



National Institute for  
Bioprocessing Research  
and Training

# Annual Report



Promoting world-class  
biopharma investment  
in Ireland

# 2019

# Thank you to all NIBRT Staff who contributed to a successful 2019

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## Who we are

- **NIBRT is a world-class institute, based in Dublin, Ireland whose mission is to deliver training and research solutions for the global biopharmaceutical manufacturing industry**
- **NIBRT partners with industry to support international best practice in all aspects of biologics manufacturing**
- **NIBRT's research and training building (6,500m<sup>2</sup>) features state-of the-art pilot scale manufacturing facilities**
- **Established with IDA Ireland, NIBRT partners with all higher education institutes to provide training and research infrastructure facilitates not previously available in Ireland**



## What we do

- **Train and educate over 4,700 people annually to work in all areas of biopharma manufacturing**
- **Collaborate with industry on scientific research to drive biopharma innovation**
- **Support major biopharma investment in Ireland**
- **Provide a test bed for new technologies and processes**

## NIBRT's vision

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

# 1 Message from NIBRT CEO



**2019 was a year of significant growth across all aspects of our business. We saw our highest yet number of trainees through the facility with expanded training solutions being availed of by our clients. We were delighted to welcome our new CSO, Professor Elizabeth Topp, to the Research team which had continued to expand its activities.**

Against a background of multiple national expansions and greenfield start-ups in Biologics manufacturing we were delighted to welcome record numbers of both education and industry clients to our facility. International Biopharma growth also saw significant increase in our international visitors. Springboard continues to be a key government initiative in providing talent for the sector.

We were delighted to see the Jefferson Institute of Bioprocessing officially open in May. We continue to support their operations in partnership.

We welcome Professor Elizabeth Topp as the new CSO. Liz will take over a research team that is growing significantly, now numbering 55 researchers. Liz joins us from Purdue University and her research in the formulation and lyophilisation arena is globally recognized.

Great progress was made on identifying the potential of Cell and Gene Therapies for Ireland. NIBRT took a lead in developing a national consensus with all stakeholders involved in this exciting and mushrooming space. This led to a White Paper being prepared with identified actions currently being worked on by the CGT Forum. I wish to thank all participants in this important work as we continue to grasp this great potential opportunity.

My 5 year tenure as CEO is coming to an end. I wish to thank the NIBRT staff for their dedication in delivering the great progress made in establishing all aspects of the business on a sustainable growth trajectory, and the NIBRT Board for their support.

I will look back on the last 5 years with great fondness and look on with great interest to NIBRT's future as it continues to increase its impact in supporting the growth of the sector. I wish my successor and all the NIBRT staff all the very best for the future. Enjoy the journey.

**Dominic Carolan**  
CEO, NIBRT

**“** We remain immensely proud to have the NIBRT world-class facility in our country. It's justifiably recognised as a global leader in the provision of cutting-edge training and is cited, time and again, as a key factor in attracting new biopharmaceutical investment to Ireland. **”**

→ **Minister Heather Humphries TD, Minister for Business Enterprise and Innovation, January 2019**

## 2 Message from NIBRT Chairman



**The global market for biopharmaceuticals is now over \$275 billion and continues to grow at 12 to 13 percent annually. The industry is now at a pivot point with evolution of advanced therapies which represent key challenges and opportunities for Ireland.**

The importance of biopharmaceuticals as a portion of total pharmaceutical revenue continues to expand, with greater than 40% of overall pharmaceutical industry R&D and products in the development pipeline being biopharmaceuticals. Nonetheless, significant challenges remain in the sector such as the fundamental complexity of bringing new therapeutics to market, pricing models, manufacturing challenges, Brexit uncertainties and global skills shortages.

Notwithstanding these challenges, in 2019 the Irish biopharma sector continued its strong performance in attracting foreign direct investment. As validation of the capabilities available in Ireland, companies with existing operations here such as MSD, Janssen, Allergan all made significant new biopharma investments in 2019. Of particular note, was WuXi Vaccines decision to invest a further €200m in Dundalk creating 200 new high value jobs. This investment builds on Wuxi Biologics current project to build the world's largest single-use facility in Dundalk, employing 400 people.

While these investments are very welcome, there is no room for complacency. In order to remain competitive Ireland needs to maintain a sharp focus on its core value proposition of compliant, reliable and cost effective advanced manufacturing. But this alone is not enough. In order to sustain and grow operations in Ireland, it is key that all stakeholders focus on developing the innovation and research capability of the sector. This will help ensure Irish operations continue to be a location of choice for future investments, in an increasingly competitive sector globally and as the industry pivots to more targeted and personalised medicines, requiring lower volumes but greater technical complexity to develop and manufacture.

In this context, the rapid advance in complex therapeutics such as cell and gene therapies represents a significant opportunity for Ireland to remain a global leader in the biopharmaceutical sector for the future. NIBRT looks forward to playing its part in advancing Ireland's capabilities in support of these exciting new advances in science, which have the potential to change the course of patient outcomes for many complex and currently unmet medical conditions.

The role of NIBRT and its partners to support these investments is key and the Board was pleased to see another very strong performance from the NIBRT team including:

- > Training 4,700 people
- > Expansion of the Global Partner Programme with partners in Philadelphia and Sydney
- > The launch of the NIBRT Online Academy
- > Progressing the Cell and Gene Forum Therapy (CGT), publishing the white paper, commencing CGT training and commissioning concept design studies with PM Group to provide future dedicated labs and training capabilities in CGT
- > Further development of the Biopharma 4.0 Alliance with BCG
- > Expansion of research activities and appointment of Prof Liz Topp as Chief Scientific Officer (CSO)

As we reflect on a very successful year, I'd like to thank the NIBRT team for their outstanding performance, as well as my Board colleagues and IDA Ireland for their continued support of the Institute. In particular, I would like to acknowledge the exemplary leadership of Dominic Carolan who steps down in Q2 2020 after 5 years as NIBRT CEO and we wish him well in his retirement.



The success of the Irish biopharma industry is well noted and built on solid foundations. The global industry is now at an inflexion point and defining a broad Government life sciences strategy between all stakeholders, will greatly enhance Ireland's competitiveness for new investments in manufacturing and research. However, there is a "need for speed" and stakeholders need to move immediately and at pace to keep pace with competing jurisdictions.

NIBRT is ready and well-positioned to support and enable this next phase and we look forward with confidence to the opportunities ahead in 2020 and beyond.

**Brendan O'Callaghan**

*NIBRT Chairman,  
SVP and Global Head Biologics Platform, Sanofi*

## NIBRT Board 2019

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

# 3 2019 NIBRT by the numbers



# 4 The Biopharma Industry in Ireland – 2019



**The biopharma industry in Ireland continues to show strong growth with significant investments announced throughout 2019. However, the future wave of biopharma investment which includes next generation biologics, provides significant challenges which requires a coordinated strategy from all stakeholders if Ireland is to maintain its leadership position in biopharma manufacturing.**

The reasons for Ireland’s success in biopharma manufacturing are multi-faceted and involve a broad alignment between collaborative stakeholders. The access to a well-educated and highly motivated workforce is at the core of Ireland’s value proposition. In addition, Ireland’s well defined corporate tax and EU membership provide a high level of certainty for investors. This is underpinned by a network of global leaders in engineering and sub-supply services. This has created a legacy and track record with excellent regulatory oversight that attracts repeat investment over many decades.

2019 was another strong year for foreign direct investment with a number of significant announcements across the regions including:

- > WuXi Biologics to build €216m vaccine production facility in Dundalk
- > Legend Biotech Ireland, Ltd. celebrates the official opening of its European HQ in Dublin, Ireland

- > Janssen invests €300m and doubles size of Cork facility
- > IQVIA Expands Presence in Ireland - creation of 100 new jobs by global human data sciences innovator
- > Drug giant MSD seeks permission for major expansion of Carlow plant - Company expects to add 170 jobs to 400-plus already working at manufacturing plant

In December 2019, NIBRT was pleased to partner with BiopharmaChemical Ireland and Irish Pharmaceutical Healthcare Association to host the BioPharma Policy Forum, which drew 60 leaders in industry, policymaking, research, academia, clinical care and patient advocacy to discuss the future for medicines innovation in Ireland. This Policy Forum aimed to align with and contribute to *Future Jobs Ireland*, the Government’s enterprise agenda.



## Europe’s Biopharma Sector

Across the EU in 2016 the biopharmaceutical industry supported:

**1.4%**  
of the EU’s  
GDP

**€206 billion**  
in gross  
added value

**2.5 million**  
jobs across the EU,  
**46%** women

Key conclusions presented by PwC at the Policy Forum highlighted the sectors contribution to economic development<sup>1</sup>, including:

- Ireland has an outsized biopharmaceutical manufacturing presence, relative to other big sectors and to other similar sized countries. High quality biopharma jobs are well distributed throughout Ireland. This should not be taken for granted, especially considering product life cycles, industry consolidation patterns and the draw of emerging markets.
- The development of next generation biologics is likely to increase significantly in the coming years. For many companies, the pipeline of complex biologic medicines is strong. Although significant manufacturing, supply chain and commercialisation challenges have to be addressed.
- Technology, medical technology and biopharmaceuticals are converging, similarly the gap between industry, policy, research and clinical leaders is also narrowing.

- Defining a broad Government life sciences strategy between all stakeholders, will greatly enhance Ireland’s competitiveness for new investments in manufacturing and research. However, there is a “need for speed” and stakeholders need to move immediately and at pace to keep pace with competing jurisdictions.

## Future Trends

While the biopharma sector is highly complex, three key trends have emerged that create significant challenges and exciting opportunities for Ireland:

### Re-skilling revolution

From 2017-2019, NIBRT have worked with The Medicine Maker on a global survey of trends in biopharma manufacturing. Over this 3 year period, the biggest challenge to the future growth of the sector cited by respondents is the access to talent.



## Ireland’s Biopharma Sector

75+

Biopharma companies

€10 billion

Capital investment since 2009

30,000

Direct employment

50%

of top 20 products were manufactured in Ireland

€73 billion

Biopharma exports 2018

15

of the top 20 biopharmas have manufacturing in Ireland

1. PwC Report Dec 2019: BioPharma Policy Forum: Medicines, Investments and Innovation An Industry Initiative, Supported by the Government of Ireland

A majority (78%) of the survey of national and international respondents had difficulty filling positions. The most important skill set for new hires was identified as scientific, engineering, and technical skills (80%), with the most effective types of training identified as practical training in a lab and/or pilot plant environment (84%) and on-the-job training (82%).

In November 2019 at the Future Jobs Ireland Forum at TCD, the World Economic Forum (WEF) delivered a keynote on “*The future of work and skills: Global megatrends and implications for Ireland - a reskilling revolution is needed*”<sup>2</sup>. Their prediction was by 2022, the core skills required to perform most roles across all sectors will change by 42% and everyone will require an extra 101 days of learning. To respond to this challenge the WEF encouraged stakeholders to focus on lifelong learning and upskilling, future readiness and employability, innovative skills funding models with a high degree of skills anticipation and job market insight.

## Cell and Gene Therapies

The commercial value of Cell and Gene Therapies (CGTs) is forecasted to grow exponentially over coming years to a very substantial \$10Bn – 30Bn by 2025<sup>3</sup>. As new pathways for disease treatment and cure command growing attention and investment, the total number of next generation biologics (the majority of which are CGTs) in the development pipeline reached 269 by the end of 2018, up from 120 in 2015. Interestingly, emerging biopharma companies now account for over 70% of this R&D pipeline, thus leading to potential collaboration and foreign direct investment opportunities. However, bringing new therapies to patients remains high risk involving long term commitment. For example, an additional four Alzheimer’s therapies were discontinued in 2018 bringing the total over the past ten years to over 85 failures, while new drugs launched in 2018 took a median of 13.6 years from the time of first patent filing to launch<sup>4</sup>.

While Ireland has some good activity in the CGT space, the overall level is modest compared to other countries. For example, Ireland initiated just four clinical trials for next generation biologics between 2014-2018<sup>5</sup>, while in UK the number of clinical trials have been growing on average of 25% year-on-year since 2013 with 127 ongoing trials in 2019 (12% of world’s total)<sup>6</sup>.

## Industry 4.0

As biopharma manufacturing becomes increasingly globalised, increasingly complex and more highly regulated, the sector must become more effective and cost efficient at manufacturing its products. However, biopharma manufacturing is currently significantly behind other advanced manufacturing sectors in its adoption of disruptive Industry 4.0 technologies. The implementation of these technologies in the biopharma industry could lead to productivity improvements of up to 40% especially when combined with lean methodologies. Whilst Europe has typically been a leader in biopharma innovation, the industry as a whole is behind other industries and the adoption of next generation technologies is key to maintaining this advantage. Furthermore, studies from the World Economic Forum indicate that 70% of businesses investing in technologies such as big data analytics, artificial intelligence or 3D printing are not able to take the projects beyond pilot phase.

## Call to action

The success of the Irish biopharma industry is well noted and built on solid foundations. The global industry is now at an inflexion point and defining a broad Government life sciences strategy between all stakeholders, will greatly enhance Ireland’s competitiveness for new investments in manufacturing and research. However, there is a “need for speed” and stakeholders need to move immediately and at pace to keep pace with competing jurisdictions.

### Killian O’Driscoll

*NIBRT Director of Projects*

2. Saadia Zahidi, Managing Director, World Economic Forum, *The future of work and skills: Global megatrends and implications for Ireland - a reskilling revolution is needed*, Nov 2019
3. IQVIA White Paper (2018): Changing the game – Cell and gene therapies lead the Advanced Therapies revolution
4. The Changing Landscape of Research and Development - Innovation, Drives of Change, and Evolution of Clinical Trial Productivity - Report by the IQVIA Institute for Human Data Science
5. Alliance for Regenerative Medicine –Clinical Trials in Europe: Recent Trends in ATMP Development
6. <https://www.biopharma-reporter.com/Article/2020/01/22/UK-clinical-trials-in-cell-and-gene-doubles>



Illustration of the proposed WuXi Vaccines Facility Dundalk

## 5 WuXi Biologics adopts Ireland as its hub for global biologics manufacturing within Europe

**On a green-field site near Dundalk, equidistant from Dublin and Belfast on Ireland's east coast, WuXi Biologics, a leading global open-access biologics technology platform company, is constructing 'The Factory of the Future' for biologics manufacturing.**

WuXi Biologics new Dundalk facility is set to become the largest biologics manufacturing facility using single-use bioreactors in the world. To employ 400 people and currently actively hiring talent to manufacture biologics for global markets, the WuXi Biologics facility will be in commercial manufacturing by 2021.

Immediately close-by on an adjoining site, its subsidiary WuXi Vaccines recently announced plans to establish a major vaccines facility on the WuXi Biologics Dundalk Campus, to employ an additional 200 people when it goes operational in 2024.

Offering end-to-end solutions to empower organizations to discover, develop and manufacture biologics from concept to commercial manufacturing, WuXi Biologics' services are designed to accelerate and transform the discovery, development and manufacturing process for the latest generation of biopharmaceutical drugs, whilst also reducing the cost of production. WuXi Biologics will use the new Dundalk facility to ensure that its innovative manufacturing technology is accessible to global clients producing leading medicines in an EU regulated environment.

The WuXi Biologics investment is a substantial win by IDA Ireland for Dundalk and Ireland, reinforcing Ireland's standing as a global hot-spot for global biopharma operation.

With substantial growth since the business was founded in 2010, WuXi Biologics is emerging as one of the most influential players in the global biologics industry. It is the only company in China to-date which has received approval from both US and EU regulators to manufacture biologics for the global market and the Dundalk facility is the company's first manufacturing investment in Europe.

Headquartered in Wuxi, Jiangsu, China with four operation sites located in Wuxi, Shanghai and Suzhou, respectively, WuXi Biologics is the dominant leader in China's biologics services market. As a contract manufacturing business, WuXi Biologics is working with 13% of all the known new drugs currently in the discovery/development phase of the global biologics pipeline and it currently counts most of the world's leading biopharma companies as customers.

The company is unique in that it operates the world's only open-access biologics technology platform. This offers end-to-end solutions to partner organisations, including some of the world's leading biopharmaceutical companies, who use it to discover, develop and manufacture biologics from initial concept through to commercial manufacturing. With world-class research expertise, state-of-the-art technologies and access to proprietary methodology, WuXi Biologics can enable partner companies identify candidate drugs for the full spectrum of disease areas.

At an investor conference in June 2018, Dr. Chris Chen, CEO of WuXi Biologics, reported that 13 of the top 20 pharma companies globally work with WuXi Biologics to support manufacturing production. He noted that 224 integrated projects were then being developed on the company's proprietary platforms, accounting for approximately 13% of global biologics development projects.

Commenting he said, the company witnessed 57 new integrated projects, making up approximately 28% of global new biologics projects, with 13 projects then at the phase 3 clinical or late stages. He noted that WuXi Biologics employs one of the largest biologic's development teams in the world. WuXi Biologics, he said, can enable global partners to submit 60 Investigational New Drug (IND) applications and 5 Biologic License Applications (BLA) each year. WuXi Biologics, he added, is poised to be a global leading CMO with total manufacturing capacity online by 2022 exceeding 280,000 L of bioreactor volume.

With state-of-art technology, fast timeline for project delivery, excellent execution track record, the company, he added, aims to grow market share in the future driven by its "Follow-the-Molecule" business model and its unique "Global Dual Sourcing within WuXi Bio" manufacturing paradigm.

*Information relating to open roles in WuXi Biologics in Ireland can be accessed at; [www.wuxibiologics.com/careers/](http://www.wuxibiologics.com/careers/)*

## Why Ireland?

WuXi Biologics' Dundalk project is the company's first European manufacturing investment, representing a major vote of confidence in Ireland as a global hub for the fast-growing biotechnology industry. WuXi Biologics looked at 10 location options in Europe before settling with IDA Ireland encouragement on a green-field site in Dundalk and the Dundalk Campus is of huge strategic significance for WuXi Biologics. Dundalk is located within an hour's drive of Dublin airport and 10 highly accomplished third level colleges which turn out great talent each year in terms of the local skills-pool.



Ireland is home to ten of the top ten biopharmaceutical companies globally. The industry is a significant contributor to the Irish economy with over \$10bn invested in new biologic production facilities in the last decade. 32,000 people are directly employed and over 90 international biopharma manufacturing operations contribute €73bn in annual exports, making Ireland one of the largest exporters of medicines and pharmaceutical products in the world.

Alongside this, Ireland supports a thriving ecosystem of activity generated by the expansive clusters of multinational and indigenous biopharmaceuticals businesses operating around the country, providing strong talent supply and an excellent research and education ecosystem which a top tier biologics operation can thrive on.

Ireland's National Institute for Bioprocessing Research and Training (NIBRT) for example, provides a global centre of excellence for training and research in bioprocessing and offers world-class facilities and expertise to ensure the industry has a sustainable supply of suitable trained staff. In addition, Ireland is the only English language speaking country in the EU post Brexit and it also happens to be well-aligned with the US FDA operation.

Operating from Ireland will see the Dundalk facility manufacture drugs for the European market. It also puts a local WuXi Biologics' presence on the map for European pharmaceutical and biopharma drug developers requiring cGMP-compliant manufacturing facilities.

## 6 NIBRT Research and Innovation



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

The NIBRT Research Team aims to be the world leader in the development of innovative technologies in biopharmaceutical manufacturing, and the premier manufacturing resource for the global biopharmaceutical industry. Inspired by the manufacturing challenges facing the industry, we strive to make transforming discoveries in bioanalysis, cell engineering, bioinformatics and bioprocess engineering. We aspire to discoveries that constitute fundamental advances in their fields, and also have practical application for manufacturing recombinant proteins, vaccines and cell and gene therapies (CGT).

The Research Team had a number of successes in 2019 that demonstrate progress toward these goals. For example, NIBRT Principal Investigators Prof. Mike Butler and Prof. Niall Barron both received funding through the Science Foundation Ireland / Enterprise Ireland Technology Innovation Development Award (TIDA) programme. TIDA enables researchers to progress their research toward commercial application. Mike's TIDA project involves chemoenzymatic remodelling of monoclonal antibodies (mAbs) to reduce the heterogeneity generated in cell culture. The approach creates a better-defined product and allows the most potent mAb forms to be identified. Niall's project involves improving CHO cell productivity using an epi-transcriptomic approach, with the goal of increasing titres and reducing the cost of recombinant protein production. NIBRT's success in TIDA demonstrates the commercial potential of many of the technologies our PIs are developing.

In 2019, NIBRT PI Colin Clarke launched STACCATO, a Marie Skłodowska-Curie European Industrial Doctorate programme.

Colin serves as the lead for the four-year, €2.9 million international project. In collaboration with industry partners, STACCATO is developing state-of-the-art single cell analysis methods to characterize the heterogeneity of cell populations. The methods will be applied to both recombinant protein expression and cell-based therapies and will leverage statistical and computational methods to analyse the results. STACCATO brings together academic institutions, small businesses and leading instrument manufacturers to provide unique doctoral training for a select cohort of student trainees. The project launched in Dublin in mid-November 2019, with the trainees attending immersive training in NIBRT's pilot plant facilities.

Adeno-associated virus (AAV) is a common vector for gene therapy, but there are challenges associated with manufacturing yield and quality assessment. In 2019, NIBRT PIs Prof. Jonathan Bones and Prof. Niall Barron began a new collaboration with Allergan Biologics to address three critical challenges in AAV production: optimizing the cell culture process for AAV of various serotypes, establishing vectors and transfection/transduction conditions to minimize incorrect packaging, and investigation of sensitive analytical methods to differentiate full and empty AAV capsids. The project will progress both the analytics and manufacturing process for AAVs, helping to make high quality AAV medicines a reality.

Projects like STACCATO and the Allergan Biologics project reflect a growing interest in CGTs in Ireland, and in creating programmes at NIBRT that support CGT manufacturing. NIBRT's Prof. Niall Barron leads the Cell and Gene Therapy Forum, a group comprised of industry and academic scientists interested in developing CGT in Ireland.



In 2019, the group produced a white paper entitled “*The Case for Supporting Cell and Gene Therapy Manufacturing in Ireland*”, describes the current state of play in CGT globally, outlines potential opportunities for Ireland, and is now managing the implementation of the associated action plan.

In 2019, the accomplishments of the NIBRT Research Team were recognized by a number of awards, including the Pharma Industry Project of the Year Award (Dr Colin Clarke and Siemens), and Prof. Elizabeth Topp was awarded the Michael J. Pikal Distinguished Scholar Award in Pharmaceutical Processing from the National Institute for Pharmaceutical Technology and Engineering (NIPTE, USA).

NIBRT students also had great success in 2019, particularly with regards to science communication. Hayden Wilkinson, a MSc student working in Dr Fahey’s GlycoScience lab, won the Irish final of FameLab on the 11th April with his talk about “Designer Babies - The Good, the Bad and the Ugly” – which outlined the pros and cons of using genome-editing to engineer HIV-resistant babies. Hayden also received second prize in the three-minute thesis (“threesis”) competition at the National University of Ireland Galway (NUIG) in October.

I’m honoured to join this group of innovative and productive investigators as NIBRT’s Chief Scientific Officer, a position I assumed on October 1, 2019. My own research interests are in protein formulation and stability, with particular emphasis on lyophilized solids. My addition to the Research Team helps expand NIBRT’s research scope into the drug product space, enabling us to better partner with industry. I’m grateful for the warm welcome I’ve received from everyone at NIBRT, and from scientists across Ireland, and I look forward to working with the Research Team to advance NIBRT research in the years to come.

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

## Characterisation and Comparability

2019 was another exciting year for NIBRT’s Characterisation and Comparability Lab (CCL) under the direction of Prof Jonathan Bones. The CCL group increased their focus on advanced characterisation of biopharmaceuticals using liquid phase separations coupled to high resolution mass spectrometry. Impactful output from the group included the development of ion exchange separations coupled to native mass spectrometry for characterisation of charge variants of mAbs and other biopharmaceuticals using intact mass analysis. This approach captures natural dynamic range and generates an understanding of how key posttranslational modifications are distributed across the therapeutic protein.

The CCL group were also heavily involved in the development and application of multi-attribute method (MAM) strategies for routine monitoring of product quality attributes and also the development of automated platforms for real time process characterisation.

Other outputs included advanced methods for quantitative host cell protein analysis and evaluation of HCP behaviour during optimisation of downstream process unit operations, particularly depth filtration using functionalised membranes.

The CCL continued to strengthen their collaborative interaction with Thermo Fisher Scientific and also kicked off a number of collaborative projects with Irish, UK and European based biopharmaceutical manufacturers, which broaden and diversify the group’s activities into characterisation of gene therapy and other advanced therapeutic medicinal product areas.



## Key NIBRT Research Publications in 2019

- 1 Continuous translation of circularized mRNA improves recombinant protein titer.
- 2 Comprehensive characterisation of the heterogeneity of adalimumab via charge variant analysis hyphenated on-line to native high resolution Orbitrap mass spectrometry.
- 3 NIST Interlaboratory Study on Glycosylation Analysis of Monoclonal Antibodies: Comparison of Results from Diverse Analytical Methods.
- 4 Reinventing the Wheel: Synthetic Circular RNAs for Mammalian Cell Engineering.
- 5 Improvements in single-use bioreactor film material composition leads to robust and reliable Chinese hamster ovary cell performance.
- 6 Transcriptomic analysis of IgG4 Fc-fusion protein degradation in a panel of clonally-derived CHO cell lines using RNASeq.
- 7 Cytoplasmic conductivity as a marker for bioprocess monitoring: Study of Chinese hamster ovary cells under nutrient deprivation and reintroduction.
- 8 A Robust and Versatile Automated Glycoanalytical Technology for Serum Antibodies and Acute Phase Proteins: Ovarian Cancer Case Study.
- 9 Identification and tracking of problematic host cell proteins removed by a synthetic, highly functionalized nonwoven media in downstream bioprocessing of monoclonal antibodies.
- 10 Progression of change in membrane capacitance and cytoplasm conductivity of cells during controlled starvation using dual-frequency DEP cytometry.

## Cell Engineering

The Cell Engineering Lab, led by Prof. Niall Barron, has recently moved to new dedicated lab space within NIBRT to accommodate expansion in group numbers. This includes a new PhD student (Alan Foley) who is working on mitochondrial heteroplasmy in CHO cells at the single-cell level as part of the Marie Skłodowska-Curie project “Staccato” led by Dr. Colin Clarke.

2019 also saw the completion of an SFI TIDA project by Dr. Nga Lao which identified novel epitranscriptomic-based engineering strategies for improving recombinant protein production. Group members presented their work at several international conferences including PhD student Niamh Keogh who was invited to present her work on using CRISPR libraries to engineer CHO cell lines at the PEGS 2019 conference in Lisbon.

Another exciting development was a new EI Innovation partnership project in collaboration with Allergan in the gene therapy space. This project, co-led by Prof. Jonathan Bones, will examine novel approaches to improving the production and characterisation of Adeno-associated virus as a vector for gene therapies. This project represents an important landmark in NIBRT’s ambition to increase our research activity in the area of ATMP manufacturing.

## GlycoScience

Dr Radka Fahey continues to grow her collaborative network focusing on a number of glyco-analytical projects with national and international groups (e.g. Maastricht University, NL, and University of Naples, Italy) as well as SFI funded research centres, APC Microbiome Institute and CÚRAM.

Dr Fahey with Dr Zsuzsanna Kovács have secured funding from EU Marie Skłodowska-Curie Individual Researcher Fellowship on “Identification of non-invasive clinical markers for diagnosis of endometriosis (GLYCOMENDO)”. This funding will support Dr Kovacs’ work as a Postdoctoral Researcher in the GlycoScience group. Dr Fahey and Dr Roisin O’Flaherty secured collaborative funding from Prof Arturo Gonzales-Quintela, University of Santiago de Compostela on “IgG N-glycome abnormalities in prevalent inflammatory diseases in adults”. Dr Fahey is also a collaborator on a projected funded through the ERC Proof of Concept programme, which is led by Prof Paula M Mendes, University of Birmingham. This project is focused on the development of an accurate, early diagnostic screening tool for ovarian cancer



*NIBRT's Hayden Wilkinson accepting his Fame Lab Ireland Award*

Students in the group won a number of awards with Hayden Wilkinson, Dr Fahey's MSc student, winning the Fame Lab Ireland final on the 11th April with his talk about "Designer Babies - The Good, the Bad and the Ugly". Hayden also received second prize in the three-minute thesis ("threesis") competition at the National University of Ireland Galway (NUIG) in October.

The third award was to Kieran Joyce, Dr Fahey's visiting PhD student from CURAM, who received the Trainee Podium Award for Outstanding Scientific Research at the Orthopaedic Research Society Philadelphia Spine Research Society (ORS PSRS) conference in Pennsylvania. Kieran's presentation was entitled "Identification of glycomic-based therapeutics: Complete characterization of the N-glycan profile of the intervertebral disc in IVD degeneration".

## Bioinformatics and Data Analytics

2019 was another important year for the Systems biology and Data Analytics group at NIBRT which is led by Dr. Colin Clarke. The NIBRT-Siemens collaboration was awarded "Small Project of the Year" at the Irish Pharma Awards. The STACCATO project, a European Industrial Doctorates project funded under the Marie Skłodowska-Curie Action of Horizon 2020, launched in January 2019 and all 11 ESRs have been hired across Europe. The first training event was hosted in NIBRT in November 2019 with students receiving hands-on training in the NIBRT facility. Krishna Motheramgari submitted his PhD thesis to DCU, the second PhD student from the group to successfully submit their thesis. An Enterprise Ireland project was funded in collaboration with an Irish start-up company Valitacell.



## NIBRT Research 2019

34 publications  
in 2019

18 collaborations

5 Principal  
Investigators

55 researchers

45 conference  
presentations

45.5%  
of research income  
funded by Industry

€1.2 million  
Equipment donations in 2019



The NIBRT CTG Team with the Kerry Group

## Cell Technology

The Cell Technology Group (CTG) led by Prof. Michael Butler in 2019 included 8 laboratory-based personnel: a post-doctoral Research Manager, two PhD students, four Post-Doctoral Researchers and a summer intern student. Prof. Michael Butler was awarded four new grants that promoted research into cell line monitoring in bioprocesses as well as studies on culture media formulations that support high productivity of biopharmaceuticals from key cell lines. A major innovation has been the establishment of a specific threshold of cytoplasmic conductivity that distinguishes viable and non-viable cells. This work has generated considerable interest in the possible application to on-line cell monitoring as an alternative to the century-old trypan blue methodology.

Support for this comes from Canty, Aber Instruments and Ovizio as well as being the major part of 8 of the 11 invited oral presentations this year. The research on isolation of bioactive components in plant hydrolysates continues to be supported by the Kerry Group and an SFI/EI award now supports a project on the chemoenzymatic remodelling of monoclonal antibodies to obtain higher bioactivities. The output of the group this year has included 14 oral presentations, 3 conference posters and 14 co-authored papers.



*The NIBRT and Siemens BioMAC project won the prestigious Project of the Year at the Irish Pharma Awards. The Pharma Industry Awards provide a platform from which to recognise and celebrate the leaders and innovators from across Ireland's pharmaceutical industry.*

# 7 Research Case Study

## Investigating Host Cell Contaminant Removal During Downstream Processing

Host cell contaminants, such as residual host cell DNA (hcDNA) and host cell proteins (HCPs), continue to be a hot topic in biopharmaceutical manufacturing as it is imperative to remove or reduce the presence of these contaminants to acceptable limits to minimise any potential risk to patients upon drug product administration. In June 2019, NIBRT published the output of their collaborative engagement with 3M in the *Journal of Chromatography A* that focused on identifying and tracking the behaviour of hcDNA and HCPs. The study highlighted the beneficial effects of chromatographic clarification with Emphaze™ AEX Hybrid Purifier from 3M, compared to conventional clarification processes, for early removal of problematic HCPs during downstream processing of mAbs.

Researchers from the Characterisation and Comparability Lab at NIBRT developed a suite of sensitive analytical methods based on liquid chromatography and high resolution Orbitrap mass spectrometry (LC-MS) for HCP identification and quantitation and qPCR measurement of residual hcDNA. Working in close collaboration with scientists from 3M, the team at NIBRT applied their analytical platforms to demonstrate the excellent performance of the Emphaze™ AEX Hybrid Purifier during clarification of cell culture harvest compared to conventional depth filtration. It significantly removed hcDNA (2.3 log reduction) from the process stream and Analysis revealed a 38 fold decrease of HCPs.

The removal of specific problematic HCPs was also tracked. Chromatographic clarification using the Emphaze™ AEX Hybrid Purifier combined with Protein-A affinity purification resulted in removal of histones from the process stream along with complete removal or significant reduction in the levels of potentially degradative HCPs such as 78 kDa glucose-regulated protein, nidogen-1, heat shock proteins, actin, serine protease HTRA1 and matrix metalloproteinase-19.

Potentially immunogenic HCPs such as C-X-C motif chemokine 3, protein S100-A6 and PLBL2 were also significantly reduced using chromatographic clarification with Emphaze™ AEX Hybrid Purifier and then removed from the process stream following Protein-A affinity chromatography.

Protein A cycling experiments were also performed using both the conventional and Emphaze™ AEX Hybrid Purifier clarified process streams with either no, mild or harsh sanitisation conditions to evaluate the potential beneficial effects of the modified clarification process on Protein-A lifetime. Harsh sanitisation was required when cycling process streams clarified using conventional depth filtration whereas when using the Emphaze™ AEX Hybrid Purifier minimal HCPs were found to be present post Protein-A even when no sanitisation was performed due to simplification of the cell culture fluid prior to Protein-A loading. Overall, the inclusion of the Emphaze™ AEX Hybrid Purifier offered the potential to increase Protein-A lifetime and potentially to compress the overall downstream process by removal of subsequent polishing steps.

For further information, the complete article and associated supporting information is available at <http://bit.ly/2TuPXXg>. To learn more about how NIBRT can assist you with host cell contaminant analysis contact us at [info@nibrt.ie](mailto:info@nibrt.ie).

**3M** Science.  
Applied to Life.™

# 8 Cell and Gene Therapy

## Winning the next wave of investment



*The single-use pilot plant at NIBRT*

**Ireland has established a hard won reputation as a centre of excellence in biopharma manufacturing mainly focused on monoclonal antibodies. However, the new wave of biopharma investments will include next generation biologics (mainly cell and gene therapies) which represent complex challenges to manufacture economically. How can Ireland win this next wave of manufacturing investment?**

The commercial value of Cell and Gene Therapies (CGTs) is forecasted to grow exponentially over coming years to a very substantial \$10Bn – 30Bn for 2025<sup>7</sup>. As new pathways for disease treatment and cure command growing attention and investment, the total number of next generation biologics (the majority of which are CGTs) in the development pipeline reached 269 by the end of 2018, up from 120 in 2015.

Interestingly, emerging biopharma companies now account for over 70% of this R&D pipeline, thus leading to potential collaboration and foreign direct investment opportunities.

In January 2019, the US Food and Drug Administration stated that it expects to see more than 200 applications per year by 2020 requesting permission to begin CGT trials. The agency already has more than 800 such applications on file and plans to hire some 50 clinical reviewers to handle the surge<sup>8</sup>. However, the CGT market is still emerging and uncertainties remain, in Europe 10 CGT products have been authorized since 2009 with 4 subsequently withdrawn<sup>9</sup>.

7. IQVIA White Paper (2018): Changing the game – Cell and gene therapies lead the Advanced Therapies revolution

8. <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm629493.htm>

9. <https://labiotech.eu/features/atmp-cell-gene-therapy-ema>

**“** PM Group is delighted to be appointed to work on the concept design of NIBRT’s new CGT training facility. It is an exciting next step and builds on our track record of innovation in the CGT space as well as builds on our partnership with NIBRT. **”**

→ Eileen Lee, Dublin Office Operations Manager, PM Group

Nonetheless, CGTs have shown some very promising, in some cases striking, clinical outcomes in a number of trials. For example, Novartis was the first to launch a CAR-T therapy (which is combination of cell and gene therapy), called Kymriah, in 2017. This one-time treatment for B-cell acute lymphoblastic leukaemia has shown an 83% remission rate after three months in patients that do not respond to standard treatments. However, 49% of the patients suffered strong cytokine release syndrome.

These developments have created huge interest in CGTs both in terms of new trials, manufacturing and commercial activity. Most of the large biopharma companies are now actively entering the CGT arena mainly via acquisition. Of particular interest was BMS acquisition of Celgene for \$74Bn which was completed in November 2019.

However, CGT manufacturing technology is still at a very early stage of development, equivalent perhaps to the manual roller-bottle technology of the 1980’s for early clinical manufacturing of the first approved products from recombinant CHO cells (i.e., rtPA and EPO).

As with mAbs and other recombinant proteins, the manufacturing technology around CGTs must and will improve in order to meet market demand and to ensure affordability. Each modality has its own unique challenges but some are relevant to all. Furthermore, there is no universally accepted way of generating either gene or cell therapies – therefore each company is developing their own manufacturing capability often with limited in-house expertise which is time- and resource-consuming.

Building on its pharmaceutical manufacturing legacy from the 1950s onwards, Ireland was able to successfully compete for FDI investment in biologics manufacturing winning over €10 billion of investment from 2008-2018. Government’s strategic investment in NIBRT in 2005 to provide biologics manufacturing training and research was especially helpful in winning and sustaining this investment.

For Ireland to capitalise on the opportunity presented by CGT, NIBRT established the *Cell and Gene Therapy Manufacturing Forum*<sup>10</sup> in December 2018 with stakeholders from Industry, Academia and Government.



## Growth of Cell and Gene Therapy

**\$10<sub>BN</sub> – \$30<sub>BN</sub>** Market size for 2025<sup>11</sup>

**1,028** Global clinical trials in 2018

**59,000** Target enrolment of patients<sup>12</sup>

**\$13<sub>BN</sub>** Venture capital investment

**>900** Number of start-ups

10. Representation included APC Process, BioMarin, BiopharmaChemical Ireland, Enterprise Ireland, ESP, GE Healthcare, HPRA, IDA Ireland, NUI Galway, NIBRT, NTMA, PM Group, Takeda, TCD, UCD

11. IQVIA White Paper (2018): Changing the game – Cell and gene therapies lead the Advanced Therapies revolution

12. [http://alliancerm.org/wp-content/uploads/2019/03/ARM\\_AR2018\\_Web\\_FINAL.pdf](http://alliancerm.org/wp-content/uploads/2019/03/ARM_AR2018_Web_FINAL.pdf)



This Forum produced a White Paper in May 2019 which defined a series of actions that are now been implemented to ensure Ireland can take advantage of this opportunity including:

- Workforce development: a commitment to ensuring small and large companies can source appropriately trained advanced manufacturing staff
- Research excellence: ensuring availability of scientific and engineering expertise within the national research system
- Infrastructure: providing the necessary capabilities to support investment or development (testbeds, incubators, training facilities).

Ireland has many of the components to build a successful CGT industry, including the Remedi Centre in NUI Galway who have a long history in this area. It was encouraging to see Takeda opening a facility in Grange Castle that will produce Alofisel™ - an allogeneic cell therapy approved for treating complications associated with Crohn's disease. In October 2019, NIBRT was pleased to announce the appointment of PM Group to develop a design to expand its existing facility to facilitate training and innovation for the manufacture of CGTs. NIBRT has also commenced delivering training programmes in CGT.

However, this is a highly competitive space and other jurisdictions are investing heavily to attract and support this industry. The UK has invested in a Cell and Gene Therapy Catapult in Stevenage which provides facilities to scale-up production. 30% of Europe's 400+ SMEs active in cell and gene therapies are based in the UK, and the UK have stated that the CGT Catapult will help build a £10bn industry.

NIBRT looks forward to continue working with the broad range of stakeholders on the CGT Forum to ensure Ireland continues its impressive track record of success in biopharma manufacturing by winning the next wave of CGT investment.

**Prof. Niall Barron**

*NIBRT Principal Investigator and Professor of Biochemical Engineering UCD*

# 9 Contract Bioanalytical Services

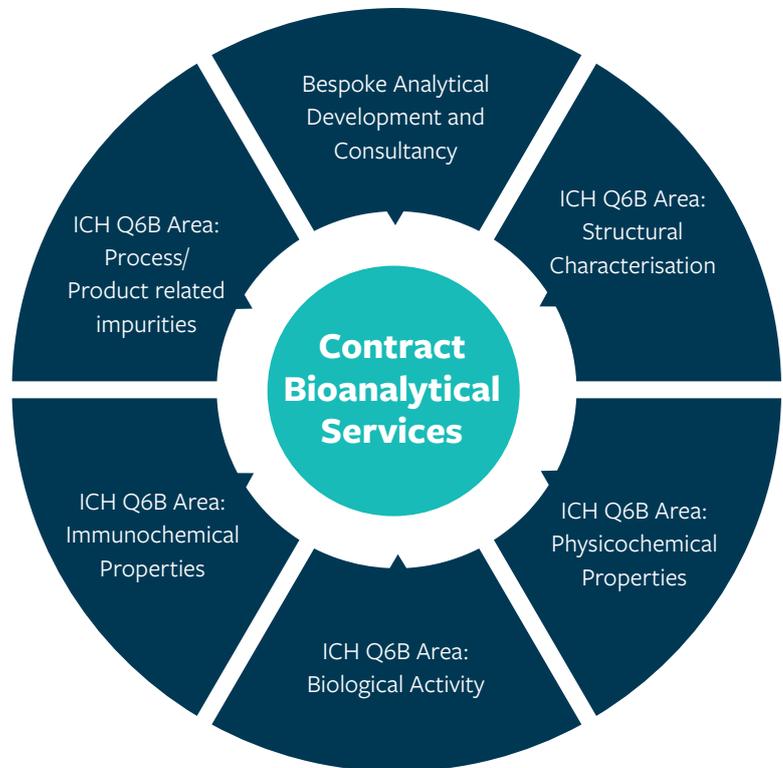
The Contract Bioanalytical Services team provide detailed characterisation of biologics in line with ICH Q6B and Q5E. New services added in 2019 now provide analytical solutions to satisfy ICH Q6B requirements for biological activity and immunochemical properties.

During 2019 Contract Bioanalytical Services provided a wide range of complex bioanalytical services to an international client base including:

- Bioanalytical characterisation studies to satisfy ICH Q6B requirements
- Feasibility/pre-validation, verification and qualification studies
- Troubleshooting of existing client methods
- Replication of methods for IP litigation

Bioanalytical characterisation and bespoke analytical development was conducted for a range of international clients including multinational biopharma companies, SMEs, virtual companies and law firms. A number of therapeutic products were studied including monoclonal antibodies, fusion proteins, gonadotropins, interferon and enzymes.

In 2020, Contract Bioanalytical Services will be expanded to support the manufacture of gene-modified cell therapies. New services will include assessment of viral packaging efficiency and AAV concentration.



*We just got news last night that our product was approved by the FDA! I just wanted to reach out to thank you and the contract research team for fantastic support and the high-quality work (as always). Your data was used in the BLA and was a part of the successful application.*

➔ **Associate Director, Biologics Development**

# 10 NIBRT Training and Education

In addition to developing customised training solutions for the biomanufacturing sector directly, NIBRT also works closely with our colleagues in the Higher Education sector to ensure that there is a strong supply of graduates in Ireland with the requisite skills and aptitudes to work in the biopharmaceutical manufacturing and related sectors.

## Industry Specific Training

2019 represented a very strong year for NIBRT Training and Education. We expanded our training team by welcoming new colleagues who will bring new expertise to our group. We were delighted to deliver over 26,000 learning days to 4,700 trainees across our various training modalities which represents the busiest year in training since we commenced our first full year of operations in 2012.

The portfolio NIBRT led courses was improved and expanded to include new course offerings delivered by our team on-site in the area of QC microbiology and single-use manufacturing.

NIBRT also was pleased to partner with third party organisations to offer new course offerings to our industrial client base in the areas of biopharmaceutical auditor training, science of human error reduction, automation and our first course addressing the manufacture of mesenchymal stem cells delivered in partnership with CCMI/REMEDI.

In 2019 customised content was delivered to the following industrial clients based in Ireland: Abbvie, Alexion, Amgen, Biomarín, Bristol Myers Squibb, Eli Lilly & Co, Eirgen Pharma, Janssen Biologics, MSD and Pfizer.



Customised training courses were delivered for the above clients in NIBRT

Vendor and service providers have continued to use NIBRT for their staff upskilling programmes in biopharmaceuticals and in 2019 we welcomed the following companies to NIBRT: Accenture, Agilent, Ansell, ArteSyn, Collins McNicholas, DuPont, Elis, John Paul Construction, OPW Global/PSG Dover, Parker, Thermo Scientific and VWR.

## Skilled Graduates

In 2019 the NIBRT training team continued in its mandate to support undergraduate and postgraduate academic programs within the higher education sector in Ireland by delivering academic modules and also by providing access for students to competency-based practical training sessions as a component of wider academic courses.

Specifically training was provided to Institute of Technology Sligo, University College Dublin, Dublin City University, Technical University Dublin, Dundalk Institute of Technology, Galway Mayo Institute of Technology, Cork Institute of Technology, Athlone Institute of Technology, Trinity College Dublin, National University of Ireland Galway, Waterford Institute of Technology, Institute of Technology Tralee and National University of Ireland Maynooth.

We were delighted in 2019 to partner on the first iteration a new accredited Graduate Internship Programme in Validation Technology, level 9 with the School of Chemical and Pharmaceutical Science at TU Dublin where internships were provided to the cohort of students by a selection of manufacturing sites (Abbvie, Alexion, Allergan, Amgen and Bristol Myers Squibb respectively). The aim of this programme is to allow graduates develop the skills and associated education necessary to take up validation roles in the biopharmaceutical industry. We will hope to build further on this initial program in 2020.

## Springboard+

In 2019 NIBRT continued to collaborate with the third level sector to support accredited training programmes to jobseekers and employed participants under the Springboard+ programme.

700 students across level 6 to level 9 were afforded the opportunity to spend time in our bioprocessing and bioanalytical training facilities respectively. These fully accredited courses are designed to enable students to upskill in key areas most relevant to the industry and have proved to be highly beneficial to those who have successfully completed their course.

## International Clients

Throughout 2019 we had the pleasure of welcoming international guests to our facility to attend open courses individually or to participate in customised training programmes with their company colleagues. Specifically, we welcomed the following international companies for customised course content; DuPont, IKA, OPW Global/PSG Dover, Roquette, SaudiVax and Thermo Scientific.

Our training team also had the opportunity to deliver off-site training courses internationally to audiences in Agilent (Germany), Lonza (UK) and Abbvie (Chile).

## Industry Masterclasses

In addition to our core curriculum we were pleased to offer a wide variety of programs to our clients in partnership with the following companies:

- > **Steris Technical Services (US):** Applied Cleaning Validation Practices
- > **Kaye:** Principles of Thermal Validation
- > **SP Scientific:** Lyophilisation Cycle Development
- > **NSF:** GMP for Biological and Biotechnology Products
- > **Inspired Pharma:** Pharmaceutical GMP Auditor / Lead Auditor Training
- > **Connect Academy:** The Science of Human Error
- > **Emerson:** Introduction and Implementation of Delta V Automation Technology





The NIBRT Training Team

## Suppliers

In 2019 NIBRT received generous donations of equipment to support our training programs from several vendor companies notably; GE Healthcare, Merck Millipore, Pall Corporation, Filtrox and Watson-Marlow.

## Future Outlook

Based on our successful 2019, we are very positive about our training pipeline and outlook for the coming year. Training offerings in development and launch in 2020 include;

- > Technical writing courses in association with CfPIE
- > Human factors in Life Sciences in association with Connect Academy
- > Introduction to Bioprocessing for non-Scientists
- > Certification of role based QRM competencies in association with PRST at TU Dublin

As NIBRT further develops its capability within the cell and gene therapy space we are particularly pleased that in January 2020 we will launch the first of three iterations of the Advanced Cell Therapy course (CELL-T1) in partnership with GE Healthcare. This course will focus on the manufacturing processes involved in CAR-T cell manufacture.

NIBRT has recently installed lyophilisation technology in our training facility and we will be developing and launching new training content for our clients in this discipline.

Finally, as we look to 2020 we will be launching a series of biopharmaceutical courses that will be hosted on the new NIBRT Online Academy (NOA) which will enable online access to best in class content for our growing client base.

**John Milne**  
NIBRT Training Director



## NIBRT Training 2019

4,700 Trainees

26,500 Training days

23 Training Team

13 Partnerships  
with Irish HEIs

700 Springboard+  
students

2 Global Partners

13 NOA courses

# 11 Training Case Study

## Takeda Dunboyne Biologics



The Takeda Dunboyne Biologics team at NIBRT

Takeda have invested over \$600M in a new state-of-the-art biologics facility in Dunboyne, Co. Meath, Ireland. This single-use and paperless facility will provide significant flexibility to meet the growing demands of biologic products and will be fully operational in 2020. Takeda Dunboyne Biologics will be at the cutting edge of innovation in the biopharmaceutical industry with a biologics product portfolio that delivers the most innovative product for patients.

Takeda's vision is to create a highly committed, agile team of champions, delivering life-changing medicines to patients where the learning environment provides individuals the opportunity to reach their full potential, customer value is constantly changing and thinking is at the edge of next. To achieve this vision, Takeda developed an innovative collaboration with NIBRT:

- To design, develop and deliver customized training programmes to enhance the biomanufacturing skills of the Takeda teams by leveraging the NIBRT-GE Single Use Technology Centre of Excellence, and Emerson manufacturing automation suite.

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“ Well done team Dunboyne on great partnership with NIBRT - great example of win:win partnership all round. How great to see how good honest partnerships flourish when based on solid values and shared values - well done all concerned and thanks for keeping our learning organization principles front and centre in this journey. ”

→ **Ann Lyons, Head of Learning, GMS at Takeda**

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“ Thank you to the great team at NIBRT for supporting the start-up at Dunboyne. We look forward to continuing to build on this important partnership to deliver our workplace of the future. ”

→ **Susan Hynes, VP and Site Lead Takeda Dunboyne Biologics**

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- > To setup a laboratory in NIBRT with Takeda qualified equipment to implement the Quality Control (QC) Teams training in NIBRT and on return to Dunboyne to successfully fast-track the technology transfer process.
- > To train the agile teams in the NIBRT facility including Manufacturing, Engineering, Facilities, Micro and Support Teams.
- > To base QC 20 employees at the NIBRT facility for nearly 12 months to support start-up activities in Dunboyne.
- > To host Takeda Careers in Biopharma events at NIBRT to help hire the best scientific and engineering talent.

## Winner of the 2019 Invest in Ireland Staff Upskilling Award



Invest  
in Ireland  
**AWARDS**

# 12 NIBRT Online Academy

**In 2019 NIBRT was pleased to launch the NIBRT Online Academy (NOA). NOA provides industry leading, elearning courses on key aspects of biopharma manufacturing.**

NOA courses can be accessed online (<https://noa.nibrt.ie>) on a range of devices to provide “just in time” learning in an engaging, stimulating format. NOA courses can also be installed on Client’s Learning Management Systems, with individual and group pricing options also available.

NOA elearning courses: release dates		
October 2019	January 2020	April 2020
Biotechnology and Biopharmaceuticals	Cell Biology and Recombinant DNA Technology	Fermentation in Biopharmaceutical Manufacturing
Overview of Biopharmaceutical Manufacturing	Bioreactors in Bioprocessing	Downstream Processing: Centrifugation
Cell Culture in Biopharmaceutical Manufacturing	Downstream Processing: Ultrafiltration and Diafiltration	Aseptic Processing - Gowning
Downstream Processing: Protein Purification - Chromatography	Freeze Drying	Aseptic Processing – Decontamination and Sterilization Technologies
Formulation in the Biopharmaceutical Industry	Aseptic Processing – Contamination Control	Clean In Place
Aseptic Processing – Concepts and Controls	Process Validation: Process Qualification and Control	Aseptic Processing - Cleanrooms and Control Technologies
Process Validation: Process Design		



*NIBRT Training Team members Shada Warreth, Kate Cotter, Alex Ostropolska at the launch of NOA*

# 13 Biopharma 4.0

**Boston Consulting Group (BCG) and NIBRT, as part of the Biopharma 4.0 (B4.0) Alliance, launched the world’s first Innovation Centre fully dedicated to biopharma operations.**

The B4.0 Alliance, is a unique collaboration led by BCG and NIBRT. Formed in September 2018, it is made up of leading players in the biopharma industry, selected innovative technology providers and industry experts. The new Innovation Centre showcases the latest Industry 4.0 (I4.0) technologies in biopharma manufacturing, quality control and training excellence. These technologies are integrated with core operating processes to enable proof-of-concept use cases on new innovations and new ways of working, situated in a Good Manufacturing Practice (GMP) simulated environment.

The Innovation Centre allows visitors and Alliance members to discover I4.0 technology demonstrated in a GMP environment, be inspired by biopharma manufacturing specific use cases and also allows companies to co-create or pilot digital solutions to their specific challenges in a safe GMP pilot environment.

The Innovation Centre is based on a B4.0 design blueprint produced earlier in 2019, outlining how biopharma companies can use cutting-edge technologies such as artificial intelligence, dynamic scheduling and augmented reality to revolutionize manufacturing operations. The blueprint contains a set of 90 key digital use cases prioritized by value. The current innovation centre is divided in to five rooms and demonstrates 30 of these key use cases, from a range of suppliers.

- > **Training Excellence:** Be immersed in a virtual GMP facility for training on technical operations, GMP behavioural training, as well as walking through a digital twin of a factory created in a single day.
- > **Evolved Upstream:** Experience the value that advanced analytics & machine learning can bring to process optimization, and how augmented reality, neural network activity recognition and dynamic real-time scheduling can help you to implement these optimization to deliver improved performance.
- > **Advanced Fill Finish:** See how simple sensors can be fitted to legacy production lines for give unparalleled visibility on performance which can then be improved using digital center-lining and analytics.
- > **QC Lab of the Future:** Schedule a lab in real-time and see how that schedule and react dynamically to changes through seamless integration with systems and live updates on availability of samples and analysts through RFID. Desktop Augmented Reality assisted training and complex workflow support is also demonstrated.
- > **QA Centre of Excellence:** Learn how data mining and visualization of complex process dynamics can focus improvement efforts as well as see capacity planning and time management applied to QA. Quality improvements can be delivered through advanced deviation root cause search and clustering as well as predictive analytics for delays.

“Biopharma has traditionally lagged behind other industries in the adoption of cutting edge technologies, and the B4.0 Alliance identified that a key barrier to this was the provision of a safe GMP space to learn about, experience and co-create digital use-cases as well as understand regulatory perspectives. We therefore hope this Centre will encourage companies to experiment with new technologies and develop talent, ensuring the industry can leverage the value from I4.0.”

→ **Frank Cordes, Managing Director & Partner at BCG, and Operations practice lead for Western Europe**

“ Takeda Dunboyne Biologics are delighted to be part of this digital demonstrator between NIBRT and BCG. As we build our new state of the art facility in County Meath, this alliance will help us in our Biopharma 4.0 journey to build the right capabilities using augmented reality to aid on demand 24/7 training. ”

→ Susan Hynes, VP & Site Lead, Takeda Dunboyne Biologics



NIBRT's Aoife Barron shows visitors how Augmented Reality can be used to improve visibility of batch progress during fermentation



# 14 Global Partner Programme

The NIBRT Global Partner Programme supports an international alliance of leading training and education organisations to help address the global shortage of a skilled biopharma workforce. In May 2019, Jefferson Institute for Bioprocessing was officially opened in Philadelphia, USA. In November 2019, University of Technology Sydney, Australia also joined the Global Partner Programme.

## Jefferson Institute for Bioprocessing, Philadelphia, USA

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

The focus of JIB is hands-on training of industry professionals through short-term trainings, certificates and hands-on education of new bioprocessing engineers and scientists at both undergraduate and graduate levels. The education and training programs in bioprocessing are anchored at the new state-of-the-art JIB facility, located minutes from Philadelphia, PA.

The institute is focused on biomanufacturing and dedicated to education and industry-based research that translates advances in the life sciences into emerging therapeutics that benefit humanity.

### Training Courses

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



*The Jefferson Institute for Bioprocessing*

## Academic Offerings

Offering both an MS in Biopharmaceutical Process Engineering and a Graduate Certificate in Biopharmaceutical Process Development (BPD Certificate), JIB is ideal for employment-focused graduates with first degrees in Life Sciences and Engineering.

Training and education in biopharmaceutical processing are exceptionally laboratory intensive. At JIB, the students spend less time in traditional classroom settings and more time in JIB's pilot-scale facility, fully equipped with the most advanced technologies and processes used by industry to manufacture biopharmaceuticals.

## More Information

For Trainings:  
Lyn Kugel at [HLynda.Kugel@jefferson.edu](mailto:HLynda.Kugel@jefferson.edu)

For Academic Programs:  
Geoff Toner at  
[Geoffrey.Toner@jefferson.edu](mailto:Geoffrey.Toner@jefferson.edu)

[Jefferson.edu/JIB](http://Jefferson.edu/JIB)

### Industry Course Offerings

- > Upstream and Downstream Operations
- > Scale Up/Scale Down
- > Quality and Regulatory Compliance
- > Continuous Bioprocessing
- > Single Use Technologies
- > Quality by Design and Design of Experiments
- > Process Modeling and Process Integration

## University of Technology, Sydney, Australia



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

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

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.

### NIBRT courses at UTS

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

## More Information

For more information on the capabilities of the UTS Biologics Innovation Facility [www.uts.edu.au/bif](http://www.uts.edu.au/bif) or contact [biologicsinnovationfacility@uts.edu.au](mailto:biologicsinnovationfacility@uts.edu.au)



*Biologics Innovation Facility at University of Technology, Sydney*

# 15 Facilities Development

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

At the heart of the NIBRT building is the bioprocessing pilot plant, consisting of extensive upstream, downstream, fill-finish, associated analytical facilities and process utilities for both stainless steel and single use bioprocessing. These facilities are all operated in a realistic GMP simulated, operational manufacturing environment. New additions to the facility in 2019 included:

- Telstar Lyobeta 3PS Lyophilisation Technology
- Emerson DeltaV Control Room
  - 5 Thinclient operator stations
  - DeltaV proplus station
  - DeltaV Control Panel (S-series controllers and CHARMS I/O)
- Biopharma 4.0 Digital Demonstrator<sup>13</sup>
  - QC lab of the Future: RFID Sample identification, Dynamic Smart scheduling, AR guided QC testing
  - Evolved Upstream: Technical and behavioural VR training, Big Data analytics, AR process performance and
  - remote maintenance
  - QA Centre: Process Mining and optimisation, Robotic Process optimisation, Scheduling and Time
  - Management



## Facilities Facts and Figures

6,500m<sup>2</sup>

Building size

0

Lost time safety incidents

-2%

Gas reduction

90

Personnel on site

-17%

Water reduction

-2%

Electricity reduction

13. See Section 13 of this Report



The NIBRT facility

## Cell and Gene Therapy

Following the publication in May 2019 of NIBRT's white paper on *"The Case for supporting Cell and Gene Therapy Manufacturing in Ireland"*, NIBRT commenced a facility concept study in partnership with PM Group. The concept study details the facility requirements that will enable NIBRT to provide training and research infrastructure to overcome the challenges associated with safe and economical manufacture of cell and gene therapies. This engineering design work will continue into Q1 2020 with construction activity to follow.

## Start-up space

Clients can also rent "start-up" space in the facility, and in 2019 NIBRT was pleased to host:

- > Takeda Quality Control (QC) Team who setup a laboratory in NIBRT with Takeda qualified equipment to implement the QC team's training in order to fast-track the technology transfer process and to support start-up activities in Takeda Dunboyne Biologics.
- > Valitacell, an early stage Irish biotechnology company with a suite of novel, intelligent analytical technology platforms, engineered to provide process control in cell-based manufacturing.

## Sustainability

The Facilities Team working closely with the NIBRT Green Committee continues to focus on reducing the environmental impact of the facility. 2019 saw a downward trend in usage of water (-17%), electricity (-2%) and gas (-2%) through a series of strategic investments and optimising building management initiatives. These reductions were realised in year that saw continued growth in the number of trainees passing through the facility and increased headcount.

## 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 2019 there were zero lost time accidents, an achievement we are proud of and made possible by our team's belief that safety is everyone's responsibility. This sense of ownership contributes to a positive safety culture and enables employees and others to actively contribute to safety, health and welfare at work.



### Explore the facility

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





1. Transition Year students at NIBRT
2. Dominic Carolan at MOU signing ceremony with Korean BioPharmaceutical Manufacturer's Association
3. Staccato team at NIBRT
4. Sara Carillo, NIBRT at Thermo Fisher, Shanghai
5. John Milne, NIBRT signing ceremony with SaudiVax representatives
6. NIBRT Team at Pharma Awards
7. Launch of Biopharma 4.0 Alliance with BCG and Takeda
8. Killian O'Driscoll at signing of MOU with Northeastern University, Boston
9. NIBRT and TU Dublin team at launch of Graduate Internship Programme

# 16 Public Engagement and Outreach

**A key component of NIBRT’s mission is to help develop the next generation of scientific and engineering talent with a number of exciting public engagement and outreach initiatives in 2019.**

**Amgen Biotech Experience (ABE)** is an innovative science education programme that empowers teachers to bring biotechnology into their classrooms. Teachers who take part in Amgen Biotech Experience have access to professional grade scientific equipment and curriculum-linked teaching materials to teach these experiments to their students in school during the academic year. NIBRT supports this initiative by facilitating a tour of the NIBRT pilot plant and hosting a workshop for secondary school teachers on career opportunities within the biopharma industry.

The **NIBRT Transition Year** program takes place every year and brings together transition year students to experience the state-of-the-art bioprocessing facilities at NIBRT and learn from scientists and engineers working in the research and training teams. Over the five-day programme, students participate in a diverse range of activities involving lectures, workshops, practicals, tours and meetings with NIBRT personnel.

NIBRT hosts an annual **Careers in Biopharma** event to showcase some of the biggest names in biopharma to prospective employees. Some of the companies showcasing the 7th annual Careers in Biopharma event included; Johnson & Johnson, Sanofi, Allergan, Amgen, Grifols, Takeda, AbbVie, WuXi Biologics, DPS Engineering, MSD and many more.

In 2019 we announced a new graduate internship programme with the School of Chemical and Pharmaceutical Science TU Dublin and selected biopharmaceutical companies. The **Graduate Internship in Validation Technology** is designed to allow graduates to gain the skills and education needed to take up validation roles in the biopharmaceutical industry. Successful students complete a pre-employment module consisting of both practical and workshop sessions in NIBRT, in addition to online academic modules, prior to an internship commencing in a biopharmaceutical facility (one year duration).

Upon completion, graduates have completed a 1 year internship in validation in a biopharmaceutical industrial environment along with a 30 credit Postgraduate Certificate in Validation Technology.

NIBRT student, Hayden Wilkinson competed for the title of **“World’s Best Science Communicator”** at FameLab international competition. FameLab challenges scientists and engineers to explain scientific concepts to a general audience in just three minutes. Having won the Irish final of FameLab on the with his talk about “Designer Babies”, Hayden Wilkinson used the topics of synaesthesia, split brains and designer babies to engage audiences in the FameLab international competition in Prague.

## Events

NIBRT also hosted 24 seminars, workshops and conferences throughout the year. These free-of-charge events provide the sector with the latest developments across a range of topics, including:

- Careers with Takeda
- 7th Annual Careers in Biopharma Event
- Analytics Institute
- ISPE Global Pharmaceutical Manufacturing Leadership Forum
- Irish Mass Spec AGM
- Stanford MBA Global Seminar
- Events with Thermo, NanoTemper, Flownamics, BCG, Biomerieux, IBEC.



## International delegations

NIBRT was also pleased to host a wide variety of international delegations to our facility in 2019 including:

- Korean Pharma and Biopharma Manufacturing Association,
- University of Technology Sydney, Australia
- Kobe University, Japan
- Kangawa University, Japan
- Stanford University Graduate School of Business, USA
- 21st Century Business Herald, China
- Jiemian, China
- Secretary of Pennsylvania Dept of Community and Economic Development, USA
- Janney Montgomery Investment Bank, USA
- Kaust University, Saudi Arabia
- Pharma Innovation Programme, Singapore
- KHIDI, South Korea,
- Stanford University Graduate School of Business, USA
- Alabama Life Sciences Trade Mission, USA
- Greater Seattle Partners, USA
- Turkish Ministry of Health
- Choongbuk Provincial Office, South Korea
- BioPhorum Operations Group, IT Phorum
- Teeside University, UK
- University of Maryland, USA
- National Research Centre, Canada
- Saudi Arabia Industrial Clusters
- Russian Academy of Science
- Maeil Business News, South Korea
- Guangzhou Development District, USA
- Northeastern University, USA

# 17 NIBRT Culture

In 2019, a cross department team initiated the NIBRT Culture project to define and promote the desired ethos of the Institute and how we interact with our colleagues and clients.



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

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

**HR Figures 2019**

- 84 Employees
- 40:44 Gender balance at NIBRT (male:female)
- 13 Nationalities
- 25 New hires 2019
- 7% Voluntary turn-over

# 18 Biopharma Ambition 2020

On 3rd and 4th March 2020, at The Printworks in Dublin Castle, BioPharma Ambition will mark the impact of biopharmaceutical innovators, showcasing the economic and social value they create for Ireland. The event is a stage to celebrate the discovery, development, manufacture and delivery of innovative medicines and technologies for improving human health.

BioPharma Ambition is led by the biopharmaceutical industry’s representative bodies, IPHA and BPCI, and NIBRT. It was held before in 2016 and 2018 at the same venue. Then, we drew more than 800 delegates from across the island of Ireland and from around the world - experts in industry, policy, research, academia, clinical care, entrepreneurship and finance.

This year, we will bring even more global influencers to Dublin for a larger-scale live production. The event will strengthen our networks, research collaborations, reputation and investment proposition as we look to the future of innovation in biopharmaceutical research and manufacturing.

Further information: [www.biopharmaambition.com](http://www.biopharmaambition.com)



Minister Heather Humphries TD, with Matt Moran (BPCI), Killian O’Driscoll (NIBRT) and Oliver O’Connor (IPHA) at the launch of Biopharma Ambition 2020

2020 Hold the Date	
<b>March 3rd 2020</b>	Manufacturing Next-Generation Biologics, NIBRT
<b>March 4th 2020</b>	Biopharma Ambition, Dublin Castle
<b>March 5th 2020</b>	NIBRT Global Partners meeting, NIBRT
<b>April 18th 2020</b>	Careers in Biopharma, NIBRT

# 19 Testimonials

<p><b>Dupont Bioprocessing Operations</b></p>	<p><i>“Thrilled with not only the training I received and experience I had, but also so excited about what this institute is doing for the industry. FANTASTIC.”</i></p>
<p><b>Engineers Ireland</b></p>	<p><i>“All the lecturers were just great, very knowledgeable &amp; made the day interesting &amp; interactive. The course has given me a whole new meaning to my day job! Thank you very much.”</i></p>
<p><b>Paddy Gleeson</b> HR Director, Takeda Dunboyne Biologics</p>	<p><i>“NIBRT is a critical support as we built up our organization and facility to deliver life changing medicines for our rare disease patients.”</i></p>
<p><b>Aidan Quinn</b> Springboard+ student</p>	<p><i>“May I first take this opportunity to thank you and your colleagues at NIBRT and IT Sligo for your professionalism, support, guidance and patience during our Biotechnology Processing certificate course this year? The online lectures and lab practicals gave a great insight and understanding to a complex and very interesting subject and I believe participation in the course will greatly improve my job prospects.”</i></p>
<p><b>Nicolas Pivet</b> General Manager, Global Services, GE Healthcare</p>	<p><i>“NIBRT is an amazing institute, the place to stop by when working in the Bioprocessing space, with an impressive and growing global reach.”</i></p>
<p><b>Eva Fahey</b> Transition Year Student</p>	<p><i>“I was one of the TY students you accepted to take part in a Biopharmaceutical Training week in NIBRT. Thanks so much for taking me again for that week as I enjoyed so much and I can honestly say it has been a highlight of my transition year.”</i></p>
<p><b>Associate Vice President</b> Keytruda Quality at Merck</p>	<p><i>“Excellent Training opportunity. The instructors were highly educated, experienced and engaged every one of us by delivering even the most complicated material in an easily understood format. The combination of theoretical and hands on training in this state of the art facility is an absolute necessity for anyone seeking to gain insight into bioprocessing.”</i></p>
<p><b>Amanda Sotoodeh</b> Area Account Manager Chromatography and Mass Spectrometry at Thermo Fisher Scientific</p>	<p><i>“Thanks to NIBRT National Institute for Bioprocessing Research and Training and Thermo Fisher Scientific’s Biopharma specialists for a fantastic few days! I am delighted with my biopharma &amp; bioprocessing certificate after an extensive 3 days of hands on training on different applications in Biopharma! The highlight for me was the bioprocessing pilot plant!”</i></p>
<p><b>Kristen Mehofer</b> Associate Specialist, Engineering - MMLDP at MSD Ireland</p>	<p><i>“Thank you MSD for sending myself and other Irish-based LDPs to NIBRT for a week long training in bioprocessing! It was a fun week filled with hands-on experience in upstream and downstream drug substance processing as well as drug product and filling.”</i></p>
<p><b>Regina Carroll</b> Consultant Success Co-ordinator LSC</p>	<p><i>“Excellent Training opportunity. The instructors were highly educated, experienced and engaged every one of us by delivering even the most complicated material in an easily understood format. The combination of theoretical and hands on training in this state of the art facility is an absolute necessity for anyone seeking to gain insight into bioprocessing.”</i></p>







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