



National Institute for
Bioprocessing Research
and Training



ANNUAL REPORT

2022



*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.*

www.nibrt.ie

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1 | Introduction

1.1 NIBRT Staff

Thank you to all NIBRT Staff members who contributed to a successful 2022:

Adam Pritchard	Daniel Downing	Kate Cotter	Parbani Chaudhury
Alan Foley	Darrin Morrissey	Kathleen Hill	Patrice Knightly
Aleksandra Ostropolska	Dennis Shaw	Kelly Smyth	Paul Adams
Ales Grundzi	Dermot O'Sullivan	Kevin Byrne	Paula Kenny
Alison Quinn	Elaine O'Farrelly	Kevin Lomasney	Peter Connolly
Amy O'Neill	Elizabeth Matthews	Killian O'Driscoll	Peter O'Byrne
Andrea Silva	Elizabeth Topp	Laura Breen	Rachel Ronan
Andreea Cislaru	Emer Norton	Leticia Lemos	Radka Fahey
Anita Kelly	Eric Dumas	Lisa Murphy	Robert Byrne
Anita Murphy	Felipe Guapo De Melo	Lisa Strasser	Ryan Hagan
Ann Marie Donaghy	Florian Fuessl	Maikel Gaitkoski	Sakis Mantalaris
Anna Mulligan	Gareth Lomasney	Manuel Alfaro De Pra	Sally Koster
Anthony Raethorne	Gemma Grimes	Mariana Gavendova	Sandra Roche
Aoife Barron	Gemma Nolan	Mark Berney	Sara Carillo
Aoife Kearney	Graziela De Moura	Mary Flood	Sarah Burke
Aswathy Balakrishnan	Hannah Rushe	Maryna Startseva	Shada Warreth
Barbara Keegan	Hayden Wilkinson	Mashael Abdullah	Shane Gavin
Barry Shortt	Hugh O'Reilly	Melissa Hoare	Silvia Millan Martin
Caio de Barros	Ioanna Tzani	Michelle De Oliveira	Simeng Li
Caitriona Walsh	Jack Schofield	Mike Butler	Stephen McCann
Caragh Tisdall	James Berhanu	Mohamed Noor	Steven Ferguson
Carl Bermingham	James Flynn	Monika Samardzic	Tadeusz Tazbierski
Carlos Tamaray	Jenette Scanlon	Morandise Rubini	Tadhg Devlin
Ciara Finn	Jennifer Byrne	Neha Tushar Dalvi	Thais McNamara
Ciara McManus	Jennifer Prior	Nga Lao	Thomas Byrne
Ciara Tierney	Jessyca Ferreira	Ngoc Thanh Nguyen	Thomas McGuirk
Ciaran Buckley	Joanne Withers	Niall Barron	Tomos Morgan
Clair Gallagher	John Milne	Niamh Keogh	Yagmur Bozkurt
Colin Clarke	Jonathan Bones	Nicholas Donohue	Yongjing Xie
Conor Barry	Josh Smith	Noemi Isabel Dorival	Yuhang Tong
Cormac Costello	Karen Tsang	Nora Crushell	
Craig Jakes	Karl Kelly	Or Skornik	



1.2 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.



1.3 What we do



- ▶ Train and educate over 4,500 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.

1.4 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.



2 Governance and Performance

2.1 Message from NIBRT Chairperson

As the newly appointed Chairperson of NIBRT, it gives me great pleasure to provide the opening comments for the NIBRT Annual Report 2022.

Looking back on the year just gone, as we emerged from the lingering effects of the pandemic and faced into shifting geopolitical and economic headwinds, 2022 was a year not without its challenges. However, the biopharma sector, in which NIBRT operates, has continued to grow and the NIBRT as an Institute has gone from strength-to-strength.

Global sales of biopharmaceuticals are now over \$343 billion, with a compound annual growth rate of 12% and with approximately 60% of therapeutics in development being biopharmaceuticals^{1,2}. Even factoring in the effect of the Covid-19 vaccines on the biopharma market, there is significant growth in clinical trial and new filing activity across the sector, with large molecule monoclonal antibodies and recombinant proteins still accounting for most of the growth, while momentum is building in the advanced therapeutics field, which includes cell and gene therapies, RNA and DNA-based therapies and other novel modalities².

Within the global context, Ireland continues to be very successful in attracting the multinational biopharma industry to our shores. Over 45,000 people are now employed directly in the biopharma industry, and this represents a doubling of employment in high-expertise and high-value biopharma roles since 2014³. While this success is very welcome, it is not something about which we can become complacent.

Ireland has a unique opportunity to further build on its successes by continuing to develop itself as a consistent and dependent manufacturing location of choice for the biopharma industry, while investing in new talent, research and infrastructure to support the evolution of biopharma towards new technologies, both in the terms of advanced therapies being developed and the automation and digitisation of manufacturing.

Reflecting on 2022, I would like to acknowledge and thank the team at NIBRT for their many successes throughout the year, including:

- ▶ 24% growth in overall revenue, underpinning the highest research and training activity levels in the Institute's history.
- ▶ 75% increase in revenue from collaborative research activity.
- ▶ 34% growth in training and education revenue, resulting in over 31,000 learning days delivered to nearly 4,500 trainees and students.

Most notably, I am delighted to see NIBRT's advanced therapies building moving at pace. From IDA Ireland's approval of a €21M capital investment in late 2020, we moved steadily through the design, planning and procurement phases of the development. Construction of the building commenced in late April 2022 and is projected to open for business in April 2023, with five new research labs and two new training suites dedicated to advanced therapies and novel vaccines activities.

NIBRT's success continues to be built upon a spirit of partnership with stakeholders from across industry, academia and government. In particular, I would like to thank IDA Ireland and our colleagues in the IDA Life Sciences division for their continued support of the Institute.

1 EFPIA Pipeline Review, IQVIA, 2021

2 Biopharma Benchmarks, Nature Biotech Volume 40, December 2022, Walsh et al

3 IDA Ireland, Biopharma



September 2022 marked another important step forward in our life sciences journey when I turned the sod on the new cell and gene therapy facility at the National Institute for Bioprocessing Research and Training.

This €21 million investment in NIBRT, an important incubator for biopharmaceuticals in Ireland, underscored the Government's commitment to meeting the needs of future employers, manufacturers, and patients alike.

Through IDA Ireland, we have invested over €80 million in NIBRT. This cutting-edge, state-of-the-art facility is world class, and since 2011 has grown from strength to strength, training and preparing people in Ireland today to step into tomorrow's roles".

→ **An Taoiseach, Leo Varadkar**



I would also like to thank all the members of the NIBRT Board, who give of their time voluntarily and provide exceptionally strong oversight and strategic insight to the organisation. We welcomed new members in 2022 – Áine Hanly, Anne-Marie Healy, Brendan Hughes, Jacqueline McCormack and Rory Mullen – who have already made a significant impact around the Board table. I would like to acknowledge and thank sincerely those members who retired from the Board in 2022, Tom Kelly (from Enterprise Ireland) and Brendan O'Callaghan (Sanofi).

Most notably, I would like to extend our heartfelt appreciation to Brendan O'Callaghan, who was my predecessor as the NIBRT Chair for 10 years. NIBRT is the Institute it is today because of Brendan's years of commitment, skill and expert guidance. We were honoured to establish and fund a special academic prize for the top student in the UCD Masters in Biopharmaceutical Engineering class each year for the next ten years, and it was wonderful to see the first "Brendan O'Callaghan Award in Biopharmaceutical Engineering" awarded to Sheryl Lim in 2022.

So, as we look ahead to 2023, the NIBRT Board will continue to focus on the Institute's delivery of its central mission to address the important needs of the biopharmaceutical industry by training the talent and conducting research to improve manufacturing processes. We look forward to the finalisation of our new strategy for the business period 2024-2028, to the opening of our new Advanced Therapeutics building and to the continued growth in the number of top research and training talent joining the NIBRT team.



Julie O'Neill,
NIBRT Chairperson.

2.2 Message from NIBRT CEO

At the start of a new year, it is always worth reflecting on the year just past; on the successes, on the achievements and on where things could be improved.

2022 saw the world emerge slowly and steadily from Covid-19 pandemic. But new challenges emerged - including the Ukraine war, global inflation and geopolitical tensions - and pre-existing challenges - notably climate change and the biodiversity crisis - have come back on the radar. Against this challenging backdrop, the Irish economy and global biopharma sector continued to perform strongly and there were some significant biopharma investment announcements into Ireland - including Lilly (Limerick), MSD (Carlow) and Pfizer (Grange Castle) - as well as new and upgraded facilities opened for business - including MSD (Swords), MeiraGTx (Shannon) and Takeda (Grange Castle).

NIBRT had a highly successful year in 2022 delivering our world-leading training and research services to clients nationally and internationally. I am delighted to report that 2022 saw the organisation out-perform our targets laid out in our 2019-2023 business plan, as we achieved record levels of activity.

The demand for NIBRT's training and education services continued to grow in line with new expanding biopharma manufacturing investments in Ireland. In 2022, we:

- ▶ Delivered over 31,000 learning days to nearly 4,500 trainees, via a mixture of in-person and remote training.
- ▶ Trained 810 people through the Government's Springboard+ programme.
- ▶ Continued to grow the NIBRT Online Academy (NOA) to over 5,600 users in over 80 countries.
- ▶ Continued to strengthen our Global Partnership programme, by supporting our newest partners (K-NIBRT, at Yonsei University South Korea, and CASTL the Canadian Alliance for Skills & Training in Life Sciences) to ramp up their activities.

A particular highlight of the year for me was our delivery of training to delegates from the World Health Organisation (WHO) from a range of lower and middle-income countries. NIBRT's training curriculum is now well known and highly regarded globally, and it is wonderful to be able to use our expertise to help address the biopharma manufacturing where training and capacity needs in parts of the world delivering medicines and vaccines cost effectively to patients makes the most critical impact.

Additionally, NIBRT took a big step into the provision of training on the application of data science and digital technologies to biopharma manufacturing with the appointment of a Digital Training Manager, and the development of courses in that area.

On the research front, the NIBRT research team delivered highly impactful collaborative projects in partnership with many global and indigenous biopharma players in 2022. Companies partnering with NIBRT PIs on research projects included Astra Zeneca, Avectas, BMS, Glycoselect, Janssen, Pfizer, Thermo Fisher and many more, while some notable NIBRT research highlights included:

- ▶ Ongoing establishment of the NIBRT 'Concept' Facility which will enable researchers with a biological molecule of interest, to generate recombinant proteins, viral and non-viral based gene therapies, cell therapies or oligonucleotides, and to rapidly progress from concept to real therapeutic product. The 'Concept' facility, led by Dr Jonathan Bones, is comprised of various pieces of equipment for synthetic biology and cell line development, and was made possible with over €6M provided by a blend of SFI Strategic Research Infrastructure funding, plus IDA Ireland and industry support. 'Concept' is the first academic research facility of its kind in Ireland, and it is unique within a wider global context.
- ▶ €1.1M in SFI Frontiers for the Future for Prof Liz Topp and Prof Steven Ferguson for research on mRNA stability.
- ▶ Research findings that will have a significant impact on the manufacture and quality of biologics medicines, including:
 - *Discovery by Dr Jonathan Bones and Dr Colin Clarke's groups of a new class of Microproteins host cell impurity in mAb drug products,*
 - *Development of a new Multi-Attribute Method for analysis of mAb product quality by Dr Bones' group*
- ▶ 4 PhDs graduated
- ▶ 24 high impact publications

2022 was also a huge year for NIBRT in our continued growth and evolution into the new area of advanced therapeutics. Advanced therapeutics, which includes cell and gene therapies and novel-modality vaccines, represents a major opportunity for the next wave of biopharma manufacturing growth. In 2022, NIBRT commenced construction of a €21M IDA-funded expansion of our Foster Avenue facility that will add nearly 2,000m² of new laboratory and training space focused on the area. We expect to open the new facility in April 2023, and the expansion has already enabled us to launch a range of new training offerings in the CGT area, to expand our research programme in viral-vector based gene therapy, cell therapy and mRNA-related projects and to hire new research and training staff to meet growing demand. Most notably, 2022 saw NIBRT hire Professor Sakis Mantalaris through a unique joint appointment partnership with Trinity College Dublin. Prof Mantalaris will work on methodologies to assess the metabolomics of cell-based therapies with the aim of improving the consistency and quality of cell therapy manufacture.

2022 was an incredibly exciting year for NIBRT on the people-front. As we emerged from the pandemic and continued to grow, NIBRT has become an even more vibrant and dynamic place to work. In 2022 we welcomed 36 new members of staff from a diversity of perspectives, backgrounds and nationalities, which brings our team up to over 100 for the first time.

And to cap it all, we were honoured to achieve the silver Equality Diversity and Inclusion (EDI) award with the Irish Centre for Diversity, which is testament to the progress we have been making on developing NIBRT as an inclusive environment in which to work.

I would like to thank the NIBRT Chairperson Julie O'Neill and the members of the NIBRT board for their support throughout the year, with a very special acknowledgement of our recently departed Chairperson Brendan O'Callaghan, who retired after over a decade of dedicated service to the NIBRT cause.

Lastly, I would like to thank NIBRT staff for their continued hard work, innovation and dedication to NIBRT's training and research mission. I look forward to another successful year for NIBRT in 2023, hopefully with good luck and good health for all our staff, partners, vendors and clients.



Darrin Morrissey,
NIBRT Chief Executive Officer.

2.3 Governance

NIBRT is a private company limited by guarantee (company number 413711). The NIBRT CEO, Darrin Morrissey, reports into the Board of Directors of NIBRT.

There are 12 Board members with representatives from industry, academia and government agencies, and the Board is chaired by Julie O'Neill. The Board meets six times annually and there are three subcommittees of the Board:

- ▶ The Audit and Risk Oversight Committee, which met six times in 2022 in advance of the main NIBRT Board.
- ▶ The Resource Oversight Committee, which met twelve times in 2022, with the increased number of meetings to support the NIBRT Senior Leadership team in the close monthly monitoring of the Advanced Therapies building project.
- ▶ The Governance and Nominations Committee which met twice in 2022.

NIBRT Services Limited (NSL), company number 556310, is a limited liability company and 100% subsidiary of NIBRT. It holds all NIBRT's commercial activities which include training, education services and industry funded research. There are three members on the NSL Board, Jaqueline McCormack (Chair), Matt Moran (BiopharmaChem Ireland) and Darrin Morrissey, which met twice in 2022.

NIBRT completed eight financial audits (internal and external) in 2022 with no critical findings. FMB completed their 3-year term as NIBRT's Internal Auditors in Q1 2022, with EY appointed for the next 3-year cycle starting in Q3 2022.

NIBRT Board 2022

- ▶ **Chairperson: Julie O'Neill**
Non-Executive Director
- ▶ **Prof. Sarah Culloty**
Head of College, Science, Engineering and Food Science, University College Cork
- ▶ **Prof. Orla Feely**
Vice President for Research, Innovation & Impact (VPRII), University College Dublin
- ▶ **Prof. Norelee Kennedy**
Vice President for Research, University of Limerick
- ▶ **Dr Darrin Morrissey**
CEO NIBRT
- ▶ **Tom Murray**
Director, Friel Stafford
- ▶ **Dr Michael Thien**
Head of Pharmaceutical Services R&D, Takeda

New Board Members in 2022

- ▶ **Dr Aine Hanly**
Chief Technology Officer, Vir Biotechnology
- ▶ **Prof Anne Marie Healy**
Professor of Pharmaceutics and Pharmaceutical Technology
- ▶ **Dr Brendan Hughes**
Non-Executive Director
- ▶ **Prof Jacqueline McCormack**
Vice President for Equality, Diversity & Inclusion and Online Development, Atlantic Technological University
- ▶ **Rory Mullen**
Head of Biopharma and Food, IDA Ireland

Board Retirees in 2022

- ▶ **Brendan O'Callaghan**
Executive Vice President, Global Industrial Affairs, Sanofi
- ▶ **Dr Tom Kelly**
Divisional Manager Innovation and Competitiveness, Enterprise Ireland



2.4 2022 NIBRT by the numbers



4,500

Number of
trainees

31,000

Training days
delivered



55%

% of NIBRT research
that is funded
by Industry



810

Springboard+
students

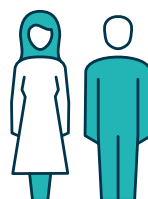


24

Peer reviewed
publications

52:48

Gender balance at
NIBRT (female: male)

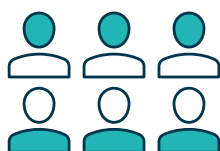


24%

Growth in overall
revenue **2022**

99

Number of **employees**



0

Lost time
accidents



60

Conference
presentations



80

Number of countries
using **NOA**



5,600

NIBRT **Online**
Academy users

20

Number of nationalities
working at **NIBRT**



3 | Strategy

3.1 The Biopharma Industry in Ireland – 2022

Strong foundations

The success of the Irish biopharma industry is well documented, with biopharma firmly established as a key pillar of the Irish economy:

- ▶ There are 84,000 highly skilled people directly and indirectly employed in the sector and the expectation is that this will increase by up to 10,000 jobs over the next 5 years.
- ▶ The biopharma and chemical sector had an export value of €106bn in 2020 – the first time a sector has exceeded the €100 billion mark in a single year.
- ▶ 85+ pharmaceutical companies operate in Ireland with exemplary regulatory track records. There are over 50 FDA approved pharma and biopharma plants including 19 of the top 20 world's biopharma companies.
- ▶ The sector has continued to be very successful in attracting international capital investments in the last decade, with approximately €15 billion of new build biopharma facilities announced since 2010.

The performance of the sector throughout the pandemic was exceptional with novel vaccines being developed at unprecedented speed within 12 months of the SARS-CoV-2 virus genome being published. As of November 2022, the World Health Organization estimates that a total of 13 billion vaccine doses have been administered globally. Many Irish sites played key roles in the global supply chains for the manufacture of vaccines and anti-viral therapies. For example, with Pfizer Grange Castle manufacturing the drug substance for Comirnaty the Pfizer/BioNTech mRNA vaccine.

Continued success in 2022

2022 again saw a strong wave of new biopharma investments in collaboration with IDA Ireland including:

- ▶ Pfizer announced plans to invest over €1.2 billion at its Grange Castle facility in Dublin. This investment will see a new facility built and will double the capacity for biological drug substance manufacturing at the facility creating 400 - 500 jobs.
- ▶ Lilly announced a €400 million investment in a brand-new manufacturing facility in Limerick, creating more than 300 jobs.
- ▶ Janssen announced the expansion of its biopharmaceutical supply chain facility in Ringaskiddy, Cork. The €150 million investment in the facility has the potential to create 180 new jobs.
- ▶ Merck announced it will invest approximately €440 million to increase membrane manufacturing capacity in Carrigtwohill and will also build a new manufacturing facility at Blarney Business Park, both in Cork. The investment, which is the largest in a single site ever for Merck's Life Sciences business sector will create more than 370 permanent jobs by the end of 2027.
- ▶ MSD announced the creation of over 100 new jobs in Carlow as part of the company's ongoing commitment to strengthening its manufacturing capabilities.
- ▶ Horizon Therapeutics plc. submitted a planning application to expand its development and manufacturing facility in Waterford. The planned facility is expected to create approximately 350 jobs over time.

In addition, 2022 saw a number of new facilities officially opening including:

- ▶ Bristol Myers Squibb opening its \$1 billion Cruiserath Biologics Facility in Dublin.
- ▶ MSD Ireland opened its €1 billion manufacturing facility in Swords, Co. Dublin.

- ▶ Grifols inaugurated a new albumin purification and filling plant at its global manufacturing and supply hub in Grange Castle, Dublin, creating 200 jobs.
- ▶ Avantor continued its support of the biopharma market with the opening of a new distribution centre.
- ▶ Takeda celebrated the opening of its innovative cell therapy production facility in Grange Castle.
- ▶ MeiraGTx formally unveiled its industry leading gene therapy manufacturing facility in Shannon.

Future Outlook

Continued growth but increased competition

Global sales of biopharmaceuticals are now over \$343 billion, with a compound annual growth rate (CAGR) of 12% and with approximately 60% of therapeutics in development being biopharmaceuticals^{4,5}. However, the level of international competition for biopharma manufacturing investments has increased considerably driven by a number of factors including post-pandemic supply chain concerns, as evidenced for example with President Biden's Executive Order on biomanufacturing⁶. While Ireland remains well positioned to continue to attract biopharma investments there is a requirement for a continued focus on Ireland's core manufacturing value proposition, including addressing cross-sector capacity constraints and competitiveness challenges.

More diverse and complex product pipelines

Monoclonal antibodies (mAbs) are predicted to remain the dominant modality in biopharma by some margin. Indeed, after 20 years+ of intensive effort, mAb manufacturing platforms are mainly well understood and characterized. However, there is a fast emerging, unprecedented diversity in therapeutic pipelines driven by excellent fundamental science including Antibody Drug Conjugates, multi-specific mAbs, multiple cell therapy modalities, gene therapies, RNA based therapeutics and vaccines, gene editing such as CRISPR/ CAS9, exosome-based therapies etc. For example, the Cell and Gene Therapy manufacturing market size is valued at US \$16.1 billion in 2020 and is anticipated to grow at a CAGR of 20% to 2030.

The relationship between manufacturing and discovery / development is increasingly important. The manufacturing process for advanced therapies are typically complex, costly and difficult to scale.

There is a considerable opportunity for Irish based organisations to lead global efforts to create standardised manufacturing platforms for advanced therapies. It is highly likely that future manufacturing investments for advanced therapies will increasingly be dependent on strong association with R+D operations.

→ PhRMA pipeline review⁵

- ▶ **7,800** biopharmaceutical products in clinical trial
- ▶ **1,000** in phase 3 clinical trial
- ▶ **2,533** are mAb based
- ▶ **348** gene-modified cell therapies
- ▶ **546** gene-based therapies
- ▶ **172** Covid vaccines



Advanced manufacturing agility and resilience

The diversity in clinical assets in manufacturing pipelines is driving fundamental changes in facility design, operations and supply chain with a focus on flexible and agile facilities with the ability to manufacture multiple products. Digitization has potential to be a key enabler of a manufacturing competitive advantage, though significant barriers remain – in particular, access to end-to-end high quality data management from research to manufacturing operations. To remain competitive there is continued demand for new efficiencies, standardisation, improved quality, and cost reductions in manufacturing processes.

Key trends, many of which rely on collaborative innovation with third parties, include:

- ▶ Supply chain agility with more flexible, modular multi-product facilities and increased resilience in manufacturing networks.
- ▶ 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.

4 EFPIA Pipeline Review, IQVIA, 2021

5 Biopharma Benchmarks, Nature Biotech Volume 40, December 2022, Walsh et al

6 "Executive Order on Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy" September 2022

- ▶ Process intensification and continuous processing, including upstream perfusion and downstream chromatography.
- ▶ Implementation of Industry 4.0 / digitalisation technologies with a particular focus on automation, paperless and data analytics.
- ▶ Evolving regulatory landscape.

Sustainability as a strategic imperative

Latest estimates indicate that the healthcare sector is responsible for 4–5% of global emissions, more than 70% of which are driven by supply chains⁷. Biopharma manufacturing typically has a comparatively high use of energy, water and plastics, and carbon emissions associated with a complex global supply chain.

The biopharma sector has been implementing a variety of noteworthy sustainability initiatives, for example Lilly's new facility in Limerick will be constructed to LEED (Leadership in Energy and Environmental Design) Gold Status. Most sites in Ireland would have policies in place to address issues such as net zero commitments, sustainable sourcing, circular lifecycles, product packaging, energy-efficient fixtures and equipment, waste minimisation, reduction of carbon emissions, incorporating green chemistry manufacturing techniques, reduction of plastic waste from single-use technology, water efficiency, local environmental impact etc.

However, it is inevitable that governance, regulatory, employee and consumer imperatives will continue to exert positive pressure on manufacturing and supply-chain operations to implement step-changes in their sustainability strategy.

The war for talent

As always access to a diverse talent pool with a broad range of multi-disciplinary skills will be a key determinant of future success. In 2021, the Financial Times working with Cytiva published the inaugural Global Biopharma Resilience Index⁸. Based on data from a survey of 1,165 biopharma executives from 20 countries, access to talent was identified as the primary weakness in the resilience of the global biopharma industry. 25% of respondents indicated that the sourcing of talent is a substantial or very substantial challenge, 50% said that the cost of talent has become a key issue. Indeed, the UK's Bioindustry Association estimates the UK alone will require 133,000 skilled life scientists by 2030⁹.

Employee focused policies on topics such as hybrid working; organisational culture; Environmental, Social, and Governance (ESG); Equality, Diversity and Inclusion (EDI) are becoming increasingly important to hire and retain the best talent.

This is not a new issue but has become more pronounced in recent years with the rapid growth of biopharma. Many regions are beginning to develop NIBRT like institutes to help address this talent gap, for example Campus Digital Biotech (France), EU Biotech Campus (Belgium), MassBio (Boston), NHC (UK) etc.

Global challenges

As noted earlier, the biopharma sector led a remarkable response to Covid-19. However, VUCA (Volatility, Uncertainty, Complexity, and Ambiguity) events will continue to stress supply chains. In particular, inflation, cost of goods, pricing pressures require a constant focus and it is vital that the supply chain agility, resilience and efficiencies identified in the pandemic be maintained and developed further.

NIBRT's response in 2022

As detailed in this Annual Report, NIBRT was pleased to play its part in contributing to the success of the biopharma industry by delivering a wide range of training programmes, and collaborating with industry on scientific research to drive innovation in biopharma manufacturing. Key achievements in the period include:

- ▶ A 24% growth in overall revenue, underpinning the highest research and training activity levels in the Institute's history.
- ▶ Expansion of NIBRT research and focus on advanced therapies as evidenced by a 75% increase in revenue from collaborative research activity.
- ▶ 34% growth in training and education revenue, resulting in over 31,000 learning days delivered to nearly 4,500 trainees and students.
- ▶ Further development of NIBRT's international training operations in Philadelphia, Canada, South Korea, China and Australia.
- ▶ Rapid progress with NIBRT's Advanced Therapies building which is projected to open in April 2023.
- ▶ Wide consultation with stakeholders in the development of NIBRT's strategy 2024-2028.

⁷ BioPhorum Environmental Sustainability Roadmap, December 2022

⁸ Cytiva Biopharma Resilience Index, Financial Times, 2021

⁹ UK Life Sciences 2030 Skills Strategy

Call to Action

While the success of the Irish biopharma industry is well established and it enjoyed another strong year in 2022, there is little room for complacency as the complexities, risks and level of competition have increased significantly year-on-year. The strong base of the sector in Ireland also provides significant opportunities for diversification and future growth. To address these challenges and to ensure the sector can fulfil its potential NIBRT is recommending the following five calls to action:

One: Assist Irish sites to develop as leaders in sustainable biopharma manufacturing for existing and novel therapies through the application of advanced manufacturing platforms, including leveraging Industry 4.0 and digital transformation technologies.

Two: 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. NIBRT looks forward to the Expert Group on Future Skills Needs publishing their report on the skills needs in the Irish biopharma sector, which is due to be released in quarter 2 2023.

Three: With the increased level of complexities and diversification in therapeutic timelines, future manufacturing investments will be closely aligned to locations with international reputations in biopharma research. While Ireland has made good progress in this regard¹⁰, further attention and focus is required here to build biopharma manufacturing research of scale, especially with regard to next generation biologics.

Four: Ireland has been very successful in attracting foreign direct investment in biopharma and chemical manufacturing, development and supply. It has been, with some notable exceptions, less successful in developing a strong indigenous biotech sector. Peer countries such as Belgium have been able to develop a robust manufacturing base alongside significant clinical research and a strong indigenous start-up sector. For example, the figures for pharmaceutical industry research and development in Belgium is €4,964 million, compared to €305 million in Ireland¹¹.

Five: The size and impact of the sector are now so significant for the Irish economy (by some estimates biopharma comprises 67% of annual exports from Ireland), that it requires a national life sciences strategy led by Government to drive effective strategic planning and coordination between all stakeholders and to ensure Ireland maximises its full potential in life sciences.

→ Belgium¹²

- ▶ **1st in biopharma R+D** investments in Europe
- ▶ **2nd in Europe** for export of chemistry and life sciences
- ▶ **Leader in market capitalisation** of all public European biotech companies
- ▶ **24%** of the EU biotech market value
- ▶ **60 start-ups** in last 5 years
- ▶ **Top 3 in EU** for clinical trial per inhabitant



Summary

2022 represented another strong year for the biopharma sector in Ireland building on the contributions of many stakeholders. The sector is well positioned for future diversification and growth. However, it is essential to remember that what has brought success in the past may not be enough to guarantee future success. The well-publicised words, *“The pace of change has never been so fast, but it’ll never be this slow again”*

neatly summarise recent developments within the industry.



Killian O'Driscoll
NIBRT Chief Commercial Officer.

→ Calls to Action

- ▶ Drive sustainable, agile advanced biopharma manufacturing
- ▶ Continued focus on workforce development
- ▶ Building biopharma manufacturing research of scale
- ▶ Development of a thriving indigenous and start-up ecosystem
- ▶ Create a national Life Sciences Strategy



¹⁰ Ireland ranks 11th strongest innovator on the European Innovation Scoreboard, and 19th overall on the Global Innovation Index

¹¹ The Pharmaceutical Industry in Figures 2022, EFPIA

¹² Belgium – big in biotech, Essencia 2022

- ▶ *An Taoiseach, Leo Varadkar, officially launches NIBRT ATMP construction extension*



3.2 Advanced Therapies Manufacturing

Over the past two decades Ireland has established itself as a global leader in biopharmaceutical manufacturing and has been tremendously successful in attracting multinational companies to establish manufacturing operations across the country.

In recent years there has been an upsurge in research and development in the next generation of biologic medicines, Advanced Therapy Medicinal Products (ATMPs). ATMPs include cell-based, gene-based, and oligonucleotide-based therapies as well as novel-modality vaccines. At the end of 2022 there were about 1,000 ATMPs in clinical development and it is widely predicted that ATMPs collectively represent the next big wave of biopharma innovation and growth. During the pandemic industry's focus on ATMPs became even more intense with several Covid-19 vaccines launched and in development, incorporating mRNA and viral vector technologies, being advanced much more quickly than previously thought possible.

It is clear that Ireland, given its previous success in biopharma, has much of the required collateral, in terms of facilities, experienced workforce, supply chain, cost benefits etc., that can be utilised to advance its leadership position in ATMP manufacturing. Ireland had already had some notable success in attracting large scale biopharma investments in ATMP manufacturing, with 2022 seeing:

- ▶ Takeda's launch of its €36 million expansion to its Grange Castle facility to manufacture cell therapy.

- ▶ Meira GTx's launch of its Shannon facility for the cGMP and commercial manufacture of viral vector and plasmids.
- ▶ Pfizer's announcement of a €1.5 billion investment in expanding its Grange Castle facility for the manufacture of advanced therapies.

Nonetheless, there is more that can be done to ensure that Ireland's fully grasps the opportunity. In 2018, NIBRT established the Cell and Gene Therapy (CGT) Forum, a group of like-minded stakeholders from across industry, academic researchers and government agencies, with the aim of making Ireland a global leader for the development, manufacture, supply and adoption of advanced therapies and novel vaccines. 2022 saw considerable progress on a number of key initiatives including:

- ▶ At the start of the year IDA Ireland confirmed a €21 million capital investment in NIBRT to enable the construction, equipping and staffing of a 1,800m² extension which will focus on research and training in the manufacture of advanced therapies. Construction of the NIBRT Advanced Therapies building extension commenced in early May 2022 and is progressing at pace. The new facility will add five new laboratories and additional training spaces when it opens fully in Q2 2023.

13 <https://www.atmp.ie/>

- ▶ NIBRT commenced the establishment of its new “Concept” Facility. Concept, which will be housed within the Advanced Therapies building, will enable researchers with a biological molecule of interest, to generate recombinant proteins, viral and non-viral based gene therapies, cell therapies or oligonucleotides, and to rapidly progress from concept to real therapeutic product. The “Concept” facility, led by Dr Jonathan Bones, is comprised of various pieces of equipment for synthetic biology and cell line development, and was made possible with over €6M provided by SFI Strategic Research Infrastructure funding, plus IDA Ireland and industry support.
- ▶ NIBRT started hiring the staff for its new Advanced Therapies building. Most notably, 2022 saw Professor Sakis Mantalaris join NIBRT through a unique joint appointment partnership with Trinity College Dublin. Prof Mantalaris is the Panoz Chair of Pharmaceutical Biology at Trinity and he will be based between the Trinity Translational Medicine Centre at St James’s Hospital Dublin and NIBRT, where he will conduct his pre-GMP manufacturing research. He has come to Ireland from his previous post as Professor in the WH Coulter Department of Biomedical Engineering, at the Georgia Institute of Technology, having previously worked for many years at Imperial College London. Prof Mantalaris research will explore the metabolomic profiles of novel cell therapies.
- ▶ NIBRT continued to build out its portfolio of ATMP training programmes during 2022.
- ▶ NIBRT also continued a number of very interesting ATMP research projects in collaboration with industry on topics such as characterisation of viral capsids, formulation and stabilisation of mRNA vaccines.
- ▶ Launch of the Advanced Therapeutics Ireland website, as Ireland’s one-stop web portal with details on the latest activities in advanced therapeutics.

NIBRT looks forward to continuing to help capitalise on this opportunity with all stakeholders to ensure Ireland continues its impressive track record of success in biopharma manufacturing.

→ Advanced Therapies Training at NIBRT

- ▶ Introduction to ATMPs/CGT
- ▶ Advanced Cell Therapy Manufacture, in collaboration with Cytiva
- ▶ Introduction to Stem Cell Therapy
- ▶ Fundamentals of Stem Cell Manufacture, in association with the Centre for Cell Manufacturing (CCMI), University of Galway.
- ▶ Introduction to Gene Therapy Manufacturing
- ▶ Manufacture of Viral Vectors
- ▶ Fundamentals of Vaccine Manufacture
- ▶ NIBRT Online Academy: Vaccine Manufacturing; Cell Therapy; Gene Therapy



3.3 NIBRT Strategy 2024-2028

NIBRT's strategic mission is to address the important needs of the biopharmaceutical manufacturing industry in Ireland and internationally, and ultimately to help bring biologic-based medicines to people who need them.

To deliver this mission, we:

- ▶ Train the people who make life changing medicines.
- ▶ Undertake research that grows the fundamental understanding of complex biopharmaceuticals.
- ▶ Deliver impactful solutions that improve the processes for manufacturing biologic medicines.

2022 was the penultimate year of NIBRT's five-year strategic business plan cycle (2019-2023), as agreed with the NIBRT Board and IDA Ireland. As reported at the end of the year, the organisation achieved or exceeded the large majority of its key performance metrics across Financial, Training, Research and Reputational categories. The only areas of under delivery versus the metrics, were due to the challenges experienced hiring well-trained research staff for our growing research portfolio, which resulted in delayed start dates for a number of research projects. In response to these hiring challenges, NIBRT partnered with Fastnet Recruitment during the year, and this has led to significant improvements in our hiring success and recruitment timelines.

The process of developing the NIBRT next strategic business plan 2024-2028, has been underway for the last 12 months and it is currently in the final drafting stage. By engaging with a range of stakeholders and analysing the wider biopharma operational environment, a number of important trends have been identified, which are discussed in detail in the *Biopharma in Ireland 2022*, section 3.1.

In response to these trends, associated opportunities and aligned with NIBRT's core mission, we have developed an ambitious strategy that focuses on the following five strategic priorities.

- ▶ **Priority 1:** NIBRT will continue to grow and diversify our world-leading training and education activities through an expanding range of customised training services for clients both nationally and internationally.
- ▶ **Priority 2:** NIBRT will build a strong international reputation as an open research institute that partners with companies and other leading research institutes to conduct highest quality research, delivering innovation in biopharma manufacturing science and technology.
- ▶ **Priority 3:** NIBRT will improve and upgrade its own digital environment, infrastructure and capabilities and will provide world-class biopharma 4.0 training services to meet the needs of our clients.
- ▶ **Priority 4:** NIBRT will be a well-recognised and employer of choice for professionals in biopharma manufacturing research and training, based on its core workplace values and its dynamic and supportive working environment.
- ▶ **Priority 5:** NIBRT will strive to ensure financial resilience of the Institute by delivering consistent and sustainable revenue growth and diversified research and training activities, while operating at the highest standards of environment, social and governance practice.

The final approved *NIBRT Strategy 2024-28* will be published during the summer 2023.

Strategic Priority 1: Training and Education Growth and Diversification

Strategic Priority 2: Research excellence, reputation, and impact through partnership

Strategic Priority 3: At the forefront of the Data Revolution in Biopharma manufacturing

Strategic Priority 4: Our people. Employer of choice

Strategic Priority 5: Financial resilience. Consistent and sustainable growth

Long-term Reputational Objective: To build NIBRT's reputation as a trusted opinion leader in biopharma manufacturing

Strategic Key Performance Metrics 2022

Financial	Category	Basis	2022
Group financial targets	1	Exceed	Achieved
IDA core investment	1	Not to exceed	Achieved
Capital expenditure funding	1	Match	Achieved
Approval of clean audited group accounts	1	Board approval	Achieved
Core grant funding target (deficit plus capital)	2	Exceed	Achieved
Competitive grant funding target (Irish public and EU)	2	Exceed	Achieved
Industry funding target (awards/contracts/donations)	2	Exceed	Achieved

Training			
Training income	1	Exceed	Achieved
Trainees per year	2	Exceed	Achieved
Training days (onsite, offsite, plus online)	2	Exceed	Achieved
Active international franchising agreements	2	Exceed	Achieved

Research			
Funded and collaborative research Income	1	Exceed	Partial
Number of principal Investigator teams	2	Exceed	Achieved
Number of researchers	2	Exceed	Partial
PhDs completed	2	Exceed	Achieved
Applications for large funded/collaborative awards	2	Exceed	Achieved
Conference presentations	2	Exceed	Achieved
Proportion of research between TRL 4 and TRL 9	2	Match	Achieved

Reputation			
Lost time injuries target	2	Not to exceed	Achieved
Net promotor score achieved for training	2	Exceed	Achieved
NIBRT support for major Biopharma events	2	Exceed	Achieved
Collaborations (Industry, Academia, sector bodies)	2	Exceed	Achieved



4 | Research

4.1 Message from NIBRT Chief Scientific Officer

NIBRT Research saw important growth in 2022, with the addition of a new Principal Investigator, new research initiatives and outputs, and a significant expansion in the Research Office.

In 2022, NIBRT welcomed Professor Sakis Mantalaris as our newest Principal Investigator (PI). Professor Mantalaris also holds a joint appointment with Trinity College Dublin as the Don Panoz Chair in Pharmaceutical Biology. Prior to joining Trinity and NIBRT, Professor Mantalaris was a Professor in the Department of Biomedical Engineering at Georgia Tech and Emory University. His research addresses challenges in the development of continuous manufacturing, new process analytical tools, single-use systems, process intensification, and the use of quality-by-design to improve process robustness and predictability.

In late 2021, NIBRT was awarded €4.5M from Science Foundation Ireland (SFI) to create and equip CONCEPT, a national synthetic biology and cell line development facility. Led by NIBRT PI Jonathan Bones, CONCEPT will enable researchers to rapidly generate optimized cell lines and biological materials. CONCEPT's suite of instruments will support workflows for producing recombinant proteins and monoclonal antibodies (mAbs), oligonucleotides and mRNA lipid nanoparticles, adeno-associated viral vector gene therapies, and cell-based therapies. The leading-edge facility will advance biologics manufacturing in Ireland, providing equipment and capabilities currently not available at NIBRT or widely available in the Irish academic research community.

In 2022, NIBRT investigators discovered a new class of microprotein impurities in mAb products, as a subset of the broader class of host cell protein (HCP) impurities. Using ribosome footprint profiling (Ribo-seq) and mass spectrometry, NIBRT PIs Colin Clarke and Jonathan Bones and their groups identified thousands of previously uncharacterised non-canonical proteoforms in CHO cells, which were then identified in a mAb drug product. The microprotein population changed over time in cell culture and in response to a change in temperature.

This discovery enables a more comprehensive characterisation of HCPs in antibody drug products.

In addition to these projects, NIBRT PIs engaged in projects across a broad range of biomanufacturing areas, including mRNA stability, AAV vector manufacturing and analysis, glycoengineering, glycan analysis, the creation of a CHO cell digital twin, and extractables and leachables analysis. These projects are described in greater detail in the research group sections of this report.

Aligned with the expansion of the NIBRT Research team, 2022 saw significant growth in the NIBRT Research Office. Caragh Tisdall joined the team as Research Officer and will be working closely with NIBRT staff to provide assistance across the funded research project lifecycle, with a focus on pre-award support. Caitriona Walsh has taken on the role of Research Infrastructure Manager. This new role has responsibility for the establishment, management, and daily operation of a Core Facility within the Institute, providing services to enable research projects. In addition, Clair Gallagher has joined as the new CONCEPT Facility Manager and, in collaboration with other CONCEPT stakeholders, is spearheading the design, launch and operation of this new state-of-the-art research facility.

We look forward to continued growth in NIBRT Research in 2023, as well as greater synergies with industry and Higher Education Institutes across Ireland and throughout the world.



Elizabeth M. Topp, Ph.D.
Chief Scientific Officer.

→ NIBRT's Scientific Advisory Board

- ▶ **Chair, Dr. Brendan Hughes**
formerly Senior Vice President, Global Manufacturing Operations, BMS
- ▶ **Susan Abu Absi**
CTMO, 2seventy bio
- ▶ **Dr. Robert Baffi**
formerly President of Global Manufacturing and Technical Operations, BioMarin
- ▶ **Prof. Imre Berger**
Professor of Biochemistry, University of Bristol
- ▶ **Dr. Jim Faulkner**
Venture Partner, Apple Tree Partners
- ▶ **Dr. Patrick Gammell**
VP Global Manufacturing Sciences, Biogen
- ▶ **Prof. Cleo Kontoravdi**
Professor of Biological Systems Engineering, Imperial College London
- ▶ **Prof. Shirley O'Dea**
Associate Professor of Biology, NUI Maynooth
- ▶ **Richard Snyder**
VP Science and Technology, Pharma Services, Viral Vector Services at Thermo Fisher Scientific
- ▶ **Ligang Zhang**
Senior Director, Alnylam Pharma

4.2 Updates from Research Groups

Cell Engineering Group, Prof Niall Barron

The Cell Engineering Group (CEG) welcomed a new member in the lab, Dr. Simeng Li, who joined as a Postdoctoral Researcher in the area of Cell Therapy. Simeng joins Dr. Nga Lao working on approaches to improving the production of gene-modified cells as therapies in collaboration with Irish companies Avectas and Bluebridge Technologies. The team have generated various chemically and structurally modified RNAs as a means to re-program patient immune cells using a novel gene transfer device.

This past year also saw the successful conclusion of a gene therapy-focused collaboration with Allergan (now part of Abbvie) and Pharmaron where we developed novel approaches to improving AAV vector manufacture and characterisation with colleagues in the Characterisation and Compatibility Lab in NIBRT. Much of this work has been published and there's more to come in 2023!

Dr. Nicholas Donohue was awarded NIBRT Seed Funding to explore an innovative mutant library-based approach to engineer and identify improved AAV gene therapy vectors. This initiative demonstrates the ongoing commitment to novel research into cell and gene therapy manufacturing.

Cell Technology Group, Prof Mike Butler

The Cell Technology Group (CTG) was successful in 2022 in initiating three research projects supported by Enterprise Ireland and several companies associated with the biopharma industry.

We were very pleased to collaborate with GlycoSelect, a Dublin based company that is interested in the selection of specific glycoform antibodies based on an array of prokaryotic lectins. This work extends the CTG expertise in glycoengineering with the goal of preparing and isolating monoclonal antibodies with targeted structures and properties. Elizabeth Matthews is the lead post-doctoral scientist in this research along with Neha Dalvi, a recent Masters graduate from UCD. This research area has also involved a collaboration with Maynooth University with support for Andreea Cislaru who is working toward her PhD.



A second round of funding from JM Canty International Ltd. involves the application of optical systems for monitoring bioprocesses. The Pharmaflow high resolution cell monitoring enables the continuous identification of cells at different stages of a bioprocess. This work also involves an evaluation of the BioCam with the ability of monitoring and controlling foam that can arise from excessive sparging in a bioreactor. This research is led by Laura Breen and James Flynn, who was recently recruited from the University of Limerick.

We continue with a project supported by the Kerry Group in collaboration with ValitaCell to investigate the activities and content of various protein hydrolysates on the productivity of cell-based bioprocesses. The hydrolysates are highly complex chemically and we have shown their ability to support both the growth and specific antibody productivity of host cells. Sandra Roche is the lead post-doctoral scientist in this research with support from Thais McNamara, who was recently recruited from the University of Galway following her Masters course.

Agilent Technologies continues to provide support for a study on a unique fluorescent label that allows high-throughput and high-sensitive profiling of glycosylation. The application of this analysis has allowed us to map the evolution of COVID-19 spike protein variants as well as analyse a panel of COVID-19 infected human serum to determine any changes from normal controls.

This work which is led by Yongjing Xie has allowed several publications in peer-reviewed international journals as well as provide webinars and application notes for Agilent's web-site.

Two PhD students (Adam Bergin and Leticia Mota) successfully defended their PhDs this year and have now both secured key research positions in the biopharma industry. Publications are being prepared from these PhD theses. One publication arising from Adam's thesis on the application of bio-capacitance was supported by Aber Instruments Ltd and highlighted recently by Aspen Alert, which is a key provider of novel developments in the biopharma industry globally.

Characterisation and Comparability Lab, Prof Jonathan Bones

2022 was another productive year for NIBRT's Characterisation and Comparability Laboratory (CCL) under the direction of Dr Jonathan Bones, with further developments relating to the characterisation of AAV based gene therapy products and the multi-attribute method (MAM) reported. In what was a more normal year relative to those just past, a key activity for the group was recruitment and on-boarding of new researchers as new research projects commenced.

AAV based gene therapy characterisation remained a strong focus area for the group, with outputs describing strategies for peptide mapping and posttranslational modification analysis of AAV capsid proteins using semi-automated sample preparation and LC-MS analysis reported. The analysis of process contaminants was explored, which revealed insights into the manufacturing process and the host cells response to viral production. Additionally, method for capsid protein analysis designed for deployment in the regulatory laboratory were also developed. These methods were designed to allow for simplified identity testing of AAV products using regulatory compliant data systems.

The multi-attribute method, or MAM as it is commonly referred to, was another strong focus area during the past year. In addition, further to development of 'traditional' peptide-based MAM, the group also reported a different MAM approach based on intact mass analysis using either denaturing or native LC separation modes such as size exclusion chromatography or cation exchange chromatography coupled to the MS. The advantage being that minimal sample preparation was required. Termed 'iMAM', the developed method adhered to the traditional MAM ethos consisting of a discovery and application phase, with the application phase including the use of targeted workbooks and a new peak detection step.

The resulting research paper was published in the *European Journal of Pharmaceutics and Biopharmaceutics* and a feature article on the iMAM approach was published in *Genetic Engineering and Biotechnology News*, in August.

The group was also focused on new analytical technologies, including assisting with the launch of Thermo Scientific's 'Direct Mass Technology Mode' option on the Q Exactive UHMR mass spectrometer. Designed to enable the direct analysis of complex glycoproteins and viral particles, CCL used Direct Mass Technology Mode for the analysis of empty and full AAV capsids generating high quality analytical data that will be published shortly.

The group grew substantially in 2022, with new arrivals bringing to eight the number of different nationalities present within a diverse CCL. New projects were commenced with several industry partners focused on process analytical technology, residual contaminant analysis and advanced characterisation studies. We're proud of all the team and the excellent science that they perform and spotlight key achievements by Craig Jakes who successfully defended his PhD thesis in June and Dr Sara Carillo, who was listed as one of LCGC's 'Rising Stars in Separation Science' in July¹⁴.



→ Rising Star in Separation Science, Sara Carillo¹⁴



NIBRT's Sara Carillo completed her Ph.D. in chemical sciences in 2013 at the University of Naples "Federico II" in Italy. Under the guidance of Professor Corsaro, she focused on the structural characterization of polysaccharides and glyco-conjugates from Gram-negative bacteria via NMR and mass spectrometry techniques, focusing on the immunological properties and potential of extremophiles endotoxins. After a period at the University College of Dublin, in 2015 she joined Jonathan Bones's research group at NIBRT, working on the understanding of the effects of extractables and leachables from single-use bioreactors on CHO cells N-glycome and produced monoclonal antibodies. She is now working at NIBRT in collaboration with Thermo Fisher Scientific as Bioanalytical Research Lead for the development of new analytical approaches in biopharma.

Downstream Processing, Dr Steven Ferguson

Dr. Ferguson remained active in a number of major biopharmaceutical research initiatives within the Irish research landscape in 2022. As a SSPC Theme Lead for Manufacturing and Member of the SSPC leadership team his group continues to conduct significant research into the manufacturing, purification and formulation of drugs, in addition to contributing and coordinating national level meetings throughout the year at the academic industrial interface. Dr. Ferguson leads the EPSRC-SFI Centre for Doctoral Training (CDT) in Transformative Pharmaceutical Technologies at UCD and NIBRT. This program is a key training hub for PhD students entering the (bio)pharmaceutical sector in the UK and established a joint graduate school between University of Nottingham, University College London and SSPC (UCC, TCD, UCD) and now NIBRT. NIBRT participates in jointly delivered taught modules and conducted its first in person training module as part of the programme in May 2022, hosting cohorts from UK and Irish Institutions.

The research highlight for the year within Dr. Ferguson's lab is the expansion in mRNA related research activity through a collaborative effort between Dr. Ferguson and Professor Elizabeth Topp. Building on the work associated with the SSPC-CDT where a co-advised PhD student is developing characterization and quantification protocols for mRNA stability for vaccine applications. A major SFI Frontiers of the Future award with Prof. Topp as the lead and Dr. Ferguson as a co-applicant was secured in 2022.

¹⁴ LCGC Chromatography Online, July 2022

This award aims to elucidate the mechanisms of degradation of mRNA, develop synthetically modified stabilized mRNA for vaccine applications and new manufacturing techniques to enable unprecedented control of mRNA, speed of production and output. This work will be supplemented by an additional SSPC-CDT student recruited in 2022, working on the development of mRNA pro-drugs. In addition to this work, Dr. Ferguson, through a continuing industry collaboration between BMS-NIBRT and UCD in multiscale characterization and modelling of downstream membrane separation processes has produced new multiscale modelling approaches for membrane separation systems and is guided by best-in-class proteomics workflows in Dr Bones' group.

Dr. Ferguson continued to contribute to the organization of international events working on the organizing committee for an M-Cersi workshop co-sponsored by the US FDA and serving as co-editor for an associated special issue of the journal of pharmaceutical sciences.

GlycoScience, Dr Radka Fahey (Saldova)

The GlycoScience group published 7 publications in 2022. Key publications include Mimura et al, 2022, [Frontiers in Immunology](#), Ronan et al, 2022, [JPR](#), and two papers from ERA-Net collaboration Abril-Parreño et al. in Glycobiology and Biology of Reproduction ([Paper 1](#), [Paper 2](#)).

Dr Radka Fahey was invited to deliver an oral presentation "Advanced glycoanalytics to characterise glycosylation for improved development of ATMPs", at the 3rd Global bioprocessing, Bioanalytics and ATMP Manufacturing Congress, 16th May 2022, Dublin and webinar for European Glycoscience Community Webinar Series entitled: "Epigenetic regulation of glycosylation and the impact on chemoresistance in ovarian and breast cancer", 19th May 2022.

Büşra Günay was awarded best student Oral Presentation Award: Gunay B, Fabra G.T, Laanglard L, Schmitz T, Ito K, Tryfonidou MA, Saldova R, Pandit A. "Glycomic enhancement of hyaluronic acid-based hydrogel with notochordal cell-derived matrix for disc regeneration." 2022 eCM20: Cartilage and Disc Repair and Regeneration, 15 – 18th June 2022, Congress Center, Davos, Switzerland.

The GlycoScience Team hosted two visiting students from CÚRAM from September 2022 to January 2023:

- ▶ Yagmur Bozkurt who is working on characterisation of protein N-glycome in Multiple Sclerosis as her PhD subject.
- ▶ Jack Schofield who is working on N-glycome changes in corneal neovascularization.

Formulation and Stability, Prof Liz Topp

Research in the Formulation and Stability Lab addresses the chemical and physical degradation of biologics, with special emphasis on dry powder formulations produced by lyophilization. The group had several notable accomplishments in 2022, including:

- ▶ The successful completion of an industry-sponsored project evaluating the effects of a novel coating process on the stability and processability of lyophilized and spray dried protein formulations.
- ▶ The launch of a new industry-sponsored project on the stabilization of mRNA lipid nanoparticles. Sponsored by a major multinational biopharmaceutical company, the project is being conducted jointly with investigators at Purdue University.
- ▶ Participation in a recently funded Horizon Europe Marie Skłodowska-Curie Doctoral Training Program entitled "Greener Recombinant Protein Production (greenerRPP)". The project will develop more sustainable protein manufacturing methods; the greenerRPP student in the F&S lab will develop methods to inhibit protein aggregation, thereby increasing yields and reducing environmental impact.
- ▶ The receipt of the Letter of Offer for our Science Foundation Ireland proposal on mRNA stabilization, a project that also involves Dr Steven Ferguson. Objectives include improving our understanding of mRNA degradation, the synthesis of modified mRNA with improved stability, and the development of novel liquid-phase synthesis methods.
- ▶ Completion of review paper summarizing the excipients used in lyophilized drug products and quantifying their utilization from 1955-2021. A LyoHUB "best practices" paper, the manuscript includes authors from five multinational pharmaceutical companies. Kevin Lomasney of the NIBRT Training Team is also a co-author.



The Formulation and Stability Lab welcomed Manuel Alfaro de Prá as a research assistant in the fall of 2022. Manuel holds a Ph.D. in Biotechnology and Biosciences from University Federal of Santa Catarina in Brazil and has previous experience as an R&D coordinator and technical manager. In addition, a new Ph.D. student has been identified for the greenerRPP project and plans to join the group in January 2023.

Systems Biology and Data Analytics, Dr Colin Clarke

The Systems Biology and Data Analytics group at NIBRT had an exciting year in 2022. In collaboration with the CCL and CTG groups in NIBRT a new type of host cell protein contaminant in monoclonal antibody drug product called microproteins was [discovered](#).

STACCATO, the Marie Skłodowska-Curie European Industrial Doctorate project coordinated by Dr. Clarke, hosted a single cell omics for biopharmaceutical manufacturing workshop at the 27th ESACT (European Society for Animal Cell Technology) meeting held in Lisbon in June.

The collaborative research project with Accenture (funded through the Enterprise Ireland Innovation Partnership Programme) is progressing well. This project is focused on the application of single cell analysis to develop a digital representation of aspects of a CHO cell to enhance the efficiency of process and cell line development.

Dr Clarke co-edited a special issue in Current Opinion in Chemical Engineering on [Mechanistic and data-driven modelling of biopharmaceutical manufacturing processes](#).

PhD candidate in the Systems Biology and Data Analytics team, Dr Marina Castro Rivandeneira successfully defended her thesis entitled: *"Understanding Chinese hamster ovary cell translation at sub-codon resolution"* in August 2022.

→ NIBRT Research 2022

24 Peer reviewed publications

86 Collaborations

8 Principal Investigators

48 Research staff

44 Conference presentations

→ Professor Sakis Mantalaris



NIBRT is delighted to welcome the newest PI to the team, Professor Athanasios (Sakis) Mantalaris. As the Don Panoz Chair of Pharmaceutical Biology at the School of Pharmacy & Pharmaceutical Sciences,

Trinity College Dublin (TCD), Sakis has joined NIBRT as a joint appointee of TCD conducting complementary fundamental cell research and clinical translational research at Trinity's Translational Medicine Institute (TTMI) which will provide a strategic bridge between the two institutions. Prior to joining TCD and NIBRT, Sakis was Professor in the W.H. Coulter Department of Biomedical Engineering at Georgia Tech & Emory since August 2018 before which he held the position of Professor of BioSystems Engineering in the Department of Chemical Engineering at Imperial College London.

Since graduating from the University of Rochester with his PhD in Chemical Engineering in 2000, Sakis has published over 200 papers, 30 book chapters, and co-edited a book, as well as having developed several patents and formed spin out companies earning him the recognition of an exceptional international researcher in his field. Sakis has competed at the highest levels in obtaining international competitive research securing some \$40M for over 50 projects, from funding agencies in the UK, EU and US, as well as from industry and charities. He has graduated 45 PhDs, many of whom are themselves in academia. Sakis has received several awards including the Junior Moulton Award for best paper by the Institute of Chemical Engineers (IChemE) in 2004. In 2012, he was elected Fellow of the American Institute for Medical & Biological Engineering, in 2013 he received an ERC Advanced Investigator Award and achieved the Donald Prize (2015) awarded by the UK Institute of Chemical Engineering for his work on bioprocessing.

Sakis has expertise in modelling of biological systems and bioprocesses with a focus on mammalian cell culture systems, stem cell bioprocessing, and tissue engineering. One of NIBRT's strategic research goals is to play a leadership role in developing Ireland as a preferred location for the manufacture of advanced therapies. As a senior leader in the field of bioprocessing and cell manufacturing, Sakis's research interests align strongly to these goals.

4.3 PhD Graduates from NIBRT in 2022

NIBRT was delighted to see four of our team successfully defend their PhDs in 2022.

Adam Bergin, Cell Technology Group

Adam's thesis (entitled: "*The use of Process Analytical Technologies to examine the viability of CHO cells*") developed technologies around high-resolution optics and capacitance to monitor cells continuously in a bioreactor. This work has attracted the likes of Canty Engineering and Aber Instruments who have donated instrumentation and cash to the project. It is clear from Adam's work that the use of the PharmaFlow imaging system and the Futura capacitance probes from these companies are important steps toward the automated on-line monitoring steps in bioprocessing. During the course of the work, Adam has delivered several sponsored webinars and conference presentations that have been well recognised and acclaimed by the international scientific community. Adam will continue some of this work in his new industrial position and is planning some key publications from his thesis.

Leticia Mota, Cell Technology Group

Leticia's thesis is entitled: "*Chemoenzymatic in vitro glycoengineering in liquid and in solid phase to produce defined IgG glycoforms*". Here she has explored methods to modify the glycan profiles of antibodies that appear heterogeneous as they emerge from a bioreactor. In particular the patented solid phase transformation of therapeutic antibodies offers an efficient method of obtaining single glycoform antibodies that have enhanced therapeutic efficacy. This work has been presented at several international conferences and earned Leticia a presentation prize at last year's Bioprocessing Summit Europe. The method that Leticia has pioneered has attracted considerable industrial attention and will continue at NIBRT with the recent Enterprise Ireland grant awarded in collaboration with GlycoSelect Ltd.

Marina Castro-Rivadeneyra, Systems Biology and Data Analytics Group

In late 2017, Marina joined Dr. Colin Clarke's lab in NIBRT as a predoctoral researcher to evaluate the utility of ribosome footprint profiling (Ribo-seq) to identify translation of novel coding regions of CHO cell transcriptome and highlight routes towards enhanced biopharmaceutical manufacturing. A key novel aspect of this approach was the combination of multiple translation inhibitors for Ribo-seq to enable the simultaneous analysis of translation initiation and elongation for the first time.

As a result of her work, thousands of novel previously uncharacterised open reading frames (ORFs) including those non-AUG start codons were found in CHO cell transcriptome, comprised of N-terminal extensions of canonical proteins, ORFs found in genes previously thought to be non-coding and those found in the 5' leader sequence of mRNAs (i.e. upstream ORFs).

Furthermore, and through the use of Ribo-seq and RNA-seq data, these upstream ORFs were found to have a repressive effect on the translation efficiency of the main ORF. In addition, following comparison of CHO cells at day 4 and day 7 of cell culture as well upon a reduction of cell culture temperature, genes undergoing differential translation were identified. A number of these genes did not have a corresponding change in gene expression, confirming that Ribo-seq can provide an additional dimension regarding gene expression regulation compared to using RNA-seq in isolation. The use of ribosome profiling further enabled the computation of transcriptome wide decoding times for each codon, and revealed influence of codon context on translational rate. Overall, these data provide a potential route towards more efficient codon optimised transgene sequences in CHO cell hosts.

As part of the expanded CHO cell proteome, this work identified thousands of novel small open reading frames (sORFs) predicted to encode microproteins (i.e. proteins < 100aa). In collaboration with Dr. Jonathan Bones' lab, host cell protein analysis revealed that 8 newly discovered microproteins were present in marketed mAb products, confirming that microproteins are a novel class of potential process related impurity.



Dr Craig Jakes and Dr Marina Castro-Rivadeneyra.

Voice of a NIBRT PhD Candidate: Craig Jakes, Characterisation and Compatibility Laboratory

My first experience with NIBRT was as a trainee in 2015 as part of my master's in biotechnology. Following graduation, I began working in a regulations role but was desperate to get into a lab-based position. I remember scrolling through pages of advertisements on irishjobs.ie before coming across one as a research assistant in NIBRT. The job specification asked for knowledge or experience in LC-MS and I thought I had no chance at the role as I had no idea what LC-MS even was at the time. I decided to throw in an application anyway and hope for the best. Fortunately, I got an interview and was offered the position.

The project was a collaboration between Thermo Fisher Scientific and NIBRT and the aim was to develop workflows for monoclonal antibody characterisation. I started out with bioreactors and upstream cell culture bioprocessing but as the project progressed there was a need for me to be more involved in the running of the UHPLCs. It's funny looking back on the lab in 2016 compared to where we are today, in 2016 we had three Thermo UHPLCs and zero mass spectrometers while today we're running out of space because of the amount of mass spectrometers we have now. After a year of working and during my annual review I was offered the opportunity to undertake a PhD, something I had wanted to do in the past but had given up on the idea of following my masters. At the time the Thermo project was progressing from application notes to published papers, so it made sense to get a PhD from the work we would be doing anyway. My PhD focused on the development of analytical strategies for the characterisation of biotherapeutics.

Some of my favourite work in my final thesis included the development of the multi attribute method (MAM) and the development of a native protein A mass spectrometry workflow. Both of these applications are continuing to be utilised and further developed in our lab today. Doing a PhD during the pandemic was difficult but NIBRT made it very achievable by getting us back into the lab, helping set up a home office and by working diligently to provide us with a flexible working environment that kept us safe.

Following the awarding of my PhD, I've continued to work in NIBRT and have taken up projects that are focusing on the next wave of therapeutics. I'm now developing analytical workflows for the characterisation of mRNA using LC-MS. This has required me to learn a number of molecular biology techniques and NIBRT have been fully supportive of my career progression. For example, earlier this year, shortly after my PhD defence, I was sent on a two-week molecular biology bootcamp course in Smith University, Northampton. This course provided me with the necessary skills to produce our own models for in-house mRNA production.

NIBRT has continued to support me throughout my time here and are always looking at ways to improve my skillset. The work is constantly evolving to keep in line with the needs of the biopharmaceutical market. I'm forever thankful to Jonathan & NIBRT for their investment in my career and of course to my colleagues in CCL for their continued support.



Key publications in 2022

NIBRT PI Group	Title	Publication
Bryan et al. (Barron Lab)	Differential expression of miRNAs and functional role of mir-200a in high and low productivity CHO cells expressing an Fc fusion protein.	<i>Biotechnol Lett.</i> doi: 10.1007/s10529-021-03153-7
Millán-Martín S et al. (Bones Lab)	Comprehensive multi-attribute method workflow for biotherapeutic characterization and current good manufacturing practices testing.	<i>Nature Protocols</i> doi: 10.1038/s41596-022-00785-5
Carillo S et al. (Bones Lab)	Intact multi-attribute method (iMAM): A flexible tool for the analysis of monoclonal antibodies.	<i>Eur J Pharm Biopharm</i> doi: 10.1016/j.ejpb.2022.07.005
Trappe A et al. (Bones Lab)	Correlative N-glycan and charge variant analysis of cetuximab expressed in murine, chinese hamster and human expression systems.	<i>J Chromatogr B Analyt Technol Biomed Life Sci.</i> doi: 10.1016/j.jchromb.2022.123186
Guapo F et al. (Bones Lab)	Fast and efficient digestion of adeno associated virus (AAV) capsid proteins for liquid chromatography mass spectrometry (LC-MS) based peptide mapping and post translational modification analysis (PTMs).	<i>J Pharm Biomed Anal.</i> doi: 10.1016/j.jpba.2021.114427
Bergin A et al. (Butler Lab)	Improving productivity in cell culture manufacturing with bio-capacitance.	<i>Biotechnology Advances</i> doi: 10.1016/j.biotechadv.2022.108048
Xie Y and Butler M	Serum N-glycomic profiling can produce potential signatures for diagnosis and surveillance of COVID-19.	<i>Glycobiology</i> doi: 10.1093/glycob/cwac051
Mimura Y et al. (Salдова Lab)	Enhanced Immunomodulatory Effect of Intravenous Immunoglobulin by Fc Galactosylation and Nonfucosylation.	<i>Frontiers in Immunology</i> doi: 10.3389/fimmu.2022.818382
Ronan R et al. (Salдова Lab)	Distinct glycosylation responses to spinal cord injury in regenerative and non-regenerative models.	<i>Journal of Proteome Research</i> doi: 10.1021/acs.jproteome.2c00043
Castro-Rivadeneira et al. (Clarke Lab)	Found in translation: Microproteins are a new class of potential host cell impurity in mAb drug products.	<i>BioRxiv</i> doi: 10.1101/2022.01.20.475618v1
Silvano M et al. (Clarke Lab)	Gene Expression Analysis of Adapted Insect Cells during Influenza VLP Production Using RNA-Sequencing	<i>Viruses</i> doi: 10.3390/v14102238
Virgolini N et al. (Clarke Lab)	Transcriptome analysis of Sf9 insect cells during production of recombinant Adeno-associated virus	<i>Biotechnology Journal</i> doi: 10.1002/biot.202200466
Renawala HK and Topp EM	Fibrillation of human insulin B-chain by pulsed hydrogen/deuterium exchange mass spectrometry.	<i>Biophysical Journal</i> doi: 10.1016/j.bpj.2022.10.042

→ Nature Protocols Paper

This high impact paper from Dr Jonathan Bones' CCL group entitled "Comprehensive multi-attribute method workflow for biotherapeutic characterization and current good manufacturing practices testing" describes an end-to-end multi-attribute method (MAM) workflow developed at NIBRT. Publication of the workflow provides the wider MAM Consortium with a foundational platform method, that can be applied and further developed by all industry members within the Consortium with an interest in implementing MAM within their own companies. This key publication was developed by NIBRT's Silvia Millán Martín, Dr. Craig Jakes, Sara Carillo and Jonathan Bones together with their co-authors on Da Ren (Amgen) and Rich Rogers (Umoja Pharmaceuticals).

→ Research Integrity

All NIBRT researchers are mandated to complete research integrity (RI) training delivered by the Epigeum platform, a recognised gold standard for RI training nationally. In addition, NIBRT are part of the National Research Integrity Forum Communities of Practice for research integrity. NIBRT is a founding member of the Cross Institutional Research Integrity Training (CIRIT) which delivers research integrity training workshops nationally. To date CIRIT have trained over 200 members of the research community in Ireland and Northern Ireland and will continue to evolve and incorporate new training elements in 2023.



4.4 Research Case Study:

NIBRT, Abbvie and Pharmaron successfully completed their AAV focused research project in 2022.

The project, funded by Enterprise Ireland, and lead by NIBRT PIs Niall Barron and Jonathan Bones explored strategies for optimisation of AAV-based gene therapy production, purification, and characterisation of the produced viral capsids. The team of four talented postdoctoral scientists working on the project made excellent progress, with some exciting papers already published (1,2,3,4) and more to come in 2023.

Upstream processing and engineering activities were performed in the Cell Engineering Group. Investigations into the expression system, either mammalian or insect cell host cells, were undertaken to investigate the effect on titres and fill states of the produced viral capsids. Using advanced molecular biology methods, optimisation of the plasmids was also performed to increase overall capsid production and increased levels of viral particles containing the gene of interest.

Purification activities and analytical characterisation workflows were developed in the Characterisation and Comparability Laboratory to enable characterisation of the materials produced by the Cell Engineering Group and to further optimise their activities based on the associated analytical data.

abbvie



New characterisation workflows for the analysis of various product quality attributes including titre, empty full ratio, capsid mass, viral protein ratio, viral protein posttranslational modification and process contaminant levels to name but a few were developed during the project.

The project has resulted in three publications so far with many more in preparation. One study, which investigated the proteomic landscape of AAV producing HEK cells featured in the list of the most downloaded papers in the International Journal of Molecular Sciences in 2021 and considering that the paper was only published on October 25th highlights the impact of the study. Another paper emanating from the project, which described the use of native mass spectrometry for the assessment of empty and full capsids was published in September 2021 and has been downloaded >4,050 times since, again testament to the impact of the research performed at NIBRT. The project has provided an excellent foundation in all aspects of AAV manufacture and analysis and with more outputs to come in 2023, there are exciting times ahead.

4.5 Research Case Study:



NIBRT collaborate with JM Canty International to apply advanced optical systems for monitoring and control of mammalian cell bioprocesses.

The collaboration is supported by Enterprise Ireland and involves the application of two imaging systems to mammalian cell bioprocesses. The PharmaFlow™ system is capable of analysing the morphological changes associated with the metabolic state of the cells as they progress through the bioprocess. This system allows on-line detailed monitoring of cells during biopharmaceutical production that match the alternative off-line measurements in terms of total cell density, viable cell density and overall culture viability.

The BioCam™ system is capable of automated monitoring the generation of foam in the bioreactor. In industrial bioprocessing the generation of foam and resultant risk of filter blockages limit the maximum volume of the culture, and thus restrict the product output per batch.

The research will investigate the use of antifoaming agents that can be administered automatically through a vision based, integrated feedback system that monitors the foam level, maximising throughput by running cultures that use the full vessel volume available.

This research collaboration programme is conducted within the Cell Technology Group at the state-of-the-art facilities at NIBRT under the guidance of Prof. Michael Butler with Drs Laura Breen and James Flynn as research scientists.



Canty's collaboration with NIBRT has allowed the two groups of highly skilled research and industrial professionals to align their goals on a project that will serve to develop an invaluable tool for process control in the bioprocess industry."

→ **Tod Canty,**
CEO Canty



NIBRT's Prof Mike Butler and Laura Breen with the Canty team.

5 Training and Education

5.1 Training and Education in 2022

2022 represented a very positive year for NIBRT Training. We were pleased to see our onsite trainee numbers return to near pre-pandemic levels with continuing strong demand for our competency-based training solutions. We successfully delivered over 31,000 learning days to over 4,500 trainees across our different training modalities including onsite and distance learning delivered to industry and academia. In addition, the NIBRT Online Academy now has over 5,600 users from 81 countries.

With the continued focus on the workforce development our customised training offerings were in high demand and we were able to offer an extensive and flexible curriculum to our existing clients and to welcome new clients to NIBRT. Our support and collaboration with the Higher Education Institutes is still one of our core offerings and this year marked the return of our student cohorts for full face-to-face engagement.

Industry Training

Workforce development, building and retaining talent is a critical area of focus for biopharma manufacturers given the pace of development of new therapeutic modalities and the complexity in manufacture. NIBRT has further developed and refined its offering to industry and now offers a best-in-class curriculum focused on drug substance and drug product manufacture, quality control and an exciting new offering in the cell/gene therapy and vaccine area that has been piloted in 2022 with our first clients.

Our client list for customised training courses in 2022, as shown below, illustrates the reach of our programs to a wide audience including biopharma manufacturers, vendors and representative bodies.



→ Customised training courses were delivered for the above industry clients in 2022.

Academic Training

In 2022 NIBRT continued to provide access to our curriculum and subject matter experts for third level students from our academic partners. A positive development with the commencement of the current 2022/2023 academic year was that we could welcome students back for full onsite practical engagement that had been curtailed over the previous two years due to the pandemic.

Academic institutes clearly have an increasingly key role to play in talent generation for our industry across all disciplines, with more noticeable demands for graduates and postgraduates with requisite skills that can serve as a foundation to build successful careers in the industry. NIBRT's ongoing collaboration in life science and engineering programs affords real value to students in these programs and students can really contextualise their academic modules by practical training in the NIBRT pilot-production training plant.

Springboard+

NIBRT was pleased to continue its collaboration with our academic partners in ATU Sligo, TU Dublin and TUS Limerick respectively in the delivery of accredited training as part of the wider Government supported Springboard+ initiative. Over many years this program has proved to be highly beneficial to students from a variety of backgrounds and disciplines by providing them with access to excellent accredited training and where NIBRT is involved includes time in our training facility experiencing operations and equipment in a real life configuration. In 2022, 810 students participated in Springboard+ courses at NIBRT, in courses ranging from QQI level 6 to QQI level 9.



→ Academic courses were delivered to the above HEIs in 2022.

International Clients

With the return of international travel to more normal numbers in 2022, we were delighted to increase our number of international based clients who sent colleagues to our facility in Dublin. These trainees came from both established manufacturers and also from some specialised technical providers who have a key role to play in supporting industry.

Vendors/Suppliers

Vendors and technical providers are intrinsically linked to successful biomanufacturing and NIBRT has further strengthened its interactions with this community in 2022. The strength of our training curriculum, trainee numbers, client companies and international partner network all provide a benefit to technical providers and the placement of relevant equipment in NIBRT provides tangible benefits and clearly strengthens our offering to all our trainees.

→ Key Training Metrics

4,500	Number of trainees
31,000	Number of learning days
810	Number of Springboard+ students
5,600	Number of NOA users



Springboard+ is co-funded by the Government of Ireland and the European Union.



Rialtas na hÉireann
Government of Ireland

HEA
HIGHER EDUCATION AUTHORITY
AN tArdánas um Ard-Oideachas

FUTURE JOBS
IRELAND
Preparing Now for Tomorrow's Economy



NIBRT Online Academy (NOA)

The NIBRT Online Academy (NOA), launched in 2020, continues to grow from strength-to-strength with over 5,600 users in 81 countries. NOA provides online access to more than 60 interactive elearning courses which cover all aspects of the biopharma manufacturing process. New NOA courses added in 2022 include:

- ▶ Introduction to QC Testing
- ▶ Trends in Biopharma Manufacture
- ▶ Cleanrooms and Cleanroom Behaviours
- ▶ Viral Vector Production for Gene Therapy, 4 courses

New courses offered in 2022

In addition to ongoing development of our existing curriculum, we were pleased to be able to offer new courses to our clients. These courses, a blend of theory and practical sessions included:

- ▶ Introduction to Commissioning, Qualification and Validation in Biopharmaceutical Production.
- ▶ Introduction to Lyophilisation for Biopharmaceutical Fill-Finish Operations.
- ▶ Introduction to Advanced Therapy Medicinal Products (ATMP).
- ▶ Introduction to Cellular Immunotherapy.
- ▶ Introduction to Gene Therapy Manufacturing.
- ▶ Introduction to Stem Cell Manufacturing.
- ▶ Introduction to Data Reliability and Integrity (in partnership with ERA Sciences).

Biopharma 4.0

The adoption of Industry 4.0 across many aspects of biopharma operations is a key trend shaping our industry. There is strong industry interest in deploying advanced digital technologies to drive sustainable operational efficiencies.

NIBRT has already developed a Biopharma 4.0 Strategic Workshop in partnership with Boston Consulting Group (BCG). We were delighted post-pandemic in 2022 to reinstate our face-to-face workshops with BCG and a series of clients. These customised workshops are designed for senior industry leaders focused on strategies to develop and optimise digital manufacturing. These jointly delivered workshops typically include a focus on current trends in digital transformation, case studies, assessment of 4.0 technologies including mixed reality and data analytics with practical demonstrations using technologies deployed within NIBRT.

In response to this developing interest in Biopharma 4.0, NIBRT Training have been developing new practical oriented programs for operators, laboratory scientists and IT managers that will be first offered in 2023 and that will cover:

- ▶ Data Analytics for Biopharma Manufacturing (Introductory and Advanced courses)
- ▶ Customised programs will also be offered that can include topics such as machine learning, multivariate statistics, electronic batch records, advanced process control for biomanufacturing and application of extended reality in biopharma operations.



John Milne
NIBRT Training Director.

5.2 Training case study:



About Wuxi Biologics

WuXi Biologics is a leading global biologics CRDMO (Contract Research, Development and Manufacturing Organisation) offering end-to-end solutions which enable partners to discover, develop and manufacture biologics from concept to commercial manufacturing for the benefit of patients worldwide.

What training has NIBRT provided to WuXi Biologics?

NIBRT has delivered a number of customised training courses to WuXi Biologics staff over the last two years, both online and onsite in NIBRT. Courses have included manufacturing from inoculum through to upstream and downstream processing to highly customised courses in Quality Control.

The attendees interviewed for the purpose of this case study work in downstream processing. The course was delivered in online lectures for 3 days followed by 3 days practical study at NIBRT. These practicals were carried out in NIBRT's pilot plant and lab facility with sessions customised to WuXi Biologics processes and unit operations.

How did participants rate training at NIBRT?

Overall course experience average rating 9/10

90%

Respondents rated our trainers 9/10 or above

100%

Respondents would very likely recommend this course to a friend

85%



What did trainees say about NIBRT?

"The training today was great. It was great to see the equipment first hand and get the experience from it because I am normally more theory and desk based".

Caoimhe Duffy - Bioprocess Associate, WuXi Biologics

"I would definitely recommend the downstream processing course in NIBRT as it gives very in depth practical and theoretical knowledge of the downstream process".

James Downey - Bioprocess Associate, WuXi Biologics

"As a Finite Scheduler and new to the business of biopharma it is going to benefit me in learning different parts of the process and how the process actually works".

Ross Halpin - Finite Scheduler, WuXi Biologics



5.3 Training case study:



About Astellas

Astellas is at the forefront of healthcare change in turning innovative science into value for patients. The Astellas business philosophy is to “Contribute towards improving the health of people around the world through the provision of innovative and reliable pharmaceutical products”.

What training has NIBRT provided to Astellas?

NIBRT have a strong relationship with Astellas, working together on training courses for over 10 years. NIBRT have delivered training to Astellas online, onsite in NIBRT and onsite at Astellas. NIBRT were delighted to develop a two-day course for the Astellas Graduate programme delivered in June 2022 that this case study is based on.

Over the two days, this course delivered theoretical sessions in the classroom in NIBRT on the core unit operations of the biopharmaceutical manufacturing process from upstream to downstream to fill finish. Each theoretical session was complemented by a hands-on practical training of the equipment in these areas.

How did participants rate training at NIBRT?

Percentage of trainees that rated our trainers as excellent

86%

Percentage of trainees that were very likely to recommend this course to a friend

85%

Percentage of trainees that were very satisfied with the overall training experience at NIBRT

86%



What did trainees say about NIBRT?

“Taking time away from the office is important for training because it gives an insight into different areas in STEM. In Astellas we would not see a lot of the areas we are seeing here”.

Christine Collins - Quality Control Chemist Graduate

“This work will benefit me in the work that I do. I would definitely recommend the NIBRT course. What stood out me was the fact that all the speakers had great expertise and subject knowledge and were able to answer any questions we had”.

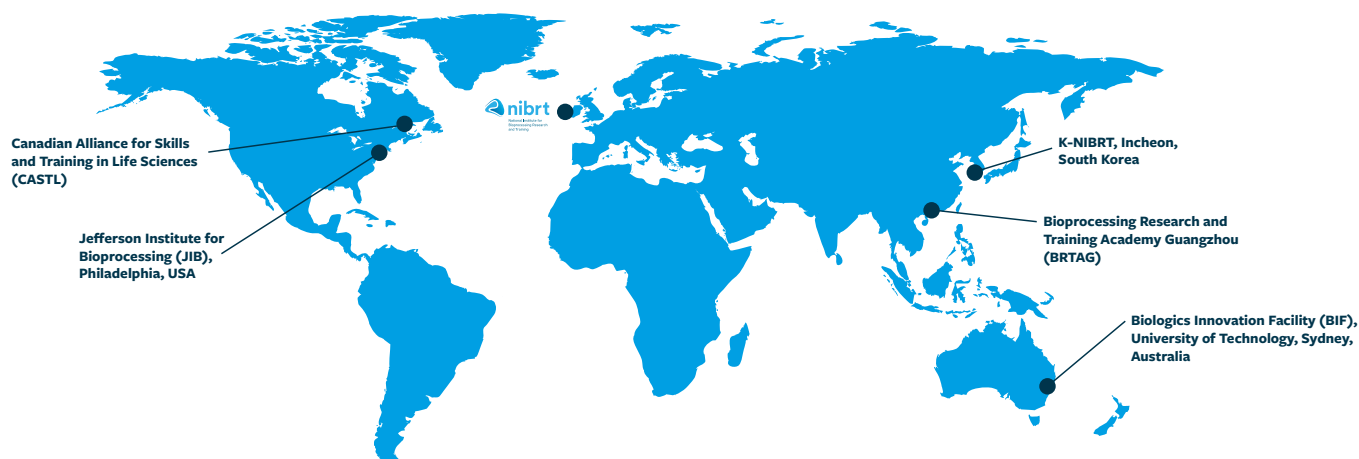
Kevin Byrnes - QA Operations Specialist

“I would definitely recommend the NIBRT course. It goes deep into the detail on the biopharmaceutical industry especially biopharmaceutical products ranging from the function of the biopharmaceutical product to the structure and how it is produced in industry”.

Aaron Cosgrave - Quality Control Chemist Graduate

5.4 Global Partner Programme

The NIBRT Global Partner Programme supports an international alliance of leading training and education organisations who licence NIBRT's training curriculum and expertise to help address the shortage of a skilled biopharma workforce in their region. In 2022, NIBRT had five global partners with negotiations at an advanced stage for new partners to join in 2023.



Canadian Alliance for Skills and Training in Life Sciences (CASTL)

The Canadian Alliance for Skills and Training in Life Sciences offers industry-informed programming, where learners gain knowledge and training valued by today's bioscience industry, and companies get access to career-ready talent. CASTL deliver NIBRT's training designed specifically for the biopharmaceutical sector in Canada within CASTL's three learning streams: New Skilling, Reskilling and Upskilling.



As part of this partnership, CASTL have access to NIBRT curriculum, collaborate on curriculum design, access new courses, and partner on the development of a new Canadian biopharmaceutical skills and training centre. CASTL offers multiple applied learning streams for individuals to acquire the academic knowledge, and technical and professional skills to have a successful career in life sciences.

In October 2022, CASTL opened its first training centre in Prince Edward Island with plans at an advanced stage for additional training centres in Montreal and Vancouver.



Korean-NIBRT (K-NIBRT)

The mission of K-NIBRT is to develop into Korea's bioprocessing workforce development institute by licensing NIBRT's world leading training and education curriculum in biopharmaceutical manufacturing. The K-NIBRT facility is scheduled to open in 2024 in Incheon with the goal of establishing industry leading biopharmaceutical manufacturing training in the Asia-Pacific region. Before the official opening of the K-NIBRT facility, training programmes have commenced at Yonsei University's International Campus from September 2021.



In 2022, K-NIBRT officially opened the interim training facility in Yonsei University and delivered a broad range of training programmes including: General Process Training, Vaccine Specialized Training and a Vaccine Manufacturing Programme in association with the Asian Development Bank to trainees from developing countries in the Asia Pacific region.



Bioprocessing Research and Training Institute Guangzhou (BRTAG)

The Bioprocess Research and Training Academy Guangzhou (BRTAG) provides NIBRT training courses in the Guangdong-Hong Kong- Macao Greater Bay Area, in southern China. BRTAG provides both theoretical and practical biomanufacturing training, devoted to cultivating high-end talent with in-depth perspectives of China's bio-industry and global pharma. In 2022, the training activities at BRTAG were curtailed due to Covid-19, but will be re-instated once restrictions are lifted.



Biologics Innovation Facility (BIF)

The Biologics Innovation Facility, based at the University of Technology Sydney, provides practical vocational and professional training, for the Australian biopharma community based on the NIBRT curriculum.



Jefferson Institute for Bioprocessing (JIB)

Based just outside of Philadelphia, since 2019 JIB through its 25,000 ft² fully flexible state-of-the-art facility, provides an immersive training experience by combining interactive presentations, workshops, hands-on laboratory and pilot-scale experience.

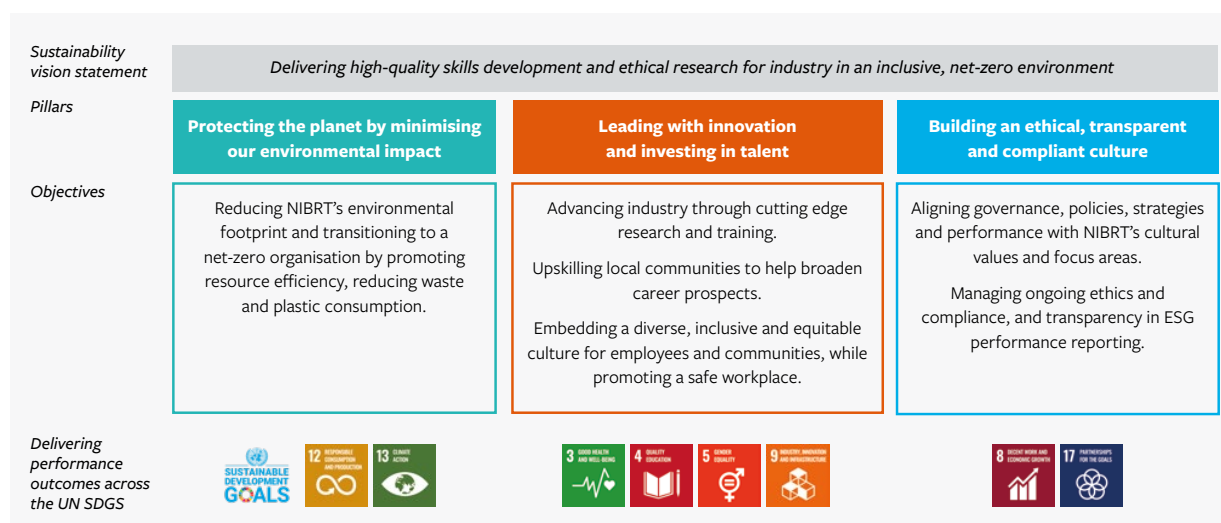


6 | Enviromental, Social and Governance

6.1 Sustainability Strategy

NIBRT's commitment to our people, our community and our responsibility towards the environment has always been an intrinsic part of our values and goals. In 2022, NIBRT developed a new sustainability strategy and roadmap to coordinate existing initiatives and efforts, enhance monitoring and reveal areas for development.

This strategy was developed with EY during 2022 through a process of stakeholder interviews, industry, and best practice review. The result is a three pillar approach, as outlined below, that reflects NIBRT's priority topics on environmental, social and governance factors (ESG), as well as their linkage to the UN Sustainable Development Goals.



Translating intent to impact

To fulfil NIBRT's ambition to become a sustainability leader, a sustainability working group will be put in place in early 2023 with responsibility for collaborating on implementing programmes and initiatives within the business to deliver on this strategy. This group will report to the NIBRT Senior Leadership Team.

A suite of key performance indicators together with progress on actions will be presented by this group to the NIBRT Board on a quarterly basis for review and consideration. An overview of progress to date and focus areas for ESG in 2023 is presented in the following sections.

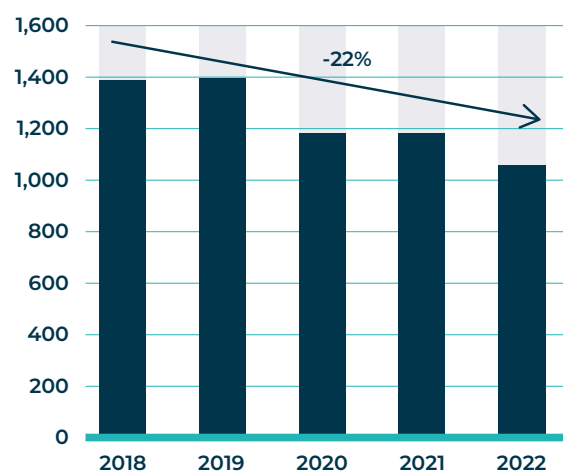
6.2 Environmental: Sustainability, Facilities

Sustainability

NIBRT is committed to conducting our business in an environmentally sustainable manner by tracking our activities and managing and improving our environmental performance across all business activities. Some key achievements in 2022 Included:

- ▶ A significant downward trend of 36% in the consumption of gas, through a combination of approaches which included challenging all set points and time schedules on the building management system.
- ▶ A key element in NIBRT's journey to go paperless saw the introduction of tablets into our training delivery, which eliminated 29,000 pages of printing.
- ▶ Overall NIBRT's CO² emissions from energy consumption has decreased by 22% since 2018. A further 25% is targeted over the next 5 years.

CO² Emissions (tonnes)



Key areas of focus for 2023 include:

- ▶ The installation of solar panels on our facility in January, which will generate circa 10% of annual consumption.
- ▶ Roll out of ESG training for all employees.
- ▶ Tracking and reduction programmes for waste, water and plastic consumption.
- ▶ An increase in biodiversity across our grounds on completion of the new Advanced Therapies facility.

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 2022 there were zero lost time accidents with 184 hours of safety training delivered to staff.

Facilities

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. New equipment/technology additions to the training facility in 2022 to further enhance our service offering included:

- ▶ Endress Kaiser Optical Raman In-Situ PAT Platform.
- ▶ Vicell Blu: an industry standard apparatus for the counting of animal cells.
- ▶ NC-202: a state-of-the-art system that utilises a cassette-based, fluidic-free system to reproducibly count the number of cells in the small volume samples that are preferred in Cell Therapy manufacture.
- ▶ Flow Cytometer: used to determine purity and safety and is the leading Quality Control test for cell therapies.
- ▶ Pall mPath IOR Concentration Monitor.
- ▶ Infors HT Multitron Shaking Incubator.
- ▶ Downstream Training Chromatography Systems Replacement.
- ▶ Downstream Training UFDF Systems Replacement.
- ▶ Ovizio Inline F Holographic Microscope.
- ▶ Automated RNA Synthesizer.
- ▶ High Performance Liquid Chromatography.
- ▶ Applied Biosystems SeqStudio Genetic Analyzer.
- ▶ Plate Reader.
- ▶ Terumo Welder & Sealer.
- ▶ Kern Digital Microscope (x4).

→ Facilities Facts and Figures

6,500m ²	Building size
1,800m ²	Advanced Therapies building
0	Lost time safety incidents
9%	CO ² reduction in 2022
36%	Gas reduction in 2022



6.3 Social: NIBRT People and Culture

Throughout 2022 the NIBRT HR team led a number of initiatives to ensure NIBRT is an attractive location for our people to successfully develop their careers.

These efforts were recognised with a number of high-profile awards in the year including:

- ▶ A HR Leadership & Management Award and a Pharma Industry Award for our new Hybrid Ways of Working Policy.
- ▶ Attaining both a Bronze and Silver Investors in Diversity Awards.

These awards represent significant acknowledgement of NIBRT's progressive culture and inclusive approach to supporting our people.

The key focus areas for People and Culture in 2022 included:

Equality, Diversity and Inclusion – we continued to transform our diversity practices and culture using a clear and structured framework and NIBRT's focus was rewarded when we achieved both the Investors in Diversity Bronze and Silver designations during 2022. Our work will continue on fairness, respect, equality, diversity, inclusion and engagement. We are partnered with the Irish Centre for Diversity for their guidance, expertise and data gathering support, we continue with internal actions for inclusion awareness and celebration of diversity in NIBRT and we have educated ourselves on Gender Pay Gap reporting and will proactively report our gap data ahead of the statutory requirement timeline.

HR Strategy for Researchers: NIBRT holds the prestigious *HRS4R* European accreditation since 2019 and continuously develops the NIBRT research environment in line with the *HRS4R* Euraxess Charter and Code. This accreditation is essential for grant applications for (European) funding and so retaining this awarded status was a critical achievement this year.

Recruitment: Strong progress was made in hiring and retaining scientific talent, despite the significant market challenges in this area. NIBRT worked with a dedicated recruitment partner in 2022 to advertise 26 new positions and was pleased to see a drop in our year-on-year turnover rate. NIBRT's interface between academia and industry and focus on supporting career development clearly appeals to prospective employees. However, ongoing attention is required in this area as considerable market pressures remain for attracting the best talent.

Retention: With respect to succession planning and talent retention a new Job Classification structure was implemented, assigning levels, agreeing job titles and salary brackets, providing our people with a structure for planning and managing their careers. For research roles, research job titles were defined that correspond to relevant academic titles but are also related to industry job titles. The job classification structure has enhanced clarity on roles, culture and communication flow throughout the organisation.

Hybrid Ways of Working: NIBRT's multi-award winning Hybrid Working strategy has been translated to a framework and guidelines for our people with a recent survey showed increased cultural satisfaction amongst our people as a result of our embracing this trusted way of flexibly working together.

→ HR snapshot 2022

99	Employees
7	Students
20	Nationalities
61% : 39%	Irish: other nationalities
52% : 48%	Gender balance, female : male



HR EXCELLENCE IN RESEARCH



NIBRT Culture:

CIRCLES

- C** COLLABORATION
- I** INNOVATION
- R** RESPECT
- C** CLIENT FOCUS
- L** LEARNING ORGANISATION
- E** EXCELLENCE
- S** SAFETY



nibrt
National Institute for
Bioprocessing Research
and Training

6.4 Social: Community Outreach and Public Engagement

Public engagement is key to develop the biopharma workforce of the future.

NIBRT works closely with a wide variety of stakeholders to increase awareness of biopharma among students, teachers, and members of the public through a number of initiatives.

▶ **Amgen's School of Biotech Excellence**

Amgen Biotech Experience (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 to bring back to their students.

NIBRT is an integral part of this initiative, inviting teachers to experience hands on the NIBRT pilot plant, meet the NIBRT trainers and learn about the various biopharma technology, processes and equipment.

NIBRT also conducts sessions with the teachers on the various career opportunities and educational courses available to their students.

▶ **NIBRT's Biopharmaceutical Science Transition Year Competition**

Each year NIBRT runs a national competition to provide secondary school transition year students with an opportunity to experience what it is like to study biopharmaceuticals and work in this life changing industry. The five-day placement in NIBRT gives students the opportunity to experience the state-of-the-art bioprocessing facilities and learn from scientists and engineers working in the research and training teams.

▶ **Careers in Biopharma**

In April 2022, NIBRT held its largest Careers in Biopharma event with over 25 companies and 900 registrants. The event featured hundreds of high skilled career opportunities in biopharma manufacturing sites across Ireland.

▶ **Support for local schools**

Throughout the year NIBRT was pleased to donate surplus equipment to schools and host visits from secondary level students.



NIBRT Careers Day 2023

6.5 Societal Impact

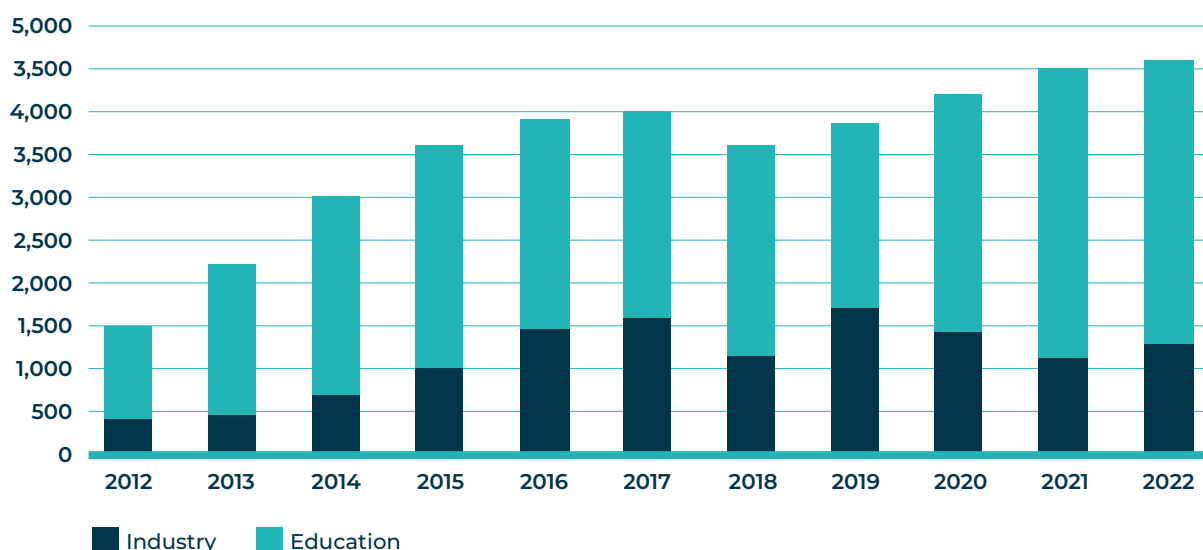
Trainees

Core to NIBRT's mission is to train the people who make life changing medicines. NIBRT now trains an average of 4,500 people per year which has had a significant positive impact on the growth of the biopharma sector in Ireland. It is targeted to increase the annual number of trainees to 5,000+ in 2023, supported in part by the opening of the Advanced Therapies building in Q2 2023. Of particular note, is the Springboard+ programme which provides free upskilling training to jobseekers and 90% funding to those in employment. In 2022 NIBRT delivered training to 810 Springboard+ trainees.

Research Knowledge Transfer

NIBRT undertakes research on the understanding of complex biopharmaceuticals and delivers impactful solutions to improve manufacturing processes. In supporting the wider research environment, our researchers issue publications and support postgraduate students in completing their qualifications, as highlighted in Section 4.

Trainee Numbers



→ Societal Impact

42,500 Biopharma employees in Ireland

€106bn Biopharma exports

4,500 NIBRT Trainees per annum

810 Springboard+ trainees in 2022

24 Research publications in 2022



6.6 Governance

See section 2 of this Report.

7 | Awards and Announcements

7.1 Awards

NIBRT is pleased to have won a wide selection of national and international awards for its training and education programmes including:

2022	Investors in Diversity Bronze and Silver Awards
2022	HR Leadership & Management Awards: Best Flexible Working Strategy
2022	Pharma Industry Awards: HR Achievement Award
2021	Pharma Industry Awards: Partnership Alliance of the Year Award for the NIBRT Global Partners Programme
2020	Pharma Industry Awards: Innovation of the Year Award for the NIBRT Online Academy
2020	Pharma Industry Awards: Project of the Year Award for the Biopharma 4.0 project with BCG
2020	Pharma Industry Awards: Partnership Alliance of the Year Award for NIBRT and MSD Dunboyne Biologics Training Collaboration
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

7.2 Announcements

Key NIBRT announcements in 2022 include:

- ▶ NIBRT Careers in Biopharma event in association with The Campus Cherrywood.
- ▶ NIBRT win the Partnership Alliance of the Year Award at Irish Pharma Awards.
- ▶ NIBRT and Watson-Marlow Fluid Technology Solutions partner for biopharma training programme.
- ▶ Emily Whitehead the first child in the world to have her immune system activated to fight cancer visits NIBRT.
- ▶ New collaboration with Kerry Group to understand variability in cell culture media.
- ▶ Global training partnership with Zifo Solutions.
- ▶ NIBRT, VivaBioCell and Accuscience announce ATMP manufacturing training collaboration.
- ▶ NIBRT announce new research collaboration with GlycoSeLect.
- ▶ The Medicine Maker and NIBRT Present the Biopharma Trends Leaders' Report 2022.
- ▶ NIBRT announces construction start for a new advanced therapies facility at its Dublin site.
- ▶ NIBRT announce a second phase of collaboration with JM Canty International.
- ▶ NIBRT Global Partner CASTL officially open new biomanufacturing training facility in Canada.
- ▶ The Forum on the Future of Medicines event at NIBRT.

Hold the Date for 2023

- ▶ **April 1st 2023** Careers in Biopharma
- ▶ **April 20th 2023** NIBRT Research Conference
- ▶ **April 21st 2023** Global Partners meeting



7.3 Testimonials

“ On behalf of all my colleagues at PSG Dover, I want to extend my heartfelt gratitude for your generous hospitality and exquisite training this past week. We all learnt a tremendous amount, owing it entirely to your expertise, dedication, and patience. I will certainly recommend that our company, PSG Dover, continue to send our employees for the worthwhile experience!”

Christopher Walsh VP

Marketing & Engineering, PSG Dover



“ I have had a fantastic few days with the NIBRT training team looking at single use technologies in the upstream/downstream processes. Having hands-on experience with the equipment of our customer's really strengthens our knowledge. The training was excellent and the passionate and devoted staff really made it fun and engaging.”

Andy Rogers

PureSU Engineer at Bio Pure Technology



“ I would just like to thank NIBRT for the assistance and tutoring provided during the L6 biopharmaceutical processing course. This has helped me secure a Senior Bioprocessing Associate role in a biopharmaceutical company in my home town, which is of great benefit to me.

The assistance provided throughout the course was greatly appreciated, without the knowledge passed on through the course, this would not have been possible.

Student

L6 Cert in Biopharmaceutical Processing

“ This course will benefit me in the work that I do. I would definitely recommend the NIBRT course. What stood out to me was the fact that all the speakers had great expertise and subject knowledge and were able to answer any questions we had.”

Kevin Byrnes

QA Operations Specialist, Astellas

“ The training today was great. It was great to see the equipment first hand and get the experience from it because I am normally more theory and desk based.”

Caoimhe Duffy

Bioprocess Associate, WuXi Biologics

“ What a great week last week at NIBRT National Institute for Bioprocessing Research and Training. NIBRT provided excellent demonstrations and practicals in their state-of-the-art training facility which were excellently delivered by highly qualified trainers.”

Conor Cahill

Bioprocessing Scientist at MeiraGTX



“ “I decided to enrol in the NIBRT/IT Sligo L6 Biopharmaceutical Process course to develop my understanding in this technology area. I chose a NIBRT course due to their reputation. The Industry in Ireland and across the globe is changing rapidly, with a shift from small molecule pharmaceuticals to large molecule biopharmaceuticals and I believe it is important to stay current and relevant. After completing the L6 course, I decided to progress to a L9 taught masters, which I am current doing and finding very rewarding. Upskilling and obtaining a biopharmaceuticals mindset and skills ahead of a potential pharmaceutical shrinkage is definitely a good thing, as most of the non-technical skills are transferable. Courses like this put Ireland in a better position to continue to lead in the biopharmaceutical area well into the future.”

Dr. Giuseppe Whelan

Manufacturing Science and Technology,
Sustainability Head at GSK

“ NIBRT consistently deliver quality in their training provision and the Introduction to ATPMs/CGT course is no exception. The course is delivered in a comprehensible way, and all topics are covered with explanations and examples that ensure clarity and understanding. Both the classroom and laboratory learning facilities are exceptional, as is the opportunity to get hands on experience of the ATPM/CGT manufacturing process.”

Linda Nugent

Tandem Project Management

“ Thoroughly enjoyed both learning experiences provided by NIBRT, the classroom trainers clearly are expertise in their field, the pace of remote training was great with lots of opportunities for questions or clarifications.”

Maria Ginnelly

Snr Process Specialist at MSD



7.4 2022 snapshots



- ▶ Emily Whitehead the first child in the world to have her immune system activated to fight cancer, visits NIBRT



- ▶ Visit to NIBRT by our Korean global partner, K-NIBRT, in July 2022



- ▶ Watson Marlow staff at a customised training course at NIBRT



- ▶ NIBRT Careers Fair 2022 in association with The Campus Cherrywood



- ▶ NIBRT went Back to the Future of Healthcare in the Road to Ireland series by Pharma's Almanac



- ▶ Minister Dara Calleary at Future of Medicines Forum with BPCI and IPHA



- ▶ UCD School of Chemical and Bioprocess Engineering announce course collaboration with NIBRT



- ▶ Students on NIBRT transition year programme 2022



- ▶ NIBRT partnered with Zifo R&D Solutions to offer a customised bioprocessing training program for IT specialists in the biotech industry

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