabilization and characterization. The group updates and Case Studies presented elsewhere in this Report provide additional information on these advances.

Cell and gene therapies are the next generation of biopharmaceutical products, and the Covid-19 pandemic has underscored the importance of novel vaccines and efficiency in their manufacturing. In 2020, NIBRT led the national cell and gene therapy (CGT) forum, expanding its scope to include vaccines. To provide information in this critical area, NIBRT launched the “NIBRT Vaccine Manufacturing Webinar Series” in September. The webinars presented in 2020 discussed the development of vaccines for Shigella, vaccine development for Covid, plant-derived vaccines, and virus-like particle production. These webinars have been recorded and are available on the NOA website; additional vaccine manufacturing webinars are planned for the spring.

In January 2020, NIBRT launched the Career Development Seed Grant Programme to support our early stage researchers. The program provides initial (‘seed’) funding to NIBRT scientists, with the goal of promoting their professional development and advancing NIBRT’s research mission.

The Seed Grant Programme is administered by the Research Office. In 2020, eight high-quality applications were submitted by NIBRT early career researchers, and three Seed Grants were awarded in April 2020. The second call for Career Development Seed Grants is planned for early in 2021.

NIBRT Research grew during 2020, adding a new PI, a new member of the Research Office and several members to the individual research groups. In December, we welcomed Dr. Steven Ferguson as NIBRT’s newest PI. Steven is an Assistant Professor in the School of Chemical and Bioprocess Engineering at University College Dublin (UCD) with research interests in bio-separations and downstream processing. Additional information on Steven and his research is presented elsewhere in this report. In May, Lara Gibney joined the NIBRT Research Office as a Research Support Administrator.

Throughout 2020, NIBRT Research worked to develop a five-year strategic plan, setting goals and a direction together with senior management, and with input from our Scientific Advisory Board and Board of Directors. As CSO, it has been a joy and a privilege to help envision the future of NIBRT research. I look forward to engaging with everyone at NIBRT, and with our stakeholders, as we work make the plan a reality in 2021 and the years to come.

Elizabeth M. Topp, Ph.D.

Chief Scientific Officer

NIBRT's Scientific Advisory Board

Robert Baffi, Chair

Special Advisor to the Chairman and Chief Executive Officer BioMarin

Martin Clynes

Professor Emeritus at DCU

Charles Cooney

Robert T. Haslam (1911) Professor of Chemical and Biochemical Engineering, MIT

Matt Croughan

Independent Consultant

Gavin Davey

Associate Professor, Biochemistry and Trinity Inst. of Neurosciences

Alan Dickson

Professor of Biotechnology, University of Manchester

Brian Glennon

Professor of Chemical and Bioprocess Engineering, Senior Director and Co-Founder at APC Ltd.

Brendan Hughes

Senior Vice President, Global Manufacturing Operations BMS

Barry Karger

James L. Waters Professor Emeritus

Barry McCarthy

Senior Director at Janssen R&D

Pauline Rudd

Emeritus Fellow at UCD and visiting Investigator at BTI AStar Singapore

Richard Snyder

Vice President, Science and Technology, Pharma Services, Viral Vector Services at Thermo Fisher Scientific

Parviz A. Shamlou

Executive Director at Thomas Jefferson University

Bioinformatics and Data Analytics, Dr Colin Clarke

In 2020 highlights from the Clarke Laboratory's work on CHO cell biology include the installation of a state of the art single cell omics analysis platform at NIBRT capable of analysing thousands of individual cells in a single experiment. The group [published](#) the first example of how single cell RNA sequencing can be utilised to capture the transcriptional heterogeneity in a cell line and how this variability influence manufacturing performance. These activities were enabled through a Horizon 2020 Marie Curie European Industrial Doctorate programme coordinated by NIBRT which is focussed on using the single cell analysis for a range of biopharmaceutical manufacturing systems.

Dr. Krishna Motheramgari received his PhD for his work on identifying long non-coding RNAs in the CHO cell genome.

The Clarke Laboratory's BioMac collaboration with Siemens to develop state of the art data analytics infrastructure for biopharmaceutical manufacturing successfully completed projects with two partner companies involved in recombinant protein and gene therapy manufacturing. The BioMac project has now entered its second phase.

Cell Engineering, Prof Niall Barron

The Cell Engineering group welcomed two new members in 2020 – Drs. Stefano Boi and Nick Donohue. Both were recruited to work on a collaborative project with Allergan Biologics focused on improving AAV-based gene therapy vector manufacturing, funded by Enterprise Ireland's Innovation Partnership scheme. The past year has seen them make great progress in establishing the two main AAV production platforms in NIBRT – the HEK293 system and the BEVS (Baculovirus) system - as well as generating a suite of modified plasmids for testing in these systems. Nick and Stefano, in collaboration with colleague Niamh Keogh, were invited to write a book chapter describing the challenges of manufacturing these gene therapy vectors which was submitted for publication in *Cell Culture Engineering and Technology* (Springer) in early 2021.

Dr. Nga Lao was awarded a NIBRT seed project aimed at using novel epi-transcriptomic engineering approaches to improve the production of lentiviral vectors (used in CAR-T therapy). This project is the first one focused on this important gene therapy platform and illustrates NIBRT's commitment to expanding our research activity in the CGT area.

This year also saw the launch of NATURE-ETN, a Marie-S-Curie ITN network focused on generating novel nucleic acid synthesis, engineering and analysis strategies. The network brings together experts from across the EU and UK and will train 15 Early Stage Researchers, one of whom will be based in NIBRT.

Cell Technology Group, Prof Mike Butler

The Cell Technology Group (CTG) like most research groups in 2020 was interrupted by the Covid crisis but continued to work at home on data analysis and writing papers during the lockdown period until the partial lifting of restrictions allowed us access to the labs. Highlights from the Group in 2020 included:

Work continued with the Kerry Group to characterise the active components in a range of non-animal hydrolysates that can be used to supplement cell culture media. A paper has been submitted in which we identify the targets of bioactivity for the hydrolysates analysed. The next phase is to identify the active chemical components in these hydrolysates.

Research into glycan analysis and glycoengineering progressed with collaboration and support from Agilent using a novel label for high sensitivity analysis of glycans from individual glycoproteins as well as human serum. Recent data from this project was presented at the 3rd Bioprocessing Summit Europe (Virtual), July 2020 winning the prize for the best conference poster.

On-line monitoring of cells in bioreactors continued with support from Canty and Aber Instruments with a recent report and poster on label-free, flow imaging microscopy for monitoring cell health and antibody production as well as cell clustering data analysis.

The Cell Technology Group combined their expertise to write a review on the critical steps in the biomanufacturing of recombinant proteins; *“Mammalian Cell Culture for production of Recombinant Proteins: A review of the critical steps in their biomanufacturing”* published in *Biotechnology Advances* by Elsevier.

In August BioProcess International announced that our article *“The case for re-evaluating cell viability in bioprocesses”* ranked among the four best articles published in the analytical category of the journal over the last year. The article also won 2nd place in BPI's 2020 Readers' Choice Award.



Characterisation and Comparability Lab, Prof Jonathan Bones

Although 2020 was a challenging year and one that changed the way in which we all worked, NIBRT's Characterisation and Comparability Laboratory (CCL), under the direction of Prof Jonathan Bones continued to make excellent progress in the development and application of new technologies to support all aspects of biopharmaceutical manufacturing and characterisation.

The key research areas for the group include advanced automated analytics for process monitoring, analysis of process contaminants along with advanced characterisation strategies such as the multi-attribute method (MAM) and biopharmaceutical analysis using native separations coupled to high resolution native mass spectrometry.

Additionally, the past year saw the CCL ramp up activities focused on the characterisation of advanced therapeutic entities, specifically AAV based gene therapy, developing new approaches for their characterisation and the processes used to generate these complex molecular entities.

The group published extensively in these exciting areas over the past year, accompanied by a number of provisional patent filings on these exciting technologies.

The CCL continued to strengthen their collaborative interaction with Thermo Fisher Scientific and were delighted to assist in the launch of Thermo Scientific's new Orbitrap Exploris 240 mass spectrometer, generating broad marketing collateral to demonstrate the instruments power and impressive capabilities for in-depth biopharmaceutical characterisation.

The group also kicked off a number of collaborative projects with Irish, UK and European based biopharmaceutical manufacturers covering all aspects of the groups research activities.



New Downstream Processing Principal Investigator, Dr Steven Ferguson

In December 2020, Dr Steven Ferguson was appointed as a NIBRT Principal Investigator to lead a research program focused on downstream processing in biopharmaceutical manufacturing research.

Dr. Ferguson's research is focuses on the development of novel technologies with the potential for commercial or societal impact primarily in the area of advanced manufacturing, separation and formulation of Pharmaceuticals, Biopharmaceuticals and ATMPs. To this end he has assembled a multidisciplinary research portfolio with expertise in separation processes, downstream bioprocessing, process simulation, flow synthesis, unit operation & reactor design, chromatography, membrane separation, crystallization and formulation; structured to be vertically integrated to bring fundamental insights from multiphase systems, reactions or separations, through simulations and prototypes to actionable technologies.

In addition, Ferguson will continue his role in UCD where he currently serves as the manufacturing theme lead for the SSPC, the Science Foundation Ireland Research Centre for Pharmaceuticals and the targeted SPOKE project lead for Pharmaceuticals in I-form, the Science Foundation Ireland Research Centre for Advanced Manufacturing, in addition to leading targeted research projects with a number of global pharmaceuticals companies.

GlycoScience, Dr Radka Fahey (Saldova)

Despite the challenges of 2020, it was a productive year for the GlycoScience group, with 14 publications published in 2020. Key publications of note include:

- ▶ Hypoxia Alters Epigenetic and N-Glycosylation Profiles of Ovarian and Breast Cancer Cell Lines in-vitro, Greville et al, 2020, [Frontiers in Oncology](#).
- ▶ Current Methods for the Characterization of O-Glycans, Wilkinson et al, 2020, [JPR](#).
- ▶ Quantitative levels of serum N-glycans in type 1 diabetes and their association with kidney disease, Colombo et al, 2020, [Glycobiology](#).
- ▶ Glycosylation in Indolent, Significant and Aggressive Prostate Cancer by Automated High-Throughput N-Glycan Profiling, Gilgunn et al, [IJMS](#), 2020.

Kieran Joyce was the recipient of the Best Poster Presentation Award for his poster entitled "A Glycoproteomic Investigation into the Role of Glycosylation in Intervertebral Disc Degeneration" (Joyce K, Devitt A, Saldova R & Pandit A) which was presented at the virtual ORS Philadelphia Spine Research Symposium in November 2020, Philadelphia, USA.

The group had several public engagement activities including Hayden Wilkinson being selected as a finalist in the following competitions, Irish Research Council and USI "[Why Research Matters Video Competition](#)" and the "[PwC/U21 Innovation Challenge](#)". Dr. Elizabeth Matthews was a judge during the ESB Science Blast which was held in March 2020

Finally, Dr. Zsuzsanna Kovacs created the Glycomendo project website in March 2020 and introduced the Glycomendo project in General Annual Meeting of EAI in February 2020.



NIBRT Research 2020

35 publications
in 2020

18 collaborations

7 Principal
Investigators

55 researchers

51 conference
presentations

45.5%
of research income
funded by Industry

€1.2 million
Equipment donations in 2019

Congratulations

- ▶ Dr. Krishna Motheramgari who successfully defended his PhD thesis entitled: *“Long non-coding RNA mediated post-transcriptional regulation in Chinese hamster ovary cells”* in April 2020.
- ▶ Prof. Michael Butler and his team as their article *“The case for re-evaluating cell viability in bioprocesses”* received the BPI Readers’ Choice Award for 2020.
- ▶ Letícia Martins Mota, recipient of the Best Conference Poster Prize at the 3rd Bioprocessing Summit Europe (Virtual), Barcelona, July 2020.
- ▶ Kieran Joyce, awarded Best Poster Presentation Prize (1st place) for his poster entitled: *“A Glycoproteomic Investigation into the Role of Glycosylation in Intervertebral Disc Degeneration”* at the ORS Philadelphia Spine Research Symposium, November 2020, Philadelphia, USA





Research Case Studies

Thermo Fisher Scientific and Prof Jonathan Bones

The collaboration between NIBRT and Thermo Fisher Scientific began in 2016 and is focused on the development of analytical solutions for the characterisation of complex biopharmaceuticals.

ThermoFisher
SCIENTIFIC

The project team, led by Prof Jonathan Bones at NIBRT, are developing analytical workflows for the complete characterisation of monoclonal antibodies, complex recombinant proteins and new modalities such as cell and gene therapies.

To do this, the team use sample preparation and automation solutions from Thermo Scientific, such as the SMART Digest range of magnetic sample preparation and digestion reagents combined with the KingFisher Duo Prime Automation Station. The team have investigated the wide range of column chemistries, such as the MAbPAC, Acclaim and Accucore products, available from Thermo Scientific for high performance separations of intact proteins, peptides, glycans, process related contaminants and raw materials using Thermo Scientific's unrivalled Vanquish UHPLC instrumentation coupled to high resolution Orbitrap mass spectrometers.

Since 2016, the project team at NIBRT have established many innovative methods for the characterisation of biopharmaceuticals. The team's activities have focused on demonstrating the power of the analytical technology, but ensuring that the developed methods are simple, user friendly and robust, without compromising the quality of the information produced. We strive to achieve these aims and to work with biopharmaceutical manufacturers to allow them to implement the developed methodology for routine applications in their R&D and quality laboratories. As part of the collaboration with Thermo Fisher Scientific, NIBRT have released many application notes and resources that are designed to provide complete workflows for a broad range of challenging attributes that need to be measured and controlled during biopharmaceutical analysis.

This multi-year collaboration allows NIBRT to access the newest chromatography and high-resolution mass spectrometry instrumentation and innovative chromatography solutions but also enables the team to shape new technology and make important and impactful contributions in the adoption of new standards in biopharmaceutical analysis. At present, the team members on this active collaborative project include Sara Carillo, Craig Jakes, Tomos Morgan and Silvia Millán Martín, however the team is continuously expanding and looking for new recruits⁹ to work on this and other exciting projects in place within the Characterisation and Comparability Laboratory.

Recent publications from NIBRT Thermo Fisher Scientific collaboration:

- ▶ Large-Scale Assessment of Extractables and Leachables in Single-Use Bags for Biomanufacturing. *Anal. Chem.* 2018, 90, 15, 9006–9015.
- ▶ Comprehensive characterisation of the heterogeneity of adalimumab via charge variant analysis hyphenated on-line to native high resolution Orbitrap mass spectrometry. *mAbs*, volume 11, 2019 - Issue 1.
- ▶ Cracking Proteoform Complexity of Ovalbumin with Anion-Exchange Chromatography-High-Resolution Mass Spectrometry Under Native Conditions. *J. Proteome Res.* 2019, 18, 10, 3689–3702.
- ▶ A streamlined workflow for two plexing of N-linked glycan analysis using light (¹²C6) and heavy (¹³C6) isotopologues of 3-aminobenzenesulfonic acid DOI. *Analytica Chimica Acta Volume 1099*, 22 February 2020.

9. Please visit <https://www.nibrt.ie/careers/> to view the current career opportunities

STACCATO, European Industrial Doctorate, Dr Colin Clarke

STACCATO¹⁰ is a European Industrial Doctorates project funded under the Marie Skłodowska-Curie Action of Horizon 2020.



Staccato Early Stage Researcher group

It is a €2.9 million, four-year project which began in 2019 and is led by NIBRT Principal Investigator, Dr. Colin Clarke.

The programme's focus is on strengthening Europe's innovation capacity and leadership in biopharmaceutical manufacturing science by providing world-class intersectoral training to 11 Early Stage Researchers (ESRs) and creating and applying pioneering manufacturing process development approaches for biopharmaceuticals. The STACCATO research programme focuses on the utilisation of single cell analysis methods to characterise the molecular heterogeneity of cell populations utilized in the biopharmaceutical industry.

The STACCATO network is composed of an industry leader in instrumentation for cellular analysis, three innovative biotech SMEs, a leading academic institution and a research-conducting biological medicines regulatory agency. STACCATO consists of eight supervisors, including NIBRT PI's, Jonathan Bones and Niall Barron. The check meeting took place virtually in June 2020, and despite the unique circumstances, the meeting turned out to be a great success.

The Staccato ESR's have also started their own blog <https://staccato-esr.eu/> which features posts about their lives as Marie Skłodowska-Curie fellows, their individual research projects and anything else that might interest the ESRs and the readers. NIBRT's ESR's include Alan Foley, Marco Romero and Ryan Hagan who are working on following projects:

- ▶ **Alan Foley:** Identification of mitochondrial DNA mutations in single cells for biopharmaceutical manufacturing.
- ▶ **Marco Romero:** Development and application of Single-Cell Proteomics to investigate cellular heterogeneity for biopharmaceutical manufacture.
- ▶ **Ryan Hagan:** Understanding CHO cell heterogeneity to enable increased production of recombinant therapeutic proteins.

In 2020, the team used Becton Dickinson's Rhapsody cell RNASeq system to study a CHO cell line that suffered from production instability. From the resulting data, they were not only able to monitor mRNA levels of the mAb heavy and light chains in more than 3,800 individual cells but also gain an understanding of the evolution of the cell line. The full version of the paper 'Tracing production instability in a clonally-derived CHO cell line using single cell transcriptomics' can be accessed via <https://www.biorxiv.org/content/10.1101/2020.11.04.368480v3>

10. For more information on the STACCATO project, please visit <https://www.staccato-eid.eu/>

Viral Vector Services Collaboration with Patheon

In August 2020, NIBRT PI Jonathan Bones team commenced a collaborative engagement with Patheon Viral Vector Services (Patheon), a division of Thermo Fisher Scientific.



With the acquisition of Brammer Bio in 2019, Patheon has become a leading Contract and Development Manufacturing Operations (CDMO) in the rapidly growing cell and gene therapy space providing end-to-end clinical and commercial manufacturing capabilities of a large variety of viral vectors for cell and gene therapies. Through this collaboration, the NIBRT team, headed by Senior Scientist Josh Smith, are working with scientists from the Patheon Science and Technology Team to develop rapid methods for the identification of adeno-associated virus (AAV) capsids and associated host cell protein (HCP) contaminants.

Utilizing state-of-the-art Vanquish UHPLC instrumentation coupled to high resolution Orbitrap mass spectrometers, the NIBRT team are developing intact LC-MS and methods for the rapid identification of AAV capsid proteins across different serotypes. Methods for the quantitative analysis of residual AAV HCP process contaminants are also in development for process impurity identification. Once optimized and evaluated, the developed AAV capsid protein identification and HCP characterization methods will be transferred to the Patheon team for implementation in their current process workflows.



Cell and Gene Therapies

Next wave of biopharma investment

In recent years there has been dramatic growth in the number of clinical trials and in the level of commercial activity with advanced therapy medicinal products (ATMPs), including cell and gene therapies (CGTs) and novel-modality vaccines, and it is widely predicted that these advanced products will collectively constitute the next significant wave of biopharma growth.

At the start of 2020 there were over 900 start-up CGT companies with increasing numbers of the large biopharma multinationals now entering the arena, mainly via the acquisition of smaller biotech players. In January 2019, the US Food and Drug Administration (FDA) stated that it expected to see more than 200 applications per year requesting permission to begin cell and gene therapy trials by the end of 2020, from a position where the agency already had more than 800 such applications on file. Since 2016/17 there has been a steady rise in the number of approvals granted by the FDA and European Medicines Agency (EMA) and market analysts are predicting that the sector will reach global market values of between \$10 billion and \$60 billion by the mid 2020's.

A major opportunity for Ireland

Over the last decade and a half, Ireland has established itself as a global centre of excellence and location of choice for the manufacture of biologics, and in particular monoclonal antibodies. With strategic foresight and investment – including the establishment of NIBRT in 2006 – Ireland positioned itself to take a leadership role in what was then the emerging generation of biologics medicines. As a result, Ireland has won over €10 billion in biopharma foreign direct investment (FDI) in the period 2009-2020, with the number of biopharmaceutical manufacturing sites growing to more than 25 nationally.

Cell therapy approvals (select): ✓

- ▶ **Kymriah** – the first approved CAR-T therapy from Novartis launched in 2017 and is now licenced for use in a number of B-cell lymphomas and leukaemias
- ▶ **Yescarta** – CAR-T therapy (from Kite/Gilead) licenced for use in large B-cell lymphoma
- ▶ **Tecartus** – CAR-T therapy (from Kite/ Gilead) licenced for use for mantel cell lymphoma.
- ▶ **Alofisel** – an allogeneic cell therapy (from Takeda) approved for treating complications associated with Crohn's disease.
- ▶ **Zynteglo** – CAR-T therapy (from Bluebird Bio) approved in Beta-thalassemia.

Gene therapy approvals (select): ✓

- ▶ **Imlygic** – a viral-vector based immunotherapy (from Amgen) for melanoma and other cancers
- ▶ **Luxterna** – a viral-vector based therapy (from Spark/Roche) for retinal dystrophy
- ▶ **Zolgensma** – a viral-vector based therapy (from AveXis/ Novartis) for spinal muscular atrophy

Recent CGT approvals by FDA and EMA

This in turn has contributed over 30,000 direct jobs and over €70bn in exports to the Irish economy. Much of this success is predicated on the availability of a highly competent workforce, a track record of operational excellence and the existence of a thriving ecosystem supporting the sector.

CGTs, while broadly similar to the previous wave of biologics, have their own unique challenges in respect of how they are manufactured and how they are supplied to health systems and patients around the world. Given the high projected growth of the CGT market, it is a very competitive space and other jurisdictions – most notably the US, UK, Belgium, Netherlands, Spain among others – are now investing heavily to attract and support the multinational industry players.

Ireland has recently been successful in attracting a number of CGT investments, most notably:

- ▶ The opening by Takeda of a manufacturing facility in Grangecastle to produce its allogeneic cell therapy Alofisel.
- ▶ The recent announcement by MeiraGTx of a viral vector manufacturing facility in Shannon to support various gene therapy products.

To further build on these initial successes and to capitalise on the opportunity in the longer-term, Ireland needs to consider targeted CGT investments aimed at consolidating its position as a world leader in biopharma manufacturing and carving out a new position as a location geared towards addressing the challenges associated CGT manufacturing.

Manufacturing challenges for CGTs

Firstly, according to recent analysis in the, the biopharma industry in a broad sense is heading for a capacity crunch globally¹¹. This is driven by the limited number of production facilities and continued growth of the mAbs market and is accentuated by the burgeoning CGT pipeline and Covid-19 production demand. Decisions will be taken in the coming months and years about where to position new cell therapy, gene therapy and novel vaccine manufacturing sites within the global networks of the multinationals.

Ireland can be a prime location for these facilities, but it must continue to invest in relevant infrastructure to enable an CGT ecosystem, including world class training facilities, research capabilities, supply chain / logistics expertise and digital capabilities.

Secondly, CGT manufacturing technology is still at a very early stage of development, equivalent perhaps to the manual roller-bottle technology first used for recombinant protein manufacturing in the 1980's. As with monoclonal bioprocessing, the manufacturing technology around CGTs must improve to ensure that production yields and quality is maximised, that market demand is met, and that advanced medicines and vaccines can be as affordable as possible. Ireland has built significant research capability over the past decade, both at NIBRT, CCMI and in other research centres around Ireland. Investment in CGT-focused analytics and manufacturing research can help make Ireland a global centre of excellence for CGT research and a recognised leader in the optimisation of advanced cell, gene and vaccine manufacturing.

Thirdly, there continues to be a critical global shortage of skills and capabilities to meet the needs of biopharma manufacturing. This need for well-trained individuals is even more pronounced in CGT manufacturing, particularly when the growing need for biopharma 4.0 skills – in data analytics, informatics, AI, etc – are factored in. NIBRT with its higher education partners, has built significant strengths in the training and education of top talent for the biopharma industry over the last 10+ years. This capability must now be adapted and applied to generate the skills needed for the manufacturing of next wave of advanced new medicinal products in Ireland.

Novel Covid-19 vaccines

A notable feature of many of the Covid-19 vaccines in development is the level of novel and advanced technologies being deployed and adopted for the first time. Within the first wave of new Covid-19 vaccines are the two recently-approved mRNA-based vaccines, while a number of the yet-to-be-licensed vaccine candidates are incorporating other innovative viral vector and novel recombinant protein technologies.

11. 17th Annual Report and Survey of Biopharmaceutical Manufacturing



The CGT extension at NIBRT

Cell and Gene Therapy Forum

At a national level, NIBRT led the establishment in 2018 of the *Cell and Gene Therapy Forum* along with many stakeholders from industry, academia and government. The CGT Forum produced a White Paper in 2019 which laid out a series of recommendations for increased investment in workforce development, research excellence and national infrastructure which are now being implemented. Moreover, the CGT Forum white paper was important in underpinning a business case that led to a decision, in recent months, to expand the NIBRT facility to incorporate more ATMP research and training capacity. This expansion is currently under planning review and it is anticipated that construction will start in 2021 and will be open for business in 2022.

The CGT extension at NIBRT

On the skills front, NIBRT has introduced a number of CGT-related courses into its training curriculum with further expansion planned for 2021. In research, a team of researchers at NIBRT has recently commenced a significant collaboration with Allergan, co-funding from Enterprise Ireland, focused on viral vector characterisation and optimisation of the manufacturing process, with potential applied uses in gene therapy and vaccine manufacturing.

In conclusion

The manufacture of advanced therapy medicinal products, including cell and gene-based medicines and novel-modality vaccines, for the supply of global markets represents a major opportunity for Ireland in the coming years. NIBRT looks forward to continuing partnering with key stakeholder to ensure the Irish biopharma sector can capitalise on this opportunity.

Darrin Morrissey
NIBRT CEO



Contract Research

The Contract Research team provide detailed characterisation of biologics in line with ICH Q6B and Q5E. The mission of the group is to exceed our customers' expectations with innovative and bespoke analytical services providing detailed characterisation of their biologics during development and process change.

During 2020 Contract Research conducted a wide range of complex characterisation services to satisfy ICH Q6B and Q5e requirements for a range of international clients. Services included:

- ▶ Host Cell Protein (HCP) analysis by mass spectrometry
- ▶ Aggregation analysis by analytical ultracentrifugation (AUC)
- ▶ N-glycan characterisation using a combination of technologies
- ▶ Peptide mapping by mass spectrometry

Contract Research have also partnered with law firms in 2020 to provide bespoke analytical development for IP litigation.



Case Study: Generation of biosimilar characterisation data for use in regulatory submission

Challenge

A client requested the assistance of NIBRT Contract Research to provide detailed comparability testing of their biosimilar alongside its innovator product, in which, reported characterisation data would feature as part of a regulatory submission. To align with this request, it would be necessary to prepare a bespoke characterisation service package, which would cover a range of analytical testing methods, such as N-glycan analysis, primary structure analysis, product-related variant analysis, particle and aggregation analysis, and protein concentration determination. In accordance with client expectations, method performance would need to be assessed prior to proceeding with the analysis of biosimilar and innovator samples.

Solution

NIBRT Contract Research prepared a comprehensive, characterisation service package, covering a wide range of analytical techniques across several platforms, including peptide mapping and N glycan site occupancy by LC-MS; N-glycan characterisation by HILIC, WAX and LC MS; oxidation analysis by RP UPLC; aggregation analysis by AUC; protein concentration by SEC; and charge heterogeneity analysis by cIEF. To further expedite data reporting, analytical testing was divided into individual workflows, and each assigned to a dedicated analyst and subject matter expert. Throughout the lifespan of the project, contemporaneous updates were maintained, and weekly meetings put in place to deep dive experimental findings and discuss the possible need for any further method optimisation. Method verification was performed by assessing the parameters; specificity, accuracy, precision, and linearity, limit of detection (LOD), limit of quantification (LOQ), range, and robustness. It was crucial that the agreed performance criteria were met for each analytical method. Verified methods were subsequently used to analyse innovator and biosimilar samples provided by the client.

Outcome

For each analysis workflow, two comprehensive reports were provided to the client, detailing the results of method qualification (report 1) and analysis of biosimilar and innovator samples (report 2). The data provided was featured as part of the regulatory submission dossier for the biosimilar, enabling its successful launch to market.

10

NIBRT Training and Education

In 2020 NIBRT continued to support investment in Ireland through the development of customised training courses for the biopharmaceutical manufacturing sector. NIBRT also worked closely with our colleagues in the Higher Education Institutes to offer support to their respective undergraduate and postgraduate academic programs.



Industry Training

2020 was a year like no other due to the inherent challenges presented by Covid-19. The NIBRT training team adapted to new ways of working with a greater dependency on remote delivery of content for clients who could not travel to the facility. Essential practical sessions were delivered at NIBRT safely in full adherence with robust physical distancing and hygiene requirements.

We were pleased to deliver over 31,000 learning days to 4,000 trainees across our various training programmes which represents the busiest year in terms of total learning days training since we commenced our first full year of operations in 2012.

The portfolio of NIBRT courses was improved and expanded to include new refreshed course offerings delivered by our team. For example, our first course in advanced cell therapy addressing the processes involved in CAR-T cell manufacture was successfully delivered in association with Cytiva in Q1 2020.



Customised training courses were delivered for the above industry clients in 2020

In 2020 customised training content was delivered to the following industrial clients based in Ireland: Abbvie, Almac, Amgen, BioMarin, Eisgen Pharma, Janssen Biologics, MSD, Mylan, Pfizer and Takeda Dunboyne Biologics.

Vendor and service providers have continued to use NIBRT for their staff upskilling programmes and in 2020 we were pleased to engage with the following companies: Accenture, Asahi Kasei, Biopharma Process Systems, Commissioning Agents International, Carten Controls, CPL Recruitment, GE Healthcare, Engineers Ireland, Ernst & Young, Sartorius, Sisk Group and Thermo Scientific.

Academic Training

Through 2020 the NIBRT training team continued to support undergraduate and postgraduate academic programs in life science and engineering through the delivery of academic modules and competency-based practical training sessions. Due to the necessary decision taken by the Higher Education Institutes for course content to switch from traditional face-to-face to remote delivery, NIBRT commenced offering online delivery of practical content using live streaming of practical sessions by NIBRT trainers, where operations could be demonstrated and discussed in detail with students.

We were delighted in 2020 to successfully complete the first iteration of a newly accredited Graduate Internship Programme in Validation Technology, at QQI level 9 in partnership with the School of Chemical and Pharmaceutical Science at TU Dublin. Academic modules were delivered, and industry internships of 12 months were provided to the first cohort of 7 graduates with Abbvie, Alexion, Allergan, Amgen and Bristol Myers Squibb.



Academic courses were delivered for the above third level institutes in 2020



Springboard+

In 2020 NIBRT continued to collaborate with Higher Education Institutes to support accredited training programmes in biopharmaceutical manufacturing and bioanalytics under the Springboard+ programme. This programme continues to be an extremely positive initiative to enable students to upskill in key areas most relevant to the biopharmaceutical industry and students who have completed their programmes have provided feedback as to the benefit and further opportunity that completion of a course has presented to them. In 2020, 775 students participated in Springboard+ courses from QQI level 6 to QQI level 9 where NIBRT led or supported the programmes.

International Clients

While international travel was severely curtailed in 2020, we had the pleasure of welcoming international guests to our facility in Q1. SaudiVax and RPD Innovations attended NIBRT for customised training programmes before restrictions were imposed and we had to then switch to remote delivery to complete these international training courses.

Suppliers

In 2020 NIBRT received generous donations of equipment/technologies to support our training programs from several vendor companies notably: Aber, Asahi Kasei, Avantor, Biomerieux, Chemometec, Cytiva, Filtrox, Ecolab, GoPro, Orbis/Thermo Scientific, PMT and 3M. These collaborations afford NIBRT to use best in class equipment and provide an opportunity for vendors to showcase their technologies to the NIBRT client base.



Delivery of training in a socially distanced environment (June 2020)

Future Outlook

Based on a successful 2020, NIBRT are very positive about the training pipeline and outlook for the coming year. We continue to develop and expand our training offerings through new course content developed in-house or in partnership with industry subject matter experts. We look forward to bringing exciting new courses to our clients most notably in the area of cell/gene therapy and vaccine manufacturing which are now clearly emerging as important classes of therapies for the future.

NIBRT has recently completed the installation and commissioning of both lyophilisation technology and inline dilution technology, the latter in partnership with Avantor and we will be developing and launching new training content for our clients in these disciplines in 2021.

Training offerings in development and launch in 2021 will include:

- ▶ Introduction to Delta V TM
- ▶ Biopharma 4.0 Innovation Centre for Operations Tour
- ▶ Introduction to Cellular Immunotherapy
- ▶ Introduction to Gene Therapy
- ▶ Introduction to ATMPs/CGT
- ▶ Introduction to Stem Cell Therapy
- ▶ Introduction to Viral Vector Manufacture
- ▶ Introduction to Vaccine Manufacture

Finally, as we look to 2021 we will be continue to further expand our portfolio of courses that will be hosted on the NIBRT Online Academy (NOA) which was formally launched in 2020. This will enable online just in time access to best in class content for our growing client base.

John Milne

NIBRT Training Director



NIBRT
Training 2020

4,000 Trainees

31,856 Training days

24 Training Team

10 Partnerships
with Irish HEIs

775 Springboard+
students

3 Global Partners

32 NOA courses

11

Training Case Study

Pfizer Grange Castle

Engineering as a discipline will always be crucial to the successful manufacture of biopharmaceutical products.



With constantly evolving pipelines and production scenarios engineers will continue to play a key role within our manufacturing sites. With the emergence of newer more flexible unit operations, innovative production methodologies and the developing interest in the manufacture of more complex products, there is a focus from engineers to upskill accordingly or perhaps transition to a different role within their company.

It is becoming more apparent that engineers who perhaps traditionally remained in the background focusing on utilities and equipment support, are now playing a more important role to support front line manufacturing operations. Therefore, training programmes that help to increase engineers fundamental bioprocessing knowledge are deemed to be highly beneficial.

In 2013 Pfizer Grange Castle first contacted NIBRT to collaborate on the development of a customised training program for their Engineering colleagues.

The pilot program was designed to deliver training on the overall process of biopharmaceutical production and the key operations involved including upstream processing, downstream processing and concepts in bioprocess engineering. Additional sessions were included focusing on current and emerging trends within bioprocessing.

Based on the success and positive feedback from attendees the course has been further developed and refined and to date several iterations of the course have been held, with the latest iteration started in October 2020. Over 100 employees have successfully completed the programme drawn primarily from the Engineering discipline, although the course has also been attended by employees from other disciplines such as process sciences and quality assurance.

The current program is delivered on site in the Grange Castle facility and involves ten half day sessions covering all aspects of biologics manufacturing that are delivered by subject matter experts from NIBRT along with guest presenters drawn from industry and academia respectively. Trainees are then given the opportunity to build on the theoretical knowledge gained with subsequent hands-on practical training in the NIBRT production training facility. The course is finally completed by a written examination based on the content covered throughout the course.



The Pfizer Facility at Grange Castle



The Bioprocessing for Engineers Programme authored and delivered by NIBRT offers our staff a unique and very worthwhile development opportunity to increase knowledge of bioprocessing optimisation.

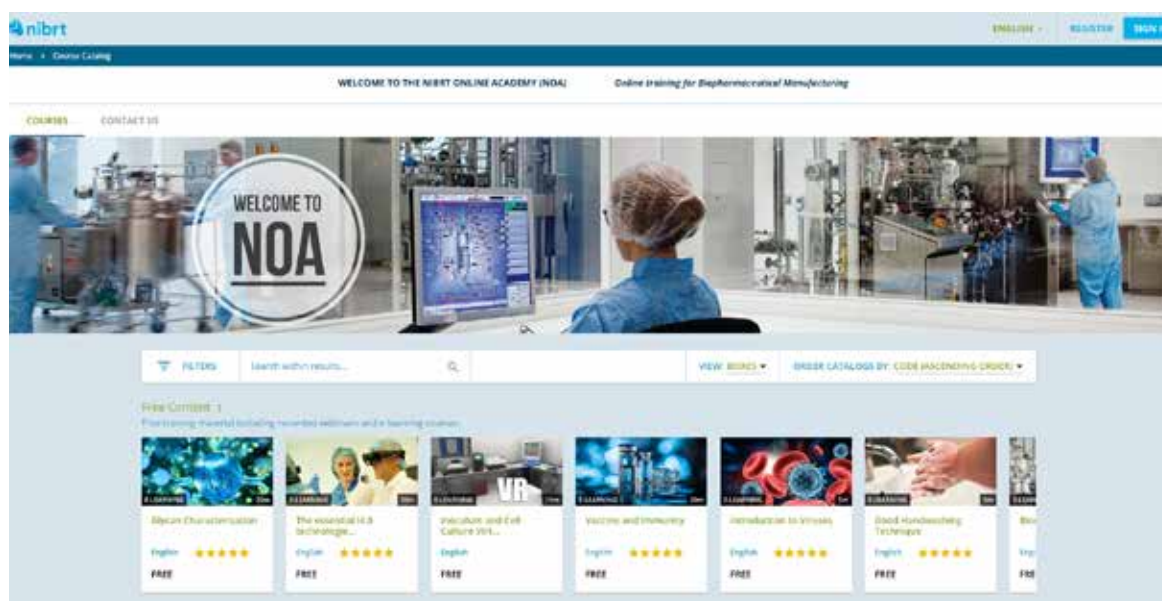


→ **Jim Conerney, Training Specialist, Pfizer Grange Castle**

12

NIBRT Online Academy

In 2020 NIBRT was pleased to have the commercial launch of the NIBRT Online Academy (NOA). NOA provides industry leading, eLearning courses on key aspects of biopharma manufacturing.



The NIBRT Online Academy, <https://noa.nibrt.ie>

NOA courses can be accessed online (<https://noa.nibrt.ie>) on a range of devices to provide “just in time” learning in an engaging, stimulating format.

NOA was awarded “Innovation of the Year” at the 2020 Irish Pharma Awards.



NOA eLearning curriculum

General Overview

- ▶ Cell Biology and Recombinant DNA Technology
- ▶ Overview of Biopharmaceutical Manufacturing
- ▶ Biotechnology and Biopharmaceuticals

Upstream Processing

- ▶ Cell Culture in Biopharmaceutical Manufacturing
- ▶ Bioreactors in Bioprocessing
- ▶ Bioreactor Operations (free)
- ▶ Fermentation in Biopharmaceutical Manufacturing

NOA eLearning curriculum

Downstream Processing*

- ▶ Downstream Processing: Centrifugation
- ▶ Downstream Processing: Protein Purification - Chromatography
- ▶ Downstream Processing: Ultrafiltration and Diafiltration

Formulation, Fill Finish and Aseptic Processing*

- ▶ Aseptic Processing: Cleanrooms and Control Technologies
- ▶ Aseptic Processing: Concepts and Controls
- ▶ Aseptic Processing: Contamination Control
- ▶ Aseptic Processing: Decontamination and Sterilization Technologies
- ▶ Aseptic Processing: Gowning
- ▶ Clean in Place
- ▶ Formulation in the Biopharmaceutical Industry
- ▶ Freeze Drying

Process Validation

- ▶ Process Validation: Process Qualification and Control
- ▶ Process Validation: Process Design

Coronavirus related (short free courses)

- ▶ Good handwashing techniques
- ▶ Introduction to viruses
- ▶ Introduction to vaccines
- ▶ Vaccine manufacturing webinar series

Cell and Gene Therapy

- ▶ Introduction to Cell Therapy
- ▶ Introduction to Gene Therapy

Virtual Reality

- ▶ Inoculum and Cell Culture

Coming Soon

- ▶ Cleanroom Behaviours
- ▶ Vaccine Manufacturing
- ▶ Trends in Biopharma Manufacturing
- ▶ Quality Risk Management

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Biopharma 4.0

Boston Consulting Group (BCG) and NIBRT created the world's first Innovation Centre fully dedicated to biopharma 4.0 operations.



NIBRT's Aoife Barron shows visitors how Augmented Reality can be used to improve understanding of batch progress during cell culture

In 2020 NIBRT and Industry 4.0 experts, Boston Consulting Group (BCG), further developed the Biopharma 4.0 Innovation Centre for Operations (B4.0 ICO) at the NIBRT site in Dublin. The ICO is focused on showcasing cutting-edge technologies such as augmented reality (AR), virtual reality (VR), artificial intelligence (AI), machine learning and big data analytics in a GMP-replica environment, to demonstrate the revolutionary benefits of these technologies to the biopharmaceutical production process.

The ICO demonstrates how these technologies can be seamlessly integrated with core operating processes to enable proof-of-concept studies on new innovations and new ways of working. Visitors to the centre experience an interactive and immersive journey into biopharma 4.0.

NIBRT and BCG were delighted to win Project of the Year Award at the Irish Pharma Awards 2020.

In 2021, NIBRT are offering a variety of different B4.0 ICO packages, which cater to the various needs of biopharma industry and academic clients. In these packages (including tours, bespoke client-focused deep dives or interactive training courses), NIBRT and BCG will answer all of your questions on all things 4.0; What is Industry 4.0 and more specifically, biopharma 4.0? What technologies are out there and currently available? How are they suitable for GMP cleanroom environments and heavily regulated biopharma processes?



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Global Partner Programme

The NIBRT Global Partner Programme supports an international alliance of leading training and education organisations to help address the global shortage of a skilled biopharma workforce. In September 2020, the Guangzhou Bioprocess Research and Training Academy (GBRTA) joined the Global Partners Programme.

Guangzhou Bioprocess Research and Training Academy (GBRTA), Guangzhou, China



GBRTA team with Ms Therese Healy, Charge d'Affaires, Embassy of Ireland and Mr. Zhewei Zhang, China Director, IDA Ireland at the launch ceremony in Guangzhou, September 2020

Launched in 2020, GBRTA is a Chinese Government funded GMP bioprocessing facility equipped with cutting-edge single use technology from Cytiva. GBRTA joined NIBRT's global partnership programme to deliver localized NIBRT training courses in the Guangdong-Hong Kong-Macao Greater Bay Area, an active economic area in southern China attracting millions of high-tech talents as well as 10,000+ thriving biological companies.

GBRTA provides both theoretical and practical biomanufacturing training based on the NIBRT curriculum, devoted to workforce development for China's biopharma industry and global pharma. GBA is located in the International Bio Island and operated by a subsidiary of Guangzhou Hi-tech Investment Group, under the administration of Guangzhou Development District.

GBRTA is the first NIBRT partner in the Greater China area and provides a bioprocess training facility with a full range of single-use upstream and downstream equipment, offering trainees hands-on practical opportunities ranging from fundamental aseptic skills to complex biomanufacturing and bioprocessing procedures in a GMP environment. For more information on GBRTA, please contact gtc@bio-island.com.



Jefferson Institute for Bioprocessing (JIB), Philadelphia, USA



The Jefferson Institute for Bioprocessing

In the spring of 2019, Jefferson officially opened the doors to the first - and only - specialized education and training institute for biopharmaceutical processing in North America that combines commercial single-use processing equipment with the internationally recognized NIBRT curriculum.

The focus of JIB is hands-on training of industry professionals through short-term trainings, certificates and hands-on education of new bioprocessing engineers and scientists at both undergraduate and graduate levels. The education and training programs in bioprocessing are anchored at the new state-of-the-art JIB facility, located minutes from Philadelphia, PA. The institute is focused on biomanufacturing and dedicated to education and industry-based research that translates advances in the life sciences into emerging therapeutics that benefit humanity.

Training Courses

JIB understands the critical need to rapidly develop and advance the skills and knowledge of scientists, engineers and technicians who work in process development and biomanufacturing of biopharmaceuticals and biologics. They provide a broad-range of trainings in commercial single-use processing equipment as well as customized trainings to meet the full needs of the industry. Through its 25,000 sq. ft. fully flexible state-of-the-art facility, JIB provides a truly tactile training experience by combining interactive presentations, workshops, hands-on laboratory and pilot-scale experience.



Academic Offerings

Offering both an MSc in Biopharmaceutical Process Engineering and a Graduate Certificate in Biopharmaceutical Process Development (BPD Certificate), JIB is ideal for employment-focused graduates with first degrees in Life Sciences and Engineering. Training and education in biopharmaceutical processing are exceptionally laboratory intensive. At JIB, the students spend less time in traditional classroom settings and more time in JIB's pilot-scale facility, fully equipped with the most advanced technologies and processes used by industry to manufacture biopharmaceuticals.

Industry Course Offerings

- ▶ Upstream and Downstream Operations
- ▶ Scale Up/Scale Down
- ▶ Quality and Regulatory Compliance
- ▶ Continuous Bioprocessing
- ▶ Single Use Technologies
- ▶ Quality by Design and Design of Experiments
- ▶ Process Modelling and Process Integration
- ▶ Analytical Methods and Applications
- ▶ Process Tech Transfer, Qualification, and Validation
- ▶ Aseptic Process and Cleaning Operations

More Information

For Trainings: Lyn Kugel at HLynda.Kugel@jefferson.edu

For Academic Programs: Geoff Toner at Geoffrey.Toner@jefferson.edu

Web: Jefferson.edu/JIB

Biologics Innovation Facility (BIF), University of Technology, Sydney, Australia



Biologics Innovation Facility at University of Technology, Sydney

An alliance agreement between University of Technology Sydney (UTS) and NIBRT to deliver selected NIBRT courses utilising the purpose built \$11.5m UTS Biologics Innovation Facility (BIF) launched in July 2019.

The UTS Biologics operation, designed for practical vocational and professional training, is a strategic investment between UTS and the NSW Government aimed at building a future workforce with high quality transferable STEM skills for the biopharma industry. Key stakeholders include the federal Government through the National Collaborative Research Infrastructure Strategy and global biopharma company Cytiva.

BIF replicates the NIBRT's Irish facility including separate teaching and process spaces and a full range of single-use upstream and downstream equipment, giving operators and technicians training opportunities ranging from fundamental sterile production techniques to complex biomanufacturing processes in a GMP environment.

The University of Technology, Sydney is in the southern part of Sydney's CBD near Central Station, which is only a 20-minute train ride from Sydney Airport.

NIBRT courses at UTS

- ▶ Introduction to Single Use Technologies
- ▶ Bioprocessing for Engineers
- ▶ Introduction to Upstream Processing Operations
- ▶ Introduction to Downstream
- ▶ Processing Operations
- ▶ Introduction to Fill Finish Operations



More Information

www.uts.edu.au/bif or contact
biologicsinnovationfacility@uts.edu.au

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Facilities Development

The NIBRT facility is a purpose-built, multi-functional building (6,500m²) which replicates the most modern industrial bioprocessing facility and laboratories.



At the heart of the NIBRT building is the bioprocessing pilot plant, consisting of extensive upstream, downstream, fill-finish, associated analytical facilities and process utilities that can support both stainless steel and single use bioprocessing strategies. These facilities are all operated in a realistic GMP simulated, operational manufacturing environment. New equipment additions to the training facility in 2020 included:

- ▶ Lyobeta 3PS Lyophilisation Technology
- ▶ Freeze Drying Microscopy
- ▶ In-line Automated Buffer Dilution Technology
- ▶ Range of equipment to support new QC Microbiology training portfolio
- ▶ CAR-T cell therapy manufacturing technologies
- ▶ Single-use buffer mixing technology
- ▶ AKTA Process chromatography system

Cell and Gene Therapy

In 2020 NIBRT completed conceptual and basis of design studies in partnership with PM Group focused on the expansion of the current training facility to address the requirements of cell/gene therapy process flows. These studies will be used as a basis for the preparation of a detailed design for this expansion that will enable NIBRT to provide academic and industry training into the future to support future investment in Ireland by companies focusing on these new modalities. It is envisaged that construction of this expanded training facility will commence in 2021.

Start-up space

Clients can also rent “start-up” space in the facility, and in 2020 NIBRT was pleased to host Valitacell, an early stage Irish biotechnology company with a suite of novel, intelligent analytical technology platforms, engineered to provide process control in cell-based manufacturing.

Sustainability

The Facilities Team at NIBRT continued its focus on reducing the environmental impact of the facility. 2020 saw a downward trend in usage of water (-27%), electricity (-20%) and gas (-15%) through optimisation of ongoing building management initiatives. These reductions were also further enhanced in 2020 by the decrease in footfall due to maintaining the facility for essential access only particularly in the second half of the year.

Safety

Safety is a cornerstone of the culture at NIBRT, where each day the team proactively strive to ensure a safe and environmentally sound workplace through safe work practices and positive engagement. In 2020 there were zero lost time accidents, our facility remained Covid-19 free and this is a particular achievement we are proud of and was only possible by our team's professionalism and collective efforts to ensure the safety of our staff, clients and visitors.



Facilities Facts and Figures

6,500m² Building size

90 Personnel on site

0 Lost time safety incidents

-27% Water reduction

-15% Gas reduction

-20% Electricity reduction



Explore the facility

To explore an online virtual tour of our facilities, please click on www.nibrt.ie/about/ or scan the following QR code:





1. Carlos Tamaray with donations of PPE for local hospitals
2. Katie Hill, Adam Bergin, Niamh Keogh as judges for ESB Science Blast
3. Signing of an MoU with KHIDI, South Korea
4. Jo Withers, Darragh O'Brien, Shada Warreth, Alex Ostropolska at BioPharma Ambition
5. Jonathan Bones manufacturing lysis buffer for Covid-19 test
6. Colin Clarke presenting at Siemens's digitalisation event
7. Darrin Morrissey at remote signing of MoU
8. Visitors to NIBRT's Biopharma 4.0 centre (pre Covid)
9. Matt Moran (BPCI), Killian O'Driscoll (NIBRT), Minister Heather Humphries TD, Oliver O'Connor (IPHA)

A key component of NIBRT's mission is to help develop the next generation of scientific and engineering talent with a number of exciting public engagement and outreach initiatives in 2020.



Transition Year students at NIBRT

Amgen's School of Biotech Excellence (ABE) is an innovative science education programme that empowers teachers to bring biotechnology into their classrooms. ABE-Ireland offers training in molecular biology experiments for secondary school teachers at locations in University College Dublin, Dublin City University and NIBRT.

NIBRT's Biopharmaceutical Science **Transition Year Competition** is a very popular annual competition which invites transition year students to submit an essay focusing on the biopharma sector in Ireland. The successful students get a one week structured placement in NIBRT where they get the opportunity to experience the state-of-the-art facilities and learn from scientists working in the research and training team.

NIBRT researchers had several public engagement activities including Hayden Wilkinson being selected as a finalist in the following competitions, Irish Research Council and USI ["Why Research Matters Video Competition"](#) and the ["PwC/U21 Innovation Challenge"](#). Dr. Elizabeth Matthews was a judge during the ESB Science Blast which was held in March 2020

Running since 2013 NIBRT's annual **Careers in Biopharma** is a very popular event to connect the Industry with high quality prospective employees. Unfortunately, due to Covid-19 this event was cancelled in 2020. However, the event will be held virtually in 2021.

Events and International delegations, NIBRT typically hosts a large number of events and international delegations each year but these visits were ceased in 2020 due to the impact of travel restrictions with Covid-19.

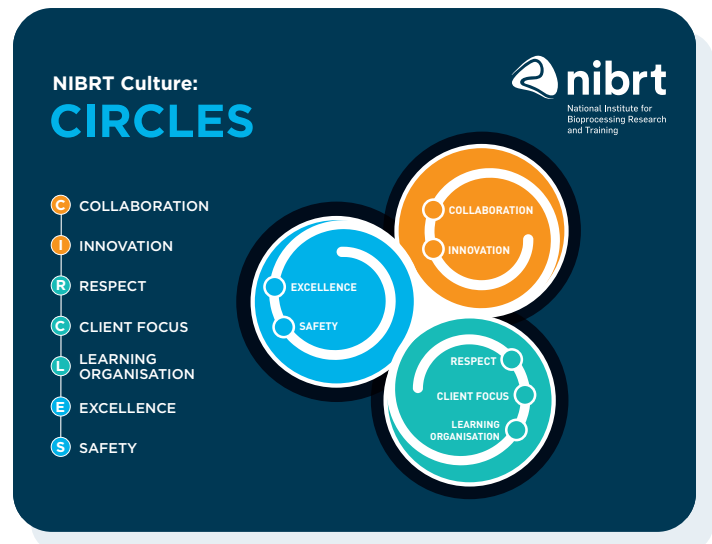
In 2020 NIBRT launched the **Covid-19 Vaccine Manufacturing Webinar series**. The free series of webinars includes seven separate webinars which brings together leading experts in vaccine manufacturing to share their perspectives on the challenges involved in manufacturing vaccines. Topics range from vaccine development for Covid-19 to world-wide vaccine formulation and distribution. NIBRT was also pleased to provide a range of [free Covid-19 related eLearning](#) on the NIBRT Online Academy.

Culture

Throughout 2020, a cross department team drove the NIBRT Culture project to promote the desired ethos of the Institute and how we interact with our colleagues and clients.

Our Culture is summarized by “CIRCLES” logo which represents the interdependency and collaboration between our three main areas of activity: training, research and operations. “CIRCLES” is also an acronym for our seven value statements of Collaboration, Innovation, Respect, Client focus, Learning organization, Excellence and Safety.

Exemplifying the CIRCLES culture, a number of cross-departmental teams focused throughout the year on key areas of interest including Sustainability, Sports and Social, Culture and Safety.



HR Focus Areas

In 2020, the key areas NIBRT prioritised for our people were: employee well-being, career development, diversity and inclusion, communication and collaboration, and Covid-19 response. Through a number of key initiatives and a constant focus on these areas, NIBRT are proud to confirm that our employees, via our annual Employee Engagement survey, noted significant improvements in all focus areas when compared with 2019 scores.

HR Excellence in Research Award (HRS4R)



NIBRT were also pleased to secure the “HR Excellence in Research Award”. This European Commission award reflects an organisation’s commitment to continuously improve their human resource policies in line with the *European Charter for Researchers* and the *Code of Conduct for the Recruitment of Researchers*.

HR Figures 2020

86 Employees

50:50 Gender balance at NIBRT (male:female)

16 Nationalities

2% Absence rate

19 New hires 2020

On March 3rd and 4th 2020, BioPharma Ambition drew some 400 delegates to NIBRT and Dublin Castle to explore the themes defining biopharmaceutical innovation right across the lifecycle of medicines.



Minister Simon Coveney TD, with organisers and speakers of BioPharma Ambition

The event was held just as Covid-19, later a global pandemic, began to dominate the news agenda and prompt policymakers to consider their response. The event was held before restrictions were announced. The disease, on which biopharmaceutical innovators globally are working to find vaccines and treatments, was the backdrop to BioPharma Ambition 2020. It brought into sharp focus the purpose of medicines innovation – our shared journey in discovering, developing and making available quickly the best medicines to stop sometimes deadly diseases.

BioPharma Ambition 2020 was the third time the Irish Pharmaceutical Healthcare Association (IPHA), BioPharmaChem Ireland (BPCI) and NIBRT came together to create a thought-leadership platform for biopharmaceutical innovation. The aim of BioPharma Ambition is to position Ireland at the nexus of globally networked innovation. It was a whole-of-industry event, drawing on experts' perspectives to share an exciting story of medicines discovery, development, manufacture and adoption.

Download the conference report [here](#).



Awards

NIBRT is pleased to have won a wide selection of national and international awards for its research, training and education programmes.

In 2020, the NIBRT team was delighted to win three awards at the 2020 Irish Pharma Awards including:

- ▶ Innovation of the Year Award for the NIBRT Online Academy
- ▶ Project of the Year Award for the Biopharma 4.0 project with Boston Consulting Group
- ▶ Partnership Alliance of the Year Award for NIBRT and MSD Dunboyne Biologics training collaboration

In addition, recently retired NIBRT CEO, Dominic Carolan, was presented with the Leader of the Year Award.

Previous NIBRT Awards

- ▶ 2019 Invest in Ireland Staff Upskilling Award with Takeda Dunboyne Biologics
- ▶ 2019 Pharma Industry Awards: Project of the Year Award with Siemens
- ▶ 2018 Pharma Industry Awards: Pharma Research Centre of the Year
- ▶ 2017 SFI Industry Partnership Award
- ▶ 2017 Postgraduate Course of the Year Award in Health Sciences
- ▶ 2017 Pharma Industry Awards: Partnership Alliance of the Year with GE Healthcare
- ▶ 2016 Pharma Industry Awards: Pharma Education and Training Award
- ▶ 2015 Pharma Industry Awards: Pharma Education and Training Award
- ▶ 2015 Pharma Industry Awards: Partnership Alliance of the Year with Bristol Myers Squibb
- ▶ 2012 ISPE Facility of the Year Award “Novel Collaboration”
- ▶ 2012 Bioprocess International “Manufacturing Collaboration of the Decade” Award



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Testimonials



Since undertaking the NIBRT/Sligo IT L9 Diploma course I have moved job to a leading biopharmaceutical company and the information I have learned, particularly around regulations and single use plastics has been interesting and I believe has assisted me in my career within my current company”.

Frances Doherty Springboard Student



I want to thank everyone that has been involved in the Graduate Programme The course is highly focused on the area of validation. The staff have been really helpful (special thanks for the staff in NIBRT which gave us a 3 months hands on experience before actually going into our internship). One of the skills which I found really useful from NIBRT was how to properly gown, which I have used every day in my internship.

Thank you everyone that has given me this opportunity, and I highly recommend it for anyone who wants to have a future path in the area of validation because this can open many doors, not just one.”

Student TU Dublin and NIBRT Graduate Program



I would strongly recommend Bioreactor Operations to anyone looking for an introduction to the biopharmaceutical industry. It gives an overview of the types of bioreactors, monitoring and modes of operation, using informative graphics and follow-up questions at the end of each section to strengthen learning, as well a final quiz assessment. The course material is clearly explained and is easy to understand to someone relatively new to concepts in biopharmaceutical technology.”

NOA student, Sakshi Hans
Medical Lab Aide at TTM Healthcare Group



The course is well structured and well explained with interesting content. The course was informative and helpful. It discussed the important aspects of the bioreactor in detail including the insights on dealing with the troubleshooting. The course was interactive and had many questions-answer rounds which were very useful, touching upon the all the technical elements of the bioreactor relevant to my current work. The questions were analytical and extra study material was provided in addition to the course content, level and depth of the information just right.

Overall my experience with NOA has been great and these learning experience will aid in future development.”

NOA Student, Preeti Saroha Indian Institute of Technology



We studied a number of technologies including single use technology and wave reactors it's been phenomenal. Our experience with the NIBRT trainers has been excellent. They have made us really comfortable with hands on experience”

Global Business Development Manager
Asgard Cleanroom Solutions



Fantastic friendly, enthusiastic and knowledgeable trainers who were always so helpful. Small groups worked really well to have better interaction with trainers and easier to ask questions. An overall fantastic experience”.

MSD



Thank you very much, this was a very informative, educational and very fun training course”.

Engineers Ireland attendee



“Brilliant opportunity to get hands on experience with equipment in a small group. All trainers were excellent in their delivery and made sure the experience was both enjoyable and entertaining”.

MSD Biotech



Even with COVID restrictions I got a lot from the practical's. Great facilities and great to see subjects in practise. Very well managed with social distancing.”

Pfizer



NIBRT has outstanding trainers who are not only professional and knowledgeable, but really encouraging and patient for questions”

Saudi Vax

Notes

Notes



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