



**SHORT COURSE**

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

Understanding the fundamental aspects and skills of downstream bioprocessing underpins innovation in the biopharmaceutical industry.

This three-day course introduces you to key downstream bioprocessing approaches and techniques. Take a proactive approach in applying these skills to downstream operations and discover single-use technology solutions for downstream bioprocessing.

### **About this Course**

Single-use technology is widely used within the biopharma 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 downstream bioprocessing operations, focusing on single-use technology.

Gain hands-on practical experience operating downstream purification processes, including chromatography and UF/DF.

### **Key Topics Covered**

- Fundamentals of downstream processing for product recovery
- Single-use technologies in downstream processes
- Overview of chromatography
- Overview of ultrafiltration/diafiltration
- Viral clearance technologies
- Preparation and operation of a single-use chromatography system
- Preparation and operation of a single-use UF/DF system.

# Course Structure

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

You will expand your knowledge on downstream bioprocessing through theory and hands-on practical sessions exploring aseptic connections, a single-use liquid chromatography system and an ultrafiltration/diafiltration system.

You will also have the opportunity to practice key downstream bioprocessing principles and skills by preparing and running designed plot-scale protocols in a GMP-lite environment.

**Course price:**  
**\$3,600**

## Learning Outcomes



- Describe the methods available for downstream processing and protein purification.
  - Explain the basic principles of chromatography, filtration, and viral clearance in downstream processing.
  - Perform the key process operations of a single-use chromatography system.
  - Develop the skills to prepare and operate a single-use UF/DF system.
  - Practise GDP to follow and complete SOPs, batch records and logbook.
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- Those wishing to increase their knowledge of downstream 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.**

## Who is this Course For?

### 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-lite environment.

For more information, email BIF at [bif@uts.edu.au](mailto: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 Downstream Bioprocessing Operations 2021

		Lesson Name	Topics Covered
Day 1	AM	<b>Lecture 1</b> – Introduction to Downstream Processing and Protein Products	<ul style="list-style-type: none"><li>• Introduction to Biopharmaceuticals</li><li>• Harvest</li><li>• Stages of Downstream Processing</li><li>• Protein Stability</li><li>• Development of a Purification Strategy</li></ul>
		<b>Lecture 2</b> – Single Use Technologies	<ul style="list-style-type: none"><li>• Principles and Applications of Disposable Technologies:<ul style="list-style-type: none"><li>○ Industry Trends</li><li>○ Advantages and Disadvantages</li></ul></li><li>• Examples of Disposable Technology:<ul style="list-style-type: none"><li>○ Equipment and Components Used</li></ul></li><li>• Regulation<ul style="list-style-type: none"><li>○ Guidance and Issues</li></ul></li></ul>
	PM	<b>Lecture 3</b> – Introduction to Chromatography	<ul style="list-style-type: none"><li>• Principles of Chromatography</li><li>• Overview of Chromatography Infrastructure</li><li>• Typical Chromatography Operations</li><li>• Examples of Chromatography Techniques<ul style="list-style-type: none"><li>○ Affinity</li><li>○ Ion-exchange</li><li>○ Hydrophobic Interaction</li></ul></li><li>• Single Use and Continuous Chromatography</li></ul>
		<b>Practical 1</b> - Chromatography	<ul style="list-style-type: none"><li>• Set-up and Operation of Cytiva AKTA Ready/AKTA Ready Gradient</li></ul>

		Lesson Name	Topics Covered
Day 2	AM	<b>Lecture 4</b> – Introduction to Filtration	<ul style="list-style-type: none"> <li>Principles of Filtration</li> <li>Normal Flow Filtration</li> <li>Tangential Flow Filtration</li> <li>UF/DF Operations</li> </ul>
		<b>Lecture 5</b> – Viral Clearance Technologies	<ul style="list-style-type: none"> <li>Overview of Viruses</li> <li>Virus Clearance Studies</li> <li>Viral Clearance Technologies</li> <li>Viral Segregation</li> </ul>
	PM	<b>Practical 2</b> – Filtration: UF/DF	<ul style="list-style-type: none"> <li>Set-up and Operation of Cytiva AKTA ReadyFlux</li> <li>Trainees become familiarised with using a batch record</li> <li>AKTA Ready Set-up, Installation, and Operation</li> </ul>

		Lesson Name	Topics Covered
Day 3	AM	<b>Practical 3</b> – Mock Run Chromatography	<ul style="list-style-type: none"> <li>Trainees are given the opportunity to handle Cytiva AKTA Ready equipment</li> <li>Trainees become familiarised with using a batch record</li> <li>Installation of components of the Cytiva AKTA Ready</li> </ul>
	PM	<b>Practical 4</b> – Mock Run Filtration: UF/DF	<ul style="list-style-type: none"> <li>Trainees are given the opportunity to handle Cytiva AKTA ReadyFlux equipment</li> <li>Trainees become familiarised with using a batch record</li> <li>AKTA ReadyFLUX Set-up and Flow Kit Installation</li> <li>AKTA ReadyFlux Blue Dextran/Riboflavin Separation</li> </ul>