

#### Single Use Technologies in Upstream Bioprocessing **Operations**

Innovation in the biopharmaceutical industry is driven by adapting fundamental bioprocessing strategies and technologies.

This course will introduce you to key upstream bioprocessing concepts and techniques, and bring them into practice through practical experiences operating single-use bioreactors. Explore single-use technology solutions for upstream bioprocessing

#### **About this Course**

Single-use technology is widely used within the biopharmaceutical industry and has quickly become a mainstay within the sector as it facilitates faster, secure, and economical biologics production.

This three-day course combines the NIBRT curriculum with industry-focused practical training from UTS to provide a holistic introduction to upstream operations, with a focus on single-use technology.

You will gain hands-on practical experience operating both small scale and large scale single-use bioreactors in a GMP-like environment.

## **Key Topics Covered**

- Overview of the biopharmaceutical production process
- Introduction to bioreactor design and operations
- Single-use technology landscape, applications, advantages, and disadvantages
- Aseptic operation of biosafety cabinets and bioreactors
- Set up and operation of single-use 50L WAVE bioreactor system and 200L bioreactor
- Mock run of typical upstream processes under cleanroom environment.

#### **Course Structure**

This three-day course incorporates both theory and a practical learning experience by combining the NIBRT industry training curriculum with hands-on, practical sessions from UTS.

You will gain a foundation knowledge of key upstream operations, highlighting the application of single-use technologies in upstream processing. Engage in hands-on practical experiences using aseptic connections, WAVE bioreactor systems, and a traditional upright 200L single-use bioreactor.

You will also have the opportunity to prepare and run designed pilot-scale upstream protocols in a GMP-Lite cleanroom environment.

An assessment will be conducted at the end of the course to certify proficiency in the theory and practical content which has been covered.

Course price: \$3,600

### **Learning Outcomes**

- Describe the aseptic culturing of mammalian cells from small to large scale
- Understand the principles and applications of single-use technology.
- Discuss the advantages and disadvantages of single-use technology in upstream processing
- Complete SOPs, batch records, and logbook
- Demonstrate key procedures in the preparation and operation of a single-use WAVE system and 200L bioreactor.

# Who is this Course For?

- Those wishing to increase their knowledge of upstream operations in a modern bioprocessing plant, including: Operators, Technical staff, Engineers, and Managers.
- This course is also recommended for individuals who are new to single-use technologies, including: Development scientists, Process engineers, and Manufacturing operators.

#### **About the Providers**

#### **Biologics Innovation Facility (BIF)**

BIF is an Australia-first training and bioprocessing facility based at the University of Technology, Sydney.

BIF aims to drive the development of the biotech industry by offering a platform for innovation in biopharmaceutical research, as well as providing professional training in bioprocessing techniques in a GMP-like environment.

For more information, email BIF at bif@uts.edu.au

# National Institute of Bioprocessing Research and Training (NIBRT)

NIBRT is a global centre of excellence for training and research in biopharmaceutical manufacturing. NIBRT is located in a world class facility in Dublin, Ireland.

This facility is purpose built to closely replicate a modern bioprocessing plant with state-of-the-art equipment and enables NIBRT to offer the highest quality training and research solutions.

NIBRT's mission is to support the growth and development of all aspects of the biopharmaceutical manufacturing industry.

# **Course Content**

# Single Use Technologies in Upstream Bioprocessing Operations 2021

		Lesson Name	Topics Covered
Day 1	AM	Lecture 1 – Introduction to Biopharmaceutical Processing	<ul> <li>Introduction to Biopharmaceutical Industry</li> <li>Biopharmaceutical Production Process         Overview     </li> </ul>
		<b>Lecture 2</b> – Cell Culture and Upstream Processing	<ul> <li>Cell lines and cell banking         <ul> <li>Different cell types in drug production</li> <li>The process of cell banking</li> <li>Virus testing in cell lines/banks</li> </ul> </li> <li>Overview of Upstream Processing         <ul> <li>The cell culture process</li> <li>Equipment required in a cell culture factory</li> <li>Stages of cell kinetics</li> </ul> </li> </ul>
	PM	Practical 1 – Aseptic Operations	<ul> <li>Aseptic techniques when working with cells</li> <li>Methods of cell counting         <ul> <li>Manual and automated cell counting methods</li> </ul> </li> <li>Cell culture scale up calculations</li> <li>Aseptic connections         <ul> <li>Cytiva Hot Lips Tube Sealer</li> <li>Cytiva Tube Fuser – Dry</li> <li>Sterile Connectors</li> </ul> </li> </ul>
		<b>Lecture 3 –</b> Single Use Technologies	<ul> <li>Principles and Applications of Disposable Technologies:         <ul> <li>Industry Trends</li> <li>Advantages and Disadvantages</li> </ul> </li> <li>Examples of Disposable Technology:         <ul> <li>Equipment and Components Used</li> </ul> </li> <li>Regulation         <ul> <li>Guidance and Issues</li> </ul> </li> </ul>

		Lesson Name	Topics Covered
		<b>Lecture 4</b> – Bioreactor Operations	<ul> <li>Bioreactor Design</li> <li>Process requirements for bioreactors</li> <li>Basic principles of agitation and aeration</li> <li>Advantages and disadvantages of various bioreactor systems</li> </ul>
Day 2	AM	<b>Lecture 5 –</b> Single Use Upstream Processing	<ul> <li>Introduction to Single Use technology in Upstream bioprocessing</li> <li>Single Use Upstream processing equipment</li> <li>Modes of Single Use technology utilisation</li> <li>Advantages and disadvantages of Single Use technology in Upstream bioprocessing</li> </ul>
	PM	<b>Practical 2 –</b> WAVE Bioreactor	<ul> <li>Set-up, Installation, and Operation of Cytiva WAVE Bioreactor</li> </ul>
		<b>Practical 3 –</b> 200L Disposable Bioreactor	<ul> <li>Set-up, Installation, and Operation of Cytiva 200L Disposable Bioreactor</li> </ul>

		Lesson Name	Topics Covered
Day 3	AM	<b>Practical 4 –</b> Mock Run WAVE Bioreactor	<ul> <li>Trainees are given the opportunity to handle Cytiva WAVE Bioreactor system</li> <li>Trainees become familiarised with using a batch record</li> <li>Set-up, Installation, and Operation of Cytiva WAVE Bioreactor</li> </ul>
	PM	<b>Practical 5 –</b> Mock Run 200L Disposable Bioreactor	<ul> <li>Trainees are given the opportunity to handle Cytiva 200L Disposable Bioreactor equipment</li> <li>Trainees become familiarised with using a batch record</li> <li>Set-up, Installation, and Operation of Cytiva 200L Disposable Bioreactor</li> </ul>