JEFFERSON INSTITUTE *for* BIOPROCESSING

Winter/Spring 2020 Training Catalog

Jefferson
Thomas Jefferson University
HOME OF SIDNEY KIMMEL MEDICAL COLLEGE

ABOUT US

The Jefferson Institute for Bioprocessing (JIB) offers a broad range of trainings in commercial single-use processing equipment to advance the skills and knowledge of scientists, engineers, and technicians who work in process development and biomanufacturing of biopharmaceuticals and biologics. Through its 25,000 sq. ft. fully flexible state-of-the-art facility, JIB is able to provide truly tactile training by combining interactive presentations, workshops, hands-on lab and pilot-scale experience. Training subjects include all unit operations and topics critical to industry success—upstream, downstream, analytics, quality, regulatory, and process design.

In addition to open enrollment courses, JIB also offers customized trainings to meet industry needs. JIB develops specialized courses developed through detailed collaborative planning that can be delivered either at JIB or at a company site. JIB is the only education and training institute for biopharmaceutical processing in North America that combines a commercial scale GE FLEX Factory with the internationally recognized National Institute for Bioprocessing Research and Training (NIBRT) curriculum.

CONTENTS

MAMMALIAN CELL CULTURE PROCESS DESIGN

Course Program Synopsis

Chinese Hamster Ovary (CHO) is the cell expression system of choice in the growing field of both monoclonal antibody manufacturing and proteins with complex post-translational modifications. In traditional deep-tank mechanically stirred bioreactors, production levels have increased 10,000-fold during the past two decades and product protein titers are now routinely measured in grams per liter. These achievements are leading to significant cell culture bioprocess sophistication, and, along with emerging single-use and continuous technologies, are making the future of flexible bioprocess manufacturing a distinct possibility. This three-day hands-on intensive course is designed and delivered by industry experts at Jefferson's state-of-the-art facility located at Jefferson Institute for Bioprocessing. The course is intended for professional scientists and engineers who wish to enhance their knowledge and training in the upstream functional area of cell culture process design and operation. The primary goal of the course is to update the participants' background in mammalian cell biotechnology; from bioreactor design and scale-up/scale-down, to basic process operation and control.

Course Overview

This three-day course is intended for industry professionals new to and/or responsible for mammalian process design and operations in a biomanufacturing setting. Scientific, engineering, and practical industrial aspects will be presented in a series of interactive presentations and workshops complemented with case studies and laboratory demonstrations. Course attendees will gain first-hand experience in principles of mammalian cell culture technologies, process development, scale-up and scale-down, control and measurement of dissolved oxygen, pH and temperature, setting up and running experiments, and analyzing data from high cell-density, fed-batch and perfusion cultures in lab and pilot-scale bioreactors.

Topics Covered and Key Learning Outcomes

- Commercial scale applications of mammalian cell culture for biologics
- CHO platform process: batch vs. fed-batch vs. perfusion bioreactors
- Cell-line vs. media vs. bioreactor design
- Bioprocess design and operational aspects of CHO culture operations
- Vial to production bioreactors
- Understanding oxygen transfer rate and oxygen uptake rate
- Understanding mixing and shear in bioreactors
- Understanding volumetric oxygen transfer rate (kLa)
- Impact of bioreactor operation on kLa
- Impact of kLa on cell density and productivity
- Understanding impact of cell culture operation on product impurities and critical quality attributes
- Modeling cell growth in cell culture in bioreactors
- Scale-up and scale-down. Cell culture operations in wave bag bioreactors. Industry case studies—including proteins and monoclonal antibody therapeutics
- Continuous cell culture operations
- Analytical, monitoring and control of cell culture operations
- Future trends and directions

Format

This three-day course is highly experiential and integrates seminars and presentations in a group setting with lab work or advanced projects gauged to the experience level of each participant. Typically, presentations and workshops will take place in the morning, with case studies, lab demonstrations, and advanced project discussions in the afternoon. Breakout sessions will be based on participants' experience. This format maximizes content appropriateness for each participant by offering the opportunity to apply knowledge gained in the morning to a lab and pilot-scale operation or project/computational design and case studies in the afternoon. Sessions are structured to provide ample time for interaction between participants and speaker.

PREPARATIVE CHROMATOGRAPHY

Course Program Synopsis

Preparative chromatography is a critical unit operation in the biopharmaceutical industry for purification of biologics. A modern platform process for purification of monoclonal antibodies, for example, includes two or more chromatography steps. The impact of chromatography on product quality attributes and process economics is significant. Major advances in scale-up and scale-down methods combined with the introduction of new resins and column packing techniques are transforming the way chromatography columns are designed and operated. While batch chromatography continues to be the unit operation of choice in industry, development of new continuous chromatography technologies promises radically new approaches to the downstream purification of biologics. These advances, combined with increasingly stringent regulatory expectations for biotherapeutics, require highly focused (re)training of industry professionals responsible for this unit operation.

Course Overview

This three-day course is intended for industry professionals new to and/or responsible for chromatography process design and operations in a biomanufacturing setting. Scientific, engineering, and practical industrial aspects of chromatography will be presented in a series of interactive presentations and workshops complemented with case studies and laboratory demonstrations. Course attendees will gain first-hand experience in principles of chromatography process development, scale-up and scale-down, control and measurement, monitoring and running experiments, and analyzing data.

Topics Covered and Key Learning Outcomes

- Commercial scale applications of process chromatography for biologics
- Chromatography platform process—affinity, ion exchange, hydrophobic and mixed mode
- Bioprocess design and operational aspects of chromatography
- Understanding linear and non-linear adsorption equilibria
- Understanding resolution, purity and yield
- Understanding gradient and step elution
- Packing techniques and evaluation for commercial-scale chromatography
- Impact of packing on column purification performance
- Understanding column pressure drop and its impact on column performance
- Scale-up and scale-down methods in chromatography
- Modeling chromatographic operation
- Industry case studies—including proteins and monoclonal antibody therapeutics
- Column sanitization, resin life time
- Recent advances in chromatography—towards continuous and single-use chromatography
- Chromatography control and monitoring
- Process optimization and tech transfer to manufacturing

Format

This three-day course is highly experiential and integrates seminars and presentations in a group setting with lab work or advanced projects gauged to the experience level of each participant. Typically, presentations and workshops will take place in the morning, with case studies, lab demonstrations, and advanced project discussions in the afternoon. Breakout sessions will be based on participants' experience. This format maximizes content appropriateness for each participant by offering the opportunity to apply knowledge gained in the morning to a lab and pilot-scale operation or project/computational design and case studies in the afternoon. Sessions are structured to provide ample time for interaction between participants and speaker.

PRIMARY RECOVERY AND TANGENTIAL FLOW FILTRATION IN BIOMANUFACTURING

Primary Recovery in Biopharmaceutical Processing

Synopsis

Major process improvements in upstream operations have been achieved over the past decade leading to high cell-density, high-titer cell cultures. The high cell-density combined with low cell viability on day of harvest can and often does increase levels of process impurities, including host cell proteins, DNA, RNA, lipids, and cell debris. These impurities can cause issues in primary recovery and downstream purification. For example, cells with low viability are more sensitive to shear forces prevailing in industrial centrifuges. If this happens, the resulting fines and colloids generated from shear breakage of the cells may remain in the supernatant, causing fouling of the depth filters as well as the 0.2 µm membrane (bioburden) filter and potentially the purification columns that follow harvesting.

This section of the training addresses primary recovery in the downstream processing of biopharmaceuticals including proteins and monoclonal antibodies. Topics covered will address the challenges associated with primary recovery of high cell-density and low cell viability.

Topics Covered and Key Learning Outcomes

- Centrifugation, Microfiltration, Depth, and Membrane filtration
- Process integration–Primary recovery platform design
- Scale-up and scale-down approaches
- Impact of cell culture bioreactor operation
- Flocculation and cell culture conditioning as an aid to primary recovery
- Precipitation and filtration of host cell proteins and mAbs
- Single-use centrifugation

Tangential Flow Filtration in Biomanufacturing

Synopsis

Tangential Flow Filtration is a major operation in downstream purification of monoclonal antibodies and proteins. Often it is the last operation in the API process and is performed prior to storage. The growing demand for biologics, in combination with an increase in drug product dose concentrations exceeding 200mg/mL, has made high protein concentration TFF operation the holy grail of bioprocessing. The impact of protein concentration on TFF operation and product quality is one of the most important aspects of tangential flow filtration. For example: the potential of product aggregation and generation of sub-visible particles, caused by several hours of pumping and excessive shearing of the protein solution during the TFF device, can have profound effects on critical product attributes since no further purification of the TFF material is possible.

This section of the course will address the theory and practice of tangential flow filtration (TFF), including current methods and techniques for technology selection and process operation.

Topics Covered and Key Learning Outcomes

- Tangential Flow Filtration, mode and mechanism of operation
- Primary and secondary concentrations
- Diafiltration
- Process design, technology selection and process optimization platform design
- Scale-up and scale-down approaches
- High viscosity TFF operation: challenges and opportunities
- Formation and mitigation of sub-visible particles in TFF operation

Format

This three-day course is highly experiential and integrates seminars and presentations in a group setting with lab work or advanced projects gauged to the experience level of each participant. Typically, presentations and workshops will take place in the morning, with case studies, lab demonstrations, and advanced project discussions in the afternoon. Breakout sessions will be based on participants' experience. This format maximizes content appropriateness for each participant by offering the opportunity to apply knowledge gained in the morning to a lab and pilot-scale operation or project/computational design and case studies in the afternoon. Sessions are structured to provide ample time for interaction between participants and speaker.

LARGE SCALE FREEZING OF BIOPHARMACEUTICALS

Course Program Synopsis

One of the major supply chain challenges in biomanufacturing is the storage and transportation of large volumes of active (bio)pharmaceutical ingredients (Bio-API). While lyophilization may be used in early phase processes, often freezing is the preferred choice for late-phase operation and commercial use. Freezing offers major advantages over other methods, and has widespread application despite proven difficulties in design and scale-up. Another often overlooked design challenge comes with the thawing of the frozen bulk Bio-API material prior to drug product formulation.

This three-day course provides the scientific and engineering bases for the design and scale-up of both passive and active freezing and thawing of bulk Bio-API materials in a biomanufacturing setting.

Course Overview

Participants attending the course will learn how to combine and use basic knowledge of heat transfer, scale-down, first principle modeling, DOE and QbD to design unit operations for freezing and thawing of bulk Bio-API in a biomanufacturing setting.

Topics Covered and Key Learning Outcomes

- Freezing of bulk Bio-API including proteins and monoclonal antibodies
- Cryo-concentration and its effect on product quality attributes
- Scale–down models (10-20ml) for freezing bulk Bio-API
- Definition and characterization of commercial freezing as a scalable unit operation
- First-principle modeling of freeze-thaw operation
- Predicting freeze rate and freeze time in commercial scale operation
- Impact of time-temperature on stability of frozen Bio-API during storage
- Container-closure for freeze operation
- Monitoring freeze-thaw operation
- Impact of freeze operation and protein concentration on sub-visible particles
- DOE and QbD issues in Bio-API freeze-thaw operation

Format

This three-day course is highly experiential and integrates seminars and presentations in a group setting with lab work or advanced projects gauged to the experience level of each participant. Typically, presentations and workshops will take place in the morning, with case studies, lab demonstrations, and advanced project discussions in the afternoon. Breakout sessions will be based on participants' experience. This format maximizes content appropriateness for each participant by offering the opportunity to apply knowledge gained in the morning to a lab and pilot-scale operation or project/computational design and case studies in the afternoon. Sessions are structured to provide ample time for interaction between participants and speaker.

INTRODUCTION TO BIOPHARMACEUTICAL PROCESS ENGINEERING

Course Program Synopsis

The nature of the work performed by bioprocess scientists and engineers changes throughout process development, its optimization, characterization, transfer to manufacturing, and validation as drug candidates move from pre-clinical to early-phase and then late-phase clinical and commercial launch. A phase-appropriate process development strategy is reiterative in nature, starting with a simple process that is defined and executed to provide preclinical and phase I clinical material. If—and only if—supported by good clinical data, the process progresses through increasingly complex development, optimization, and characterization stages with the intent to produce consistent and reproducible material for late-phase clinical use and launch. A well-defined, characterized, and validated process will maximize productivity while critically and simultaneously meeting pre-defined critical quality attributes ensuring safety, efficacy, purity, and identity of the drug for its intended use. These considerations make biomanufacturing one of the most challenging aspects in the commercialization of biopharmaceuticals and biologics.

This three-day course will increase the skills and knowledge of anyone working directly or indirectly in biopharmaceutical and process development. Participants will gain insight into the practical challenges of working in a highly regulated industry, especially in the launching of a new biomolecule beyond candidate selection. The course will introduce the participants to standard (good) industry practice, through specific examples and case studies based on industry experience, focusing not only on success, but critically on failures.

Topics Covered and Key Learning Outcomes

- Processes for commercial launch, from top clone to scale-up of API
- The role of process development: platform vs. non-platform processes
- First generation to next generation bioprocesses
- Batch vs. continuous bioprocessing
- Process flow diagram and process flowsheet
- Upstream, downstream, buffer exchange and concentration, storage and transportation operations
- Risk-based approach and Quality by Design (QbD) concepts
- Phase appropriate process design and development: practical applications
- Regulatory impact on process design and development
- The role of bioanalytical methods throughout all stages of process development
- Integration of cell culture processes with downstream product recovery and purification
- Quality control and assurance
- Tech transfer and validation
- Process performance qualification

Format

This three-day course is highly experiential and integrates seminars and presentations in a group setting with lab work or advanced projects gauged to the experience level of each participant. Typically, presentations and workshops will take place in the morning, with case studies, lab demonstrations, and advanced project discussions in the afternoon. Breakout sessions will be based on participants' experience. This format maximizes content appropriateness for each participant by offering the opportunity to apply knowledge gained in the morning to a lab and pilot-scale operation or project/computational design and case studies in the afternoon. Sessions are structured to provide ample time for interaction between participants and speaker.

INTRODUCTION TO UPSTREAM PROCESSING OPERATIONS

Course Program Synopsis

In biopharmaceutical process industries, upstream operations deal with the growth of living cells (host organism). The sole purpose of upstream operations in biomanufacturing is to create the optimum environment for cells to grow and make a target therapeutic protein produce a product. Currently, the most important commercial protein is monoclonal antibodies, and Chinese Hamster Ovary (CHO) is the industry's cell line of choice. With CHO the product is excreted into the growth medium continuously from the point when the production bioreactor is inoculated to the point when the bioreactor is harvested.

This two-day course is intended for technicians, operators and process design and development professionals new to upstream operations. The course provides a basic overview to upstream operations carried out in a biopharmaceutical manufacturing facility. This course will include both hands-on practical and classroom components. During the course trainees will be introduced to cell culturing techniques, removing a cryovial from the Dewar vessel, and seeding and expansion from shake flasks to wave bags and production bioreactors. Trainees will then gain hands-on, practical experience using bench top stirred tank bioreactors.

Topics Covered and Key Learning Outcomes

- Working with CHO cells in an upstream processing environment
- Batch records
- Air classification in upstream operations
- Gowning
- HVAC systems
- Clean air and environmental monitoring
- Open vs. closed processing
- Aseptic processing of cell bank vials in a biological safety cabinet, seeding and expansion in shake flasks and/or spinner flasks
- Best practice in "sub-culturing" (passaging) of cells
- Frozen CHO cells in the cryovials
- Handling cryovials and processing them safely and consistently from inoculation room to production bioreactor
- Pros and cons of CHO cells
- Minimizing risk of contamination
- Stainless steel vs. ready-to-use cell culture bioreactors
- Media selection and preparation (dispensing) facility–manual vs. electronic systems
- Bioreactor operation and control (pH, CO2, dissolved oxygen and temperature)
- Mixing and oxygen transfer in bioreactors. Understanding OUR vs OTR
- Volumetric oxygen transfer rate
- Types of bioreactors (batch vs. fed-batch vs. perfusion)
- Bioreactor processing strategy: closed processing, tube sterile connector and welding
- Cell counting and viability measurement
- Metabolite monitoring and control
- Feeding strategy
- Cell culture harvesting strategy
- Preparation of cell-free-medium for downstream purification

Format

This two-day course is highly experiential and integrates seminars and presentations in a group setting with lab work or advanced projects gauged to the experience level of each participant. Typically, presentations and workshops will take place in the morning, with case studies, lab demonstrations, and advanced project discussions in the afternoon. Breakout sessions will be based on participants' experience. This format maximizes content appropriateness for each participant by offering the opportunity to apply knowledge gained in the morning to a lab and pilot-scale operation or project/computational design and case studies in the afternoon. Sessions are structured to provide ample time for interaction between participants and speaker.

INTRODUCTION TO DOWNSTREAM PROCESSING OPERATIONS

Course Program Synopsis

In biopharmaceutical process industries, downstream operations deal with removal of soluble and insoluble impurities, including both process and product related impurities. The intent of downstream operations in biomanufacturing is to create the optimum process environment for removal of these impurities by selecting an appropriate purification strategy.

This three-day course is intended for technicians, operators and process design and development professionals new to downstream operations. The course provides a basic overview to downstream operations carried out in a biopharmaceutical manufacturing setting. This course will include both hands-on practical and classroom components. During the course trainees will be introduced to basic downstream operation techniques and strategies for removal of impurities including host cell protein, host cell DNA, product aggregates and fragments, viruses and other impurities.

Topics Covered and Key Learning Outcomes

- Working in a downstream processing environment
- Batch records
- Air classification in downstream operations
- Gowning
- HVAC systems
- Clean air and environmental monitoring
- Open vs. closed processing
- Aseptic processing
- Minimizing risk of contamination
- Buffer selection and preparation (dispensing) facility–manual vs. electronic systems
- Chromatography operation and control (flow rate, pH and temperature)
- Column packing
- Measurement of column performance
- Types of and modes of chromatography (AC, IEC, HIC, mixed mode)
- Understanding binding capacity
- Closed processing, tube sterile connector and welding
- Measurement and monitoring
- Column control and operation
- Column resolution
- Product buffer exchange and concentration
- Bulk API presentation (Freeze-thaw) of API
- DOE based evaluation and implementation of robust and economic operations that meet regulatory expectations

Format

This three-day course is highly experiential and integrates seminars and presentations in a group setting with lab work or advanced projects gauged to the experience level of each participant. Typically, presentations and workshops will take place in the morning, with case studies, lab demonstrations, and advanced project discussions in the afternoon. Breakout sessions will be based on participants' experience. This format maximizes content appropriateness for each participant by offering the opportunity to apply knowledge gained in the morning to a lab and pilot-scale operation or project/ computational design and case studies in the afternoon. Sessions are structured to provide ample time for interaction between participants and speaker.

INTRODUCTION TO QUALITY BY DESIGN (QbD) IN BIOPHARMACEUTICAL PROCESSING

Course Program Synopsis

Since its introduction by the FDA in the early 2000s, Quality by Design (QbD) methodology has become the standard good practice in biopharma for commercialization of bioproducts. Defining and agreeing upon the critical quality attributes (CQAs) of the target product early in process development, and protecting the CQAs of the product building quality in process design during development, tech transfer and manufacturing are the foundational principles of QbD.

This three-day course introduces the basic concepts and principles of QbD to professional scientists and engineers who are new to the field.

Topics Covered and Key Learning Outcomes

- What is and is not QbD and why is it so important in the highly regulated environment of biomanufacturing
- Tools for implementation and use of QbD
- ICH Guidelines Q8, Q9 and Q10
- Simple (practical) implementation of QbD into and throughout the process design: building quality into design and not testing the product as an afterthought
- Understanding (defining) CQAs of a therapeutic product that impact safety, efficacy, potency and identity of the product
- Understanding (designing) a risk-based process to protect the product's CQAs throughout the manufacturing operations and product's life cycle
- Identifying and justifying Critical Process Parameters (CPPs)
- Statistical methods, Design of Experiments, first-principle methods, scale-up and scale-down techniques
- Root-cause analysis: Failure-Mode-Effect Analysis process and product related impurities and their impact on CQAs
- Quality Risk Management (QRM)
- Process optimization and characterization: ranges, design space and response surface methodology
- The key steps of QbD in case studies

Format

This three-day course is highly experiential and integrates seminars and presentations in a group setting with lab work or advanced projects gauged to the experience level of each participant. Typically, presentations and workshops will take place in the morning, with case studies, lab demonstrations, and advanced project discussions in the afternoon. Breakout sessions will be based on participants' experience. This format maximizes content appropriateness for each participant by offering the opportunity to apply knowledge gained in the morning to a lab and pilot-scale operation or project/computational design and case studies in the afternoon. Sessions are structured to provide ample time for interaction between participants and speaker.

INTRODUCTION TO SINGLE-USE TECHNOLOGIES

Course Program Synopsis

Fully flexible ready-to-use technologies offer tremendous opportunities to the biopharma industry. Since 2014 when the first major manufacturing company opened the first fully flexible single-use biomanufacturing facility, several other companies have followed suit, and the trend toward single-use biomanufacturing continues to accelerate.

This two-day course will provide hands-on training in single-use biomanufacturing process technologies. The course will cover both upstream and downstream operations using a mammalian cell culture-based process to provide hands-on experience across multiple steps and operations. Participants will gain laboratory experience in media and solution preparation (single-use mixing systems, CHO culture (wave bag and deep-tank geometry), cell harvest depth filtration), as well as other downstream operations. The course provides full hands-on experience with the process, addressing many of the common questions asked when using single-use processes, including open vs. closed processing, sterile connections and tube welding, environmental monitoring, gowning, economic analysis and comparison with stainless steel processing.

Topics Covered and Key Learning Outcomes

- Introduction to single-use (SU) technologies
- Sterile weldable and heat sealable connections
- Leak-proof molded connection and tubing
- Regulatory guidelines on materials used in components in single-use products
- Sterilization techniques for components
- Sterility assurance validation
- Impact of SU components on product CQAs
- ISO and USP standards and European Pharmacopoeia 3.2.2.1 standards
- "Extractable" and leachable tests
- Master Files with the U.S. Food and Drug Administration
- Intensive hands-on training in setting up and connecting SU equipment across multiple operations in upstream and downstream processes
- Current limitations to SU technologies
- Cost comparison with traditional stainless steel operations

Format

This course is highly experiential and integrates seminars and presentations in a group setting with lab work or advanced projects gauged to the experience level of each participant. Typically, presentations and workshops will take place in the morning, with case studies, lab demonstrations, and advanced project discussions in the afternoon. Breakout sessions will be based on participants' experience. This format maximizes content appropriateness for each participant by offering the opportunity to apply knowledge gained in the morning to a lab and pilot-scale operation or project/computational design and case studies in the afternoon. Sessions are structured to provide ample time for interaction between participants and speaker.

INTRODUCTION TO CMC REGULATORY AND QUALITY COMPLIANCE

Course Program Synopsis

Manufacturing of recombinant proteins and monoclonal antibodies is an exceptionally specialized and highly regulated industry, requiring expert knowledge of national and international regulatory guidelines; for example, ICH Q7, Q8, Q9, Q10 and Q11. In addition, biosimilars and gene and cell-based therapeutics have started receiving commercial approval in the U.S. The increasing sophistication of biologics and the growing therapeutic modalities have led to very high standards of product and process performance making effective Chemistry, Manufacturing & Controls (CMC) regulatory compliance an essential component for success.

This three-day training addresses many of the key challenges and concerns associated with creating and implementing an effective CMC regulatory compliance strategy that can meet FDA requirements and expectations at each stage in the development of bio-therapeutics, from early (phase I) through late-phase (II & III) and commercialization. The course will introduce the concepts and requirements for global pharmaceutical quality and regulatory compliance.

Course Overview

This introductory course provides the basic principles of QbD, PAT and CQAs using case studies, definitions, and terms relevant to understanding how modern biopharmaceutical products are developed and marketed in a highly regulated environment. These techniques are used by industry professionals to create the foundation for ensuring that product quality, safety and efficacy are built into process during design and not introduced as an afterthought.

Topics Covered and Key Learning Outcomes

- CMC tools including Quality by Design (QbD), Quality-Risk Management (QRM) and Pharmaceutical Quality Systems
- CMC expectations, definitions, and responsibilities
- ICH Q7, Q8, Q9, Q10 and Q11 review and case studies
- FDA CMC Review: organization and processes, CDER and CBERS, CTD, ICH and ICH M4
- Gene therapy and cell therapy reviews & case studies
- Writing and reviewing BLAs
- FDA Guidelines on biosimilars
- Gene therapy products
- Cell-based products
- Viral vectors
- Biologic vaccines

Format

This three-day course is highly experiential and integrates seminars and presentations in a group setting with lab work or advanced projects gauged to the experience level of each participant. Typically, presentations and workshops will take place in the morning, with case studies, and advanced project discussions in the afternoon. Breakout sessions will be based on participants' experience. This format maximizes content appropriateness for each participant by offering the opportunity to apply knowledge gained in the morning to a lab and pilot-scale operation or project/computational design and case studies in the afternoon. Sessions are structured to provide ample time for interaction between participants and speaker.

INTRODUCTION TO DESIGN OF EXPERIMENTS

Course Program Synopsis

Success in implementing Quality by Design (QbD) in the biomanufacturing of biologics depends heavily on the ability to apply a number of tools. Mathematical and statistical methods are examples of these tools, used routinely by bioprocess scientists and engineers in combination with other tools, including scale-down techniques and a risk-based methodology, to identify critical and non-critical process parameters, their target settings and ranges. Displaying, summarizing, analyzing and interpreting large amounts of data requires knowledge of basic first principle mathematical methods and established statistical techniques. If used correctly, these tools can help reduce deviations, and enhance process robustness and efficiency.

This three-day course is intended for industry professionals working in bioprocessing and biomanufacturing who are new to these techniques. The course is focused heavily on application and will be based on standard Design of Experiments (DOE) approaches used in industry for designing experiments, carrying out the experiments, analyzing the data, reporting and presenting the results.

Course Overview

This introductory course provides the basic principles of mathematical and statistical methods using case studies, definitions and terms relevant to understanding how modern biopharmaceutical products are developed and marketed in a highly regulated environment. These techniques are used by industry professionals to create the foundation for ensuring that product quality, safety, and efficacy are built into process during design and not introduced as an afterthought.

Topics Covered and Key Learning Outcomes

- Understand the statistical concepts of bias, variability, and sampling distributions
- Select the appropriate statistical method for a given data set
- Factorial and fractional factorial designs
- Evaluate the quality of data collected from observational and experimental studies
- Design simple studies
- Use statistical computer software to explore and analyze data
- Understand statistical language as used in bioprocess development and biomanufacturing
- Interpret statistical results and communicate them to other scientists and engineers
- Hypothesis testing
- Regression analysis
- ANOVA
- Confounding & Blocking Design
- JMP analysis

Format

This three-day course is highly experiential and integrates seminars and presentations in a group setting with lab work or advanced projects gauged to the experience level of each participant. Typically, presentations and workshops will take place in the morning, with case studies, lab demonstrations, and advanced project discussions in the afternoon. Breakout sessions will be based on participants' experience. This format maximizes content appropriateness for each participant by offering the opportunity to apply knowledge gained in the morning to a lab and pilot-scale operation or project/computational design and case studies in the afternoon. Sessions are structured to provide ample time for interaction between participants and speaker.

INTRODUCTION TO ASEPTIC PROCESSING

Course Program Synopsis

Biopharmaceutical drug products are normally in liquid form and often are delivered to patients directly through intravenous (IV) or subcutaneous (Sub-Q) injection. As such, manufacturers are required to provide significant assurance regarding the safety of drug products since the method of delivery effectively bypasses the patient's natural defenses against any infection caused by the drug or the device, or both. A major challenge with biologics is their structural sensitivity to heat and irradiation which effectively rules our terminal sterilization techniques as a method for sterile processing.

This three-day course in intended for industry professionals working in the biopharma industry who wish to learn about basic drug substance and drug product process operations under all types of clean room, aseptic, and sterile environments.

Topics Covered and Key Learning Outcomes

- True aseptic processing (terminal sterilization)
- Documentation procedure and methods
- Heat and irradiation sterilization
- Sterilization equipment and components
- Sanitization
- Laminar airflow hoods, isolators or restricted access barrier systems
- Sterilizing filters, autoclaves, depyrogenation for endotoxins removal
- Controlled processing environment. Clean room layout and classification (particle counts, temperature, humidity and pressure)
- Clean room monitoring and sampling
- Open vs. closed processing
- Environmental monitoring
- Risk assessment of clean room environment
- Using QRM as a tool to ensure product safety
- Minimizing the risk of microbial, particulate and pyrogen contaminant
- Sources of contamination
- Operators
- Raw material
- Movement of personnel
- Gowning
- Drug substance vs. drug product processing environment
- Container closure
- HVAC and air flow and air changes per hour

Format

This three-day course is highly experiential and integrates seminars and presentations in a group setting with lab work or advanced projects gauged to the experience level of each participant. Typically, presentations and workshops will take place in the morning, with case studies, lab demonstrations, and advanced project discussions in the afternoon. Breakout sessions will be based on participants' experience. This format maximizes content appropriateness for each participant by offering the opportunity to apply knowledge gained in the morning to a lab and pilot-scale operation or project/computational design and case studies in the afternoon. Sessions are structured to provide ample time for interaction between participants and speaker.

INTRODUCTION TO COMPUTATIONAL FLUID DYNAMICS (CFD) IN BIOPROCESSING

Course Program Synopsis

Developing, testing, validating, and implementing scale-down models of commercial scale biomanufacturing operations are important parts of Quality by Design (QbD). Developing proper scale-down models for commercial scale operations requires the application of a number of established scientific and engineering tools. These include the computational fluid dynamics (CFD) technique, used specifically to quantify the complex flow environment in commercial scale process equipment, including bioreactors, mixing tanks, centrifuges and filters, chromatography columns, filling machines and delivery devices. Recreating the prevailing flow environment in a scale-down model and then using it to test the impact of process and operational parameters on product quality is the ultimate aim of CFD in bioprocess operations. Applied correctly, CFD enables process design teams to reduce risks associated with product failure, optimize process related design, and reduce time-to-market through in-silico testing of design ideas.

Course Overview

This hands-on three-day CFD course introduces the participants to the applied aspects of CFD using ANSYS FLUENT software. Through specific examples and case studies participants will gain knowledge of how to apply CFD techniques to solve serious bioprocess challenges in a biomanufacturing environment.

Topics Covered and Key Learning Outcomes

- Selecting a CFD model that best describes a specific process challenge in terms of boundary conditions and material properties
- Steady state vs transient simulations
- Turbulence models
- Discretization
- Geometry design/import
- Mesh generation
- Mesh types
- Mesh statistics
- 2D and 3D drawings
- Importing CAD files
- Boundary conditions/solver
- Setting rotating reference frames
- Post processing
- Fluid flow in specific single process situations, e.g. mixing tanks, pumps, pipes, etc.
- Mixing time and shear study set up
- Tracer injection and tracking
- Determining convergence
- Single-phase vs. multiphase problems with specific case studies, e.g. gas liquid flow in bioreactors
- Analyzing CFD simulation results, plotting data

Format

This three-day course is highly experiential and integrates seminars and presentations in a group setting with computer lab work or advanced projects gauged to the experience level of each participant. Typically, presentations and workshops will take place in the morning, with case studies, lab demonstrations, and advanced project discussions in the afternoon. Breakout sessions will be based on participants' experience. This format maximizes content appropriateness for each participant by offering the opportunity to apply knowledge gained in the morning to a lab and pilot-scale operation or project/computational design and case studies in the afternoon. Sessions are structured to provide ample time for interaction between participants and speaker.

INTRODUCTION TO VIRAL SAFETY STRATEGY IN BIOPHARMACEUTICAL MANUFACTURING

Course Program Synopsis

Implementing a robust viral strategy to deal with adventitious agents including bacteria, mycoplasma, adventitious viruses, endogenous retroviruses, fungi/molds and prions, is one of the most critical aspects for any biotherapeutic manufacturer. Viral contamination is rare, thanks to a combination of regulatory expectations and guidance, and significant advancements in the industry's understanding of how to deal with these contaminants. Understanding the regulatory drivers for product safety means that bioprocess scientists and engineers must stay up-to-date and apply best practices and available tools and guidelines to prevent, detect, and clear viruses at every point in the process, raw materials, upstream and downstream steps. These guidelines evaluate potential risk and establish testing requirements for the entire biomanufacturing process.

In this three-day course, participants will hear from several industry subject matter experts and government regulators who are closely involved on a daily bases in viral safety in biomanufacturing. The course offers an introduction to viral safety and looks at areas of risk, the regulatory guidelines, testing requirements, and critical steps in the biologics manufacturing process.

Course Overview

Using case studies and real-life examples, the course will focus on major viral safety issues that manufacturers of biologics encounter, and the practical and pragmatic solutions bioprocess scientists and engineers have developed to address these concerns.

Topics Covered and Key Learning Outcomes

- Virus types and classifications
- Effective viral clearance and removal strategies
- Enveloped vs. non-enveloped viruses
- Chemical inactivation vs. heat inactivation vs. irradiation inactivation vs. physical separation
- Technologies and equipment
- Viral clearance studies using scale-down models, their validation and implementation into commercial scale process
- Unit operations directly targeting viral clearance and virus removal
- Chromatography operation for viral clearance
- Meeting regulatory expectations in Log Reduction Values for API and release specification
- Analytical methods
- Case studies

Format

This three-day course is highly experiential and integrates seminars and presentations in a group setting with lab work or advanced projects gauged to the experience level of each participant. Typically, presentations and workshops will take place in the morning, with case studies, lab demonstrations, and advanced project discussions in the afternoon. Breakout sessions will be based on participants' experience. This format maximizes content appropriateness for each participant by offering the opportunity to apply knowledge gained in the morning to a lab and pilot-scale operation or project/computational design and case studies in the afternoon. Sessions are structured to provide ample time for interaction between participants and speaker.

INTRODUCTION TO CONTINUOUS BIOPROCESSING

Course Program Synopsis

Continuous bioprocessing has significant promise in terms of product improvement and facility utilization. Multiple technologies are already available and more are being developed to allow an end-to-end continuous process for the manufacture of next generation biologics. That said, many practical challenges, both in technology gaps and process and analytical control strategies, need to be addressed.

This three-day hands-on course introduces participants to challenges and opportunities offered by continuous bioprocessing across upstream and downstream operations.

Course Overview

The course focuses on the recent and ongoing development of technologies and their potential transfer to manufacturing. Through specific examples and case studies, participants will gain knowledge on how to apply bioprocessing techniques to create a continuous unit operation and link these operations to create a conceptual end-to-end continuous process.

Topics Covered and Key Learning Outcomes

- Regulatory drivers and considerations
- Continuous vs. batch processes overview
- Upstream operations
- Perfusion bioreactors
- Process Analytical Technologies (PAT)
- Continuous harvesting operations
- Continuous viral clearance and inactivation processes
- Continuous chromatography processes
- Single pass continuous TFF
- Process modeling and integration
- Process control and monitoring
- Scale-down models of continuous bioprocess operations

Format

This three-day course is highly experiential and integrates seminars and presentations in a group setting with lab work or advanced projects gauged to the experience level of each participant. Typically, presentations and workshops will take place in the morning, with case studies, lab demonstrations, and advanced project discussions in the afternoon. Breakout sessions will be based on participants' experience. This format maximizes content appropriateness for each participant by offering the opportunity to apply knowledge gained in the morning to a lab and pilot-scale operation or project/computational design and case studies in the afternoon. Sessions are structured to provide ample time for interaction between participants and speaker.

INTRODUCTION TO BIOPROCESS CONTROL & AUTOMATION

Course Program Synopsis

As manufacturing of biologics transitions from traditional batch to semi-batch and eventually to fully continuous processing, bioprocess scientists and engineers need to embrace and deal with the challenges of automation, process control and integration, and the large amount of data generated by such processes.

Automation combined with process control and process integration provides significant opportunities for process efficiency throughout the manufacturing facility, including upstream and downstream operations.

Course Overview

This three-day course offers an introduction for professionals in biomanufacturing industries who wish to learn more about the practical (application) aspects of automation and process control as applied specifically to bioprocess development.

Topics Covered and Key Learning Outcomes

- Process development vs. manufacturing vs. material supply
- Process integration and effective data management
- Quality by Design (QbD) and Process Analytical Technology (PAT)
- Hard and soft sensors and process controllers
- Smart instrumentation
- Matching automation capabilities to process needs and process understanding in a highly regulated GMP environment
- Electronic batch records
- Manufacturing Operations Management (MOM) and Manufacturing Execution Systems (MES)
- Distributed Control System (DCS) vs. non-DCS systems
- Automated process management systems
- Supervisory Control And Data Acquisition (SCADA) control
- Delta V
- Automation of single-use vs. stainless steel facilities
- The Internet of things (IoT)

Format

This three-day course is highly experiential and integrates seminars and presentations in a group setting with lab work or advanced projects gauged to the experience level of each participant. Typically, presentations and workshops will take place in the morning, with case studies, lab demonstrations, and advanced project discussions in the afternoon. Breakout sessions will be based on participants' experience. This format maximizes content appropriateness for each participant by offering the opportunity to apply knowledge gained in the morning to a lab and pilot-scale operation or project/computational design and case studies in the afternoon. Sessions are structured to provide ample time for interaction between participants and speaker.

INTRODUCTION TO PROCESS CHARACTERIZATION AND VALIDATION

Course Program Synopsis

Guidelines introduced by the FDA and the European Medicines Agency (EMA) represent a paradigm shift in the process validation approach. These guidance documents incorporate the "lifecycle" concept into the validation process. These guidelines are not based on conformance to a fixed set of protocols, but are designed using a risk-based approach that identifies and controls potential risks within the manufacturing process. These guidelines consider the validation as an exercise that is meant not only to achieve process understanding and consistency, but also to provide ongoing verification, which makes sure that the process remains within its validated design space and consistently produces a product that meets all specifications. Manufacturing processes for biopharmaceuticals must be designed to produce products that have consistent quality attributes. Manufacturing processes should be validated by applying a scientifically rigorous and well-documented exercise demonstrating that the process, and every equipment used in it, consistently performs as intended, and that the process, when operated within established limits, generates a product that routinely and reliably meets its required quality standards.

This three-day course introduces the basic concepts and principles of pharmaceutical process validation to professional scientists and engineers who are new to the field.

Topics Covered and Key Learning Outcomes

- The principles described in the ICH Q8, Q9, and Q10 & Q11
- Different stages of process validation
- Role of Quality by Design (QbD) approach in process design and FDA's view of QbD
- How to use the available data to do initial and late stage risk assessments
- How to demonstrate that the scale-down model is appropriate
- Which response variables should be studied in an experimental design
- How many experiments need to be conducted to prove that a potential critical parameter is not critical
- How to state statistically that a parameter is key, non-key, critical or non-critical
- How to statistically define normal operating and proven acceptable ranges
- How to stack together multiple DoEs to identify optimization potential and predict out of specification (OOS) events

Format

This three-day course is highly experiential and integrates seminars and presentations in a group setting with lab work or advanced projects gauged to the experience level of each participant. Typically, presentations and workshops will take place in the morning, with case studies, lab demonstrations, and advanced project discussions in the afternoon. Breakout sessions will be based on participants' experience. This format maximizes content appropriateness for each participant by offering the opportunity to apply knowledge gained in the morning to a lab and pilot-scale operation or project/computational design and case studies in the afternoon. Sessions are structured to provide ample time for interaction between participants and speaker.

ROLE OF LIQUID CHROMATOGRAPHY AND MASS SPECTROMETRY (LC–MS) IN CHARACTERIZATION OF MONOCLONAL ANTIBODIES

Course Program Synopsis

Protein biopharmaceuticals have a complexity far exceeding that of small molecule drugs. The structural characteristics of these proteins, together with their stabilities, have to be revealed during the development phase, and also need to be closely monitored prior to clinical or commercial release. Not only in assessing these characteristics, but also in demonstrating comparability, e.g., between originator and biosimilar, a significant number of analytical tools have to be employed. This training provides insights into the importance and use of liquid chromatography and mass spectrometry technique for mAbs (biologics and biosimilars) discovery, development and release.

This three-day course is intended for technicians, operators and analytical/bioanalytical scientists new to biopharmaceutical operations. This course will include both hands-on practical and classroom components. During the course, trainees will be introduced to basics of chromatography and mass spectroscopy including the regulatory requirements of LCMS method validation and the concept of Analytical Quality by Design (AQbD).

Topics Covered and Key Learning Outcomes

- Discuss characterization and QC testing of biopharmaceuticals, structure and functional complexity of biopharmaceuticals, describe the critical quality attributes (CQAs) of biopharmaceuticals and list some key analytical methods used in the analysis of biopharmaceuticals
- Have a basic understanding of the role of chromatography in the analysis of biopharmaceuticals, basic understanding of common chromatographic separations of proteins with an emphasis on size exclusion chromatography (SEC), Ion Exchange Chromatography (IEX) and Reverse Phase Liquid Chromatography (RP-LC)
- Understand the theory of mass spectrometry and use of various mass spectrometric techniques in characterization and quantification of monoclonal antibodies
- Understand ICH and FDA guidelines for analytical and bioanalytical method validation

Format

This three-day course integrates seminars and presentations in a group setting with lab work or advanced projects gauged to the experience level of each participant. Typically, presentations and workshops will take place in the morning, with case studies, lab demonstrations, and advanced project discussions in the afternoon. Breakout sessions will be based on participants' experience. This format maximizes content appropriateness for each participant by offering the opportunity to apply knowledge gained through different case studies. Sessions are structured to provide ample time for interaction between participants and speaker.

INTRODUCTION TO ANALYTICAL TECHNIQUES FOR CHARACTERIZATION OF MONOCLONAL ANTIBODIES (mAbs)

Course Program Synopsis

Protein biopharmaceuticals have a complexity far exceeding that of small molecule drugs. The structural characteristics of these proteins, together with their stabilities have to be revealed during development and subsequently need to be closely monitored prior to clinical or commercial release. In assessing these characteristics and in demonstrating comparability, e.g., between originator and biosimilar, a significant number of analytical tools have to be employed. This training provides insights into the chromatographic, electrophoretic and immunoassay techniques most commonly used in industry for mAbs discovery, development and release.

This three-day course is intended for technicians, operators and analytical/bioanalytical scientists new to biopharmaceutical operations. This course will include both hands-on practical and classroom components. During the course trainees will be introduced to basic analytical techniques used in biopharmaceutical industry for protein characterization.

Topics Covered and Key Learning Outcomes

- Discuss characterization and QC testing of biopharmaceuticals, structure and functional complexity of biopharmaceuticals, describe the critical quality attributes (CQAs) of biopharmaceuticals and list some key analytical methods used in the analysis of biopharmaceuticals
- Be familiar with the importance of immunoassays and bioassays, learn the basic principles of immunoassays including ELISA, Western Blotting and Surface Plasmon Resonance
- Have a basic understanding of the role of chromatography in the analysis of biopharmaceuticals, basic understanding of common chromatographic separations of proteins with an emphasis on Size Exclusion Chromatography (SEC), Ion Exchange Chromatography (IEX) and Reverse Phase Liquid Chromatography (RP-LC)
- Understand the theory and practice of slab gel electrophoresis, able to describe different types of protein gels and what information each can provide about proteins
- Be able to describe electrophoresis principals in its use in the biopharmaceutical industry, advantages of CE over traditional gel labs. Understand and run gel electrophoresis
- Be able to describe the issue of Host Cell Protein (HCP) contaminations and detection of HCP using immunoassay techniques
- Importance of protein purity in biopharmaceutical industry and analysis of protein purity by SDS PAGE

Format

This three-day course integrates seminars and presentations in a group setting with lab work or advanced projects gauged to the experience level of each participant. Typically, presentations and workshops will take place in the morning, with case studies, lab demonstrations, and advanced project discussions in the afternoon. Breakout sessions will be based on participants' experience. This format maximizes content appropriateness for each participant by offering the opportunity to apply knowledge gained through different case studies. Sessions are structured to provide ample time for interaction between participants and speaker.

CURRENT 2020 DATES

COURSE	DATE	PRICE
Preparative Chromatography	1/22 – 1/24	$3,000
Bioanalytical and Quality Control Testing for Biologics and Biosimilars	2/10 – 2/12	$3,000
Mammalian Cell Culture Process Design	2/19 – 2/21	$3,000
Introduction to Downstream Processing Operations	2/26 – 2/28	$3,000
Introduction to Biopharmaceutical Process Engineering	3/9 – 3/11	$3,000
Introduction to Upstream Processing Operations	3/19 – 3/20	$2,000
Primary Recovery and Tangential Flow Filtration (TFF) Operation	3/23 – 3/25	$3,000
Introduction to Single-Use Technologies in the Biopharmaceutical Industry	3/30 – 3/31	$2,000
Introduction to Analytical Techniques for Characterization of Monoclonal Antibodies (mAbs)	4/6 – 4/8	$3,000
Introduction to Aseptic Processing	4/13 – 4/15	$3,000
Introduction to Process Characterization and Validation	4/16 – 4/18	$3,000
Introduction to Quality by Design (QbD) in Biopharmaceutical Processing	4/20 – 4/22	$3,000
Design of Experiments for Biopharmaceutical Process Development	4/27 – 4/29	$3,000

Please contact **Lyn Kugel** at **HLynda.Kugel@jefferson.edu** to inquire about additional courses and dates or to discuss group rates or multiple training registrations.

Customized Training

In addition to open enrollment courses, JIB also offers customized trainings to meet industry needs by providing specialized courses developed through face-to face planning and delivered either at JIB or at the company site. JIB can customize training tailored to address the learning goals of a company or work group, including supplementing on-boarding training with hands-on laboratory and pilot-scale experience.

JIB Bioprocessing Solutions

In addition to training, JIB offers global bioprocessing solutions, including consultative services, working with clients on new technology assessment/validation, process development, and bioanalytical services in our 25,000 sq. ft. state-of-the-art GLP pilot-scale facility, featuring single-use end-to-end production capabilities. For more information or to discuss a potential project, please contact **Lyn Kugel** at **HLynda.Kugel@jefferson.edu**.

JIB TRAINING TEAM

Parviz Ayazi Shamlou, PhD

Executive Director

Parviz received both his BTech and PhD in Chemical Engineering from the University of Bradford, UK. As a chemical engineer, Parviz combines 37 years of academic and industry experience in bioprocessing with the focus on biopharmaceutical and biologic process development.

As Executive Director for JIB, Parviz leads all of the Institute's activities including designing and delivering education and training, budgeting and financing, research and development, recruitment, program development, and fundraising for research and future growth.

At the core of Parviz's philosophy and vision for education is the development and implementation of industry-facing programs to address the growing need for a skilled workforce in biomanufacturing.

Cameron Bardliving, PhD

Director of Process Development & Operations

Cameron received his BS in Chemical Engineering from UMBC and his PhD in Biomedical Engineering from Cornell. While overseeing training and research activities in the JIB single-use flex factory, Cameron also specializes in process development, biopharmaceutical process modeling, fermentation and CHO cell culture.

Jasbir S. Arora, PhD

Director Bioanalytical, Regulatory and Quality

Jasbir received both his BS, MS and PhD in Chemistry from Guru Nanak Dev University, India. Along with setting up the bioanalytical laboratory with all the analytical tools required for characterization and quality control of monoclonal antibodies, Jasbir teaches and trains both students and scientists on the analytical tools of bioprocessing.

Cianna Cooper

Laboratory Operations Manager

Cianna received her BA in Biochemistry from Manhattanville College and her MA in Biochemistry from Boston University. Beyond managing operations in the lab, Cianna specializes in mammalian cell culture and protein purification techniques including lab scale chromatographic methods, bioanalytical immunoassay development, GLP.

Laura Chinn

Upstream Bioprocessing Instructor

Laura received her AS in Science from Wabaunsee Community College and her BS in Biology from Northern Michigan University. At JIB, Laura provides trainees with hands-on laboratory training including: aseptic technique, mammalian cell culturing, small and pilot-scale bioreactor operation, and single-use technology.

Samantha Heidlebaugh

Downstream Bioprocessing Instructor

Samantha received her BS in Chemical Engineering from the University of Pittsburgh and her MS in Biochemical Engineering from the University College London. At JIB she trains industry professionals on filtration and chromatography processes and technologies. She also specializes in protein purification, column packing, chromatography, tangential flow filtration, depth filtration and single-use technologies.

Will Vines

Upstream Bioprocessing Instructor

Will received his BS in Biology from Longwood University and his MS in Bioscience Technologies from Thomas Jefferson University. At JIB, Will provides trainees with hands-on laboratory training including: aseptic technique, mammalian cell culturing, small and pilot-scale bioreactor operation, and single-use technology.

Samantha Nemeth

Downstream Bioprocessing Instructor

Samantha received her BS in Biology from Rowan University. At JIB she provides trainees with hands-on laboratory training including liquid chromatography, depth filtration and TFF on both a small and pilot-scale.

ABOUT NIBRT

The National Institute for Bioprocessing Research and Training (NIBRT) is a global center of excellence for training and research in bioprocessing. NIBRT is located in a new, world class facility in Dublin, Ireland. This facility is built to closely replicate a modern bioprocessing plant with state-of-the-art equipment.

NIBRT arose from an innovative collaboration between University College Dublin, Trinity College Dublin, Dublin City University and the Institute of Technology, Sligo. NIBRT was primarily funded by the Government of Ireland through Ireland's inward investment promotion agency, IDA Ireland (Industrial Development Agency), which is responsible for the attraction and development of foreign investment in Ireland.

NIBRT offers a quality training and research experience not previously possible anywhere in the world.

More information at: **NIBRT.IE**

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