



National Institute for
Bioprocessing Research
and Training

NIBRT Training Catalogue 2019





National Institute for
Bioprocessing Research
and Training

About Us

The National Institute for Bioprocessing Research and Training (NIBRT) is a global centre of excellence for training and research in bioprocessing.

NIBRT's unique bioprocessing training facility allows trainees the opportunity to learn and practice complex technical bioprocessing procedures.

NIBRT provides a range of programmes which are specifically tailored to meet the needs of trainees who wish to develop their careers in the bioprocessing industry.



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1 Why train with NIBRT?

State-of-the-art facilities

NIBRT is an award winning institute based in Dublin, Ireland that provides training and research solutions for the biopharma industry in state-of-the-art facilities. NIBRT provides clients with an unrivalled opportunity to develop their biopharma knowledge, skills and experience in a safe, simulated GMP and cost-effective manner.

Tailored to your specific requirements

NIBRT's programmes are designed in partnership with industry to deliver flexible, competency based learning solutions that deliver immediate cost-effective benefits in the work place. Our training solutions can be customised to meet your requirements using the latest instructional design and online learning techniques to provide accelerated learning solutions.

Putting theory into practice

We offer trainees unrivalled access to a fully operational manufacturing plant, in a simulated GMP environment that ensures trainees gain hands-on experience with both the equipment and the regulations of a cGMP plant. Courses are designed to maximise trainees' hands-on practical exposure to all equipment, with a trainee to instructor ratio of approximately 5:1.

Global Leader

NIBRT is a global leader in biopharma training and in 2018, we delivered 18,200 learning days to 4,300 trainees across our client base.





NIBRT upstream pilot plant

2 NIBRT Training Facilities

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

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.

These facilities are all operated in a realistic GMP simulated, operational manufacturing environment.

+ Laboratory scale aseptic processing, cell bank, inoculum and protein purification suites.
+ Upstream Suite: 1 x 30 litre and 2 x 150 litre stainless steel bioreactors and 200L single use STR, perfusion system, disc stack centrifuge, depth (stainless steel and single use) and micro-filtration skids.
+ Downstream Suite: 2 x ultrafiltration/diafiltration automated systems, 2 x automated process chromatography systems, automated column packing technologies, viral inactivation vessels and a number of integrity test stations.
+ Fill-finish suite: a vial filling machine under LAF and RABS with associated preparation room and aseptic gowning room, a modular aseptic workstation with integral HPV bio-decontamination.
+ Manufacturing Support: Buffer and media preparation suites utilising both stainless steel and disposable technologies; equipment preparation including parts washer and autoclave.
+ Central clean utilities suite including highly purified water, clean steam and CIP skids and clean air generating systems
+ Suite of analytical laboratories for product and process characterization.
+ The NIBRT-GE Single-Use Centre of Excellence is run by NIBRT, and GE is the technology provider delivering a fully integrated biomanufacturing platform based on single-use technologies to the centre.
+ Prometheus NT.48 (Nanotemper Technologies), Labchip (Perkin Elmer), Milliflex membrane filtration system (Merck), Endotoxin reader (Lonza), Biotrak particle counter (PMT).

**NEW FOR
2019**



3 NIBRT Training Team

NIBRT's training team has a broad range of industry and academic experience, please see below for profiles of some key members of our team:



**John Milne, PhD,
Director of Training**

John has a BSc in Biochemistry and a PhD in molecular enzymology from University College, Dublin. He has direct industry experience (15+ years) in all aspects of the manufacture of biological products including process development, optimisation, scale-up, clinical production and ensuring GMP compliance in regulated facilities. John joined NIBRT in January 2013, in the role of Training Manager and is now NIBRT Director of Training.



**Kate Cotter, PhD,
Bioprocessing
Programme Manager**

Kate has a BSc in Analytical Science from DCU and a PhD in molecular and cellular biology from UCD. Kate spent time working as part of the filter support team in Gilroy Automation and Filtration. Kate then spent much of her research career in the Greenebaum Cancer Centre, Baltimore, Maryland researching cancer genetics. Kate joined NIBRT in summer 2010, specialising in cell culture and upstream processing.



**Shada Warreth, BSc, MSc,
Senior Bioprocessing Trainer**

Shada graduated from Trinity College Dublin in 2010 with an MSc. in Pharmaceutical Medicine. Shada has over three years industry experience from Pfizer Ireland Pharmaceuticals and Gilead Sciences Limited in QC, QA and production/packaging. She has a Certificate in Training and Continuing Education and a Diploma in Business Management and Psychology. Shada joined NIBRT in November 2010 and specialises in Aseptic Processing and Fill Finish Operations. Shada is consultant lecturer for Distance (Online) Learning at IT Sligo in several modules including cleanroom design and operation, and formulation and filling.



**Melissa Hoare, PhD,
Senior Bioprocessing
Trainer**

Melissa has a BSc in Biotechnology, a PhD in cell biology, and a Postgraduate Diploma in Education from NUI Galway. After working in a teaching role, Melissa joined NIBRT in November 2013 and specialises in Downstream Processing Operations. Melissa is a consultant lecturer for Distance (Online) Learning at IT Sligo in several modules, including Biocontamination Control and Downstream Processing.



**Maja Kristek, PhD,
Senior Bioprocessing
Trainer**

Maja's PhD concentrated on gut immunology and the elucidation of the mechanism of action of anti-TNF block-buster drugs in inflammatory bowel disease. After finishing her PhD she continued working as a lead researcher on projects collaborating with different Irish pharmaceutical and biopharmaceutical companies and as an assay development scientist in collaboration with Mayo Clinic. Maja joined NIBRT in 2015 as a Bioprocessing Trainer where her area of expertise is bioanalytical techniques, cell culture and aseptic processing. She is also a lecturer in Bioanalytical Techniques and Quality Analytics for IT Sligo Online Learning.



**Adam Pritchard, PhD,
Senior Bioprocessing
Trainer**

Adam received a M.Sc. in Neuroscience from Trinity College Dublin in 2010. He was awarded a Trinity College Postgraduate Studentship to conduct a research Ph.D. in Molecular Neuropharmacology within the Physiology department. During this time, he undertook a placement in Novartis, Basel, relating to drug discovery in the field of neuro-inflammation. Adam's expertise ranges from cell culture and cellular signalling to protein and immune-based assay techniques. Adam joined NIBRT in December 2014 and his role focuses on training in upstream processing.



**Aoife Barron, BSc,
Senior Bioprocessing
Trainer**

Aoife obtained her Bachelor's degree in Biological Sciences from the National University of Ireland Maynooth, where she was awarded an entrance scholarship. Her final year project focused on the areas of microbiology and immunology; the content of which was included in a published scientific paper. Aoife has 6 years' experience of working in both the pharmaceutical and biopharmaceutical industry, including a start-up Pfizer Biotechnology site, in a QC Microbiology capacity. These roles included working with aseptic filling isolators and RABS technology. Aoife joined NIBRT in January 2015, specialising in the areas of aseptic processing and Fill Finish. Aoife also lectures in Sterile Fill Finish and Cleanroom Operations and Design (Level 6) for IT Sligo.

4 Customised Courses

NIBRT specialises in designing, developing and delivering customised training programmes to meet the requirements of industrial clients. All aspects of the course can be customised in discussion with the client including:

+ Customised Content	We will develop and implement course content to your specifications in order to replicate how operations, processes and procedures are applied in your organisation.
+ Customised Scheduling	We can organise training courses to suit your business priorities and work schedules.
+ Customised Delivery	NIBRT can deliver courses to clients via online learning or by on-site visits if required.



Customised training solutions delivered for the clients above in 2018



Takeda Dunboyne Biologics at NIBRT

5 Short Courses

NIBRT's highly popular portfolio of short, intensive courses provides:

- + Access to state-of-the-art NIBRT facility and equipment
- + Focus on the equipment and solutions to the real challenges you face in your own workplace
- + Opportunities to share experiences with people from a variety of organisations
- + Undisturbed time for training away from workplace interruptions

Introduction to Bioprocessing for Engineers	
<i>Course Descriptor:</i>	The aim of this course is to introduce the biopharmaceutical industry and its associated processing principles and techniques to those from a non-biopharma background. The course will expand attendees' knowledge and understanding of all aspects of the bioprocessing industry. The course is offered in association with Engineers Ireland.
<i>Who should attend:</i>	Engineers and managers working in the biopharma and related industries who wish to further their understanding of all aspects of biopharma manufacturing.

An Introduction to QC Micro

NEW FOR
2019

<i>Course Descriptor:</i>	This one-day course is designed to provide the trainee with an introduction to microbiology and its practical application in a GMP biopharmaceutical manufacturing environment. Classroom-based lectures and hands-on practical sessions will introduce the aseptic practices of environmental monitoring and water sampling as well as the use of common microbiology lab equipment such as BSCs, microscopes and gram staining equipment.
<i>Who should attend:</i>	<ul style="list-style-type: none">+ New recruits to QC who are looking to familiarise themselves with the theory and practical elements of standard micro testing.+ Lab management personnel who want to refresh their knowledge on testing protocols and requirements.+ QA, Manufacturing or Engineering personnel who have an interest in what happens in the laboratories.

Boiler Operation, Maintenance & Safety Workshop

<i>Course Descriptor:</i>	This course is delivered in conjunction with ESS Ltd, a Maintenance Outsourcing and Asset Management company. This course is designed to teach building and facility maintenance personnel about boiler operation, maintenance and safety. The course will include hands on time covering the operation and maintenance of the NIBRT Wee Chieftain boiler.
<i>Who should attend:</i>	<p>This course is designed for anyone who needs to understand fundamental operation of boilers in order to improve efficiencies and safety at their industrial plants and large building facilities. Individuals involved with residential hot water systems will also find this course extremely valuable.</p> <p>Attendees come from a wide variety of industries, skill-levels, company sizes, and job titles. Suitable participants include Building Maintenance Personnel, Building Engineers, Plant & Facility Maintenance Personnel and Managers, Apprentice and Experienced Boiler Technicians, Energy Managers, Purchasing Managers, any Technician needing to develop Multi-Craft skills.</p>

BPS Crowthorne present Lyophilisation Technology: Products, Process and Systems

<i>Course Descriptor:</i>	This course provides a comprehensive insight into a wide range of elements in freeze drying, including details on the concepts and practical aspects of each step of the process, principles and methodologies for formulation development and characterization. Additionally, it covers approaches to cycle development and scale-up including Quality by Design, fundamental equipment features of refrigeration, vacuum and control systems i.e. PAT tools, and aspects of troubleshooting, maintenance and qualification.
<i>Who should attend:</i>	Suitable for people working in biotechnology, pharmaceuticals, freeze drying formulation and cycle development, diagnostic industries.

Introduction to Thermal Validation	
<i>Course Descriptor:</i>	This one-day intensive course provides a detailed insight into the history, current trends, regulatory requirements, and methodologies of Thermal Validation. Dennis Plante is the Senior Validation Market/Product Specialist for Kaye instruments located in Billerica MA. With his engineering background and his 37+ years with Kaye Instruments, Dennis has a deep understanding of the applications, regulatory requirements and process technologies related to Thermal Validation.
<i>Who should attend:</i>	Validation engineers and managers wishing to further their understanding of all aspects of Thermal Validation.

Reliability Centered Maintenance for the Pharmaceutical Industry	
<i>Course Descriptor:</i>	<p>In addition to providing a comprehensive introduction to the RCM process, this 3-day course will cover all that needs to be done to realise the full potential of RCM and gain real business benefit, by addressing questions such as:</p> <ul style="list-style-type: none"> + Why reliability is not just about maintenance. + How RCM deals with failures that are caused by factors that maintenance cannot address, such as human factors, design shortcomings and operations and maintenance practices and procedures. + How to determine which assets and processes to apply RCM to. + How to ensure that the best information is captured in the RCM analysis, about what really happens to your assets in their operating context. + How to manage assets that are not subject to full RCM analyses.
<i>Who should attend:</i>	Personnel with responsibility for effective and efficient management of physical assets and processes including Managers, Superintendents, Specialists, Leaders, Supervisors, Foremen, Planners, Technicians, Operators and Engineers.

QC Micro Skills for Biopharma	
<i>Course Descriptor:</i>	This comprehensive 4-day course is designed to equip new QC analysts with the main theory and practical experience required to develop their skills in the microbiology laboratory. Classroom-based lectures on microbiology basics and the main aspects of contamination control will introduce the various hands-on sessions over subsequent days, covering basic micro culturing techniques, IDs and use of microscopes, water and in-process testing methods of bioburden and endotoxin / sterility testing for the support of manufacturing and utilities, as well as validation tests such biological indicators. The course will also focus the use of Quality Management Systems, GxP Audits and Regulations.
<i>Who should attend:</i>	<ul style="list-style-type: none"> + New recruits to QC who are looking to familiarise themselves with the theory and practical elements of standard Micro testing. + Lab management personnel who want to refresh their knowledge on testing protocols and requirements. + QA, Manufacturing or Engineering personnel who have an interest in what happens in the laboratories. + QC lab in the support of Manufacturing and in Product Release.

**NEW FOR
2019**

Introduction to Downstream Processing	
<i>Course Descriptor:</i>	This course is designed to deliver an introduction to the typical downstream operations used in a biopharmaceutical production process. This course includes both hands-on practical and lecture components covering topics such as ultrafiltration/diafiltration, viral clearance and chromatography. During this course trainees will be introduced to the basics of UF/DF and chromatography in a theory session before building on this knowledge and performing these operations using a practical component.
<i>Who should attend:</i>	Suitable for: operators, technicians, engineers & managers This course is designed for those that are new to downstream processing including operators, technical staff, engineers and managers who need to increase their basic knowledge of actual operations in a modern downstream processing biopharma plant.

Introduction to Upstream Processing Operations	
<i>Course Descriptor:</i>	This two day course provides an introduction to the typical upstream operations carried out in a biopharmaceutical manufacturing facility. This course will include both hands-on practical and theory components. During this course trainees will be introduced to cell culturing techniques using small scale shake flasks. Trainees will then gain hands on practical experience using both stainless steel and disposable bioreactor systems. Trainees will prepare and run a steam in place cycle on a stainless steel bioreactor and then inoculate a production batch into a stainless steel bioreactor.
<i>Who should attend:</i>	This course is designed for operators, technical staff, engineers and managers wishing to increase their knowledge of the upstream operations in a modern bioprocessing plant.

Introduction to Fill Finish Operations	
<i>Course Descriptor:</i>	This three day programme is designed to provide an introduction to current aseptic techniques related to working in an aseptic filling environment. This blended programme provides both a theoretical introduction to contamination control, environmental monitoring, filter integrity testing and filling systems, while also allowing trainees hands-on interaction with both isolator and RABs units while conducting glove integrity tests, media fills and troubleshooting. An introduction to Grade B gowning will also be included in the programme.
<i>Who should attend:</i>	<ul style="list-style-type: none"> + Manufacturing + QA/QC + Engineering Technicians + Specialists + Operators

Navigating QC Testing for Biologics and Biosimilars

<i>Course Descriptor:</i>	This three-day course guides trainees through the Critical Quality Attributes of biologics (ICH Q6B) as well as core analytical platforms routinely employed in a QC testing environment in order to measure them. Using a combination of lecture sessions and hands-on practical training, the course will cover methods such as electrophoretic separations (capillary electrophoresis, slab gels), HPLC/UPLC methods (peptide mapping, SEC, etc), nanoDSF (label-free nanoscale Differential Scanning Fluorimetry) and immunoassays (ELISA).
<i>Who should attend:</i>	This course is suitable for graduates seeking to gain entry into the area of biopharma QC, those currently working in QC/QA (small molecule or large), those working in product or process development/characterisation or anyone looking to increase and expand their understanding of QC testing for biologics and biosimilars.

Introduction to Continuous Chromatography

<i>Course Descriptor:</i>	The focus of this course delivered by subject matter experts from Chromacon AG will be to provide an introduction to continuous chromatography using novel capture and polish processes for biomolecules and will include hands-on practice. Continuous chromatography is attracting much attention as it can lead to significant improvements in productivity and reduce manufacturing costs.
<i>Who should attend:</i>	This course is aimed at industry and academic separation scientists and bioprocess development engineers who already have some familiarity with single column chromatography and who want to broaden their understanding of chromatographic processes and look at new and more efficient ways to purify biomolecules.

The Science of Human Error

<i>Course Descriptor:</i>	This is a one-day course for all personnel interested in human error reduction. Most human error is the result of predictable patterns of human behavior. This course will teach you a scientific and proven method for managing and reducing the incidence of human error in your operations. Participants will gain powerful insights into why human error occurs. Management and employees can learn how to reduce these errors and their resulting impact on production, quality, safety and costs.
<i>Who should attend:</i>	The training will be useful for all leaders and personnel with an organisational goal of human error reduction. The learnings are applicable to all industries. The training is particularly useful for personnel from Training, Quality, Manufacturing, Engineering & Regulatory.

The current schedule¹ for short courses in 2019 is shown below.

Course	2019 dates	€	
Introduction to Bioprocessing for Engineers	+ 13th February + 24th April + 29th May + 25th Sept + 23rd Oct + 20th Nov + 11th Dec	€495	
Introduction to QC Micro	26th April	€650	NEW FOR 2019
Boiler Operation, Maintenance & Safety Workshop	19th February	€490	
BPS Crowthorne present Lyophilisation Technology: Products, Process and Systems	5-7th March	€2,220	
Introduction to Thermal Validation	14th March	€500	
Reliability Centered Maintenance for the Pharmaceutical Industry	30th April	€1,650	
QC Micro Skills for Biopharma	4-7th June	€2,250	NEW FOR 2019
Science of Human Error	2nd May	€1200	
Introduction to Upstream Processing Operations	+ 15-16th April + 10-11th June + 13-14th August + 26-27th August + 2-3rd December	€ 1,300	
Introduction to Downstream Processing Operations	+ 17-18th April + 12-13th June + 15-16th August + 28-29th August + 4-5th December	€ 1,300	
Introduction to Fill Finish Operations	+ 7-9th May + 26-28th June + 3-5th September + 9-11th December	€2,250	
Navigating QC Testing for Biologics and Biosimilars	+ 15-17th July + 2-4th Oct	€2,250	
Introduction to Continuous Chromatography	22nd March	€1500	

¹ All price and course details are correct at time of publication but are subject to change, please refer to <https://www.nibrt.ie/training-and-education/training-courses/> for the most current information and full course details, or contact us on training@nibrt.ie

6 Principal Investigator Series

NIBRT is pleased to announce the inaugural Principal Investigator Series, in which leading NIBRT research teams provide expert level insight into key biopharma topics.

Bioanalytical Science for Biopharmaceutical Characterisation

NIBRT Principal Investigator:
Prof Jonathan Bones



Aims and purpose:

This course will provide attendees with fundamental and applied knowledge on analytical and bioanalytical techniques used for the characterisation of biopharmaceuticals and the monitoring of processes used for biopharmaceutical production. Participants will receive an appreciation on how to assess the quality of analytical data using statistical techniques and will learn the theoretical aspects of spectroscopic, chromatographic, electrophoretic and mass spectrometric approaches for the characterisation of recombinant proteins. An understanding as to the practical usage of these methods to answer key challenges within the biopharmaceutical manufacturing industry will also be presented.

Learning Outcomes:

On completion of this course participants should be able to:

- + Understand the regulatory requirements for biopharmaceutical characterisation and apply their theoretical knowledge to devise strategies for biopharmaceutical characterisation.
- + Evaluate and critique the quality of analytical data using appropriate statistical tests.
- + Understand the fundamentals of optical spectroscopic techniques and their quantitative application in analytical and bioanalytical assays.
- + Understand the fundamentals of analytical separations, particularly chromatography and electrophoresis, and the application of these techniques for the characterisation of biopharmaceuticals and monitoring bioprocesses.
- + Appreciate the importance of mass spectrometry for biopharmaceutical characterisation and understand how mass spectrometry can be applied to tackle key challenges in biopharmaceutical characterisation.

Date: Friday April 12th 2019

Cost: €1,000

Molecular Biology and Bioinformatics Techniques and Applications for Biopharma production

NIBRT Principal Investigator:
Prof Niall Barron and Dr Colin Clarke



Aims and purpose:

This course will provide attendees with fundamental and applied knowledge on the techniques used to generate recombinant cell lines for therapeutic protein production. The course will also provide a theoretical background to learn the skills involved in DNA manipulation. The purpose of the course is to develop an appreciation and understanding of the complexity of gene expression and its control, with an emphasis on eukaryotic expression systems. Attendees will also understand how bioinformatics and statistics are utilised to analyze and integrate “omics” data in order to develop an awareness of databases and genomics resources available for CHO cell systems biology.

Learning Outcomes:

On completion of this course participants should be able to:

- + Understand the structure and functioning of genes, particularly in regard to transgenics
- + Assess the complexity of gene expression in eukaryotes
- + Evaluate the important features of vectors used in gene cloning, the enzymology of gene cloning, the strategies used in the construction and screening of clone libraries
- + Understand the application and challenges associated with “omics” analysis to biomanufacturing systems
- + Appreciate the utilisation of appropriate data analysis approaches

Date: Friday Sept 13th 2019

Cost: €1,000

7 MSc Programmes

M.Sc. in Biopharmaceutical Science		ONLINE
Summary:	The post-graduate programme in biopharmaceutical science aims to provide students with a comprehensive grounding in critical aspects of biopharmaceutical processing and their support services, with specific focus on the product lifecycle of biopharmaceutical products and their associated processes.	
Duration:	A part-time programme delivered by online learning which can be completed in a 2-3 year timeframe. A part-time programme delivered by online learning which can be completed in a 2-3 year timeframe.	
Price:	€12,000 (EU students)	
Accrediting body:	IT Sligo, Level 9, 90 credits	
Delivery:	Online Masters	

M.Sc. in Bioprocess Engineering	
Summary:	The M.Sc. is an interactive and dynamic programme that will develop your knowledge and appreciation of the conceptual and factual bases for bioprocess design and operation. It also develops your understanding of bioprocessing, particularly the structures, roles and experimental methods associated with biopharmaceuticals, their analysis, production methods and technology for monitoring and control of bioprocesses.
Duration:	The full-time programme is offered on a one year full time and up to 4 years part-time
Price:	€6,272 (EU students)
Accrediting body:	Dublin City University, Level 9, 90 credits
Delivery:	Classroom

WINNER OF POSTGRADUATE COURSE OF THE YEAR AWARD IN HEALTH SCIENCES AT THE GRADIRELAND HIGHER EDUCATION AWARDS 2017 AND 2018.

IM.Eng.Sc. in Biopharmaceutical Engineering	
Summary:	This is an advanced postgraduate degree programme offering a combination of lectures, tutorials, practicals and project work delivered by university and industry experts.
Duration:	The full-time programme is completed in one year and the part-time programme can be completed over 2 or 3 years.
Price:	€7,040 (EU students)
Accrediting body:	University College Dublin, Level 9, 90 credits
Delivery:	Classroom

8 Major Award Programmes

NIBRT's major award programmes are delivered by online learning techniques. These programmes are accredited by the Institute of Technology Sligo including hands-on practical training in the NIBRT biopharmaceutical plant.

BSc (Ordinary) in Biopharmaceutical Science	
Summary:	The course is aimed at production, technical grade and supervisory / managerial staff and provides trainees with the skills necessary to work in a changing, highly regulated and technology driven manufacturing environment.
Duration:	2 years part-time
Price:	€7,200
Accreditation:	IT Sligo, Level 7, 60 credits



BSc (Hons) in Biopharmaceutical Science	
Summary:	This course is geared towards graduates who can assume positions of responsibility in the pharmaceutical industry. It is a broad based and multi-disciplinary course.
Duration:	2 years part-time
Price:	€9,000
Accreditation:	IT Sligo, Level 8, 60 credits





The NIBRT reception

9 Certificate Programmes

NIBRT'S certificate programmes are short, accredited, training programmes that have been designed in association with industry partners. These programmes focus on upskilling clients on the key competencies required in biopharma manufacturing. They are intensive programmes which are delivered via a blend of online learning and practical modules in the NIBRT facility.

Certificate in Science			
Title	ECTS Credits ²	Price (€)	Level ³
Certificate in Biopharmaceutical Processing	40	€4,500	7
Certificate in Biopharmaceutical Engineering	40	€4,500	7
Certificate in Biopharmaceutical Science	40	€5,600	8
Certificate in Biopharmaceutical Technologies	40	€5,600	8
Postgraduate Diploma in Biopharmaceutical Science	60	€10,000	9
Certificate in Biopharmaceutical Science	40	€6,000	9
Certificate in Quality Analytics	20	€2,200	9

² European Credit Transfer and Accumulation system

³ National Framework Equivalent, accredited by IT Sligo

10 Springboard+ 2019

What is Springboard +?

Springboard+ is a Government funded upskilling initiative in higher education offers free courses at certificate, degree and masters level leading to qualifications in areas where there are employment opportunities in the economy.

How much does the programme cost?

- + Courses are free for unemployed jobseekers.
- + For employed participants on courses NFQ level 7 – 9, 90% of the course fee will be funded by the Government, with participants required to contribute just 10% of the fee.

NIBRT and Springboard+

NIBRT programmes are specifically designed to meet the requirements of the biopharmaceutical industry and the job seeking candidate including:

- + A strong track record of NIBRT Springboard+ graduates obtaining employment in the biopharma sector.
- + All lectures are delivered online with hands-on practical placements in NIBRT's award winning facilities to provide candidates with the practical skills and experience required by Industry.
- + Modules in career support and development.
- + Instructors with extensive experience in training the biopharmaceutical industry.

What courses are available?

Springboard+ 2019 courses			
Title	Duration	ECTS Credits	Level
Certificate in Biopharmaceutical Processing	9 months	30	6
Certificate in Pharmaceutical Technology	9 months	40	7
Certificate in Science Biopharmaceutical Processing	9 months	30	7
Certificate in Quality Analytics for Biopharma	5 months	10	9
Certificate in Science in Biopharmaceutical Science	9 months	30	9

Application Process

Please contact springboard@nibrt.ie with any queries you may have.





Transition Year Students at NIBRT

11 Secondary Schools

A key component of NIBRT’s remit is to help develop the next generation of biopharma talent with a number of exciting initiatives throughout 2019 including:

Amgen’s School of Biotech Excellence (ABE) 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.

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 received a one week structured placement in NIBRT where they had 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** continue to be very popular events to connect the Industry with high quality prospective employees.



BMS at NIBRT’s Career Day

12 NIBRT International: Jefferson Institute for Bioprocessing

On February 21, 2018, Jefferson (Philadelphia University + Thomas Jefferson University) announced a partnership with NIBRT to create the Jefferson Institute for Bioprocessing (JIB), the first - and only - education and training institute for biopharmaceutical processing in North America that combines commercial single-use processing equipment with the internationally recognized NIBRT curriculum.

While more than 40% of therapeutics currently in research and development are biopharmaceuticals, there exist only a handful of places throughout the world dedicated to training people to produce these potentially life-saving drugs, a gap that the JIB intends to close.

The JIB is expected to serve 2,500 people annually through workforce training and bioprocessing certifications, in addition to enrolling 70 additional Jefferson students in bioprocessing, engineering and other related majors. The focus of the JIB is hands-on training of industry professionals through workshops and certificates and hands-on education of new bioprocessing engineers at the undergraduate and graduate levels

JIB will leverage partnerships with industry, academia, and government agencies to provide an industry-

facing, global dimension to transdisciplinary, hands-on learning in the growing biopharmaceutical manufacturing industry. JIB will also deploy cutting-edge biopharmaceutical manufacturing technology to support current and future workforce demands while promoting community outreach and engagement for students and practicing professionals.

In December 2018, Dr Parviz Shamlou, PhD, the George B. and Joy Rathmann Professor of Bioprocessing and director of the Amgen Centre for Bioprocessing at Keck Graduate Institute in Claremont, California., was announced as the Executive Director and Head of JIB.

The official opening of JIB is scheduled for 31st May 2019.



Minister Heather Humphries TD with members of NIBRT, Jefferson University and IDA at the launch of the NIBRT-Jefferson partnership



Takeda Grange Castle employees attending Aseptic Processing and Cell Culture Course at NIBRT

13 Training Case Study: Takeda Ireland Ltd Grange Castle

The largest pharmaceutical company in Japan, Takeda first set up operations in Ireland in 1997 manufacturing products for global markets.

In 2002 Takeda chose Dublin as the location for its first active pharmaceutical ingredient (API) facility outside of Japan. In 2017 Takeda also announced an investment in the construction of a stand-alone production facility for the manufacture of part of their oncology portfolio at Grange Castle.

The latest investment by Takeda will expand the existing Grange Castle site's footprint, with the construction of a new standalone modular cell therapy facility dedicated to manufacturing the novel stem cell therapy product "Alofisel" (darvadstrocel). Alofisel is a suspension of allogeneic expanded adipose-derived stem cells (eASC) locally administered for the treatment patients with perianal fistulae associated with Crohn's disease.

The new facility will be in full commercial operation by 2021, requiring personnel to demonstrate a unique set of skills, mind-set and behaviours. To address these needs Takeda requires that all personnel undergo an introduction into aseptic processing and cell therapy as part of Takeda's on-boarding. Takeda and NIBRT formed a collaboration to develop a customised baseline training program for the Alofisel team. This introduction is a prerequisite to all subsequent training, providing the foundation for Grange Castle to become the centre of excellence for stem cell manufacturing within the Takeda network.

The customised course for the ALOFISEL manufacturing process is a very hands on approach with the extensive use of NIBRT's facilities and laboratories. The training curricula includes an assessment of competency pre and post the training which will form part of the overall training records for Takeda personnel with special focus on working in biological safety cabinets and the use of isolator technology.

The NIBRT team provided an excellent service in putting together a comprehensive three day training course which comprises of a balance of lectures and practical's, covering general aseptic processing, cleanroom design & contamination control and specific human stem cell culture techniques.

With the first Takeda core team being successfully trained in October 2018, the collaboration between Takeda and NIBRT continues with further fine-tuning and optimization of the course scope and content, an extension of the participants group to Grange Castle site leadership team level and scheduling of multiple training sessions for 2019.

Orla Doran – QC Bioprocessing Manager,
Takeda Grange Castle

Benjamin Gysi – Director Site Projects, Takeda

14 Client Testimonials



1. Careers in Biopharma
2. NIBRT Transition Year Program
3. MSD trainees in NIBRT
4. NIBRT at springtime
5. Students from AIT
6. Mersus Technologies team in NIBRT
7. NIBRT Training in ABEC
8. Marie Skłodowska-Curie European Industrial Doctorate programme launch
9. NIBRT training in Janssen

“ 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. ”

Aidan Quinn
Springboard+ student

“ NIBRT provided me with great insight into the Biopharmaceutical industry. It's a great facility to be able to see first-hand what the day to day activities with a bio site could be. My training with NIBRT was the driving force behind my transition from 20 years manufacturing experience with Hewlett Packard to my current role with Alexion. I am currently still studying and will be attending two lab practical days next week. Looking forward to it. ”

Margaret Stagg
Alexion

“ 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. ”

Associate Vice President
of Keytruda Quality at Merck

“ I decided to enrol in the Level 9 Biopharmaceutical Engineering Springboard+ course after learning about it at the NIBRT career fair. 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

“ I was one of the TY students you accepted to take part in a Biopharmaceutical Training week in NIBRT from the 29th of January to the 2nd of February. 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. ”

Eva Fahey
NIBRT TY Student

“ Great few days of training on Upstream Processing at NIBRT National Institute for Bioprocessing Research and Training this week via The Institute of Technology, Sligo. ”

Maria Aldridge
Quality Specialist at AbbVie

“ Great course delivered by NIBRT Team of Aoife, Adam and Melissa. ”

Kieran McAtamney
Construction Manager, Jacobs

“ NIBRT is a critical support as we built up our organization and facility to deliver life changing medicines for our rare disease patients. ”

Paddy Gleeson
HR Director, Takeda Dunboyne Biologics

“ Congratulations on pharma awards. It's another proof that we are learning from the best in the industry. ”

Aleksander Kostrzewski
L7 Student

“ Visiting NIBRT was fascinating. Such a great training site for pharmaceutical companies and biotech to learn to manufacture Biologic in the most productive fashion. This was a unique experience. ”

Stephane Perrey
General Manager at GE Healthcare LS
Japan, Australia, New-Zealand

“ NIBRT is an amazing institute, the place to stop by when working in the Bioprocessing space, with an impressive and growing global reach. ”

Nicolas Pivet
General Manager, Global Services, GE Healthcare

“ Fantastic couple of days spent at NIBRT. Particular thanks to John for a great tour of the facility. Really impressive setup! ”

Caroline Brady
Global Commercial Operations Leader GE Healthcare

15 Coming soon

Emerson

Building on the collaboration with Emerson, NIBRT is delighted in 2019 to be able to offer real life scenario based DeltaV Batch training courses that is representative of biopharmaceutical manufacturing sites. The system configuration has capabilities such that specific training can be tailored for operators, maintenance personnel and technicians who can in turn navigate around a graphical representation of the instruments and equipment of a typical biological facility. The system architecture is capable of providing both software and hardware related training. This training capability will be included in both academic and industrial courses and will be delivered in conjunction with Emerson.



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

Cell and Gene Therapy

Cellular and gene therapies are beginning to emerge as future therapeutic options and NIBRT plans to be able to address such developments with respect to appropriate industry focused training programmes. In 2019 NIBRT in conjunction with our collaborators will begin to offer practical based courses to address the particular requirements that these modalities present.



NIBRT Online Academy

In quarter 2 2019, the NIBRT Online Academy (NOA) will be officially launched. NOA offers a constantly updated library of interactive, online training courses on key aspects of biopharma manufacturing. Courses can be accessed online on a range of devices to provide “just in time” learning in an engaging, stimulating format.



NIBRT Online Academy: Bioreactor Operations module launching Q2 2019

Biopharma 4.0 Digital Demonstrator

NIBRT in partnership with the Boston Consulting Group (BCG) have established the *Biopharma 4.0 Alliance* which provides the platform, capabilities and expertise needed to deliver a step change in performance through smarter adoption of disruptive Industry 4.0 technologies. Throughout 2019, a digital demonstrator is being established in NIBRT to provide an immersive training experience, which will allow participants from across the biopharma industry and beyond to experience new 4.0 technologies (such as AR, VR, robotics, data visualisation) first hand.



Representatives from NIBRT, Pfizer, GE and the Medicine Maker discuss impact of 4.0 on biopharma

Contact Us

Book a course directly via www.nibrt.ie or contact us at training@nibrt.ie or +353 1 215 8100 to speak with one of our training team.

For more information, please visit our website at **www.nibrt.ie**. Here you will find up-to-date information about course schedules, descriptions, registration, location and contact information.

Clients are very welcome to visit us at:

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