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2017 Annual Report

Promoting world-class biopharma investment in Ireland

Who we are

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

What we do

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

NIBRT's vision

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



Message from NIBRT CEO

Investigators to the team.

2017 was another excellent year for NIBRT, a year which saw our activities continue to grow on the back of a robust and thriving biopharma sector. In particular, NIBRT research activity expanded

significantly with the addition of new Principal

The biopharma manufacturing sector continues to grow in Ireland. It was great news to see the existing major start-up companies of BMS, Alexion and Shire joined by major expansion news from existing companies, Janssen, Merck & Co, Regeneron, and others. This is a major confidence statement from these companies in their success in Ireland and in their ability to source the talent for their expansions.

Training activity continued at an exceptionally busy pace through the year, not only for the start-up and expansion companies, but also for services companies to the sector. This is further evidence of the growth in the biopharma ecosystem in Ireland and the demand for bioprocessing training across a broad spectrum of companies. We were delighted to see the expansion of the Springboard Programme to include upskilling of personnel already in employment. As the country gets closer to full employment, this support for upskilling is a very welcome development, and a critical component of the action plan to ensure Ireland can meet the 8,400 jobs requirement identified in the Future Skills Needs of the Biopharma Industry in Ireland report (2017 to 2020). It was also great to see the training budget for upskilling significantly increased by government.

The expansion in NIBRT's Open Courses activity let to a 40% increase in this activity year on year. The NIBRT training model has been receiving great international attention, with many countries looking to replicate in some way the NIBRT model. Discussions are at an advanced stage regarding a NIBRT franchising arrangement with a major University on the East Coast, USA.

Research activity continues to grow and we were delighted to have the addition of Prof.

Niall Barron to the NIBRT team. With the teams of Prof Michael Butler, Dr Jonathan Bones,
Dr Colin Clarke and Dr Radka Fahey, NIBRT research now has excellent coverage in the areas of Cell Biology & Engineering, Bioanalytics,
Advanced Manufacturing Technologies,
Bioinformatics and Data Analytics. All focussed on enhanced product quality and productivity of biopharmaceuticals. Contract Research, supporting industry needs, particularly in the area of bioanalytics continues to be a growing and significant part of the business.

Unfortunately, the Bio-Logic Research Centre application to SFI did not receive funding despite receiving excellent scientific reviews from the international review panel and being approved in principle for funding by the SFI Board. NIBRT are now working with the 27 companies who were interested in this consortium to hopefully progress with the excellent research opportunities that have been identified.

2017 was a great year for collaborations coupled with significant state-of-art equipment additions to the facility. The NIBRT-GE Single Use Technology Centre of Excellence was completed and SUT training commenced. We look forward to expansion of the training offered in 2018 and to having proof-of-concept services on offer. The Thermo-Fisher collaboration was expanded on during the year and continues to provide next generation bioanalytical solutions to industry. The Pfizer/Thermo-Fisher/NIBRT collaboration on PAT solutions commenced.

In December we announced an exciting collaboration with Emerson which will see the establishment of an Emerson Room at NIBRT to provide state-of-art control systems for bioprocessing.

As we move into 2018 we look forward to continuing to work with our many clients in providing them with their customised training needs, expansion of our open courses, launch of the NIBRT On-Line Academy (NOA), expansion of our research activities by providing research solutions to industry and expanding on our collaboration agenda.

My appreciation goes to all the NIBRT staff who continue to be the back-bone to our activities and deliver great performance in achieving our mission.

Dominic Carolan CEO, NIBRT



Message from NIBRT Chairman



The biopharma industry continued its impressive growth throughout 2017 and despite headwinds related to weak global economies, the challenges with R&D productivity, drug pricing and Brexit, the global biopharma sector remains on course to deliver annual growth rates of 6.5% and total revenues exceeding \$1Trn by 2022.

On a national level, this growth was mirrored in 2017 by significant investment decisions from Merck, Janssen, Eli Lilly, Regeneron and others to further increase their advanced biopharma manufacturing capacities and capabilities in Ireland, in support of this growth.

Similarly, the pace of change in new therapeutic modalities and corresponding manufacturing technologies is also accelerating rapidly. The 46 NME's approved by US FDA in 2017, included the first 2 approvals of CAR-T therapies and the first gene therapy approval in the USA. Hence, while biopharma pipelines will continue to be dominated by CHO based antibody production for the foreseeable future, it's clear that there is an increasing diversification in life saving therapies for patients. In response, the manufacturing sector needs to develop technology platforms that can support these new modalities and ensure cost effective access to these specialty therapies for patients. Biopharma manufacturing sites are therefore increasingly focused on developing technologies such as intensified, continuous, single use bioprocessing, leveraging data analytics, real time characterisation and digital capabilities to drive both increased quality, operating agility and cost efficiency. NIBRT is uniquely positioned to support companies in developing "proofs-of-concept" for such factory-of-the-future technologies, through the strategic partnerships with GE, ThermoFisher and Emerson, all of which were announced within the last year. In addition, the growing capability in our Research teams, with the addition of another PI in Niall Barron during 2017 was another step on the path to assembling a truly world class research capability

covering the areas of Cell Biology & Engineering, Bioanalytics, Advanced Manufacturing Technologies, Bioinformatics and Data Analytics.

Of course, advances in science and technology are one thing, access to the talent needed to realise such advances is quite another and will remain a key differentiator for the sector. I am delighted to report that in this regard, 2017 saw NIBRT train a record number of trainees at the facility and continue to build a reputation globally for the quality of its training solutions and their relevance to industry.

This success is of course not possible without the commitment and dedication of the NIBRT team, the strong support of my Board colleagues and the many positive collaborations with our academic, industry and government partners.

For 2018 we look forward to a number of exciting strategic initiatives as NIBRT develop its international training partnerships and continues to broaden the scale of its research activities. In addition, the NIBRT management team will continue their engagement with key external stakeholders as the business plan for 2019-2023 is developed. The Board looks forward to these opportunities to build on NIBRT's success to date and to position the Institute firmly as a global leader in biopharmaceutical manufacturing research, education and training solutions.

Brendan O'Callaghan, Chairman, NIBRT

3 2017 NIBRT by the numbers

€5.9m

Value of equipment donations in 2017



4,012

Number of trainees in 2017



19,070

Number of training days delivered



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



Number of Springboard students trained in 2017

396 SPRINGBOARD

% of NIBRT research that is funded by Industry

46% (III)



peer reviewed publications in 2017

Gender balance at NIBRT 50:50

Number of events, conferences held in NIBRT



O LOST TIME

LOST TIME ACCIDENTS

81%.

% of survey respondents who are highly/moderately optimistic for the future growth of the biopharma industry

Growth of the Biopharma Industry



10 years and over €10 billion of investment

Over the last decade the Irish biopharma sector has seen €10 billion in capital investment in new facilities which represents close to the largest wave of investment in biopharma manufacturing anywhere in the globe. There was further good news for the Irish biopharma sector throughout 2017 with the announcement of several major investments including:

- Merck & Co. investing €280m in their latest commitment to their Irish biomanufacturing sites
- Janssen's \$350 Million expansion of their Ringaskiddy site
- Waters expands Manufacturing Centre of Excellence in Wexford, Ireland
- Regeneron's announcement of 300 additional jobs in Limerick
- Synexa Life Sciences opening their International Headquarters in Dublin
- SK Biotek's acquisition of Bristol-Myers Squibb's Active Pharmaceutical Ingredients manufacturing facility in Swords

- Theravance Biopharma's opening of a new corporate office and labs in Dublin
- Aerie Pharmaceuticals new manufacturing plant in Athlone

NIBRT works with all stakeholders from Industry, Government and Academia to support the development of the sector by providing bespoke training and research solutions in state-of-the-art facilities. NIBRT continued to have a very strong 2017 with a number of significant developments across its research, training and facility development operation.

Biopharma continues to develop at a rapid pace and in NIBRT's Annual Survey 81% of respondents indicated they are "highly optimistic" for the future growth of the sector. The survey also indicated that a majority (86%) of the respondents had difficulty filling one or more positions, in particular bioprocess engineers and manufacturing science and technology staff. To address this challenge the most effective types of training identified were onthe-job training (90%) and practical training in a lab and/or pilot plant environment (87%).

The biopharma industry in Ireland¹



10 OF THE TOP 10

world's pharmaceutical companies



7TH LARGEST EXPORTER

of medicinal and pharmaceutical products in the world in 2014



€39BN IN ANNUAL EXPORTS

of pharma, bio and chemistry produce



75
PHARMACEUTICAL
COMPANIES

operate in Ireland



40 FDA APPROVED

pharma and biopharma plants

 $^{1. \}quad https://www.idaireland.com/doing-business-here/industry-sectors/bio-pharmaceuticals$



While current investment is focused mainly on CHO based production of monoclonal antibodies, it's clear that there is an exciting diversification in product pipelines. Most notably in 2017 was the breakthrough in CAR-T cancer therapy with FDA approval for Novartis and Gilead. These therapies combine aspects of personalised medicine, cell and gene therapy to provide a new frontier in cancer treatment while posing many manufacturing and supply chain challenges.

The underlying manufacturing technologies are also constantly evolving with continuous manufacturing, single use and real-time analytics being key focus points. A significant debate in 2017 focused on "Industry 4.0" and the impact of digitization, automation, robotics and related technologies on manufacturing strategies. NIBRT's recently announced partnerships with Emerson, GE and Thermo Fisher will ensure the Institute drives advances in these areas. In 2018, NIBRT will also be launching its Online Academy

to assist the sector in keeping current with this face paced change.

In Feb 2018, the Irish Pharmaceutical Healthcare Association and BioPharmaChem Ireland, representing the research based and manufacturing biopharmaceutical industries respectively, together with NIBRT will host BioPharma Ambition for the second time, this is a multi-platform event to inspire and showcase innovation. With international policy leaders, renowned researchers and senior industry personnel, the event will highlight the ambition of the industry for the health and well-being of populations. It will also highlight where the research is pointing and how all stakeholders in Ireland will support innovation in discovery, development, manufacturing and healthcare solutions to ensure Ireland builds on its success in establishing a thriving biopharma sector.

Killian O'Driscoll, NIBRT Director of Projects

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

Minister Mary Mitchell O'Connor, TD

Shire grows presence in Ireland

In April 2016, Shire announced plans to invest \$400M in a new state-of-the-art biologics manufacturing facility in Piercetown, Dunboyne, County Meath.



This investment compliments an important and growing presence of the global company's footprint in Ireland.

The new state-of-the-art Greenfield site at Piercetown will adopt single use technology in the manufacturing processes, will be a highly automated facility and will also be the European Quality Control Hub for the Shire biologics portfolio. Construction started on the site in late 2017 and the plant is planned to be operational in 2020 after a period of operational qualification in 2019.

Approximately 400 people will eventually be employed at the site across multiple functional areas including manufacturing, quality assurance, quality control, engineering, finance, supply chain, automation, human resources and environmental health and safety.

Baggot Street is the group headquarters of Shire and has a growing presence with approximately 300 employees in corporate services, technical operations, commercial and treasury. Shire is the world's leading biotechnology company focused on rare diseases. In Ireland, it is estimated that 1 in 12 people suffer from a rare disease, with 75% of those patients children². Together these are one of the most over-looked patient populations in the world. Shire is their champion. We believe that there is a better future for the people with rare diseases and it means having the courage to do things differently.

Patient demand for innovative medicines is driving a need for more production capacity. The implementation of next generation technology at our Piercetown, Dunboyne site will enable quicker production and mean that we can bring medicines to the patients that need them faster.

Part of doing things differently at Shire means working with strategic partners like NIBRT to find innovative ways to recruit, train and grow our people.

With the NIBRT-GE single use centre of excellence coming on line this year and the NIBRT-Emerson collaboration announced in December 2017 this provides a unique opportunity for Shire to work with NIBRT at their centre of excellence. This is both to use their latest technology to support our new plant as well as leveraging their strong analytical capabilities to support the establishment of our European QC hub at Piercetown.



This expansion of our biologic manufacturing capability in County Meath will enable us to meet increasing product demands, support our pipeline and ultimately help more patients.



Matt Walker, Head of Technical Operations, Shire

NIBRT Research and Innovation



Message from Prof Mike Butler, NIBRT Chief Scientific Officer

In 2017 the research programme at NIBRT saw a significant expansion of research teams with the appointment of two new Principal Investigators, Prof Niall Barron and Dr Colin Clarke.

This expanded team have developed a comprehensive strategy for research in biopharma manufacturing around the theme of *Enhanced Product Quality and Productivity* which includes overlapping sectors in the areas of Cell Bioengineering, Bioanalytics, Bioinformatics and Advanced Manufacturing. This strategy was presented at the NIBRT Research Day with an open invitation for potential industry and academic partners to collaborate under these themes.

In the first half of the year, the Bio-Logic Research Centre application backed by strong external scientific reviewer support was "Approved in Principle" by SFI. However, due to budgetary constraints SFI are not in a position to fund the application at this time. Nonetheless, NIBRT are continuing an active engagement with the 27 partners that supported the Bio-Logic application and anticipate alternative arrangements to develop active programmes around our theme of *Enhanced Product Quality and Productivity*. This will add to the strong and on-going collaborations NIBRT have already with Pfizer, Thermo Fisher Scientific and others.

The output of NIBRT researchers in 2017 was represented by 31 peer-reviewed papers in scientific journals. In addition, NIBRT was delighted to win several prestigious awards including the SFI Industry Partnership Award 2017 (in partnership with SSPC) which celebrates SFI collaboration between an academic research group and industry.

Our research teams also had a strong presence in international meetings represented by 33 oral presentations and 25 posters. The many international meetings included ACTIP (Nantes), ESACT (Lausanne), PEACe (Valencia), Bioprocess International (Amsterdam), GlycoBiotec (Berlin) and Cambridge-Healthtech (Bethesda and Boston). These meetings have been key to develop and continue engagements and collaboration with academic and industrial colleagues, an activity so important to initiate new research proposals particularly to European agencies. This will be an essential part of our strategy going forward in an effort to expand our research and provide a pool of talented highly qualified personnel required to sustain biopharma in Ireland. Some further highlights of a busy year in NIBRT Research are included below.

Prof Mike Butler *NIBRT CSO*



Bioanalytical Characterisation

The new NIBRT-**Pfizer Grange Castle** collaboration which is funded through the Enterprise Ireland Innovation Partnership Programme launched in August 2017. This two year project aims to reduce the requirement for offline analytical testing by integrating automated sampling and analytical characterisation using high resolution liquid chromatography mass spectrometry directly with the bioreactor systems.

Dr Jonathan Bones' collaborative research project with Thermo Fisher Scientific which commenced in 2016 is progressing well and has moved into its second year. The focus of the collaboration is on the development of high impact customer ready solutions for complex biopharmaceutical characterisation. NIBRT are developing workflows on the Thermo Scientific biomolecule column range with its associated consumable portfolio in conjunction with sophisticated Thermo Scientific liquid chromatography systems and advanced Thermo Scientific Orbitrap high resolution mass spectrometers. These workflows and methods are uploaded to the Thermo Scientific AppsLab library³. This unique cloud-based applications compendium allows scientists across the globe to access and download these total analytical solutions directly to their instruments enabling them to simplify their analysis, generate highly

informative characterisation data faster and enhance understanding of their complex molecules.

The science-based technology company **3M** also began a collaborative research project with NIBRT. The first study, is examining the effect of chromatographic clarification on host cell DNA, and the specific type and quantity of host cell proteins removed prior to downstream processing.

Pfizer are excited to collaborate with Dr. Jonathan Bones, Dr. Colin Clarke and their teams at NIBRT to develop and apply more automated process and analytical characterisation platforms for the near real time analysis of biopharmaceuticals during the manufacturing process. The range of information we can get from such integrated systems will be a real step forward and can really help us to develop a much greater understanding of our manufacturing processes and their influence on the characteristics of our products.

Brian Fitzpatrick, Senior Director,
 Bio Aseptic Sciences, Pfizer

Bioinformatics and Data Analytics

Dr. Colin Clarke's team specialises in the application of multivariate statistics and machine learning algorithms for the analysis of complex CHO cell datasets. In 2017, Dr Clarke began his SFI Career Development Award (CDA) focussed on understanding the molecular processes driving biopharmaceutical production. In collaboration with Prof. Niall Barron, Dr Clarke had a landmark publication in the prestigious *Metabolic Engineering* journal on their work sequencing and analysing the CHO mitochondrial genome. In recognition of these achievements, Dr Clarke was awarded the Young Leader of the Year 2017 at the Irish Laboratory Awards.

Glycan Analytics

Dr. Radka Fahey and Prof. Pauline Rudd commenced their SFI Fixed Spoke project entitled "Microbe Mom" in July 2017. Led by Prof Douwe van Sinderen in the APC Microbiome Institute (UCC), this is a collaborative project between APC (UCC and Teagasc), UCD, and NIBRT with one industry partner, Alimentary Health. Dr Fahey is also collaborating on a number of glyco-analytical projects with groups from UCD, RCSI and Curam.

Cell Technology

Led by Prof. Michael Butler, the cell technology group lab space is now completed. The lab has full functionality in cell culture, bench scale bioprocessing (both batch and continuous systems) and in supporting bioanalytical techniques. Two PhD students have also begun their postgraduate studies in Prof Butler's lab, in conjunction with the School of Chemical Engineering in UCD, in the areas of Continuous Processing and Solid Phase Enzymatic Remodelling.

Cell Engineering

Prof Niall Barron joined NIBRT on the 1st July 2017 under a joint appointment with UCD as Professor of Biochemical Engineering. Prof Barron brings a wealth of experience in Mammalian Cell Engineering to NIBRT particularly in relation to the engineering CHO cells for biopharmaceutical production. Prof Barron's lab is in phase one of development with a senior post-doctoral research scientist recruited to facilitate the setup of Prof Barron's research space as well as a PhD student to work in the labs thematic areas of CHO cell genetic engineering.

SFI Industry Partnership Award 2017

NIBRT was delighted to receive the SFI Industry Partnership Award 2017 which celebrates SFI collaboration between an academic research group and industry. This collaboration with the SSPC SFI Research Centre was in partnership with Pfizer, MSD, Sanofi, BioMarin, JnJ, Allergan and Eli Lilly and Co. The research focused on enabling the plastic factory by assessing innovative single-use disposable systems for bioprocessing.

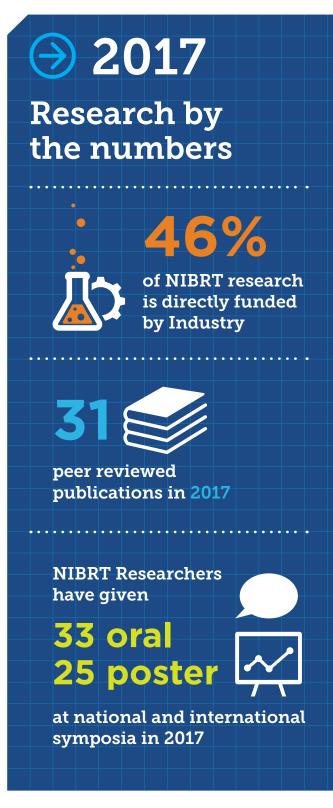


Research Excellence

NIBRT Researchers have been awarded the following awards in 2017:

- SFI Industry Partnership Award for "Advanced Biopharmaceutical Technologies" an SFI-Spoke collaborative project.
- Dr. Noemí Dorival-García was the recipient of a poster prize at the J&J EMEA Engineering Showcase in Cork.
- Dr Colin Clarke was awarded Young Leader of the Year at the Irish Lab Awards.
- Dr. Florian FuessI was awarded a CASSS student travel award to attend CASSS Mass Spec in Boston in September 2017, this was the fourth consecutive award to a member of the CCL group to attend this conference.
- Ms. Anne Trappe, won a California Separation Science Society (CASSS) student travel award to attend the Analytical Technologies Conference in Brussels in March 2017.
- Prof. Pauline Rudd was awarded the International Glycoconjugate Organization Award for exceptional contributions to the field of Glycobiology.
- Prof Pauline Rudd and Dr Jonathan Bones were both recognised within the Medicine Maker's Top 100 Power List.





Research Collaboration Case study: **Thermo Fisher**



The NIBRT and Thermo Fisher Scientific Teams at the launch of their collaboration.

In describing the collaboration with NIBRT Dr John Rontree, Senior Director of Marketing, Pharmaceuticals and Biopharmaceuticals, Thermo Fisher Scientific commented "A key challenge is the need for more 'global' workflows and 'platform technologies' that can easily be re-purposed from one drug molecule to the next. We are partnering with Dr Jonathan Bones at NIBRT to address this particular bottleneck – to bring fit-for-purpose, freely available methodologies which are applicable to a range of monoclonal antibody-based therapies, directly to our customers".

The focus of the collaboration is on the development of high impact customer ready solutions for complex biopharmaceutical characterisation. NIBRT are developing workflows on the Thermo Scientific biomolecule column range with its associated consumable portfolio in conjunction with sophisticated Thermo Scientific liquid chromatography systems and advanced Thermo Scientific Orbitrap high resolution mass spectrometers. These workflows and methods are uploaded to the Thermo Scientific AppsLab library⁴. This unique cloud-based applications compendium allows scientists across the globe to access and download these total analytical solutions directly to their instruments enabling them to simplify

their analysis, generate highly informative characterisation data faster and enhance understanding of their complex molecules.

Building on their successful research partnership, NIBRT was delighted to open the Thermo Scientific biopharma characterisation lab with sophisticated liquid chromatography systems and advanced Orbitrap high resolution mass spectrometers. "Analytical characterisation of biopharmaceuticals remains a challenge for scientists and requires cutting edge chromatography solutions and mass spectrometry detection," commented Jakob Gudbrand, President of Chromatography and Analytical Technologies at Thermo Fisher. "NIBRT is an independent centre of excellence with collaborations across the major biopharmaceutical companies in the industry. This allows them to provide valuable insights to improve the technology, simplify analysis, generate informative characterisation data and understand these complex molecules - ultimately enabling scientists to move from sample to knowledge quickly and efficiently."

Thermo Fisher SCIENTIFIC

NIBRT Research Day

Building effective collaborations

The "sold out" sign was put up in NIBRT for the Institute's annual Research Day on Friday November 24th 2017. The theme of this year's event was building effective collaborations, which was well received by the full house of attendees from major biopharma companies and higher education institutes.

NIBRT CEO, **Dominic Carolan**, opened proceedings with a summary of NIBRT's Research Strategy which is focused on "enhancing product quality and manufacturing productivity" incorporating four thematic areas including:

 Cell Biology and Engineering led by Prof Niall Barron and Dr Radka Fahey

- Bioanalytics led by Dr Jonathan Bones
- Bioinformatics and Data Analytics led by Dr Colin Clarke
- Advanced Manufacturing led by Prof Mike Butler

The key message was NIBRT has an "open door" policy for collaboration with Industry and Academia. Throughout the day NIBRT gave examples of their collaborations of various size and duration with companies including Pfizer, BioMarin, JnJ, MSD, Allergan, Sanofi, Lilly, GE and ThermoFisher involving most of the Higher Education Institutes in Ireland. Speakers highlighted the various funding mechanisms from EI, SFI, IDA and Horizon 2020 to implement such collaborations.



Prof Gavin Davey (TCD) and Gerald Kierans (Pfizer) accepting the SFI Industry Partnership Award.

My research is all about delivering solutions to enable people to understand their processes and products more to empower them to deliver better medicines to benefit patients that need them. There's a lot of exciting things going on currently. My group is actively working on extractable and leachable analysis of single use bioprocessing solutions and the data is fascinating. We hope that, once published, it will really help the industry in their choices to adopt and implement new technologies with confidence.

Medicine Maker, Power List 2017, Masters of the Bench: Dr Jonathan Bones

Earlier this year, NIBRT led a consortium of 27 partners to successful win approval-in-principle for the "Bio-Logic" SFI Research Centre, an ambitious €40million 6 year research programme. While government funding for this Centre is not currently available, NIBRT outlined how they are nonetheless proceeding with bilateral projects with interested parties.

NIBRT Principal Investigator, **Dr Jonathan Bones** kicked-off the scientific presentations and outlined his teams approach to develop "excellent research to deliver solutions".

Dr Bones's research focus includes taking bioanalytical characterisation analysis to the point of manufacture to facilitate continuous manufacturing. With the increase in complexity of therapeutic molecules such as bi-specifics and ADCs, Dr Bones outlined how these therapeutics present complex characterisation challenges. Dr Bones gave compelling characterisation case studies using charge variant analysis with mass spectrometric detection to characterise biologics in their native state.

Prof Mike Butler, NIBRT's Chief Scientific Officer, outlined his team's strategy in using bench top bioreactors to devise control strategies for biopharma manufacturing. Focusing in on three examples, Prof Butler outlined methodologies to control glycosylation of biologics via

- Glycoengineering of cell lines
- Substrate limitation in culture media
- Enzymatic re-modelling of glycosylation in downstream processing

A guest speaker, **Dr Ioscani Jiménez del Val** from the School of Chemical and Bioprocess Engineering, University College Dublin summarised his talk as "adding maths to biopharma". Dr del Val's work focus on

synergising multi-scale computational modelling with advanced experimental strategies to:

- Define bioprocess control strategies that lead to optimal product yield and quality
- Identify cell engineering strategies for optimal bioprocess performance
- Help design bioprocesses with optimal yield and quality reducing time to market and improving bioprocess flexibility

Dr Colin Clarke gave an overview of the Bioinformatics and Data Analytics group in NIBRT. Earlier this year Dr Clarke and collaborators using ultra-deep next generation sequencing techniques published the first mitochondrial genome sequencing in Chinese hamster ovary cells. The audience heard how innovative bioinformatics techniques such as ribosomal foot printing are revising our understanding of the "central dogma" of molecular biology. Such techniques are now being applied to optimise CHO cells production of increasingly complex non-native molecules.

Dr Clarke's talk was complemented by **Prof Niall Barron's** presentation on "Cell Engineering Approaches to Improving Biopharmaceutical Production in CHO Cells". Prof Barron, who has recently joined NIBRT, gave an overview of his team's impressive range of collaborations including Lilly, Biogen and Lonza. Prof Barron outlined how productivity in CHO cells for complex molecules can be improved using cutting edge molecular biology techniques such as CRISPR/CAS9 editing and knock-outs of micro RNA expression.

Dr Radka Fahey completed the scientific presentations and building on the world leading research of Prof Pauline Rudd outlined her team's advances in the understanding of the regulation of glycosylation and its role in disease and biopharma manufacturing. In particular, Dr Fahey discussed how her team's development of advanced high throughput analytical techniques has facilitated real time optimisation, fault detection and troubleshooting of glycosylation of biologics manufacturing

The agenda also featured **Dr Marion Boland,** Head of Post-Award at Science Foundation Ireland who outlined how sustained strategic investment has resulted in Ireland being listed an impressive 10th in the global scientific rankings. Dr Boland also gave an overview of the various current and future funding models from SFI to build collaborations based on excellent science delivering economic and societal impact.

Further emphasising the theme of collaboration, **Dr Sarah Hudson** from UL gave an overview of the development of the Bernal Institute and the current investment in biologic infrastructure.

The busy day included a tour of NIBRT with a specific focus on the new GE Single Use Centre of Excellence and ThermoFisher Characterisation laboratory. NIBRT also provided an overview of their contract research capabilities including glycan analysis, host cell protein analysis and single use process development capabilities.

Concluding events, the NIBRT team again emphasised the "open door" policy to collaboration which has seen the Institute and its partners deliver such impressive results.

Pauline's passion for glycans started early – extracting sugars from natural products in her kitchen as a teenager. Now at NIBRT, her research group focusses on developing advanced glycoanalytical technologies to analyze glycosylation in biotherapeutics and systems biology. In 2010, she was awarded the James Gregory Medal and an Agilent Thought Leader award.

Medicine Maker, Power List 2017, Masters of the Bench: Prof Pauline Rudd



Contract Research

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

In 2017 the contract research group worked with numerous multinationals biopharmaceutical companies and biotech start-ups, providing best in class analytical data to support process optimisation and the characterisation of new clinical candidates.



Analytical platforms provided by NIBRT Contract Research.

Client Case Study Levicept



NIBRT worked with Levicept through 2015 and 2016 and it was especially satisfactory to hear the recent news of the Levicept clinical candidate (Levi-04) progressing to phase 1 clinical trials. Levicept, a UK based biotech company led by CEO Dr. Simon Westbrook is currently developing the novel biological therapeutic candidate for the safe and efficacious treatment of osteoarthritis and chronic pain commented:

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

NIBRT Training and Education

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

Industry Training

2017 was a very busy and productive year for NIBRT training. We were pleased to deliver over 19,070 learning days to 4,012 trainees. In addition to strengthening training links with existing clients, new courses were delivered to a series of new national and international clients.

Manufacturing clients in 2017 included Abbvie, Allergan, Amgen, Alexion, Alkermes, Amneal, Baxter, BioMarin, Bioreliance, Bristol Myers Squibb, Compliance Group, Eirgen Bio, Eli Lilly, Fujifilm Diosynth, GSK, Janssen Biologics, Mallinckrodt, Merck Sharp Dohme (MSD), Pfizer and Sanofi Genzyme.

Vendor and professional service companies that attended for training programs included, Bioreliance, Collen Construction, Collins McNicholas, Compliance Group, Eurofins Lancaster Labs, Hewlett Packard, Lennox, Life Science Consultants, Sartorius Stedim Biotech, VWR, W.L.Gore and 3M.

Industry representative bodies who attended programmes included ISPE, PDA and PIC/s respectively.



TVIDICI TIGITINI G TCGIT



NIBRT's Industry Training Clients in 2017

Skilled Graduates

In 2017, NIBRT partnered with 10 Higher Education Institutes to deliver practical, experiential training to their students including University College Dublin, Dublin City University, Institute of Technology Sligo, Trinity College Dublin, Dundalk Institute of Technology, Dublin Institute of Technology, Cork Institute of Technology, Galway Mayo Institute of Technology, National University of Ireland Galway, and Limerick Institute of Technology.

Jobseekers

In 2017, NIBRT partnered with six Higher Education Institutes to provide free training programmes to 369 jobseekers under the Springboard+ programme.

On average, 65% of NIBRT trainees secure employment after participating in these very popular courses which are designed to meet the needs of the fast growing biopharma industry.

International Clients

International clients who travelled to NIBRT to access the state-of-the-art pilot plant facilities included a global training programme with AbbVie for Key Opinion Leaders and Health Care Practitioners and a series of bioprocessing courses for Allergan Biologics, Fujifilm Diosynth, GSK, Janssen Biologics, MSD, Sartorius Stedim Biotech, VWR and 3M.

NIBRT were also pleased to progress discussions with Philadelphia University and Thomas Jefferson University regarding a joint training partnership to be announced in 2018.

I completed the L6 Biopharmaceutical Processing course in 2016 and I have progressed onto the L7 Biopharmaceutical Science BSc course in 2017. Because of this I have secured full time employment with Regeneron as a Biotech Production Specialist. Seriously worth my while and so rewarding.

Mark Hannigan Biotech Production Specialist, Regeneron

SPRINGBOARD Building our future



Lydia Slattery PhD, Senior Manager Biopharmaceutical Chemistry, Eurofins Lancaster Labs

Eurofins Lancaster Laboratories based in Dungarvan, County Waterford is undergoing a large expansion phase by adding 4,400 m2 to its footprint with laboratories designated specifically to bioanalytics and molecular cell biology. This expansion will introduce new technologies to the site such as bioassay, ELISA and qPCR. The expansion will be ready for operational use by Q4 2018. The requirement to maximize the Eurofins training programme for its analysts led Eurofins to engage with NIBRT to develop a bespoke training programme with a bioanalytical and molecular cell biology focus. Eurofins Lancaster Laboratories fully invested in this programme and Eurofins technical leads worked closely with NIBRT to develop the bespoke programme and the first programme was delivered to Eurofins trainees in September 2017.

The Eurofins / NIBRT Bioanalytical & Molecular Cell Biology Training Course has accomplished many key objectives for our business. It has introduced and developed the candidates' scientific knowledge of the biopharmaceutical industry from the early stages of developing a biologic drug product from genetic engineering through to the production process and the analytical requirements to assess the critical attributes of a biologic product. The candidates were introduced to the science behind the suite of bioanalytical testing required and during each module their competency was continuously assessed through multiple choice question exams and hands-on practical exercises in the laboratory.

The NIBRT team was extremely adaptable to Eurofins Lancaster Laboratories requirements and provided an excellent service. This training has given the candidates an all-encompassing experience and has allowed them to take on more challenging analysis early on in their career with Eurofins Lancaster Laboratories. This collaboration is continuing to work on further optimizations of the programme. Given the success of our September intake we are delighted to be running this programme again at the NIBRT facility in April 2018.

After graduating with a BEng in Electronic engineering from UCD, I worked within a manufacturing industry until I was made redundant. I decided to enrol in the Level 9 Biopharmaceutical Engineering course after learning about it at the NIBRT career fair. I really enjoyed the course and felt it was organised and delivered perfectly. The practical training allowed me to gain a very in depth understanding of the processes involved which we studied in the lectures. In addition, the CV and interview workshops were very beneficial in allowing me to perform confidently in interviews. 3 job offers upon conclusion of the course is a testament to how highly the course is regarded. I would highly recommend this course to anyone looking to enter the industry.

🕣 Apurva Malkan, Commissioning, Qualification and Validation Engineer – Eli Lilly, Kinsale

Industry Masterclasses

In addition to NIBRT's highly valued practical based master classes in upstream processing, downstream processing, aseptic processing, and bioanalytics, we also offered a portfolio of relevant training programs for industry. In 2017 NIBRT built on its ongoing partnership with Engineers Ireland and Steris Technical Services.

New courses launched in 2017 included courses with:

- Chromacon AG (continuous chromatography)
- ISPE Florida (facility commissioning)
- BPS Crowthorne (lyophilisation cycle development)

- Charles River Laboratories (viral clearance)
- A new NIBRT program in Single-use
 Technologies held in the newly commissioned
 NIBRT-GE centre of excellence for single-use
 technologies.

Suppliers

In 2017, NIBRT partnered with several vendor companies to install new equipment in the NIBRT facility to complement our training offering. These included GE Healthcare, Endress+Hauser, Emerson, Sartorius Stedim Biotech, Pall, Bioquell, Lennox, Pendotech, Biomerieux and Ecolab.

My time at NIBRT was hands-down, one of the most enjoyable, rewarding and valuable experiences in my career to date. The knowledge and practical experience gained is absolute gold dust for anyone who has the desire to work in the biopharmaceutical industry. To me personally, the respect that NIBRT commands became immediately obvious through its impact on my employability. I obtained multiple interviews and job offers which I am convinced would not have been possible without my training at NIBRT. If your goal is to work in Biopharma, a course in NIBRT is the best first step you could take.

(A) Kevin Lomasney, NIBRT Springboard Graduate

11 Careers in Biopharma

New technologies and advancements are creating fundamental changes in how we work

These changes are particularly palpable in the biopharma sector. It would not be a giant leap to say that, 10 years from now, the workplace and workforce will look very different. That change will span industries and sectors, and will very much affect the way we do work. Here, Killian O'Driscoll, Director of Projects at the National Institute for Bioprocessing Research and Training (NIBRT), gives us some insight into the future of work within the biopharma sector.

What challenges and opportunities face the workplace and workforce of the future?

The biopharma industry is seeing a period of robust growth, with the number of new jobs in Ireland predicted to grow by 8,400 before 2020. This growth is replicated internationally and, as a consequence, there is a global shortage of skilled biopharma professionals. Bioprocess engineers, commissioning staff, automation engineers and downstream processing

expertise are in particularly high demand. A key challenge for the biopharma industry, therefore, is to ensure that there is a sufficient pool of talent attracted to the sector to support the anticipated growth.

What key trends do you foresee in relation to intra-team behaviour, management-employee interactions or other workplace dynamics?

Much of the work done in biopharma is project-driven, with a significant emphasis on genuine collaboration, effective team work across all levels and effective communications. These skills are seen as core competencies and will be sought after by hiring managers.

How will the workplace change as the Baby Boomers and Generation X age out of the workforce, and it becomes millennial-driven?

Are the differences between the generations overstated? Biopharma is driven by people with



Minister Mary Mitchell O'Connor, TD with members of the NIBRT Team at the Careers in Biopharma Event.

a passion to cure unmet medical needs using cutting-edge science and technology, and this is consistent across all generations.

What part will diversity and inclusion play in the make-up of the workforce of the future?

The biological sciences are fortunate to have a good gender balance, although this can be harder to achieve within some engineering disciplines. The reasons are well documented and persistent, although many worthwhile initiatives are ongoing to highlight the opportunities for all in STEM-based careers. We're also beginning to see a welcome increase in the number of highly trained and motivated non-nationals looking to Ireland for careers in biopharma.

Work-life balance is arguably central to job satisfaction. How can it be better achieved?

Most companies in the sector have a defined culture and values with a focus on providing excellent, balanced career opportunities for staff. Those who don't have such a culture in place risk an increase in staff turnover in a highly competitive marketplace.

We've seen immense increases in salary, particularly in tech. Do you think salaries in your sector will trend upwards, or will we start to see other benefits coming to the fore?

Salary rates in biopharma tend to be competitive without being excessive. Employees are well rewarded with attractive benefit packages from pension, healthcare, social clubs etc. A key motivating factor is also the inherent nature of the work, developing and delivering therapies for patients. It's been described as 'careers with purpose'.

We're currently deep in the world of data. What part will data play in developing the future of work?

Data analytics is a core function in biopharma and will be of increased significance in coming years. Data analysis underpins our fundamental scientific understanding of the biological process, including everything from genomic analysis to protein characterisation. The use of data analytics in the optimisation of the manufacturing process and the overall supply chain is an area that has very significant potential.

We're looking at a more automated future, as AI and bots become more sophisticated. How do you think this will affect roles in your sector?

This is an area where we're beginning to see some really interesting concepts. As Manufacturing 4.0 gathers momentum, we're seeing prototypes of the 'connected biopharma worker' and 'facility of the future' – involving technologies such as augmented reality, robotics, real-time sensors, internet of things etc. – which will drive advances in the sector.

What are the sectors of the future? Where do you believe we will we be seeing job growth and development?

The biopharma industry is still relatively young, having its roots in the biotech start-ups in Boston and the Bay Area in the mid-1980s. Today, six of the top 10 highest-selling drug products are biotech products, but, in reality, the industry is only getting started. We're seeing advances across the biological sciences increasing the variety of biotech products coming through clinical trial, including bispecific antibodies, cell therapies, gene therapies and an evolution towards precision medicine. This provides incredibly exciting career opportunities for talented scientists and engineers. To quote Steve Jobs: "I think the biggest innovations of the 21st century will be at the intersection of biology and technology. A new era is beginning."

What will companies need to do to attract and support the best talent?

Paradoxically, despite the opportunities in biopharma, the industry has a relatively low public profile in Ireland. The first challenge industry needs to address is effectively telling its story of careers with purpose. The second challenge is to maintain its level of ambition. The ultimate objective is that Ireland would be a genuine biotech hub to rival locations such as Boston, with a thriving start-up, indigenous and FDI cluster.

How do companies need to change right now to be ready for the future of work you have envisioned here?

Right now, biopharma companies need to tell their story and ensure the talent of the future is aware of these careers with purpose, bringing life-changing biotech products to patients.

Facility Development

NIBRT-GE Single Use Centre of Excellence

June 2017 saw the official opening of the NIBRT-GE Single-Use Centre of Excellence featuring the latest single use technologies that will further boost biomanufacturing skills and expertise in Ireland, Europe and globally. The new centre also supports the GE BioPark Cork; a GE-managed campus including four prefabricated, off-theshelf biologics factories owned by independent biopharma companies manufacturing proprietary medicines, creating up to 500 jobs. Commenting on the opening David Radspinner, General Manager, BioPark, GE Healthcare stated "The biopharma industry is growing rapidly; of the top ten therapeutics on the market today, eight are biopharmaceuticals. Our customers are constantly looking for flexible ways to improve capacity and the efficiency of their manufacturing operations. We need to foster innovation and partner with the best to respond to this need - with the NIBRT partnership and GE BioPark Cork we are doing exactly this."

Thermo Fisher Scientific Biopharma Characterisation

Building on their successful research partnership, NIBRT was delighted to open the Thermo Scientific biopharma characterisation lab where NIBRT will develop workflows on the Thermo Scientific biomolecule column range with its associated consumable portfolio in conjunction with sophisticated Thermo Scientific liquid chromatography systems and advanced Thermo Scientific Orbitrap high resolution mass spectrometers.

Emerson Control Room

In December 2017, NIBRT was delighted to announce its partnership with Emerson to establish state-of-the-art process control and automation capability throughout NIBRT's pilot plant.



Dominic Carolan (NIBRT), Mike Train (Emerson), Martin Shanahai (IDA) at announcement of Emerson NIBRT collaboration.

Public Engagement and Outreach

A key component of NIBRT's remit is to help inspire the next generation of biopharma talent with a number of exciting initiatives launched in 2017 including:

- programmes which provides young people growing up in difficult or hostile city environments with after-school and out-of-school educational support. Citywise's educational programmes raise the sights of young people, giving them an enthusiasm for learning and open up possibilities for further education.
- which is an innovative science education programme that empowers teachers to bring biotechnology into their classrooms. ABE-Ireland offers training in molecular biology experiments for secondary school teachers at locations in University College Dublin, Dublin City University and NIBRT.
- The launch of NIBRT's Biopharmaceutical Science **Transition Year Competition.** The very popular competition invites transition year students to submit an essay focusing on the biopharma sector in Ireland. The successful students will then receive a one week structured placement in NIBRT where they will have the opportunity to experience the state-of-the-art facilities and learn from scientists working in the research and training team.
- NIBRT's **Annual Careers Day** and Biotech Cluster at **CareerZoo** continue to be very popular events to connect the Industry with high quality prospective employees.
- Working with Siliconrepublic.com* focusing on how the biotech talent pipeline could be developed and improved.

*www.siliconrepublic.com/careers/life-sciences-talentpipeline-jobs





















- 1. Teachers on the Amgen Biotech Experience
- High school students of Tilemannschule Limburg, Germany
- 3. Dublin City Radio
- 4. Prof Pauline Rudd and Vice President Joe Biden
- 5. CityWise Biotechies
- 6. CareerZoo
- 7. Visiting delegation from Taiwan
- 8. RTE News at NIBRT
- 9. Lithuanian Ambassador

14 2017 Awards

The ongoing success of NIBRT was reflected in a number of prestigious national and international awards in 2017:

- SFI Industry Partnership Award 2017 which celebrates SFI collaboration between an academic research group and industry.
- Dr Colin Clarke wins Young Leader of the Year award at the Irish Lab Awards.
- Prof Pauline Rudd and Dr Jonathan Bones were both recognised within the Medicine Maker's Top 100 Power List.
- NIBRT was shortlisted for the CPHI Bioprocessing Award.
- DCU whose MSc in Bioprocess Engineering (in partnership with NIBRT) won Postgraduate Course of the Year Award in Health Sciences at the gradireland Higher Education Awards.
- Amgen Biotech Experience programme, won the Best Education Outreach award at the 2017 Education Awards ceremony. These awards recognise, encourage and celebrate excellence in the third level education sector on the island of Ireland from both State and privately funded institutions.
- NIBRT and GE won the Collaboration of the Year Award at the Irish Pharma Awards.









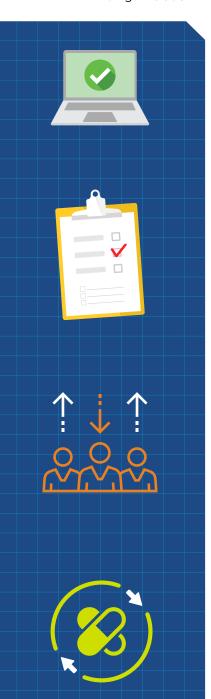






2017 Trends in Biopharma Survey

NIBRT was pleased to publish the results of its "2017 Trends in Biopharma Survey" in association with The Medicine Maker (a Texere Publication). The survey of over 200 key stakeholders assesses the trends in biopharma pipelines, manufacturing technologies and staff development. Key findings include:



Future growth: overall, **81%** of respondents are highly/moderately optimistic for the future growth of the biopharma sector.

Product Pipelines: Of the currently available biopharma therapeutic products, the two that were considered to be the most commercially important were monoclonal antibodies (mAbs) (73%) and vaccines (50%).

Regarding the biopharma therapeutic products that were likely to be the most important in the next 5 to 10 years, survey respondents most often cited mAbs (56%), cell therapies (43%), and gene therapies (42%). Ab drug conjugates (29%), vaccines (28%), RNA-based therapies (16%), and non-mAb recombinant proteins (15%) were cited less often

Manufacturing technologies: Survey respondents felt that the highest priority areas of biopharma manufacturing for further innovation were bioanalytical capabilities (57%) and cell line development and optimization (54%). The biggest challenges with regard to biopharma manufacturing were process reproducibility (62%), process robustness (55%), product yield optimization (51%), and product characterization (47%).

Respondents considered most of the challenges for continuous manufacturing of biopharmaceuticals to be fairly substantial obstacles: challenges in the process development of continuous manufacturing processes (54%), lack of real-time monitoring technologies (52%), regulatory uncertainties (49%), challenges in downstream processing efficiency (48%), and challenges in the tech transfer of continuous manufacturing processes (47%).

Staff Development: A majority (86%) of the survey respondents had difficulty filling one or more positions. Survey respondents had the most difficulty hiring for the following types of positions: bioprocess engineers (52%), manufacturing science and technology (39%), upstream processing (33%), and downstream processing (28%).

The most effective types of training were on-the-job training (90%) and practical training in a lab and/or pilot plant environment (87%).

Opportunities and Challenges: The biggest types of challenges for the growth of the biopharma industry concerned costs, pricing (29%) and staff, technical skills (20%). The biggest opportunities for growth of the biopharma industry concerned R&D, new products (24%), cell and gene therapy (17%), and new technologies (16%).

Biopharma Ambition 2018



Ireland has established itself as a place of global significance for the biopharmaceutical industry and is set to capitalise on this and host a major international multi-function convention in Dublin on 21-22 February 2018. The Irish Pharmaceutical Healthcare Association and BioPharmaChem Ireland, representing the research based and manufacturing biopharmaceutical industries respectively, together with the National Institute for BioProcessing Research and Training will host BioPharma Ambition®, a multi-platform event to inspire and showcase innovation.

With international policy leaders, renowned researchers and senior industry personnel, the event will highlight the ambition of the industry for the health and well-being of populations.

It will also highlight where the research is pointing and how Ireland will support innovation in discovery, development, manufacturing and healthcare solutions.

Further details available from www.biopharmaambition.com

7 2018 Hold the Date

January 27th 2018	Careers in Alexion		
February 21st - 22nd 2018	Biopharma Ambition		
March 24th 2018	Careers in Shire		
April 13th 2018	NIBRT Training and Education Symposium		
April 14th 2018	NIBRT's 5th Annual Careers in Biopharma		
November 9th 2018	NIBRT Research Day		



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