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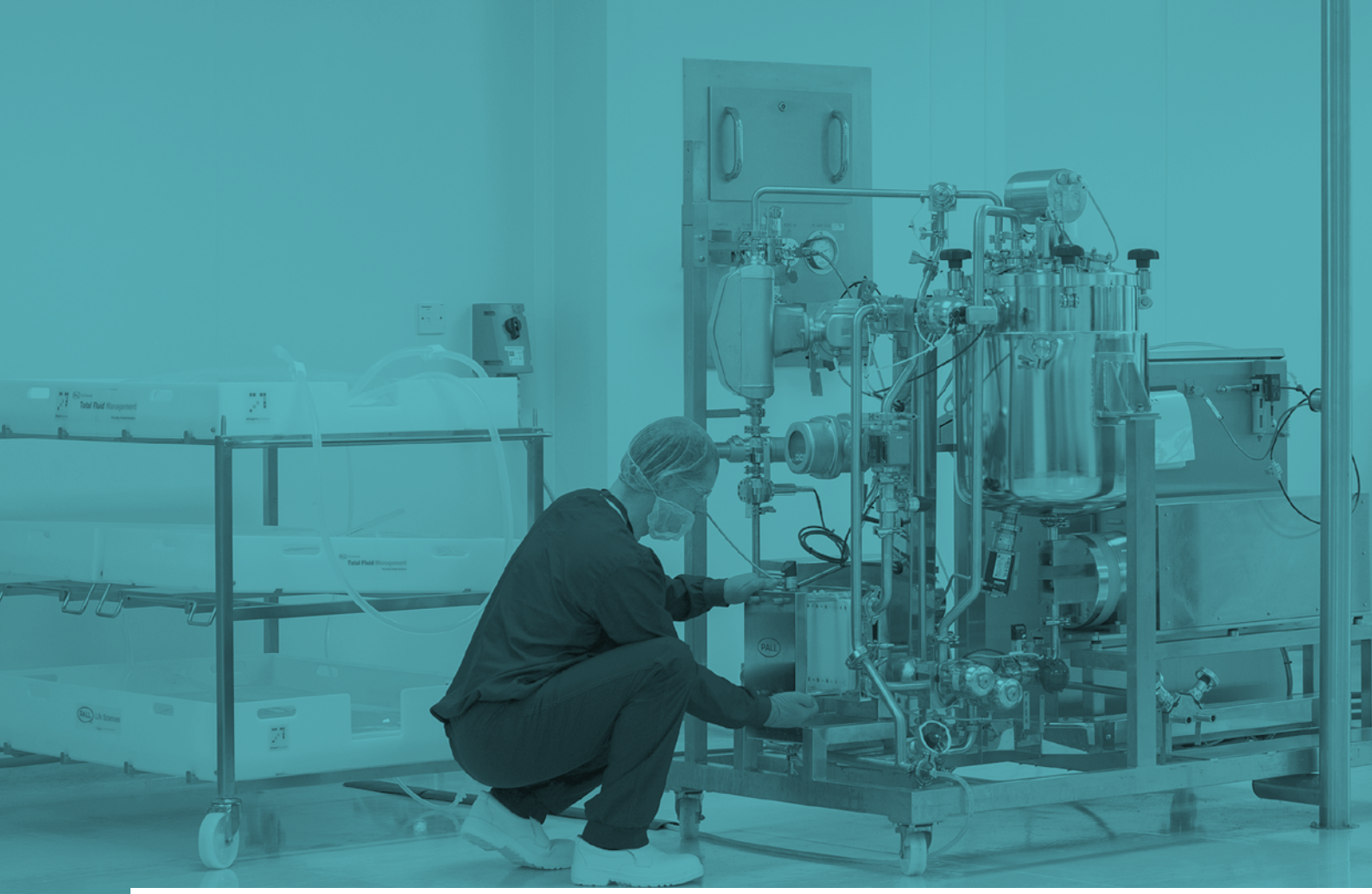
Annual Report 2023

The National Institute for Bioprocessing Research and Training (NIBRT)



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1 Introduction

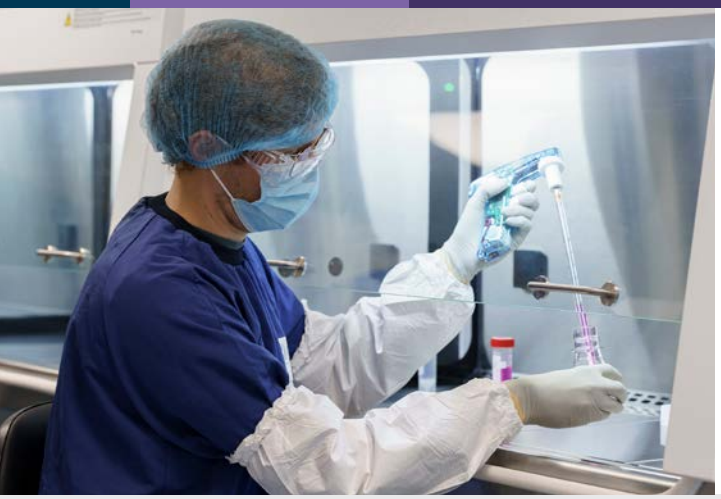
1.1 NIBRT Staff

Thank you to all NIBRT team members who contributed to a successful 2023:

Aaron Richardson	Ciaran Buckley	James Flynn	Mark Smales	Sandra Roche
Adam Pritchard	Clair Gallagher	James Berhanu	Martin Trant	Sara Carillo
Alan Foley	Colin Clarke	Jenette Scanlon	Mashael Alqasem	Shada Warreth
Alan Treacy	Conor Bain	Jennifer Byrne	Meghan Anil	Shane Gavin
Aleksandra Ostropolska	Conor Barry	Jennifer Prior	Melissa Hoare	Shannon Reilly
Ales Grundzi	Craig Jakes	Jessyca Ferreira De Medeiros	Michelle De Oliveira Chain	Silvia Millan Martin
Alison Quinn	Cristiane Delfina	Joanne Withers	Mike Butler	Simeng Li
Amy O'Neill	Daekwon Sequira	John Milne	Mohamed Noor	Sinead Marsh
Andreea Cislaru	Daniel Downing	Jonathan Bones	Molly Rose Booth	Stephen Marry
Anita Murphy	Darrin Morrissey	Josh Smith	Monika Samardzic	Stephen McCann
Ann Marie Donaghy	Dawoon Jeong	Julia Serna	Morandise Rubini	Steven Ferguson
Anna Mulligan	Dennis Shaw	Karen Tsang	Morgan Shriver	Sukhraj Pal Singh Dhami
Anthony Raethorne	Dermot O'Sullivan	Karl Kelly	Nathania Harron	Tadeusz Tazbierski
Aoibhin Ryan	Eimear Harrison	Kate Cotter	Neal Redmond	Tadhg Devlin
Aravindhanathan Venk	Elaine O'Farrelly	Katya Fraga-Burns	Neha Tushar Dalvi	Thais McNamara
Arda Deniz Tugrul	Elizabeth Matthews	Kelly Smyth	Nga Lao	Thomas Byrne
Aswathy Balakrishnan	Elizabeth Topp	Kevin Lomasney	Niall Barron	Thomas McGuirk
Barbara Keegan	Emer Norton	Kevin Byrne	Nicholas Donohue	Tope Adeshina
Barry Shortt	Felipe Guapo De Melo	Kevin Conrad	Nils Bunte	Yagmur Bozkurt
Brian Philip	Filipe Fernandes Horst	Killian O'Driscoll	Noemi Isabel Dorival Garcia	Yamsel Barandino
Caio Henrique Nasi De Barros	Fiona Killard Lynch	Laura Breen	Nora Crushell	Yongjing Xie
Caitriona Walsh	Florian Fuessl	Laura Byrne	Or Skornik	Zdravko Ivanov
Camila Andrea Meza	Gemma Grimes	Lisa Fussl	Parbani Chaudhury	
Caragh Tisdall	Genevieve Greene	Lisa Murphy	Patrick O'Rourke	
Carl Bermingham	Graziela De Moura Aguiar	Maikel Gaitkoski	Paul Adams	
Carlos Tamaray	Hannah Rushe	Manuel Alfaro De Pra	Paula Kenny	
Chantelle Rushe	Hayden Wilkinson	Manuel Herrera	Peter Connolly	
Ciara Finn	Ioanna Tzani	Marie Bishop	Peter O'Byrne	
Ciara McManus	Jack Ryan	Marina Ainciburu Fernandez	Radka Fahey	
Ciara Tierney	Jack Schofield	Mark Berney	Robert Byrne	
			Ryan Hagan	
			Sakis Mantalaris	

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 (8,300m^2) features state-of the-art pilot scale biopharma manufacturing facilities.



1.3 What we do

- Train and educate over 4,800 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

2023 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 $1 trillion with biotech products close to half of biopharma sales[1]. Within the global context, Ireland continues to be incredibly 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 2014.

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 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 the new advanced therapies in development and the integration of automation, digitisation and AI into the manufacturing process.

I would like to acknowledge and thank the team at NIBRT for their hard work and many successes during 2023, including:

- A 7% growth in overall revenue, bringing research and training activity to the highest level in the Institute's history.
- 9% increase in training activity with client companies based in Ireland.
- 28% growth in research activity, underpinned by the joint appointment of new Principal Investigators in partnership with Irish and international universities.
- The signing of two new NIBRT global partnerships in the US.

Most notably, I am delighted to see NIBRT's advanced therapies facility expansion now completed and open for business. While the SFI-funded CONCEPT facility will open new research horizons for NIBRT and for Ireland in 2024 and beyond.

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, most notably in their approval of NIBRT's new strategy and 2024-2028 business plan, along with a commitment to invest over five years up to €6M in operational and €14M in capital funding to support the growth and evolution of NIBRT.

1 Worldwide Total Prescription Drug Sales (2013-2028), Evaluate Pharma 2023

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. In 2023, we welcomed Emma Callinan from Enterprise Ireland as a new non-executive board member, as well as Mary Conneely from UCD as an external member of the Audit and Risk Committee, and both have already made a significant impact to the organisation, bringing fresh eyes, energy and insights.

So, as we look ahead to 2024, 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 implementation of our new strategy and business plan 2024-2028 and to continued growth in the number of top research and training talent joining the NIBRT team.

Julie O'Neill
NIBRT Chairperson

...the growth of the Life Sciences in Ireland has been a cornerstone of our economic success and we are proud of a thriving sector that brings high-quality jobs all around the country...in 2023 we also turned the page in terms of the types of medicines being developed in Ireland. Through IDA Ireland, the Government invested €20 million in the new Advanced Therapy expansion at the NIBRT. When the Taoiseach turned the sod at the site in 2022, we doubled down on our commitments to support innovative medical treatments and to help to train the next generation of researchers at the world leading NIBRT..."

Simon Coveney TD, *Minister for Enterprise, Trade & Employment*

2.2 Message from NIBRT CEO

As we embark on a new year, it is worth taking the time to reflect on the successes and growth areas that emerged from the year just past.

2023 saw the world continuing to deal with substantial challenges, including global inflation, geopolitical tensions, open conflict and the escalating climate and biodiversity crisis. Against this challenging backdrop, the Irish economy and biopharma sector continued to perform well. Although there were some global headwinds caused by a retrenchment in biopharma demand as the impact of Covid-19 abated, there were still a number of very positive biopharma investment announcements in Ireland; most notably:

- Astellas, who announced the creation of 330 jobs in Kerry,
- Eli Lilly who announced a €1billion investment in its new manufacturing campus in Limerick, and,
- Novo Nordisk announcement of a new €2 billion facility in Grange Castle as well as the acquisition of the former Alkermes facility in Athlone.

NIBRT had a highly successful year in 2023 delivering our world-leading training and research services to clients nationally and internationally. I am delighted to report that 2023 saw the organisation achieving record levels of activity and out-performing 21 of the 22 targets set out in our 2019-2023 business plan.

2023 saw NIBRT take another massive step into the exciting area of advanced therapeutics, with the completion of €21M IDA-funded expansion of the facility, which added 1,800m2 of new laboratory and training space dedicated to cell, gene and oligonucleotide-based therapies research and training. And, in December, we opened the new CONCEPT facility for the early-stage development of novel biotherapies.

Funded with over €6M from SFI and IDA Ireland, the CONCEPT facility will scale up its activities over 2024 and will see NIBRT expanding its services, enabling researchers with a biological molecule of interest, to generate research-grade recombinant proteins, viral and non-viral based gene therapies, cell therapies or oligonucleotides and in so doing rapidly accelerate the therapy development process.

The demand for NIBRT's training and education services continued to grow in line with new and expanding biopharma manufacturing facilities in Ireland. In 2023, we:

- Delivered over 30,500 learning days to nearly 4,900 trainees, via a mixture of in-person and remote training,
- Trained 810 people through the Government of Ireland's EU-funded Springboard+ programme,
- Welcomed 1,220 degree and master's students to NIBRT from universities and technological universities across Ireland
- Continued to deliver online training modules, through our NIBRT Online Academy (NOA) platform, to over 6,500 users in over 80 countries,
- Further strengthened our Global Partnership programme by adding two new partners, San Jacinto Community College in Houston Texas and BioHub Maryland.
- Delivered our first courses in the application of data science and digital technologies to biopharma manufacturing.
- Delivered new training courses in cell and gene therapies manufacturing.

Particular highlights of the year for me were hosting our first Global Partners conference at our facility in April, attended by delegates, from Australia, Canada, Korea and the USA, and my attendance at the WHO conference on 'Future Pandemic responsiveness' in Korea in November. Both of these demonstrate for me NIBRT's ever-growing status as an opinion leader and influencer on biopharma workforce and skills development, on the world stage.

In research, the NIBRT research team delivered highly impactful collaborative projects in partnership with many global and indigenous biopharma players in 2023. Companies partnering with NIBRT's Principal Investigators on research projects included Avectas, BMS, GSK, Janssen, Lonza, Pfizer, Thermo Fisher and many more, while some notable NIBRT research highlights included:

- 23 active research projects active across the Institute.
- The inaugural NIBRT Research Conference, 'Biopharma Focus on the Future', held at the NIBRT facility in April.
- €4.5M SFI Research Professorship funding awarded to Professor Sakis Mantalrais for research on cell therapy and minimizing heterogeneity in manufacturing processes.
- 30 high impact publications, including :
  - A paper in Nature Protocols on a novel Multi-Attribute Method for analysis of monoclonal antibody product quality, authored by Professor Jonathan Bones.
  - A paper in Nature on N1-methylpseudouridylation of mRNA and its relevance to mRNA therapeutics, co-authored by Professor Mark Smales – which is NIBRT's first attributed Nature paper!
- 3 new PhDs, bringing our total of PhDs graduated since we opened our doors to 12.
- Further expansion of our advanced therapies research programme in viral-vector based gene therapy, cell therapy and mRNA-related projects.

2023 also saw further expansion in the number of NIBRT Principal Investigators, with the appointment of Professor Mark Smales, through a unique joint Professor partnership with University of Kent in the UK.

Professor Smales' research group will work on finding new methodologies to improve the manufacturing process for protein, gene and RNA-based medicines. With his appointment, there are now nine PIs at NIBRT and in 2024 we anticipate that we will reach double figures with potential joint appointments currently in progress with UCC, UCD and UL.

2023 was an exciting year for NIBRT on the people-front. NIBRT continues to evolve as a vibrant and dynamic place to work. During the year we welcomed new members of staff from a wide range of backgrounds representing 18 different nationalities. We also rolled out an organisational ESG strategy and organised the implementation of this strategy around seven dedicated working groups involving staff from all levels and across all disciplines in the Institute. Highlights from the work of our ESG groups include:

- An increase in the number and quality of events at NIBRT celebrating cultural diversity and equality.
- Reductions in the annual electricity and gas usage of >10% and >20% respectively (in spite of a 30% increase in the footprint of the Institute).
- An increase in outreach activities involving the general public and local community, and,
- The initiation of a landscaping project to support biodiversity.

I would like to thank the NIBRT Chairperson Julie O'Neill and the members of the NIBRT Board for their support throughout the year. 2023 saw the final approval of the new NIBRT 5-year strategy by the Board and the sign-off of our 2024-2028 business plan by both the NIBRT and IDA Boards.

Lastly, I would like to thank all the NIBRT staff for their continued hard work, creativity and dedication to NIBRT's training and research mission. I look forward to another successful year for NIBRT in 2024, 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 13 Board members with representatives from industry, academia and government agencies, as well as the CEO. The Board is chaired by Julie O'Neill. The Board meets five times annually for scheduled meetings and there are three subcommittees of the Board:

- The Audit and Risk Oversight Committee, which met five times in 2023 in advance of the main NIBRT Board meeting.
- The Resource Oversight Committee, which met nine times in 2023, with the increased number of meetings to support the NIBRT Senior Leadership team in delivering the Advanced Therapies building project.
- The Governance and Nominations Committee, which met once in 2023.

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 four members on the NSL Board which met twice in 2023.

NIBRT's external auditors are Crowe while EY were appointed internal auditors in 2022.

NIBRT Board 2023

Chairperson: Julie O'Neill
Non-Executive Director

Prof. Sarah Culloty
Head of College, Science, Engineering and Food Science, University College Cork

Prof. Orla Feely
President, University College Dublin

Dr Aine Hanly
Chief Technology Officer, Vir Biotechnology

Prof Anne Marie Healy
Professor of Pharmaceutics and Pharmaceutical Technology, Trinity College Dublin

Dr Brendan Hughes
Non-Executive Director, formerly Senior Vice President, Global Manufacturing Operations, BMS

Prof. Norelee Kennedy
Vice President for Research, University of Limerick

Prof Jacqueline McCormack
Vice President for Equality, Diversity & Inclusion and Online Development, Atlantic Technological University

Dr Darrin Morrissey
CEO NIBRT

Rory Mullen
Head of Biopharma and Food, IDA Ireland

Tom Murray
Director, Friel Stafford

Dr Michael Thien
Head of Pharmaceutical Services R&D, Takeda

New Board Members in 2023:

Emma Callinan
Director of Commercialisation, Enterprise Ireland

NIBRT by Numbers 2023

6%
Growth in overall revenue 2023

4,900
Number of trainees

30,500
Training days delivered

725
Springboard+ students

6,350
NIBRT Online Academy users

33
Peer reviewed publications

74
Conference presentations

0
Lost time accidents

99
Number of employees

53:47
Gender balance at NIBRT (female: male)

18
Number of nationalities working at NIBRT

3 Strategy

3.1 The Biopharma Industry in Ireland – 2023

In 2023 the biopharma manufacturing sector continued to grow strongly in Ireland.

Amid this success there is a need for continued focus on issues such as workforce development, digitalisation, sustainability, and advanced therapies to ensure Ireland maintains its competitive edge in the rapidly evolving global landscape.

The success of the lifesciences industry in Ireland over many decades is rightly acknowledged and celebrated. Of particular note, is the growth of the biopharma manufacturing sector since the Pfizer Grange Castle facility opened in 2006 with over €15 billion of new capital investment in the intervening period. There are now over 20 large scale multinational biopharma facilities in Ireland conducting a diverse range of complex drug substance and drug product manufacturing including monoclonal antibodies, bispecific antibodies, cell therapies, plasmids, viral vectors, conjugated vaccines and mRNA vaccines.

This is complemented by a network of indigenous and international vendor and professional service companies to create a robust support system. A particular feature is the geographic spread of the biopharma sites across Ireland.

Size of Industry in Ireland[2,3]:

- Ireland is the **3rd largest** exporter of pharmaceuticals in the world
- Over **85,000 employed** directly and indirectly in the sector
- **90+** manufacturing plants, **50+** FDA approved
- Biopharmaceutical and chemical sector had an export value of **€106bn in 2020 –67%** of total goods exported from Ireland
- **25%** of all PhD researchers in the Irish industry are employed in the sector

2 https://www.idaireland.com/explore-your-sector/business-sectors/biopharma/

3 Make Ireland the Global Leader in Sustainable Biopharmaceutical and Chemical Manufacturing A strategy for the sector 2023-2027, BPCI

Led by IDA Ireland, 2023 saw further growth and announcements including a €330 million investment from Astellas in a new drug product facility in Tralee, Co. Kerry. Lilly announced a $1 billion investment in Limerick. MSD Ireland announced the official opening of a new, state-of-the-art site in Dunboyne, Co. Meath in addition to a significant expansion at its Carlow site. These projects represent a recent investment of over €1 billion across both MSD facilities. The year closed with welcome reports of Novo Nordisk submitting a planning application for a €2 billion 147,000m^2 drug product facility creating 1,100 jobs in Grange Castle. This builds on a series of significant announcements in 2022 from Pfizer, Janssen, Horizon/Amgen and others.

This success has been built up by the professionalism of many stakeholders from Industry, Academia and Government over the decades. Ireland offers regulatory stability, sub-supply capability, a talented multicultural workforce and collaboration opportunities with research partners. However, this is a highly competitive space and future success is dependent on all stakeholders addressing the key global trends and continuing to focus on improving Ireland's core value proposition as a centre of excellence for advanced biopharma manufacturing.

Global trends

Growth: The value of the biopharma market has grown to over $1 trillion with biotech products close to half of biopharma sales[4]. The strong growth is forecast to continue with an estimated increase in global manufacturing capacity from 4 billion litres currently to 6 billion litres in 2028[5].

Impact of biopharma on global health[6]:

- Since 2000, nearly **900 new medicines** have been approved by the Food and Drug Administration (FDA)
- **95%** of patients with hepatitis C can now be cured
- Since peaking in 1991, the cancer death rate in US has declined by **32%**
- COVID-19 vaccines are estimated to have saved **2 million lives** and prevented up to **17 million hospitalizations** in the United States alone

4 Worldwide Total Prescription Drug Sales (2013-2028), Evaluate Pharma 2023

5 Biopharma Manufacturing World Summit 2023, Samsung

6 The Pharmaceutical Industry in Figures, Key Data 2023, EFPIA

Diversification: While antibody-based therapies will continue to the be the dominant revenue stream the continued diversification and complexity of therapeutics continues apace, with over 80 different modalities now in clinical pipelines. For example,

- The size of the advanced therapy market is projected to increase from $6 billion in 2021 to $19.6 billion (excluding mRNA COVID-19 vaccines) in 2026 with a CAGR of 26%[7]. Indeed some projections are for the value of the CGT market to reach $240 billion by 2033[8].
- The FDA has approved a total of 27 CGT products since 2017 and expects 10-20 new approvals per year by 2025[9].
- The impact of RNA technologies was well established during the COVID pandemic with approximately $70 billion mRNA vaccine revenue in 2021, although this revenue has reduced considerably post-pandemic.
- Antibody Drug Conjugates (ADCs) continue to gather considerable momentum with projected sales of $34 billion by 2028.
- November 2023 saw the first approval of a CRISPR based gene editing therapy by the UK.
- Of particular note is the commercial impact of recombinant peptide GLP-1 products in the anti-obesity markets which are forecast to reach $71 billion in 2032[10].

And yet the FDA recently announced investigation into secondary cancer risk with CAR-T therapies is illustrative of some of the many challenges in bringing advanced therapies to market.

What's coming through the pipeline?[11]

- **12,600** projects in clinical development
- **2,533** projects using monoclonal antibodies, or conjugated monoclonal antibodies
- **545** cell therapy projects, **348** gene-modified cell therapy projects
- **281** gene therapy projects
- **265** projects using DNA or RNA therapeutics
- **133** projects using oncolytic viruses

7 Promise Fulfilled? The next decade of cell, gene, and RNA therapies, April 2022, IQVIA

8 Cell and gene therapy manufacturing market (2023), Futuremarketinsights.com

9 Gap Analysis for the CGT Sector, March 2023, Alliance for Regenerative Medicine (ARM)

10 Novo, Lilly set to dominate $71B GLP-1 drug market by 2032: J.P. Morgan

11 Innovation in the Biopharmaceutical Pipeline, Dec 2021, PhRMA

Emerging Biopharmas: Emerging biopharma (EBPs) companies are responsible for 65% of the molecules in the R&D pipeline without a larger company involved, up from 34% in 2001. EBPs headquartered in China now account for 17% of the overall EBP innovation pipeline, up from 6% just five years ago, and compares to 20% coming from Europe-based companies and 46% from U.S.-based companies[12].

Platforms and standardisation: The rapid growth and diversification of advanced therapies creates a need for standardised manufacturing and analytical platforms to help reduce the high cost of these medicines. Some good progress is being made with an example from Roche of in sourcing plasmid manufacturing to reduce costs by 50-70%, and 60-70% improvements in timelines[13], while Novartis T-Charge next generation CAR-T manufacturing platform is delivering significant operational improvements[14].

Manufacturing agility and intensification: Many manufacturing sites are now multi-product facilities with a strong focus on operational efficiencies via process technologies including cell line optimisation, media characterisation, integrated continuous bioprocessing both upstream and downstream, advanced online analytics, further adoption of single use systems etc.

Digitalisation: The application of a broad spectrum of digital technologies is seen as a key enabler of advances in manufacturing efficiency. The progress of digitalisation continues at a mixed pace with some companies leading the way towards "adaptive plants" and "self-healing" supply chains. The analysis of manufacturing data sets, the application of artificial intelligence (AI) and machine learning, enhanced use of automation are all key technologies that are seeing increased use cases in biopharma manufacturing.

For example, Astra Zeneca credit AI powered manufacturing with improving robustness and increasing yield by greater than 20%[15]. Amgen's collaboration with Amazon Web Services is expanding from initial applications in R+D to manufacturing operations including deployment of machine learning models for predictive maintenance. Sanofi have also declared its ambition to be *"the first pharma company powered by artificial intelligence at scale".*[16]

Sustainability: The healthcare sector is responsible for 4–5% of global emissions, more than 70% of which are driven by supply chains[17]. Biopharma manufacturing typically has a comparatively high use of energy, water and plastics, and carbon emissions associated with a complex global supply chain. Most biopharma companies have publicly declared their net zero intentions with significant progress underway. 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.

AstraZeneca "Ambition Zero Carbon"[14]

- By 2026 Reduce Scope 1 & 2 GHG emissions by **98%** from 2015 baseline
- By 2030 Reduce absolute Scope 3 GHG emissions by **50%** from 2019 baseline and become carbon negative for all remaining emissions
- By 2045 Achieve science-based net zero, with a **90%** absolute reduction of scope 3 GHG emissions from 2019 baseline

12 Emerging Biopharma's Contribution to Innovation, June 2022, IQVIA

13 Industrialization Challenges for ATMPs: Achilles' Heel AND Opportunity, BMWS 2023, Roche

14 Building a flexible, scalable and sustainable Cell Therapy manufacturing network to serve patients, BMWS 2023, Novartis

15 Manufacturing Strategies for Sustainable Global Growth, BMWS 2023, Astra Zeneca

16 Amgen expands pact with Amazon to usher drug manufacturing into the AI era, Nov 2023, Fierce Pharma

17 BioPhorum Environmental Sustainability Roadmap, December 2022

Talent: One of the most consistent trends is that access to a sustainable pool of talent is a key determinant for success in biopharma operations. As manufacturing technologies evolve rapidly the competencies required by operations personnel becomes more complex with a strong demand for a broad range of digital skills in particular now required to complement the core manufacturing skillset. For example, the Alliance for Regenerative Medicine (ARM) analysis indicates that 88% of US members companies manufacturing timelines are impacted by the talent gap. Critical skills required include QC, QA, manufacturing, process development, analytical development while skills needed for the future include IT, AI, automation, programming, data management and analysis.[18]

External events: Geopolitics, conflicts, pandemics have all posed significant challenges in recent times. While the sector has responded well to these external events, it highlights the continued importance of creating robust, agile, sustainable and resilient manufacturing operations.

UK cell and gene therapy skills demand[19]

- Employment has doubled over the past four years to **6,232 roles** in 2023
- Employment to grow by **63%** over the next five years
- **32% of employers** indicate that hiring for manufacturing skills is a challenge

NIBRT's response

NIBRT's core mission is to support the growth and development of the biopharma manufacturing sector in Ireland by providing training and research solutions. As detailed in this Annual Report in 2023 NIBRT focused on a number of key areas to assist Irish biopharma sites:

- NIBRT trained over 4,800 people across a wide variety of education and training programmes. A key focus was the ongoing development of a range of digitalisation courses to support the growing needs in this area.
- Training and research activity commenced in NIBRT's new Advanced Therapies extension (funded by IDA Ireland). In particular, the CONCEPT facility was launched in December 2023. CONCEPT is a core facility for early-stage biotherapy development and provides dedicated, state-of-the-art equipment and expertise for the rapid generation of optimised cell lines and biological materials.
- The scale of NIBRT's research activity continued to expand with a number of joint appointments announced with UCC, UL and University of Kent. This progress was acknowledged by the Research Centre of the Year Award at the Irish Pharma Awards.
- The global expansion of NIBRT continued with new partnerships announced in Maryland and Houston, and expansion of existing partners in Montréal and South Korea.

18 Workforce Report Gap Analysis for CGT Sector, March 2023, Alliance for Regenerative Medicine (ARM)

19 Cell and Gene Therapy Skills Demand Report, November 2023, Catapult CGT

Calls to Action

While the success of the Irish biopharma industry is well established and it enjoyed another strong year in 2023, there is little room for complacency as the complexities, risks and level of competition have increased significantly year-on-year.

However, the strong base of the sector in Ireland 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 advanced biopharma manufacturing** for existing and novel therapies through the development of standardised of advanced manufacturing and analytical platforms, including leveraging digital transformation technologies. The development of Digital Manufacturing Ireland is a welcome addition.

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 early 2024.

THREE: With the increased level of complexities and diversification in therapeutic timelines, future manufacturing investments will be more closely aligned to locations with international reputations in biopharma research. While Ireland has made good progress in this regard[20], further attention and focus is required here to **build biopharma manufacturing research of scale,** especially with regard to next generation biologics. The current SFI Research Centre call provides a significant opportunity for Irish biopharma.

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. **Benchmarking against peer countries** such as Belgium, who have been able to develop a robust manufacturing base alongside significant clinical research and a strong start-up sector, would be a valuable exercise.

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 coordinated approach by all stakeholders to drive **effective strategic planning** and coordination to ensure Ireland maximises its full potential in life sciences.

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

Benchmarking Belgium[21]

- 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

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
- Effective benchmarking, strategic planning and stakeholder coordination

Killian O'Driscoll
NIBRT Chief Commercial Officer

21 Belgium – big in biotech, Essencia 2022

3.2 NIBRT Strategy

NIBRT's 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 patients. 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.

2023 was the final year of NIBRT's five-year strategic business plan cycle, 2019-2023. NIBRT successfully achieved or exceeded all its key performance metrics for the plan period across Financial, Training, Research and Reputational categories with only one exception (as table below). The number of researchers hired was below plan due to the ongoing challenge in sourcing well-trained research staff to work in the highly competitive area where NIBRT operates. This issue, which was particularly acute in 2022, has been mitigated by partnering with Fastnet Recruitment, which has led to significant improvements in hiring success and recruitment timelines.

Strategic Key Performance Metrics at end of 2023			
Financial	**Category**	**Basis**	**2023**
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	Achieved
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

The process of developing the next NIBRT strategic business plan 2024-2028 concluded in late 2023. By engaging with a range of stakeholders and analysing the wider biopharma operational environment, a number of important trends were identified, many of which are discussed in detail in the Biopharma Industry in Ireland 2023, 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 draft strategic priorities. This new strategy and associated business plan for the period 2024-2028 has now been approved by the NIBRT Board, and core operational and capital-based state investment has been approved by the Board of IDA Ireland for delivery over the next five years.

NIBRT Strategy 2024-28

Strategic Priority 1:
Training and Education. Excellence, Growth and Diversification

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

Strategic Priority 3:
Embracing and helping drive digitisation 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

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 provide biopharma digitalisation training services to meet the needs of our clients, while conducting research that develops new approaches to analysing and harnessing data.

Priority 4:

NIBRT will be a well-recognised and highly attractive employer 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 though diversified research and training activities, while operating at the highest standards of environment, social and governance practice.

The final approved *NIBRT Strategy 2024-28* is available on the NIBRT website and a new set of performance metrics will be reported on quarterly with the NIBRT Board and IDA Ireland.

4 Research

4.1 Message from NIBRT CSO and Director of Research and Innovation

Looking back, it is evident that NIBRT's advances in biopharmaceutical research have been truly transformative this year.

This report highlights numerous research accomplishments achieved by our dedicated Principal Investigators (PIs) and their research teams, impactful events which reinforced NIBRT's role as an influential voice in the sector and marks a year of successful research.

In 2023, NIBRT expanded its research capacity growing its base of world-class PIs. Through a strategic partnership with UCC, NIBRT has jointly recruited two new PIs. The announcement of these accomplished researchers will take place in 2024, when they are expected to take up their joint NIBRT-UCC appointments. The successful candidates will conduct pioneering research at the forefront of advanced medicines, manufacturing and vaccine development.

NIBRT also has a strategic collaboration with the University of Limerick (UL), and this year recruitment began for a joint UL - NIBRT Professor in Computational Modelling and Data Analytics. Through this collaboration UL and NIBRT aim to strengthen their position as leaders in bioprocess modelling and data analysis.

NIBRT also welcomed Prof Mark Smales as its newest Principal Investigator. Prof Smales holds a Chair of Industrial Biotechnology in the School of Biosciences at the University of Kent (UoK).

He came to NIBRT through a joint appointment with UoK, bringing extensive expertise in biotechnological products and processes. In his role as a PI at NIBRT, he will oversee a team of researchers that will collaborate with other institutions, and undertake projects aimed at tackling key challenges in biopharmaceutical manufacturing.

In his short time at NIBRT, Prof Smales' collaboration with the University of Cambridge resulted in a paper, which was the first NIBRT affiliated Nature publication. This publication was the first to highlight the impact of mRNA modification on ribosomal frameshifting. The findings of this paper contribute to understanding how ribonucleotide modification influences mRNA translation, which is essential for designing effective and safe mRNA-based therapeutics.

Other achievements by our researchers this year include Prof Sakis Mantalaris' prestigious SFI Research Professorship, which will advance cell therapies for medical applications, Dr Radka Fahey's promotion to Adjunct Associate Professor in the School of Medicine at UCD, recognising her significant contributions to her field, Prof Colin Clarke's successful completion of the STACCATO Marie Curie Skłodowska European Doctorate Programme, and Prof Jonathan Bones recently awarded MBA from the UCD Smurfit Graduate Business School.

This year, three of NIBRT's PhD candidates also successfully defended their PhD theses. Their dedication and hard work contributed greatly to the excellence of our research community.

NIBRT PIs and their research groups are also involved in a broad range of biomanufacturing projects covering areas such as mRNA stability, optimisation and modification, glycan analysis, AAV vector manufacturing and analysis, glycoengineering, modification of monoclonal antibodies, advancement of analytical solutions for therapeutic modalities (with a focus on MAM), AAV-based gene therapy, process contaminant analysis, CAR T optimisation, and ACT biomanufacturing. Their collective efforts are detailed below in the subsequent sections of this report.

The *Biopharma Focus on the Future Research Conference* was held in April and was a significant milestone for NIBRT that highlighted our role in advancing biopharmaceutical manufacturing. The event included researchers, academics, clinicians, policymakers and influencers. These speakers showcased Ireland's thriving biopharma research ecosystem. Speaking at the event, Minister Coveney highlighted the industry's importance to Ireland's economy and praised NIBRT for supporting its growth.

Following the success of this event, CONCEPT at NIBRT was launched. This cutting-edge core facility for early-stage biotherapy development is led by Prof Jonathan Bones and managed by Dr Clair Gallagher.

The CONCEPT suite provides a dedicated, state-of-the-art resource for the rapid generation of optimised cell lines and biological materials. Central to its mission is ensuring that its resources are accessible to a broad base of academic research scientists, but its impact spans research, innovation, and industry, as it effectively addresses infrastructure gaps in the research environment enabling the holistic development of advanced therapies. This will empower researchers to transform concepts into tangible outputs. Through strategic collaborations with both national and international partners, CONCEPT is poised to shape the future of advanced therapies, solidifying Ireland's leading role in the development of advanced biotherapies.

I am excited about the opportunities that lie ahead for NIBRT in 2024. As our pool of exceptional researchers continues to grow, and we realise the potential in our infrastructural capacity, NIBRT's reputation as an enabler of cross-sectoral collaborations and catalyst of transformative research will strengthen our global standing as the premier hub for innovation and excellence in biopharma manufacturing research.

Dr Fiona Killard-Lynch
Chief Scientific Officer and
Director of Research and Innovation

NIBRT's Scientific Advisory Board

Chair, Dr Brendan Hughes, formerly Senior Vice President, Global Manufacturing Operations, BMS

Dr 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

Dr Richard Snyder, VP Science and Technology, Pharma Services, Viral Vector Services at Thermo Fisher Scientific

Dr Ligang Zhang, Senior Director, Alnylam Pharma

4.2 Updates from Research Groups

Cell Engineering Group, Prof Niall Barron

The Cell Engineering Group (CEG) was delighted to see two members, Dr. Niamh Keogh and Dr. Alan Foley, complete their research projects and successfully defend their PhD theses at viva. While Dr. Nicholas Donohue secured an SFI Industry Fellowship to pursue a project on AAV-based gene therapy manufacturing at Irish-owned APC Ltd. It has been a busy year for other lab members involved in industry and EU collaborative projects on ex-vivo modified cell therapies and strategies for modifying mRNA *in vitro and in vivo.*

We are also delighted to welcome the newest member of the CEG lab, Dr. Ganesh Warthi, who joins us to work on a collaborative project with GSK Vaccines in Belgium. Dr. Warthi will spend his time between the two sites applying his expertise to engineer host cell lines using CRISPR library screening.

Cell Technology Group, Prof Mike Butler

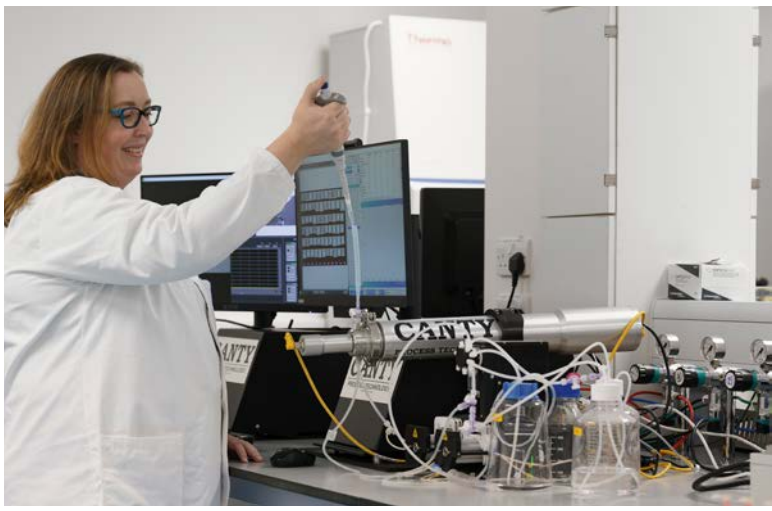
The Cell Technology Group (CTG) focuses on upstream processing and associated analytical technique development for bioprocessing.

A novel method of rapid analysis for quantitative profiling of glycans led us to analyse SARS-CoV-2 spike proteins. We were able to obtain a series of spike protein variants to determine differences in profiles between these as they evolved through the Covid pandemic. We were able to show significant differences in glycan profiles with the use of cluster analysis to classify the spike variants we obtained. These results were published in a paper in the journal *Glycobiology* of the Oxford University Press in February.

Further value was shown in the use of this method of glycan analysis by application to Adeno-Associated Virus (AAV) serotypes. Our paper describing this study was published in September 2023, also in *Glycobiology*. In this paper we characterised the N-glycosylation profiles of capsid proteins of 9 AAV serotypes using our high-throughput and high-sensitivity profiling platform. The value of this research is that it lays the foundation for gaining a good understanding of the importance of the structure of the AAV capsid surface to tissue tropism and interaction with cell surface receptors.

Analysis of the critical quality attributes of AAV particles is extremely important in the development of these as vectors for gene therapy. We tackled this by developing a multi-attribute analysis by size exclusion chromatography with fluorescence and triple-wavelength detection. The method provides AAV quantification that includes capsid concentration, empty to full capsid ratio, vector genome concentration and the detection of aggregates or fragments. The method is rapid involving 20 min chromatographic runs with minimal sample handing. The method was published in the journal, *Analytical Biochemistry* in September 2023.

The molecular distribution of glycans is critical to the therapeutic application of monoclonal antibodies (mAbs). The glycoform profile can be controlled to a certain extent by genetic engineering of the producer cells or by manipulation of the components of the culture media. We have investigated the possibility of enzymatic modifying mAbs produced by a bioprocess or by selectively removing targeted glycoforms by affinity chromatography. In 2023, we worked with an Irish company, *GlycoSelect* to develop a technology for modifying glycan profiles by lectin affinity chromatography. This study will be published in 2024.



Canty International provided us with two instruments with potential for use in bioreactor processing. One is the LabCam with associated software for analysis of foam that might be generated on the surface of cultures through excessive aeration particularly protein-rich media. We have shown the utility of this instrument in monitoring the generation and dissipation of foam and have used it to evaluate the of anti-foam agents that might be incorporated into the composition of culture media. The instrument is simple to position at the side of a bioreactor to provide a non-invasive method of analysis. The LabCam has provided us with an excellent means of evaluating foam in a bioreactor with potential feedback for anti-foam addition.

The second instrument provide by Canty is the *PharmaFlow* which is an optical system capable of showing the distribution of the size and shape of cells in a population introduced into a flow cell that is an intrinsic part of the instrument. We have data to show that the image analysis that is provided by associated software is capable of evaluating viable cell concentration and % cell viability over a culture run and correlates well with the traditionally used trypan blue exclusion analysis. The capabilities of the optical analysis of the instrument extends further to being able to distinguish apoptotic, necrotic and autophagic cells. We are presently correlating the image analysis in the death phase with alternative methods of analysis by staining. A manuscript describing the instrument and its capabilities is almost ready for submission for publication.

Our work on media development for supporting mammalian cell growth has extended to the analysis of various protein hydrolysates provided by the Kerry group. These hydrolysates particularly derived from soy, wheat and cotton have remarkable properties for promoting growth and productivity of cells in culture. We have analysed these with the aim of characterising the differential bioactivities of the hydrolysates and the individual components that they contain. Chromatographic separation and mass spectrometry analysis shows the high complexity of the components contained in the hydrolysates.

However, we have been able to identify peaks with high bioactivity and surprisingly other peaks with inhibitory activity. In particular we have shown the variety and variability of trace metals within different hydrolysates. This was reported in two international scientific meetings held in 2023.

Characterisation and Comparability Lab, Prof Jonathan Bones

Over the past year, NIBRT's Characterisation and Comparability Laboratory (CCL) under the direction of Prof Jonathan Bones, continued to deliver impactful analytical solutions for the analysis of various therapeutic modalities. With significant publication output, major activity themes for CCL this year included the further development of the multi-attribute method (MAM), characterisation of AAV based gene therapy and process contaminant analysis.

Supporting the implementation of MAM remains a key focus within CCL. In 2023, we published significant outputs relating to MAM including an end-to-end protocol published in *Nature Protocols* in collaboration with the leaders of the MAM Consortium in the United States. This was followed with an expanded protocol published in *Current Protocols in Protein Science* and a comprehensive review article in *Critical Reviews in Analytical Chemistry* that included discussion of the data management aspects required for successful implementation of MAM and its role in digitalisation of analytical testing. Complimenting these contributions to the community were additional original research publications from the group that reported the application of MAM for biosimilarity assessment on the peptide and intact protein levels.

Characterisation of viral vectors for gene therapy delivery was another significant activity area. In particular, characterisation of AAV as intact entities and the characterisation of the viral proteins that make up individual capsids. Outputs published in *Analytical Chemistry* and *Analytical Methods*, respectively, reported the application of advanced mass spectrometry methods for the analysis of capsid mass and capsid fill state assessment.

For viral protein analysis, we reported a simple workflow for AAV identity testing based on viral protein separation and identification followed by posttranslational modification analysis. An additional method for the analysis of limited sample amounts of AAV using microchip electrophoresis coupled to mass spectrometry for viral protein analysis was recently accepted for publication in *Analytical and Bioanalytical Chemistry*, performed in collaboration with 908 Devices.

Process contaminant analysis focused on continual development of our host cell protein (HCP) analysis platform including the analysis of HCP's present on viral vectors for gene therapy delivery, published in the *European Journal of Pharmaceutics and Biopharmaceutics*. Methods for other process contaminants, including additives used to prevent cell death during upstream processing and polysorbate degradation products during formulation and storage were reported in the *Journal of Pharmaceutical and Biomedical Analysis and Journal of Chromatography A*, which represented collaborative activities with Eli Lilly and Thermo Fisher Scientific, respectively.

Finally, to ensure effective dissemination of the excellent research being performed within CCL, the group had significant presence at the *American Society for Mass Spectrometry Annual Conference* and the *51st International Symposium on High Performance Liquid Phase Separations and Related Techniques,* where exciting new data was presented on the topics listed above and additional areas including mRNA analysis were reported. Group activities were also featured in four separate articles in *Genetic Engineering and Biotechnology News* throughout the year highlighting the immediate impact of group activities.

Maikel Gaitkoski, Research Associate

I've been part of the CCL group at NIBRT for nearly 18 months now. Initially joining as a Research Associate, my focus has been on collaborating for the development of the second generation of the PAT system. This system works as an automated platform, monitoring critical process and quality attributes during the manufacturing of biopharmaceutical molecules.

Our PAT 2 initiative involves collaboration with researchers from the University of Liverpool and the University of Edinburgh in the UK, expanding NIBRT's partnerships with international institutions and fostering knowledge exchange across various fields of expertise. This collaboration has proven fruitful, with PAT 2 results already presented at *SciX 2023* in Reno, Nevada, USA, in October. Additionally, we're in the process of preparing a manuscript for publication.

Beyond PAT 2, my background in molecular biology and genetic engineering has proven valuable for other projects within the CCL group. These include characterisation of mRNA-based vaccines by LC-MS and working on insect and mammal-based systems for producing AAV particles used in gene therapy.

Overall, my time at NIBRT and CCL has been incredibly fulfilling. It's not only a platform for developing and enhancing new skills but also an opportunity to contribute my research experience to support the progress of various projects.

The role of MAM in advancing innovative analytical strategies for biotherapeutics characterization and biosimilarity evaluation

*by **Dr Silvia Millán-Martín**, Senior Characterisation Scientist*

Over the last decade, biotherapeutics have become more and more complex in their structure, fostering the need for state-of-the-art analytical workflows to address these advances, and overcome the limitations posed by conventional methods, such as lack of sensitivity and the need to use multiple techniques orthogonally. The multi-attribute method (MAM) is an has gained substantial attention within the biopharmaceutical industry for improving product and process understanding during development and manufacturing of biotherapeutics and biosimilars, ensuring product quality, safety, and efficacy. The main advantage of MAM is its ability to monitor numerous critical quality attributes (CQAs) at the amino acid level of the biopharmaceutical product simultaneously and directly.

The MAM approach has been developed within the NIBRT Characterisation and Comparability Laboratory (CCL) since 2019. Several critical aspects of the workflow have been optimised through the years, such as sample preparation, LC analysis using different reversed-phase column formats and MS platforms, and data processing aspects. During 2023 significant achievements have been fulfilled by CCL scientists Dr Silvia Millán Martín, Dr Craig Jakes, Dr Sara Carillo and Dr Jonathan Bones, with two journal articles published this year in Nature Protocols (https://www.nature.com/articles/s41596-022-00785-5) and Current Protocols Journal (**https://pubmed.ncbi.nlm.nih.gov/37929772/**). These efforts focused on standardising the protocol, ensuring that all workflow steps, including sample preparation, LC-MS analysis, and data processing, are well-established and meticulously described. This comprehensive documentation aims to assist the scientific community in implementing the protocol effectively.

The team has also published a review article that highlights the current landscape of the MAM approach, with special attention given to increased analytical throughput, general requirements for quality control (QC) in terms of instrumentation and software, regulatory requirements, and industry acceptance of the MAM platform (**https://pubmed.ncbi.nlm.nih.gov/37490277/**).

The team also worked on a new perspective of the MAM approach, where the analytical similarity of seven adalimumab biosimilars was accomplished, resulting in a peer-reviewed publication highlighting the potential of MAM for use during the establishment of comparability assessment exercises (**https://www.sciencedirect.com/science/article/pii/S0731708523003126**).

A second study concentrated on employing a monodisperse strong cation exchange (SCX) column format for charge variant separation, facilitating the comparative Orbitrap MS-supported characterisation of adalimumab originator and seven EMA/FDA approved biosimilars (**https://www.sciencedirect.com/science/article/pii/S0731708523003035**).

Both studies have also been presented at the virtual symposium "The state of the art in life science analysis: advances in biopharmaceutical analysis" in October 2023, by Silvia Millán-Martín ("Multi-attribute method (MAM) to assess analytical comparability of adalimumab biosimilars") and at the Festival of Biologics conference in Basel in October 2023, by Sara Carillo ("Mass Spectrometry toolbox to support comparative analytical assessment of biosimilars").

Furthermore, the team received an invitation to participate in a MAM expert panel discussion. This opportunity was extended at the 2023 ASMS MAM workshop in Houston in June. Silvia Millán-Martín represented the team alongside individuals from industry, the FDA, USP, and instrument/software vendors representatives.

Systems Biology and Data Analytics, Prof Colin Clarke

The STACCATO EID network coordinated by NIBRT from 2018-2023 has successfully completed its training and research objectives. The consortium successfully delivered a unique training programme in biopharmaceutical manufacturing science for 11 Early-Stage Researchers (ESRs), delivering all planned training modules and incorporating additional events, such as an Entrepreneurship module. Non-academic partners played a pivotal role throughout, providing facilities and industrial expertise that equipped the ESRs with a diverse skill set.

In terms of research, the consortium was focused on enhancing Europe's innovation capacity in biopharmaceutical science. They conducted pioneering single-cell analyses of cell lines used in recombinant protein and gene therapy production, as well as cell-based medicines. This effort included transcriptomic analyses of CHO, Sf9, and HiFive cell lines at single-cell resolution, revealing unprecedented insights into cell variability. The team also explored single-cell transcriptomics for CAR-T cell production systems, potentially unlocking new avenues for CAR-T cell generation *in vivo*.

Their research progressed beyond the original plan by integrating transcriptomics with DNA and protein level data for even higher resolution analyses.

The consortium effectively disseminated their project outcomes through various communication channels, notably at Europe's largest animal cell culture conference, ESACT, with oral and poster presentations and a workshop on single-cell analysis applications. Despite challenges posed by the global pandemic, the dedication of ESRs, non-academic partners, and academic participants is testament to the achievements of STACCATO. The collaborations forged in this project will continue to enhance Europe's capacity to deliver life-saving medicines in the future. For more information see: **https://www.staccato-eid.eu**.

Prof Clarke's Lab, also collaborated with Christian Bucholz's group at the Paul Elrich Institute (PEU) to study changes in T cell lymphocyte gene expression profiles following the delivery of lentiviral vectors (LVs) including those targeted specifically targeted to CD8+ and CD4+ T cells. Transcriptome analysis revealed the upregulation of genes associated with cellular quiescence and antiviral defence mechanisms in CAR-negative cells exposed to all LVs.

→ *Successful completion of the STACCATO Marie Curie Skłodowska European Doctorate Programme*

These observations led the team to utilise rapamycin to downregulate antiviral restriction factors, including the interferon-induced transmembrane proteins (IFITMs). Rapamycin was found to enhance transduction by up to 7-fold for CD8+ and CD4+ lentiviral vectors without compromising CAR T cell activities. In a pivotal *in vivo* experiment, the kinetics of *in vivo* CAR T cell generation were improved, resulting in more effective tumour control. Future studies will aim to further refine the administration schedule of rapamycin. The work was published in the prestigious *Advanced Science* journal (**https://doi.org/10.1002/advs.202302992**).

GlycoScience, Dr Radka Fahey (Saldova)

The GlycoScience group published four publications in 2023. Of note is that two of these were published by the Nature publishing group: **Freehily et al, 2023**, Nature Communications (collaboration with MicrobeMom consortium), and **Kovacs et al., 2023**, Scientific Reports (output from Glycomendo). The other two publications, **Günay et al, 2023**, were produced in collaboration with CÚRAM, and Kileen et al., 2023, was developed in collaboration with MicrobeMom and was published in FASEB BioAdvances and accepted in Cytokines, respectively.

The GlycoScience group achieved notable success in 2023 with the publication of four research papers. Particularly noteworthy are two publications released by the Nature publishing group: **Freehily et al, 2023** in Nature Communications (in collaboration with the MicrobeMom consortium), and **Kovacs et al., 2023**, in Scientific Reports (a result from Glycomendo). Additionally, the group collaborated with CÚRAM for the publications **Günay et al, 2023**, and Killeen et al., 2023.

The latter, was developed in partnership with MicrobeMom and has been published in FASEB BioAdvances, with another acceptance in Cytokines.

We also presented our work at national and international conferences with **seven posters and three oral presentations**, showcasing collaborations with CÚRAM and the MicrobeMom consortium. Dr Radka Fahey was invited to deliver an **oral presentation** titled "Advanced Glycoanalytics to Characterise Glycosylation for Improved Development of ATMPs" at the 4th Global Bioprocessing, Bioanalytics and ATMP Manufacturing Congress on the 16th of May 2023, in Dublin.

The collaboration with CÚRAM on two research projects involving visiting students Yagmur Bozkurt and Jack Schofield continued into 2023, entering the second phase. Sample characterisation was conducted, and data analysis has been carried out remotely for most of this year.

The GlycoScience group also hosted MSc student Morgan Grey Shriver over the summer. The focus of the visit was on exploring glycosylation on CAR/T-cells within the NSF-funded project "A U.S.-Ireland Partnership for an International Graduate Research Experience in Biopharmaceutical Processing" (IRES).

In 2023, numerous collaborative projects were proposed, primarily with CÚRAM, UCD, TCD, UCC, NUIG, Birmingham University, the University of Santiago de Compostela, and the Karolinska Institute.

Downstream Processing, Dr Steven Ferguson

In 2023 the Ferguson Group continued to expand its research footprint in mRNA through the SFI Frontiers project in collaboration with Elizabeth Topp research group where is aims to develop new manufacturing methods to enable the uptake of chemically modified mRNA to improve stability and potency in vaccine applications. A further research highlight in the area of downstream processing was the development and publication of continuous spatially distributed diafiltration, a new method for conducting membrane based diafiltration operations offering unprecedent efficiency in single pass membrane units. A novel method to produce RNA oligonucleotide drugs through a new high productivity liquid phase synthesis method was presented to the American Institute of Chemical Engineers in November 2023.

Dr. Ferguson leads the SFI:EPSRC Centre for Doctoral Training in Transformative Pharmaceutical Technologies for NIBRT and UCD, where a new PhD project aiming to Ionic Liquids for oral delivery of Biopharmaceutical drugs was initiated. In addition to this NIBRT delivered a core module for the inter-institutional Centre for Doctoral Training program cohorts from SPPC (UCC, TCD, UCD & NIBRT), University College London and Nottingham taking place onsite in NIBRT in May 2023.

Advanced Cellular Therapeutics, Prof Sakis Mantalaris

In November 2023, Professor Sakis Mantalaris received a prestigious SFI Research Professorship for a project titled *"Metabolism-Driven Precision Biomanufacturing of Cellular Therapeutics,"* securing €4.9M in direct costs over a period of 5 years.

This programme of research focuses on advanced cellular therapeutics, aiming to comprehensively understand and regulate cellular metabolism and heterogeneity. The central focus of the research is on developing personalised biomanufacturing strategies.

Cell therapy, involving the transfer of cells between individuals, holds transformative potential in treating various diseases. However, challenges persist in ensuring robust manufacturing processes for widespread clinical application. With 25 FDA-approved advanced cellular therapy (ACT) products and over 10,000 clinical trials, the field spans diverse applications, from cancer to autoimmune diseases. The conversion rate from Phase 3 trials to FDA approval for ACTs is approximately 14.3%, emphasizing existing hurdles.

Clinical demands, especially for widely occurring diseases, may surpass supply if biomanufacturing scalability is not addressed early. Despite Ireland's biomanufacturing leadership in biologics, it lags in cell and gene therapeutics. ACTs demand an integrated ecosystem, linking biomanufacturing with clinical practice, requiring unique interdisciplinary training.

Cell therapy applications, especially CAR-T cells, have surged, driven by improved outcomes in incurable cancers. The COVID-19 pandemic highlighted potential uses of cell therapies in inflammation-driven tissue damage. However, reported patient response variability underscores the need for robust and reproducible biomanufacturing.

ACTs differ significantly from biologics, especially in cellular types and inherent heterogeneity. Understanding and controlling cellular metabolism, influenced by culture conditions and maturation signals, can enable regulation of cellular phenotype. Metabolic signatures change before genotype and phenotype, emphasizing the sensitivity and accuracy of metabolism as a cellular state assessor.

The objective of the research programme is to understand and control cellular metabolism and heterogeneity, focusing on developing personalised bio-manufacturing strategies. The proposal aligns with SFI's research priorities, addressing the unmet need for robust and reproducible ACT biomanufacturing.

The overarching aim is to characterise and direct cellular heterogeneity through metabolism control, enhancing ACTs for improved clinical outcomes. The research comprises five vertical work packages (WP1-5) integrated with five horizontal cell types, covering diverse clinical applications. An additional impact and administrative WP facilitate resource utilization and effective training. Six key objectives include developing a metabolism database, characterizing cellular heterogeneity, designing precision culture media, identifying metabolic biomarkers, implementing metabolism-centred biomanufacturing, and delivering impact through knowledge, training, communication, and commercialisation.

The proposed research aligns with SFI priorities, addressing the need for robust and reproducible ACT biomanufacturing with potential clinical applications. The effective management, dissemination, and outreach aspects incorporated into this project will ensure the broader impact and success of this research programme.

New Biotherapeutic Modality Design and Production, Prof Mark Smales

Prof Mark Smales took up his position at NIBRT in September 2023 through a joint appointment with the University of Kent in the UK. Prof Smales brings over 20 years of experience collaborating with academics and industry in the bioprocessing of biotherapeutics field.

At NIBRT, Prof Smales' research will focus on the design and manufacturing of various advanced biotherapies. This includes modalities such as gene therapies, RNA therapeutics for vaccines and therapeutics, and recombinant proteins with multi-specific and/or non-natural biotherapeutic properties. Manufacturing processes for advanced biotherapies are typically low yielding and inefficient.

In Ireland, addressing these challenges is considered a national strategic priority with significant potential for economic impact. This is due to the potential of these therapies to treat currently untreatable diseases and conditions.

His work will seek to generate a fundamental, transformative, and conceptual mechanistic shift in our understanding of the cell expression systems and processes used to produce these advanced biotherapeutics. Additionally, he aims to apply modern synthetic biology engineering approaches to deliver more efficient, predictable, and affordable manufacturing approaches.

In the short time since joining NIBRT, Prof. Smales has initiated and submitted a substantial application to SFI for research in these areas. He has also actively contributed to the development of various projects and funding applications, including contributing towards the development of a response to the 2023 SFI Centre call.

Formulation and Stability, Prof Liz Topp

Biologics continue to provide new treatments for humanity's most difficult diseases. The societal impact of these exciting medicines can be compromised by their fragility, however: biologics are often subject to both chemical degradation (e.g. breaking native bond structure) and physical degradation (e.g. aggregation). The Formulation and Stability Lab seeks new ways to prevent these instabilities. The group had several notable accomplishments in 2023, including:

- The launch of a new project on mRNA stabilization, sponsored by Science Foundation Ireland's "Frontiers for the Future" program. The project involves Dr. Steven Ferguson (NIBRT, UCD) and Dr. Joanna McGouran (TCD), as well as several newly hired researchers (see below). Objectives of the project include improving our understanding of mRNA degradation, the synthesis of modified mRNA with improved stability, and the development of novel liquid-phase synthesis methods.
- Notice of funding for a new project that will develop a digital twin for lyophilization. The project is funded through I-FORM, an SFI Centre for Advanced Manufacturing, and will be conducted in collaboration with LyoHUB, an industry consortium on lyophilization based at Purdue University.
- Notice of funding for a new Horizon Europe project to develop monobodies (mobs) for the treatment of infectious disease outbreaks. This project is led by ITQB Nova in Portugal. Our lab will help to formulate and stabilize promising mobs developed by other members of the consortium, supporting translation.

The Formulation and Stability Lab welcomed Arda Tugrul and Zdravko Ivanov as new Ph.D. students in 2023. We also celebrated the promotion of group member Dr. Manuel Alfaro de Prá to postdoctoral scientist. In addition, a new technician has been identified for the IFORM project and plans to join the group in March of 2024.

NIBRT Affiliated Nature Paper
Prof Mark Smales

Working in collaboration with colleagues in the University of Cambridge, Prof Mark Smales co-authored a Nature paper. This marked the first Nature publication affiliated with NIBRT.

In this paper, the authors discovered that 1-methylΨ, a modified ribonucleotide, significantly boosts +1 ribosomal frameshifting during mRNA translation. It was shown that vaccination with mRNA containing 1-methylΨ can lead to cellular immunity against +1 frameshifted products.

This is the first report highlighting the impact of mRNA modification on ribosomal frameshifting. While this affects T cell immunity, off-target effects could involve increased production of new B cell antigens. Other modification strategies, like 5-methoxyU incorporation, decrease translation efficiency, limiting clinical translation. Translation of N1-methylpseudouridylated mRNA causes +1 ribosomal frameshifting, likely due to altered aminoacyl-tRNA binding and slower translation elongation.

The findings in this publication contribute to understanding how ribonucleotide modification influences mRNA translation, which is essential for designing effective and safe mRNA-based therapeutics.

NIBRT Research 2023 key metrics

33 → Peer Reviewed Publications

1.20 → Field Weighted Citation Impact

86 → Distinct Collaborations

9 → Principal Investigators

24 → Collaborating Countries

48 → Research Staff

74 → Conference Presentations

4.3 PhD Graduates from NIBRT in 2023

In 2023, three postgraduate students in NIBRT's research team successfully defended their PhD thesis.

Alan Foley, Cell Engineering Group

In October 2023, Alan successfully defended his thesis entitled: *"Single Cell Analysis of CHO mtDNA"*. He developed a novel method to sequence mitochondrial DNA (mtDNA) from single CHO cells. This work uncovered genetic differences between individual cells, which may imply differences in energy dynamics. Considering the significant energy burden of producing recombinant proteins, Alan's work set a theoretical background for future CHO cell line engineering based on favourable genetic profiles. Alan has submitted a methods paper which is in review and is preparing a manuscript for a larger-scale research paper.

Ryan Hagan, Systems Biology and Data Analytics Group

In September 2023, Ryan Hagan a PhD student in the Clark Laboratory successfully defended his PhD thesis entitled *"Understanding recombinant therapeutic protein production at single cell resolution"* at University College Dublin. Ryan was focussed on utilising new single cell approaches to study the behaviour of CHO cells during the production of recombinant therapeutic proteins. A particular highlight of his work was the study of chromatin accessibility in individual CHO cells for the first time.

Niamh Keogh, Cell Engineering Group

In April 2023, Niamh defended her thesis entitled: *"Cell Line Engineering Approaches for the Improved Production of Advanced Biological Medicines"*.

Voice of the Researcher – Dr. Nicholas Donohue

I started in NIBRT in January 2020 as a researcher on gene therapy, which is used to treat genetic diseases. The underlying cause of a genetic disease is an error in part of a person's DNA. This can be treated by supplying a correct version of the affected DNA. The challenge is, that the error is present in every single cell of the body – which means that trillions of cells must be treated for this approach to work.

This is where viruses come in: they are the best tool to shuttle DNA into trillions of cells at once. The virus used in my research ('Adeno-associated Virus') has been modified to only carry the therapeutic DNA and cannot start an infection. Currently there are three drugs available that use this approach, and many more in the pipeline. All of these are extremely expensive, so it would be ideal to improve production methods to bring the cost down.

At NIBRT I worked on comparing the different systems used to make gene therapy drugs and how to improve product quality and safety. I was able to continue this work through a NIBRT seed award in 2022, followed by an SFI-funded Industry RD&I Fellowship in collaboration with APC Ltd. This project will establish gene therapy drug production at APC and increase yields by optimizing the components and conditions used during the process. In my view, NIBRT has been an excellent place to develop skills in this field and serves as a perfect link between academia and industry.

Dr Seán Lacey, Dr Tara Doherty, Dr Kate Dunne, Dr Caragh Tisdall, Ruth Moran, Sinéad Hanrahan and Lorna Walsh

Research Integrity

All NIBRT researchers are mandated to regularly 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 RI. while members of the NIBRT Research Office deliver further RI training via the "Cross Institutional Research Integrity Training" (CIRIT) team.

Since 2021, the CIRIT team have delivered training to approximately 350 members of the research community through online, interactive workshops. In 2023 the CIRIT team held:

- An online seminar on 'A Virtue Approach to Research Integrity & Good Authorship Practices'.
- An in-person workshop at the Academic and Research Integrity Conference Ireland.

Voice of the Researcher – Dr James Flynn

Dr James Flynn joined Prof. Michael Butler's cell technology group in May 2022, where he is developing process analytical technology (PAT) for bioprocess design, and development. Following his PhD in antimicrobial biomaterials from the University of Limerick, his aim was to upscale his bioprocessing skillset, and he is currently working in collaboration with the J.M Canty Ltd, on an Enterprise Ireland funded project.

Dr Flynn is now moving onto the training team in January. When considering this next career step, moving away from research towards training, he points to NIBRT's supportive environment as a key factor in his decision.

He was encouraged to explore his options: "NIBRT are very generous in terms of their training budget, on focusing on what you need to further yourself." He highlights "focusing on your career development is very much encouraged, and is facilitated by an enormous approachability at management and senior management level."

Dr Flynn's new role is a natural progression for him, as he will be building on many of his current skills and applying them with a new perspective. There will be many opportunities to "upskill in state-of-the-art equipment and keep on top of trends in biopharma." He looks forward to these new and exciting opportunities in NIBRT and the dissemination of knowledge to industry, students, and the wider community.

Minister Simon Coveney opening the Biopharma Focus on the Future Conference with NIBRT's Darrin Morrissey, Prof Liz Topp and Rory Mullen, IDA Ireland

The Biopharma Focus on the Future Research Conference

On the 20th of April 2023, NIBRT hosted the *Biopharma Focus on the Future* Research Conference, bringing together leading experts to explore the latest advances in biopharmaceutical manufacturing. The conference showcased Ireland's thriving biopharma research ecosystem. Minister Simon Coveney, Minster for Enterprise, Trade and Employment, opened the event and addressed the importance of the biopharma industry to Ireland's economy and NIBRT's role in supporting its growth.

Throughout the day, attendees engaged with the internationally recognised academic experts and distinguished speakers including:

- **Professor Kelvin Lee,** Director of the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL)
- **Professor Bruce Levine,** Founding Director of the Clinical Cell and Vaccine Production Facility at the University of Pennsylvania
- **Grainne Power,** Ireland's Health Products Regulatory Authority
- **Prof Elizabeth Topp,** NIBRT
- **Prof Johan Rockberg,** KTH Royal Institute of Technology, Stockholm, Sweden
- **Dr Colin Clarke,** NIBRT
- **Prof Dong-Yup Lee,** Sungkyunkwan University, Suwon, Republic of Korea
- **Prof Bjørn Gunnar Voldborg,** Technical University of Denmark (DTU), Lyngby, Denmark
- **Dr Nathan Lewis,** University of California, San Diego, USA
- **Dr Piotr Kowalski,** University College Cork;
- **Prof Jane Farrar,** Trinity College Dublin
- **Dr Sandro Matosevic,** Purdue University, West Lafayette, USA

The conference was attended by 100 delegates, and live streamed, with over 400 delegates worldwide registered. NIBRT Research was represented by two podium presentations and 24 posters on the day. Topics covered at the conference included advanced analytical characterisation of biologics and advanced therapies, systems biology for biopharmaceutical manufacturing, application of data science for biopharma manufacturing, cell and gene therapy manufacturing science and technology, clinical research, and regulatory science for new modalities. The Conference proceedings can be viewed **here**.

4.4 CONCEPT

In December 2023, NIBRT launched CONCEPT, a state-of-the-art core facility dedicated to advancing innovative biotherapy development. The facility, located in the new advanced therapies extension at NIBRT, is designed to support academic and industry researchers by providing access to next-generation instrumentation and expertise required to rapidly generate optimised cell lines and advanced biotherapies.

CONCEPT has been made possible by over €4.2M in funding from SFI's Research Infrastructure programme, as well as €2.4M in capital investment from IDA Ireland. Under the leadership of Dr Jonathan Bones, CONCEPT will assist researchers in their therapy-focused research, enabling progression from concept to research-grade biologic, cell, gene, and RNA-based biotherapies.

Key features of CONCEPT include:

- Innovative Research Spaces: The centre boasts advanced laboratories and state-of-the-art instruments to support, accelerated development of biomaterials and robust data generation.
- Expertise: A team of scientists with demonstrated expertise in advanced biotherapy and biologic development to guide and support users through every step of the process.
- Accessibility and Flexibility: Workflows and access models designed with flexibility at its heart to meet user needs.
- Interdisciplinary Collaboration: CONCEPT encourages collaboration among academia and industry professionals, fostering an atmosphere where diverse perspectives converge to address complex biopharmaceutical research and manufacturing challenges.
- Strategic Partnerships: CONCEPT is actively seeking collaborations with academic institutions and industry innovators to create a network to accelerate research for next generation biotherapies.

> ***This new facility builds upon a generation of targeted investment and has at its core a quest to deliver access and opportunity – faster, easier, and wider."***
>
> ***Dr Ruth Freeman,*** *Director, Science for Society, Science Foundation Ireland*

Prof Jonathan Bones, Dr Clair Gallagher, Dr Ruth Freeman (SFI), Dr Darrin Morrissey, Dr Fiona Killard-Lynch, Declan McAree (IDA Ireland) at the launch of CONCEPT

Voice of the Researcher – Dr Brian Philip

Dr Brian Philip trained with pioneers in CAR-T cell immunotherapy, has recently joined the CONCEPT team. He completed his PhD with Prof Martin Pulé at UCL where he developed the RQR8 marker gene/ safety switch which has subsequently been licenced for therapeutic application by Autolus, Cellectis Therapeutics and BMS amongst others.

Immunotherapy research requires effort, ingenuity and dedication to support efforts which often extend beyond the conventional work week. Solutions to challenges are rarely obvious and often answers may prove to be further questions. However, the reward from clinical realisation is beyond measure, and converts long hours of effort into time well spent.

Experience in industry working with TC Biopharm and Triumvira Immunologics offered opportunity to apply his experience and expertise to alternative immune platforms, new technologies and the challenge of scale associated with the transition from academic investigation into commercial application.

A critical outstanding challenge remains the cost associated with the development, design and production of these novel therapies. This highlights the value and vision of the NIBRT CONCEPT facility which levels the playing field. Acting as a repository for expertise, equipment and training, CONCEPT offers access to advanced technologies typically reserved to big pharma.

In such a rapidly evolving space, keeping pace with advances in technology is essential to remain competitive to enable effective problem solving for emerging challenges. The constancy of change in this field ensures that the science always remains fresh and exciting.

5 Training and Education

5.1 Training and Education in 2023

The NIBRT training team delivered another strong performance in 2023, increasing the number of trainees across all our training modalities reflective of the current focus on workforce readiness and wider skills initiatives in biopharmaceutical manufacturing. We were pleased to see the continuing strong demand and interest both nationally and internationally for our onsite competency-based training solutions delivered in our pilot production training facility. We successfully delivered over 30,500 learning days to 4,900 trainees drawn from industry and academic clients through our onsite and distance learning solutions.

A key highlight in 2023 was the completion of NIBRT's facility expansion project that has increased our training capability by providing new additional training suites, specifically dedicated for the delivery of practical training programs in advanced therapies including cell/gene therapies and vaccines. Initial roll-out of new training courses in these areas commenced this year and will be further expanded in 2024.

We were delighted to continue successful engagements with our existing education and industry clients and also welcome new clients to NIBRT who benefited from our comprehensive customisable curriculum and flexible training options to meet the specific needs and learning outcomes of their colleagues.

Training for Industry

NIBRT reacted positively to the needs of its industry clients and it was evident that the dual challenges of hiring and retention of key talent resonated strongly in 2023. Building and retaining talent requires innovative approaches to workforce management aligned with flexible options for associated training. Customising training courses to meet specific client needs is key to the NIBRT offering and this flexibility in NIBRT's approach clearly was of benefit to the wider biopharma industry.

In 2023 customised training solutions across our curriculum were developed and delivered to an expanding client list as shown below comprising biopharmaceutical manufacturers, technical providers and regulators respectively. Indeed 2023 was noteworthy with regard to the number of specialised industry relevant technical providers and vendors who received training at NIBRT which served to increase their colleague's specific product application knowledge in biopharma processing.

Training for Academia

NIBRT has worked extensively over many years with our education partners to deliver impactful training solutions in biopharmaceutical science/engineering to support wider accredited academic courses. The higher education sector continues to play a crucial role in talent generation across multiple areas by supplying industry with a pool of educated undergraduates and postgraduates with skillsets that can be further developed by prospective employers.

NIBRT's ongoing participation in biopharma science and engineering programs offered through collaboration with the education institutes shown below, affords real value to students in these programs to experience real life manufacturing scenarios through competency-based practical sessions and interaction with NIBRT's subject matter experts.

Springboard+

Springboard+ is an initiative co-funded by the Government of Ireland via the National Training Fund and the European Union which offers accredited courses at Certificate, Degree and Master's level to support skills development in areas of employment opportunities. NIBRT was pleased to continue its collaboration with academic partners in ATU Sligo, TU Dublin and UCC respectively to deliver training in the area of Biopharmaceutical Science.

Over many years NIBRT's participation has proved to be highly beneficial to students by providing them with access to excellent training opportunities and specifically the development of key practical competencies in biopharmaceutical manufacture delivered in our pilot-production training facility.

In 2023, 725 students participated in Springboard+ courses at NIBRT providing them with key industry knowledge and associated skills required to build a career in biopharmaceutical manufacturing facilities.

Digitalisation Training

Continued pressure on the biopharma industry to innovate and to deliver new molecules while keeping cost to a minimum place a requirement for organisations to have a robust digital transformation strategy. New modalities and regulatory expectations are also changing the landscape, where right first time and short turnaround time are critical for the delivery of cell therapy to patients.

Key challenges are being seen in both technology adoption and talent development. Traditional biochemistry education is no longer seen as being sufficient for the younger, digitally savvy workforce. At the same time, legacy equipment prevents the transition to a fully connected, adaptive plant.

In 2023, NIBRT has addressed these issues through a mix of open courses, client-specific customised courses and strategic workshops in partnership with Boston Consulting Group (BCG). Introductory and advanced data analytics courses cover key topics on understanding the fundamentals of statistics as well as design of experiments to enable a more efficient technology transfer from lab to GMP manufacturing. While these courses focus on biochemists, NIBRT has also seen the demand for the upskilling of IT and data scientists on the biochemistry aspects. Given the facilities available at NIBRT, the simulated GxP environment has been useful to immerse these groups on the basics of biologics manufacturing on real-life equipment while reducing interference with routine commercial manufacturing at their sites.

Springboard+ and HCI Pillar 1 are co-funded by the Government of Ireland and the European Union.

In 2024, NIBRT will be offering an expert-level course (Masterclass in Machine Learning) where topics such as multivariate statistics, time series analysis, image classification and generative AI will be covered in the context of biomanufacturing. Thus, a series of basic to expert level learning can be delivered at NIBRT for a comprehensive talent development.

NIBRT Training Facility

Vendors and technical providers to the industry are intrinsically linked to successful biomanufacturing and NIBRT further strengthened its interactions with this community in 2023. In addition to the delivery of training solutions to this group we were delighted to engage with the vendor community with respect to new equipment infrastructure.

Critical to NIBRT's offering is the pilot production training facility in which our practical curriculum in drug substance and drug product manufacture for recombinant proteins and advanced therapies is delivered. In 2023 working with specific vendors we were delighted to add new equipment that will increase our future capabilities and we would like to thank those companies for their interest in collaborating with us in the deployment of new state-of-the-art equipment to support current and future training initiatives.

NIBRT Online Academy (NOA)

The **NIBRT Online Academy (NOA)**, launched in 2020, gained over 600 new registered users in 2023 resulting in e-learning courses being delivered to 6,350+ learners in 88 countries worldwide. NOA provides online access to more than 60 interactive e-learning courses which cover all aspects of the biopharma manufacturing process. 2023 also saw the introduction of new functionality to allow clients manage their licences independently and to provide their trainees more streamlined access to the NOA platform. New NOA courses added in 2023 include:

- **SUT:** The Application of Single-Use Technologies in Biopharmaceutical Manufacturing
- **Lab Skills:** Essential Lab Skills for Biopharma
- **ATMP** Fluid & Cold Chain Management Webinar

New courses added in 2023

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

- Introduction to Commissioning, Qualification and Validation in Biopharmaceutical Production
- Introduction to Biopharma 4.0
- Introduction to Data Analytics for Biopharmaceutical Manufacturing
- Advanced Data Analytics for Biopharmaceutical Manufacturing
- Principles of Machine Learning
- Electronic Batch Record (EBR) and eForms
- Advanced Process Control (in partnership with Qubicon)
- Introduction to Biopharmaceutical Operations (in partnership with Engineers Ireland)
- Managing Asset Reliability: Biopharma Process Equipment (in partnership with Pro-Reliability Solutions)

Key Training Metrics

4,900 → Number of trainees

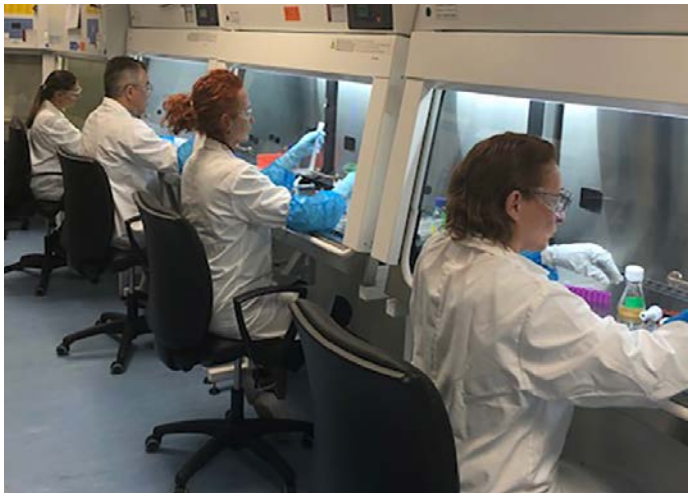
30,500 → Number of learning days

725 → Number of Springboard+ students

6,350 → Number of NOA users

5.2 Training case study: Terumo

Training case study



Enhancing the Skills of Terumo's Blood and Cell Technologies Commercial Team in Cell and Gene Therapy

Terumo BCT is a renowned global leader in the field of healthcare, specialising in medical and laboratory devices and services. With a strong commitment to innovation and excellence, and complying with Terumo Group Core Values of Respect, Integrity, Care, Quality and Creativity, Terumo BCT worked with NIBRT to develop a range of training solutions to enhance the skills and knowledge of their commercial sales and technical teams for cell and gene therapies.

NIBRT collaborated closely with the Terumo BCT team to develop a 2-day course schedule to meet their specific training needs. The key objectives of the course included:

1. Enhance Technical Understanding:

Upskill and improve commercial and technical teams' understanding of processes related to cell and gene therapy products and offerings.

2. Strengthen Industry Adaptability

Provide hands-on experience with processes to improve the ability to react to challenges and problems faced by clients in real-life work scenarios.

3. Promote Effective Communication and Collaboration

Foster a collaborative environment where teams can gain a deeper understanding of each other's roles, enabling them to work together more effectively to provide enhanced customer solutions.

NIBRT Course Delivery:

The NIBRT training programme included both theoretical and hands-on components. It commenced with theoretical sessions on Cell Therapies, serving as the foundation for the subsequent two days of practical activities. Participants had the opportunity to work with automated and suspension cell culture equipment, delve into cell therapy proliferation, and explore processing flow paths.

Terumo BCT's trainees came from various global locations, including Europe, the United States and the Asia-Pacific region. The courses not only provided valuable training but also offered a unique opportunity for colleagues from different parts of the world to come together, share insights, and foster collaboration.

Results

The training collaboration with Terumo BCT was a great success and both participants and senior managers reported a high level of satisfaction with the training overall:

80% of respondents said they would recommend this course to a friend or colleague

88% average score for overall participant course satisfaction

90% average rating for the quality of our trainers

What Participants Said About Us:

- "The format and content were great"
- "I enjoyed the hands-on activities"
- "Staff were very accommodating and great to learn from"
- "Fantastic experience with processes"

About Terumo Blood and Cell Technologies

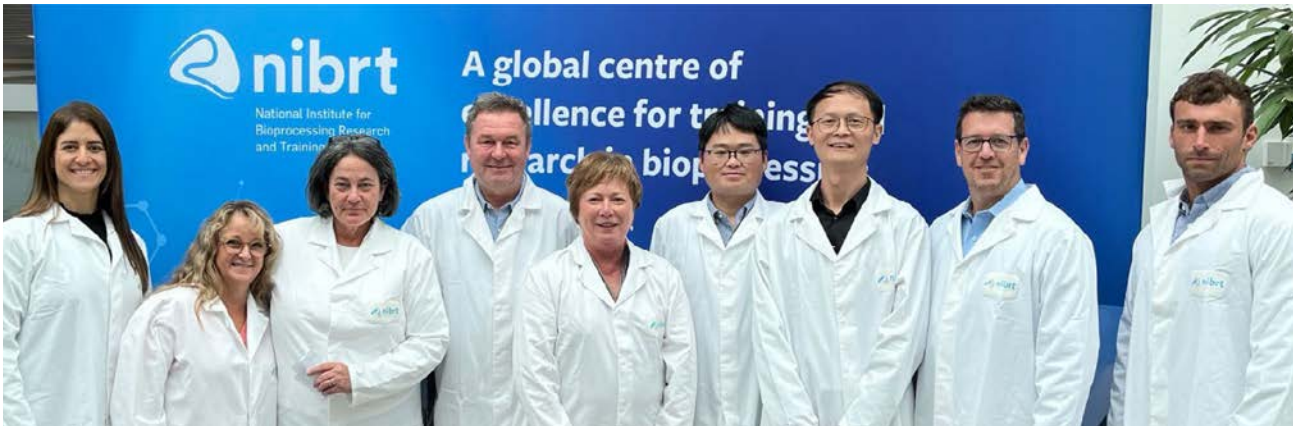
Terumo Blood and Cell Technologies is a medical technology company. Our products, software and services enable customers to collect and prepare blood and cells to help treat challenging diseases and conditions. Our employees worldwide believe in the potential of blood and cells to do even more for patients than they do today. This belief inspires our innovation and strengthens our collaboration with customers.

Terumo Blood and Cell Technologies' customers include blood centers, hospitals, therapeutic apheresis clinics, cell collection and processing organizations, researchers and private medical practices. Our customers are based in over 150 countries across the globe. We have 750+ granted patents, with more than 150 additionally pending.

We have global headquarters in Lakewood, Colorado, U.S.A., along with five regional headquarters, seven manufacturing sites and six innovation and development centers across the globe. Terumo Blood and Cell Technologies is a subsidiary of Terumo Corporation (TSE: 4543), a global leader in medical technology. terumobct.com

Outcome

The case study illustrates the successful collaboration between Terumo and NIBRT in enhancing the skills of Terumo's Blood and Cell Technologies team. Positive participant feedback, high recommendation rates, and the intention to continue training sessions demonstrate the effectiveness and value of the programme.



5.3 Trainee case study

Trainee case study

Fintan Heffernan

Fintan transitioned from working in the food industry to a career in biopharma after studying a level 9 Cert in Commissioning Qualification and Validation with ATU Sligo in partnership with NIBRT. This postgraduate certificate is designed to provide students with the necessary knowledge for engaging in the commissioning of equipment and utilities used in biopharmaceutical plants. The programme aims to empower students with the knowledge and skills essential for the commissioning of both a bioprocessing plant and the equipment associated with the biotechnology industry.

What course did you do?

''I completed the level 9 Cert in CQV with ATU Sligo in partnership with NIBRT. The course was structured as a part-time online programme which made it convenient for me to strike a balance between my studies and personal commitments''

What motivated you to choose this course?

''I was interested in entering the biopharmaceutical industry because I am aware that the sector has a reputation for innovative and operational excellence. I had extensive experience in the food industry and felt that while there were many transferable skills, taking a course would be the best approach for me to break into the industry''.

What was your experience of studying at ATU Sligo and NIBRT?

''My experience with ATU Sligo and NIBRT could be described only as stellar. My lecturers were approachable, knowledgeable and understanding, the course owners were communicative and active in assisting me and others if necessary and the standard of education provided was second to none''.

How has the course helped with your career plans?

''Since my completion of the course, I am very pleased to say that I have secured employment in the industry with Regeneron in Limerick. The role is Associate Biotech Manufacturing Specialist, is onsite in their facility in Raheen and is a full-time position''.

Would You Recommend this Course?

''I would thoroughly recommend this course to anyone seeking to break into the biopharmaceutical industry. I had no experience other than an Honours degree in Food Science and my academic experience with this course helped me to secure employment within my chosen field and the course content was highly relevant to my employment within the industry which clearly demonstrates the efficacy of the course''.

5.4 Global Partner Programme

The NIBRT Global Partner Programme supports an international alliance of leading training and education organisations to help address the global shortage of a skilled biopharma workforce. The Global Partner Programme outlines a flexible, phased approach to provide training and education capability in a Partner's region.

The programme operates on a franchise type model, where NIBRT can provide set-up and ongoing support to Partners.

In 2023, NIBRT was delighted to welcome two global partners, BioHub Maryland and San Jacinto College, Houston, Texas. In addition NIBRT was pleased to support our Canadian partners opening a new training facility in Montréal.

Canadian Alliance for Skills and Training in Lifesciences (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 delivers NIBRT's training designed specifically for the biopharmaceutical sector in Canada within CASTL's three learning streams: New Skilling, Reskilling and Upskilling. CASTL opened its first training facility in Charlottetown in 2022 and launched the latest Montreal facility in November 2023. As part of this partnership, CASTL has access to the NIBRT curriculum, collaborate on curriculum design, access new courses, and partners in the development of new Canadian biopharmaceutical skills and training centres.

Minister Pierre Fitzgibbon, NIBRT's Peter Connolly and representatives of CASTL at the opening of the new training facility in Montréal, November 2023

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.

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.

Minister Simon Coveney, Michael Lohan IDA Ireland and Darrin Morrissey NIBRT, at Korea-NIBRT, November 2023

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.

In July 2021, NIBRT announced a new global partnership with the Korean- NIBRT (K-NIBRT) to develop a world class biopharma manufacturing training and research centre in Incheon, South Korea. K-NIBRT will develop into Korea's bioprocessing workforce development institute by licensing NIBRT's world-leading training and education curriculum in biopharmaceutical manufacturing.

The K-NIBRT facilities are scheduled to open in 2024 with the vision of establishing the leading biopharmaceutical manufacturing training in the Asia- Pacific region. Before the official opening of the K-NIBRT facilities, training programmes have commenced at Yonsei University's International Campus in September 2021.

Biologics Innovation Facility (BIF), Sydney, Australia

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

The UTS Biologics operation, designed for practical vocational and professional training, is a strategic investment between UTS and the NSW Government aimed at building a future workforce with high quality transferable STEM skills for the biopharma industry.

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

BioHub Maryland, Maryland, USA

BioHub Maryland is accelerating the life sciences industry for companies and career seekers to expand the state's global innovation advantage.

NIBRT formed a partnership with BioHUb Maryland in November 2023, The partnership will provide BioHub Maryland with exclusive access to NIBRT's licensed curriculum in the National Capital Region of the United States and will upskill thousands of Marylanders to sustain industry's growth

Governor Wes Moore with the BioHub Maryland team at the launch of the NIBRT partnership, November 2023

An initiative of the Maryland Tech Council, the largest technology and life sciences trade association in the state, BioHub Maryland helps residents of all backgrounds pursue rewarding careers in life sciences by offering skills training, career resources, and access to 1,200+ job openings in life sciences. BioHub Maryland also helps life sciences companies at every stage grow by showcasing their career opportunities, training the next generation of life sciences talent, and providing strategic resources for raising capital.

San Jacinto College, Houston, Texas

San Jacinto College and NIBRT formed a partnership in October 2023 making San Jac the exclusive provider of NIBRT-licensed training in the southern part of the United States.

The new training center will offer regional biopharmaceutical training for new hires quickly, safely, and for a lower cost.

The biotechnology program will begin at the San Jacinto College South Campus in January of 2024 and will initially offer an onboarding certificate to equip new biomanufacturing professionals with the skills and knowledge they need to seamlessly enter the field. Future training offerings will encompass all aspects of biomanufacturing, specialized instrumentation, equipment training, and advanced techniques.

San Jacinto College will open The Center for Biotechnology, on the San Jacinto College Generation Park Campus in the first quarter of 2025. This state-of-the-art facility will provide comprehensive, hands-on training with realistic good manufacturing practices (GMP) simulated environments. The Center will offer an associate of applied science degree in biomanufacturing technology, and shorter credentials for post-graduates, to meet workforce needs.

6 Enviromental, Social and Governance (ESG)

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 through a process of stakeholder interviews, industry, and best practice review. The result is a three pilar 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.

Sustainability vision statement	*Delivering high-quality skills development and ethical research for industry in an inclusive, net-zero environment*		
Pillars	**Protecting the planet by minimising our environmental impact**	**Leading with innovation and investing in talent**	**Building an ethical, transparent and compliant culture**
Objectives	Reducing NIBRT's environmental footprint and transitioning to a net-zero organisation by promoting resource efficiency, reducing waste and plastic consumption.	Advancing industry through cutting edge research and training. Upskilling local communities to help broaden career prospects. Embedding a diverse, inclusive and equitable culture for employees and communities, while promoting a safe workplace.	Aligning governance, policies, strategies and performance with NIBRT's cultural values and focus areas. Managing ongoing ethics and compliance, and transparency in ESG performance reporting.
Delivering performance outcomes across the UN SDGS	SUSTAINABLE DEVELOPMENT GOALS 12 13	3 4 5 9	8 17

Translating intent to impact

To fulfil NIBRT's ambition to become a sustainability leader, 6 cross functional working groups were established in 2023, as outlined below, with responsibility for implementation of programmes and initiatives within the business to deliver on this strategy. The groups report to the NIBRT Senior Leadership team on a quarterly basis.

Working Group	Purpose
Sustainability	Continuously review the NIBRT facility with respect to energy, renewables, water, waste, transport, biodiversity and make proposals for positive change that supports the delivery of ambition in the NIBRT sustainability strategy.
Equality, Diversity and Inclusion	Drive improvements in policy, structure, and culture to promote EDI; celebrate diversity, increase understanding and respect for the diverse experiences of everyone at NIBRT.
Learning	Develop and improve the approach to site-wide learning, knowledge management and knowledge dissemination across all groups in the organisation and to develop appropriate tools to facilitate same.
Community Engagement	Develop and improve NIBRT's engagement and standing with the local community, which is defined as local residents, general public, children and schools, politicians, and civic society in general.
Safety	To maintain, improve (where necessary) and share standards of safety across NIBRT staff and external stakeholders.
Sports & Social	Support a working environment where we are creating and valuing a sense of enjoyment and fun (alongside delivery), by creating opportunities for employees to socialise, collaborate, celebrate and build relationships with colleagues through a calendar of diverse events.

An overview of progress to date and focus areas for 2023 is presented in the following sections:

Environmental:	*Sustainability, safety, facilities*	*Section 6.2*
Social:	*People and Culture*	*Section 6.3*
	Diversity & Inclusion	*Section 6.3*
	Community Engagement and Public Outreach	*Section 6.4*
	Societal impact	*Section 6.5*
Governance:		*Section 2*

NIBRT's inaugural annual ESG report will be published by 30th September 2024.

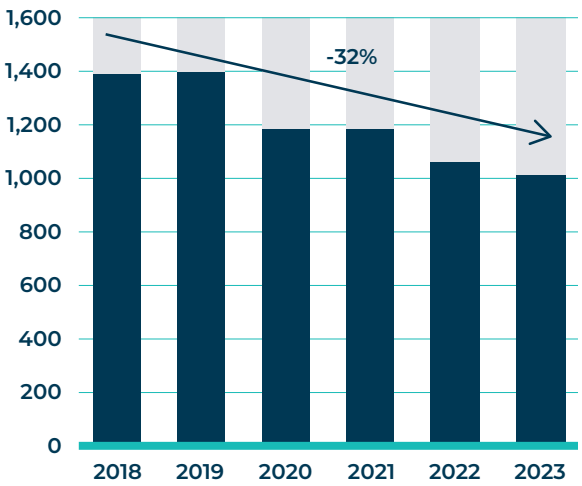
6.2 Environmental: Sustainability, Facilities

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 2023 included:

- A continued reduction in NIBRT's CO_2 emissions from energy consumption (as outlined below), a significant achievement given the fact that the facility footprint was increased by 2,000m2 in mid-2023.
- The installation of solar panels on the roof of our facility, which now generate circa 10% of annual consumption.
- The launch of a plan for the creation of a sanctuary for native flora and fauna in the grounds of the NIBRT facility, in collaboration with the Bee Sanctuary.

CO^2 Emissions (tonnes)



Key areas of focus for 2024 include:

- Completion of the calculation of NIBRT's Scope 1,2 & 3 emissions for 2022 and 2023, with periodic measurement thereafter to ensure measures and initiatives in place, are appropriate, to drive the achievement of a 10% annual reduction between 2024 and 2028.
- An increased focus on the tracking and reduction of waste across the NIBRT facility, including GMO waste.
- The continued end of life replacement of several pieces of facilities infrastructure including air compressors, air handling units and parts washers/autoclaves with more up to date energy efficient models.

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 2023 there were zero lost time accidents with 205 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 and technology additions to the training facility in 2023 to further enhance our service offering included:

- Nova BioProfile Flex 2: a cell counting nutrient and metabolite analytical instrument for integration with AMBR platforms
- Malvern Zetasizer Red Ultra: Dynamic Light Scattering (DLS) for particle size, zeta potential and molecular weight measurements
- Oxford Nanopore GridION MK1: a long read nucleic acid sequencer
- LABWIT 257L Ultimate Cell Stackable Shaking Incubator (x4)
- ExPERT STx Flow Electroporation Platform
- Downstream Training UFDF Systems Replacement
- AKTA Oligosynt
- AMBR 250 High Throughput
- Ambr 15 Cell Culture
- Biological Safety Cabinets (x12)
- CO^2 Incubator Shaker (x2)
- BioWelder & BioSealer
- Beckman Coulter HIAC 9703+ Sampler
- NucleoCounter NC-202 (x2)

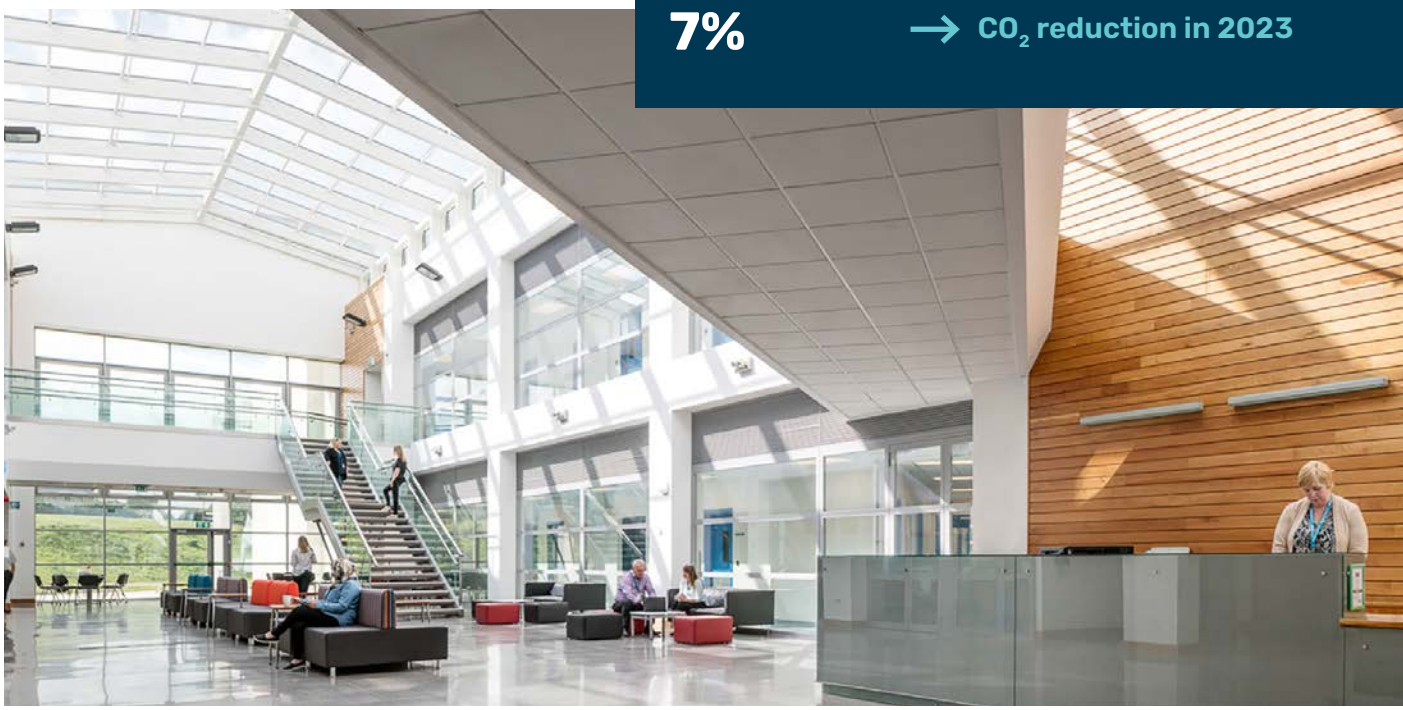
Facilities Facts and Figures

6,500m² → Building size

1,800m² → Advanced Therapies building

0 → Lost time safety incidents

7% → CO_2 reduction in 2023



6.3 Social: NIBRT People and Culture

NIBRT remains steadfast in its pursuit of being recognised as an employer of choice, dedicated to providing a unique and enriching experience for all employees and students. NIBRT strives every year to ensure that we attract and retain the world's best talent and that people who spend time in NIBRT *"shape the future of biopharma with us"*.

Pivotal to our success is our persistent focus on people and culture and 2023 was no different. We welcomed 22 new people to our team and supported 11 PhD students and hosted 18 visiting students across our research teams. Through a set of clearly defined people objectives and a committed future focused leadership team, NIBRT continues to elevate its standing as an employer of choice in the bioprocessing sector.

In 2023, our focus was on three core areas of the cultural experience in NIBRT, namely;

- Equality, Diversity and Inclusion (EDI)
- Learning, Development and Employee Wellbeing
- Reward and Recognition.

Significant strides were made in the journey toward **Equality, Diversity, and Inclusion,** with specific attention given to gender representation in leadership roles.

NIBRT boasts a 53:47 female to male gender balance. However, our responsibility as a national institute to strive towards ratios of this nature at all levels of the organisation led us to focus on our gender pay gap reporting, support frameworks like mentoring as well as the introduction of a Menopause Support Policy. Another important aspect of our EDI focus in 2023 was to deepen our understanding of cultural differences and celebrate our diverse employee community. Cultural Awareness and Inclusive Language training was provided to all staff. While our HR and Sports & Social teams prioritised many cultural events including Eid, Diwali and Hanukkah celebrations as well as International Women's Day, International Men's Day, National Wellbeing Day, Wear Red against Racism Day and Pride Month.

Learning, Development and Wellbeing are a cornerstone of NIBRT's commitment to employees. In 2023, NIBRT generously doubled its training budget per employee allowing our people to continue their personal and professional development. NIBRT also recognised that the last number of years have been challenging for some employees and students with mounting external pressures affecting financial wellbeing and mental health.

To assist with these challenges, NIBRT provided employees with access to a series of events and seminars focused on mental and physical health, financial well-being as well as a comprehensive Employee Assistance Programme available to employees and their families. Our award-winning Hybrid Working Policy continues to provide employees with vital flexibilities to balance many personal and professional priorities with 90% of NIBRT employees reporting they believe they are satisfied they can effectively manage their work life balance.

NIBRT have invested significantly in recent years in improving our **Toward Rewards** offering to employees. Decisions to increase pension contributions, enhance health care offerings, increase training budgets as well as responding to external pressures on salaries improved employee satisfaction with NIBRT's offerings by 10% in 2023. However, to ensure NIBRT remains competitive, a comprehensive Total Reward Review was undertaken by external experts to review our offering and affirmed NIBRT's competitive standing relative to its size and scale, positioning the organisation favourably to support strategic expansion plans.

The past year has seen NIBRT achieve notable success in advancing its **People Agenda**, earning recognition from peers with the HR team's inclusion as a finalist for the esteemed *HR Team of the Year Award* at the HR Leadership & Management Awards. Most importantly, 97% of respondents to an annual internal survey agreed that "NIBRT is a great place to work".

Looking ahead to 2024, a key focus will be on career planning initiatives for employees, celebrating difference and inclusion and further enhancing our innovative environment to achieve the exciting ambitions of NIBRT.

HR snapshot 2023

99 → Employees

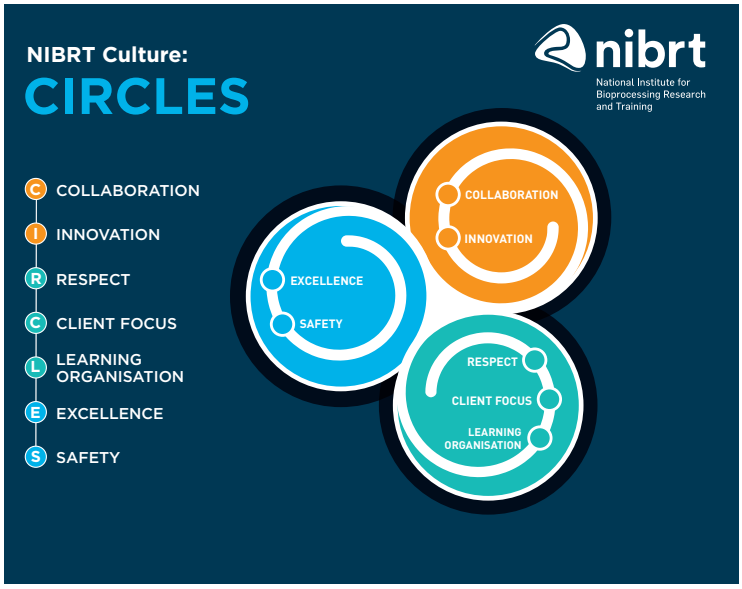
3 → Students

18 → Nationalities

16:35 → Irish: other nationalities

53:47 → Gender balance, female : male

97% → % agree NIBRT is a great place to work



NIBRT continues to foster and embed a highly open, inclusive, progressive, and innovation-friendly workplace, which recognises excellent performance while also respecting diversity and equality in all aspects of our activity. Our culture is created by our people and guided by our set of values depicted in CIRCLES.

6.4 Social: Community Outreach and Public Engagement

In 2023, the Community Engagement working group was established to further develop and improve NIBRT's engagement and standing with civic society. Key themes for the Community Engagement team included:

- Highlighting career opportunities in biopharma, especially at entry level from non-traditional sources
- Increase public awareness of the key scientific advances and challenges in biopharma
- Discuss the positive impact of biopharma on patients, the economy and society

Throughout the year the team organised a number of high impact events including:

In September, NIBRT hosted our inaugural **Culture Night** event. Culture Night / Oíche Chultúir is described as *"One Night for All …a national moment, celebrating culture, creativity and the arts and seeks to actively promote the belief that this rich and varied culture is alive, treasured and nurtured in people's lives, today and every day."*

The event at NIBRT was sold out as over 60 members of the public visiting for tours, experiment demonstrations and lively discussions on the role of biopharma in society.

The 9th annual **NIBRT Careers in Biopharma**[22] event returned to The Campus Cherrywood in April. This event is a unique opportunity for students, recent graduates, and individuals seeking to join the thriving biopharma industry in Ireland. It provides an opportunity to meet with leading employers, attend company presentations, learn about the latest training and upskilling programs, and network with industry peers. Companies attending the event included AbbVie, Amgen, APC Ltd and VLE Therapeutics, Biomarin, Bristol Myers Squibb, Cognizant, CPL, DPS Group, Eli Lilly, Eurofins, Janssen, KPC International, LSC, MSD Ireland, PDA Ireland, Pfizer, Sanofi, Takeda Ireland, WuXi Biologics and WuXi Vaccines, Zoetis.

The ever-popular **Transition Year** programme provides an opportunity for five transition year students to spend a week in NIBRT's training and research labs to gain insight and experience of the varied careers in biopharma.

The NIBRT Team at Careers in Biopharma

22 https://www.siliconrepublic.com/jobs-news/biopharma-companies-hiring-jobs-roles

The students are selected on the basis of an essay competition and in 2023 we were delighted to welcome students from schools in Cork, Dublin and Kildare.

NIBRT was pleased to host secondary school teachers on the **Amgen School of Biotech Excellence**[23] which provides training in molecular biology experiments for teachers with subsequent access to professional grade scientific equipment and curriculum-linked teaching materials to facilitate the teaching of laboratory practicals in the classroom.

For **Science Week** in November, NIBRT was delighted to host visits and tours from local secondary schools. In addition, NIBRT researchers had the great pleasure of visiting Third Class children in a local primary school to showcase some simple experiments and encourage their natural scientific curiosity.

In addition, NIBRT provided donations of lab equipment to local secondary schools and partnered with the Irish Cancer Society to provide matching funding to NIBRT's staff charity fund raising activities.

6.5 Societal Impact

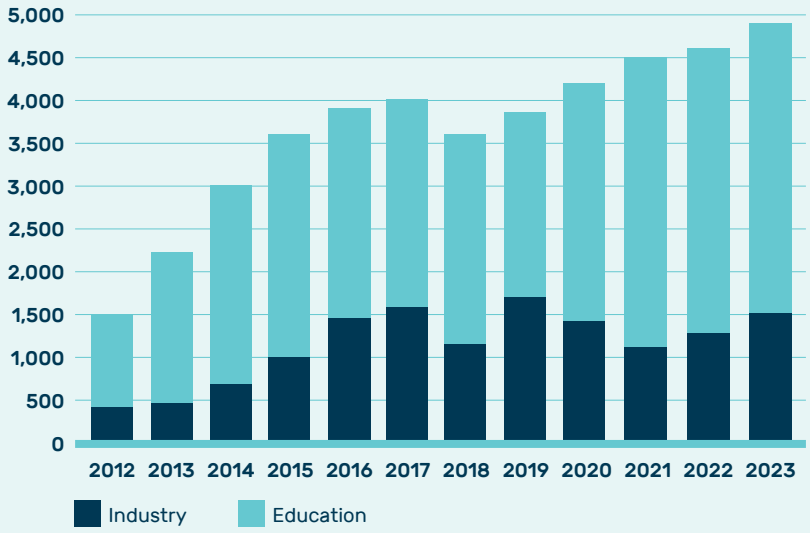
Trainees

Core to NIBRT's mission is to train the people who make life changing medicines. NIBRT now trains an average of 4,800 people per year which has had a significant positive impact on the growth of the biopharma sector in Ireland. Of particular note, is the Springboard+ programme which provides free upskilling training to jobseekers and 90% funding to those in employment. In 2023 NIBRT delivered training to 725 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

85,000+ → Biopharma employees in Ireland

€106 bn → Biopharma exports

4,900 → NIBRT Trainees per annum

725 → Springboard+ trainees in 2023

33 → Peer Reviewed Publications

6.6 Governance

See section 2 of this Report

23 https://amgenbiotechexperience.net/ie/

7 Awards and Annoucements

7.1 Awards

NIBRT is pleased to have won a wide selection of national and international awards. In 2023, NIBRT was awarded the Research Centre of the Year Award from the Irish Pharma Awards.

2023	Pharma Industry Awards: Research Centre of the Year Award
2022	Investors in Diversity Silver Award
2022	Investors in Diversity Bronze Award
2022	HR Leadership and Management Awards: Best Flexible Working Strategy
2022	Pharma Industry Awards: HR Achievement Award
2021	Pharma Industry Awards: Partnership Alliance of the Year Award for NIBRT Global Partners Programme
2020	Pharma Industry Awards: Innovation of the Year 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 2023 include:

- NIBRT launch CONCEPT a core facility for early-stage biotherapy development
- NIBRT global partner CASTL opens biomanufacturing training facility in Montreal, Quebec
- MedTrain+ Marie Skłodowksa Curie COFUND Career Development and Mobility Fellowship Programme 2023
- NIBRT hosts Chinese Minister of Education, Dr. Huai Jingping, strengthening bilateral ties in biopharmaceutical research and training
- NIBRT announces global partnership with BioHub Maryland to accelerate life sciences industry
- NIBRT and Trinity College Dublin announce the inaugural Don Panoz distinguished lecture
- NIBRT welcomes San Jacinto College as newest member of the NIBRT Global Partner Programme
- New NOA Course 'Lab Skills: Essential Lab Skills for Biopharma'
- NIBRT welcomes Professor Mark Smales as newest Principal Investigator, expanding expertise in bioprocessing research
- NIBRT appoints Dr Fiona Killard-Lynch as Director of Research and Innovation
- Free and 90% funded Springboard+ and HCI Programmes with NIBRT
- Range of New MSc programmes in partnership with ATU Sligo
- NIBRT Principal Investigators secure €1.25 million to support stable chemically modified mRNA vaccines
- Biopharma "Focus on the Future" Conference
- NIBRT welcome Professor Sakis Mantalaris to Principal Investigator team
- NIBRT research publish high impact paper in Nature Protocols

Hold the Date for 2024

April 13th 2024	10th Annual Careers in Biopharma
May 22-24th 2024	Global Partners meeting
May 24th 2024	NIBRT Research Conference

7.3 Testimonials

"When it comes to online biopharma manufacturing training, NOA is the clear leader. The courses are developed within NIBRT's state-of-the-art facility, ensuring an authentic learning experience. We trust NOA to deliver high-quality training."

Simon Covey
Training Lead WuXi Biologics

"Really enjoyable program. Perfect balance of practical application and theory from trainers who are clearly very knowledgeable. Training delivery was very clear and well structured."

Takeda Grange Castle

"NIBRT's world-class facilities and custom training programmes provide our teams with invaluable opportunities to deepen their product application knowledge in the bioprocessing and CGT fields. Feedback from colleagues has been excellent, and we look forward to honing our expertise with further NIBRT custom courses that help us excel when finding solutions for our customers' fluid path challenges."

Paul Stevens
Head of Global Training, Watson-Marlow Fluid Technology Solutions

"Fantastic facilities with great instruction, absolutely wonderful experience. The trainers made complex topics approachable and easy to understand".

BASF

"Since completing the course I have started working as an operator in Eli Lilly in Kinsale. My participation in the course definitely helped me secure this job and give me an advantage over other applicants as I had gathered some decent knowledge of the pharma industry. I had been working construction previous to doing the course so I'm gone in a completely different direction since completing. I would definitely think my career prospects have gone up significantly as there is great chance to grow within the company."

Wayne Hogan
Student, L6 Certificate in Biopharma

"The BioIndustry 4.0 course was relevant, topical and well presented, with up-to-date content and reference materials. The lecturers, and guest lectures, showcased the latest achievements and trends in biopharmaceutical production and quality-by-design, supported by smart technologies".

Richard Wareham
L9 Student, Bioindustry 4.0

"I thoroughly enjoyed my time at NIBRT and found the "Upstream and Downstream Bioprocessing" modules incredibly beneficial. It is an excellent option to get hands-on experience based on the theoretical modules learnt previously. The sessions were well-structured and delivered by highly knowledgeable tutors. The skills I gained from the modules gave me a solid foundation to enter the biopharmaceutical industry confidently. I highly recommend these modules to anyone pursuing a career in this field".

Felipe Zepeda
Student MSc in Biopharmaceutical Science

7.4 2023 snapshots

→ *Ruth Freeman, SFI at the opening of CONCEPT*

→ *Secondary school students visiting during Science Week*

→ *NIBRT team in Korea*

→ *NIBRT training team with Alfa Laval*

→ *Huai Jingping Chinese Minister for Education*

→ *Carl Bermingham at Careers in Biopharma*

→ *NIBRT team at Boston Biotech Week*

→ *NIBRT Team visiting Amgen*

→ *Biopharma Leaders Forum at NIBRT*

nibrt

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