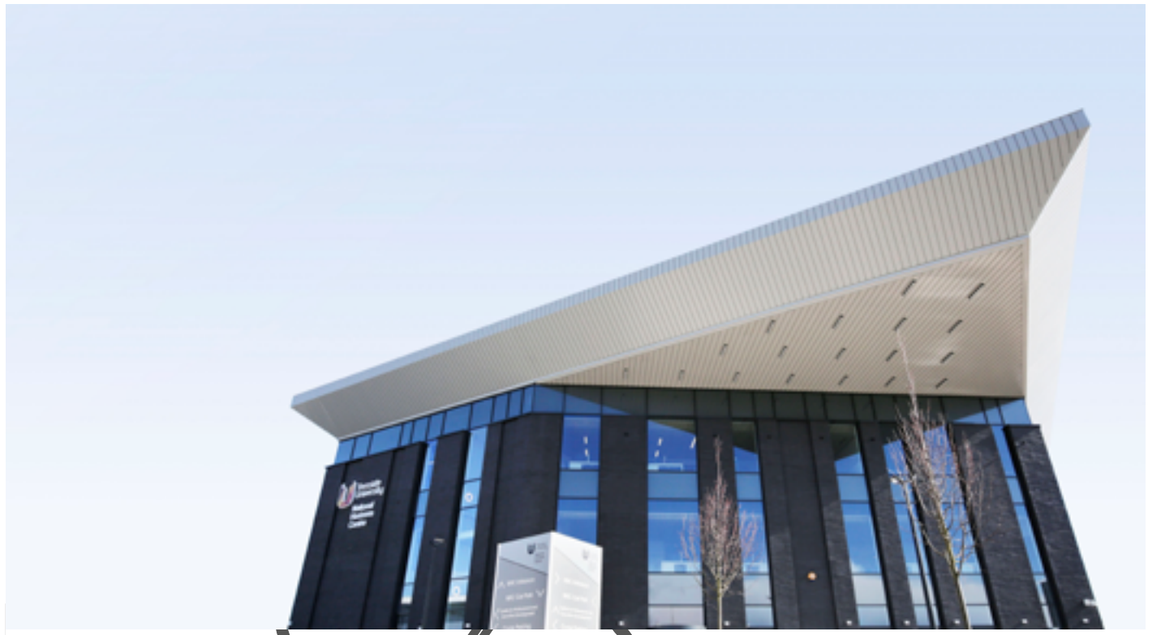

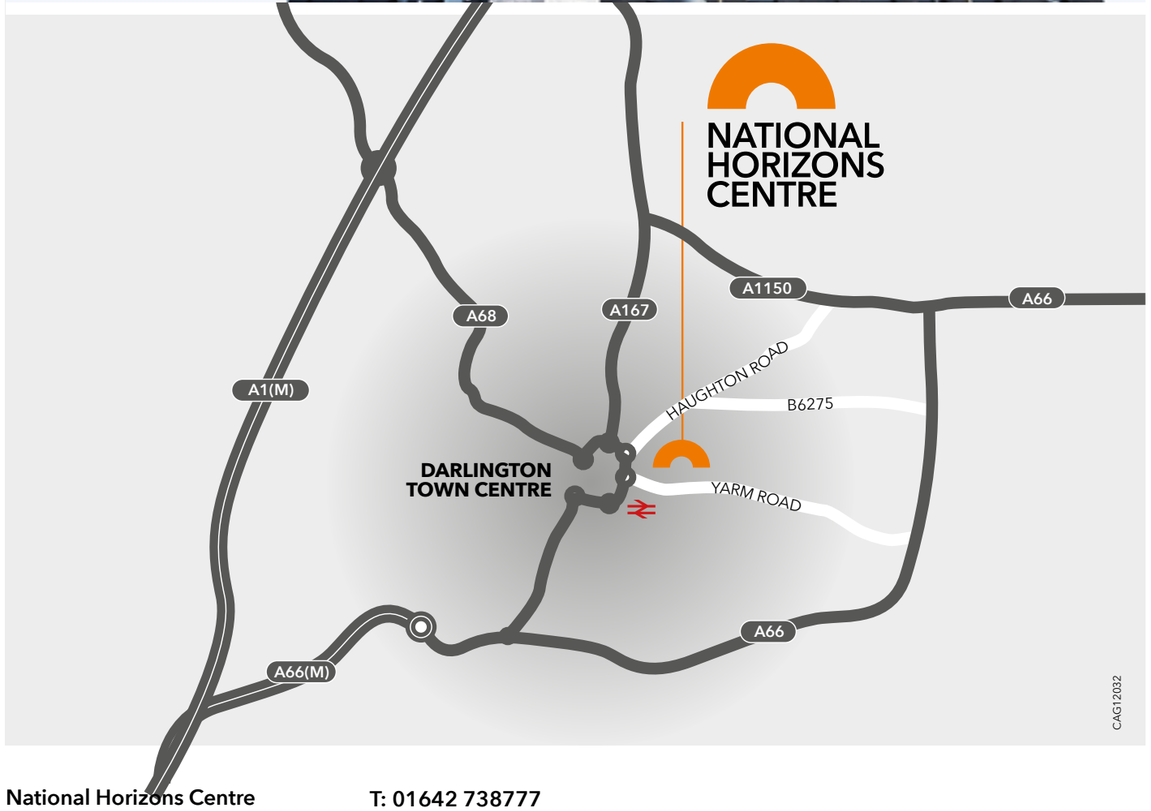

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NATIONAL HORIZONS CENTRE

Teesside University

INTRODUCTION TO DOWNSTREAM BIOPROCESSING

DELIVERED IN PARTNERSHIP WITH CYTIVA

cytiva

A UK CENTRE OF EXCELLENCE FOR THE BIOSCIENCE INDUSTRY

TRAINING

WELCOME

Dr Jen Vanderhoven

DIRECTOR

Welcome to the National Horizons Centre (NHC). We are Teesside University's centre of excellence for the biosciences and healthcare sector. With research, partnerships and training at our core, we bring together industry, academia, talent and world-class facilities to create real-world impact.

As a National Training Centre for Advanced Therapies, funded from the Department for Business, Energy & Industrial Strategy (BEIS) and Innovate UK (IUK) delivered through the Cell and Gene Therapy Catapult, our courses are industry approved and we have worked closely with key bioindustry leaders across the sector to ensure our courses have been designed to deliver vital skills needed for advanced therapies, vaccines manufacturing and bioprocessing.

The course introduces delegates to chromatography and downstream processes and the principles of purification and membrane separations.

Our unique training facility houses state-of-the-art equipment that provides delegates with the opportunity to gain hands-on practical training in complex bioprocessing procedures, including the Cytiva AKTA platform and UNICORN software.

I look forward to welcoming you to the NHC.

The NHC is one of the National Training Centres part of the ATSTN programme funded from the Department for Business, Energy & Industrial Strategy (BEIS) and Innovate UK (IUK) delivered through the Cell and Gene Therapy Catapult.

COURSE OVERVIEW

DAY 1: Introduction to downstream bioprocessing

Lecture one
Introduction to chromatography and downstream processes

Lecture two
The principles of protein purification, why proteins should be purified and the rationale for testing Host Cell Proteins (HCP)

Lecture three
Hardware and software tools for downstream process development
- >The Cytiva AKTA platform and associated hardware
- >An emphasis on UNICORN software for the control of AKTA, the generation of methods, the evaluation of results and the administration of both hardware and data
- >A brief introduction to advanced functions- multistep purification and UNICORN Design of Experiments

Lab one
Chromatography
- >AKTA hardwar
- >The AKTA flowpath
- >Pumps, valves and monitors
- >Critical housekeeping
- >Sample pump and frac pumps

Lab two
Column Packing
- >Resin slurries
- >Intro to HIScale
- >Pack a HiScale 16/20

Lab three
Imaging
- >HCP and ELISA techniques

DAY 2: Chromatography- biologics purification and membrane separations

Lecture four
Membrane materials, properties and devices

Discussion of typical materials used for biopharmaceutical filtration processes, their properties, and the configuration of different filter devices

Lecture five
Introduction to normal flow and crossflow filtration

Introduction to the scientific principles of normal flow and crossflow filtration used in biopharmaceutical production

Lecture six
Operation of a normal flow filtration process

Deeper dive into setting up and running a normal flow filtration process

Lab four
Chromatography
- >AKTA Purification
- >Program an IMAC method
- >Prepare the system
- >Purify a His-tagged protein
- >Analyse the chromatogram

Lab five
Imaging

Melanie Coverage experience of this tool used in monitoring Host Cell Protein (HCP) impurities in biopharmaceutical products.

Lab six
FUJIFILM Diosynth Biotechnologies case study

Lab seven
Introduction to ÄKTAflux S system; normal flow clarification of bovine serum albumin (BSA) and vitamin B12 from a yeast solution

Discussion of semi-automated lab-scale filtration system, which, although designed for crossflow filtration, can also be utilised for normal flow filtration. Experiment to separate BSA from a yeast solution.

DAY 3: Membrane separations

Lecture seven
Operation of a crossflow filtration process

Deeper dive into setting up and running a crossflow filtration process. Includes system design, filter choice, and critical operating parameters.

Lecture eight
Hollow fibre filter installation and testing the clean water flux of a crossflow filter

Instruction on use of a common crossflow filter type used in the biopharmaceutical industry: the hollow fibre. Clean water performance test, also called normalised water permeability, will be performed.

Lab eight
Concentration and diafiltration of clarified BSA and vitamin B12 using the ÄKTAflux S system

Experiment on a crossflow filtration process which has broad use in the biopharmaceutical industry: concentration and diafiltration of a protein solution. Analysis of results of experiments.