**Course Title: Downstream Processing Lab Practical**

**Description**

Downstream processing (also known as DSP) refers to the recovery and purification of a drug substance (DS) from natural sources, such as animal or bacterial cells. It is defined as the unit operations that follow cell growth and expansion; with a purpose to isolate, purify, and concentrate the previously synthesized drug substance or other product from the complex bulk matrix. In this course, students will learn separation techniques with hands-on experience using a small-scale Akta Prime chromatography system to perform both Anion Exchange and Hydrophobic Interaction Chromatography.

**Course Logistics**

* Face-to-face instruction
* 16 hours
* Delivery will be over two days
* 6-12 participants

**Course Objectives**

Students will:

1. Learn about Anion Exchange chromatography.
2. Learn about Hydrophobic Interaction chromatography.
3. Perform hands-on techniques in small scale chromatography.

**Outline of Instruction**

**Day 1**

1. Introduction
   1. Anion Exchange Chromatography
2. Lab: AktaPrime Chromatography ID
   1. Identification of AktaPrime Chromatography system
   2. Identification of flow path
3. Process Operation of GFP
   1. Prepare lysate sample
   2. System wash set up
   3. Column conditioning
   4. Pre-performance testing
4. GFP Chromatography Run
   1. Collect GFP fractions
   2. Post-performance testing
   3. Analyze and record fraction results
   4. AEX conditioning configuration (Method 1)
   5. AEX separation configuration (Method 2)
   6. AEX performance testing configuration (Method 4)
   7. Discuss results

**Day 2**

1. Introduction
   1. Hydrophobic Interaction Chromatography
2. Lab: Process Operation of GFP
   1. System wash set up
   2. Column conditioning
   3. Pre-performance testing
3. GFP Chromatography Run
   1. Collect GFP fractions
   2. Post-performance testing
   3. Analyze and record fraction results
   4. HIC conditioning configuration (Method 5)
   5. HIC separation configuration (Method 6)
   6. HIC performance testing configuration (Method 7)
   7. Discuss results

**Intended Audience:**

* Bioprocess Technicians, Bioprocess Engineers, Manufacturing Associates, Purification Technicians, Purification Lab Analysts, Chromatography Associates.

**Related Courses**

* Cell Culture
* Upstream Processing

**Requirements for Successful Completion of the Course**

* Attendance 80%
* Participation: Attendance
* Additional Requirements: none