Introduction to Biomanufacturing

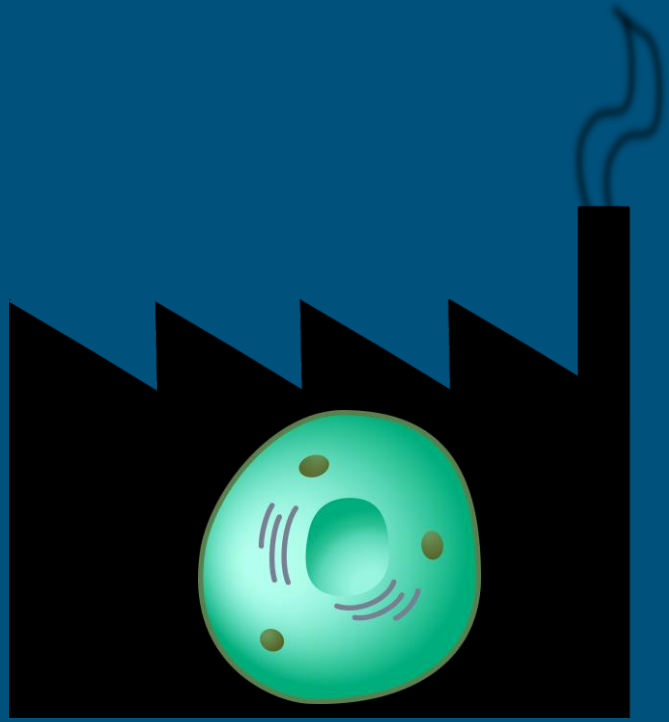
How are protein products produced in a way that is safe and reliable?

What is Biomanufacturing?

Biomanufacturing uses cells (bacteria, fungi, plant cells, or mammalian cells) to produce proteins used in therapeutics, diagnostics, and industrial applications.

These cells may be naturally occurring or genetically engineered to produce a protein of interest.

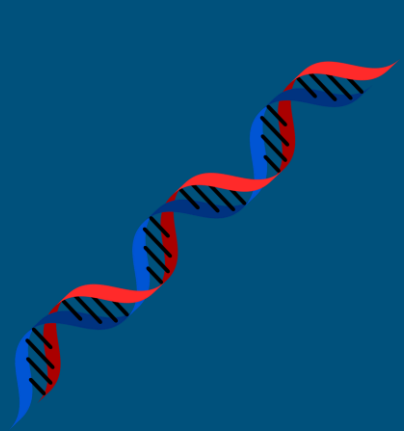
The cells act as a factory to produce the desired protein. They are nurtured and grown, then harvested to obtain the protein target.



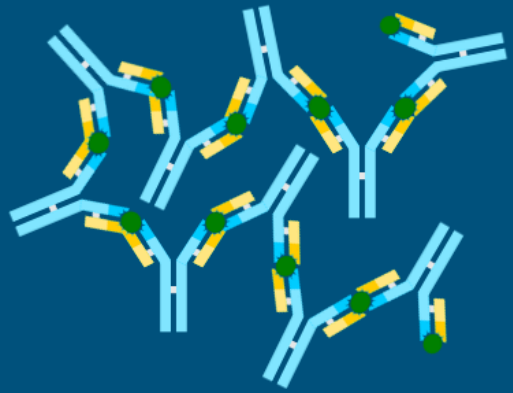
What kind of products are made through biomanufacturing?

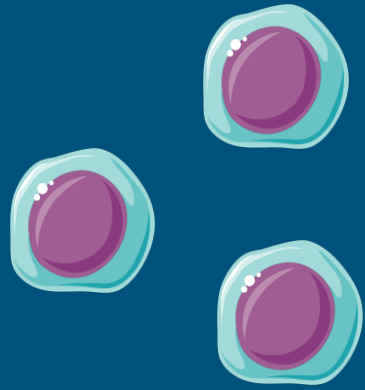
Biopharmaceuticals ~

- Hormones, Growth Factors, Blood Proteins, Clotting Factors, Enzymes, Antibodies, DNA & RNA, Stem Cells, Immunotherapeutics (like CAR T cells)

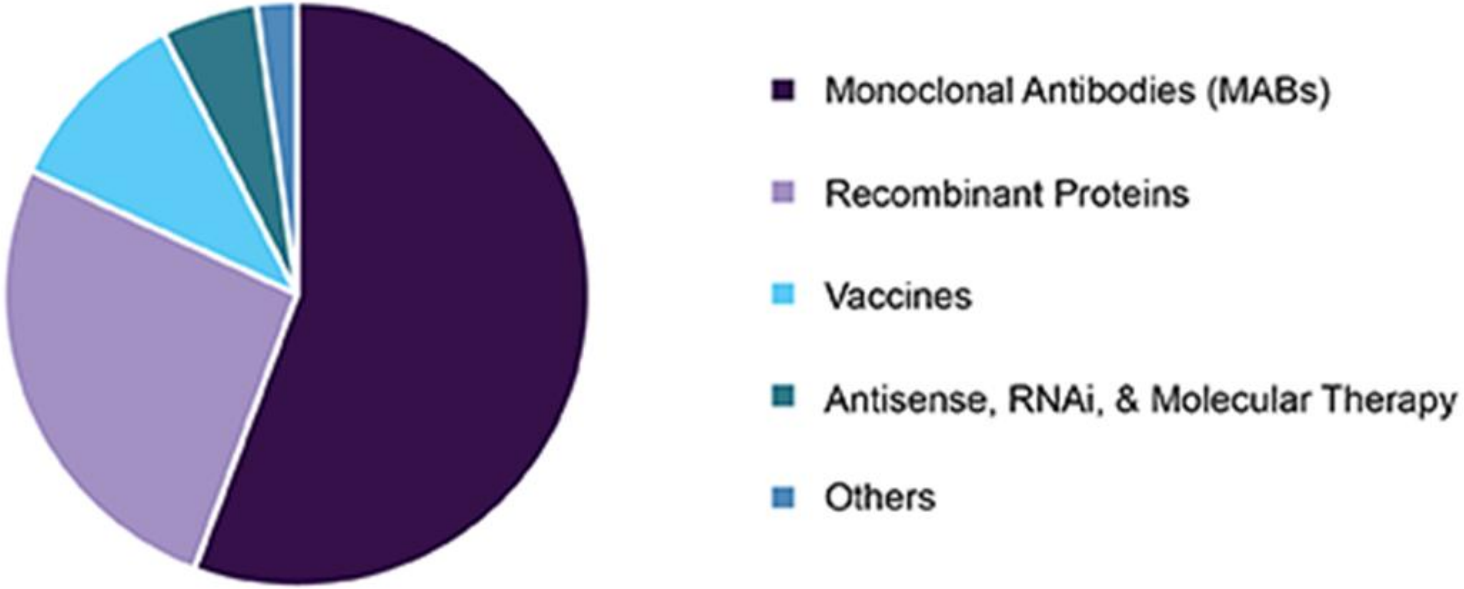








Global biopharmaceuticals contract manufacturing market share, by biologics, 2017 (%)



Source: www.grandviewresearch.com

Upstream Process

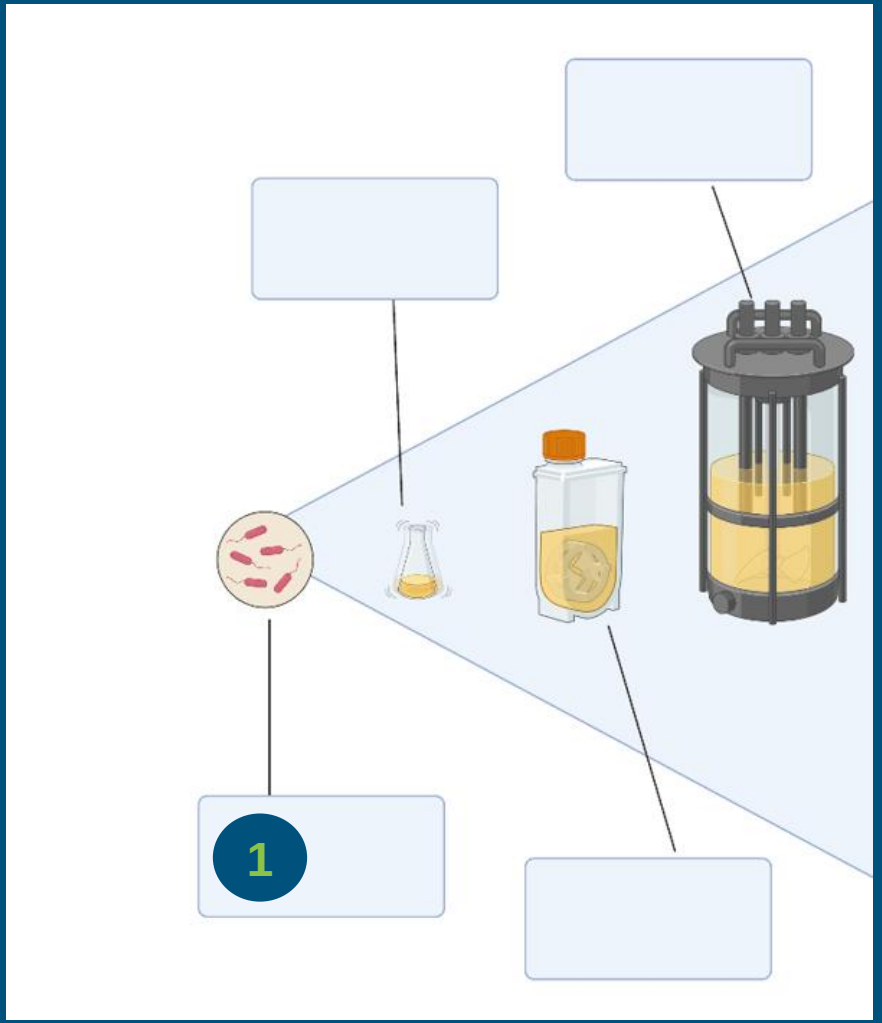
Making biopharmaceuticals starts with cells that have been engineered to produce a specific protein product.

Small quantities of these cells need to be **scaled up** to huge volumes - enough to mass produce the product. The process of scaling up is termed “**Upstream**”



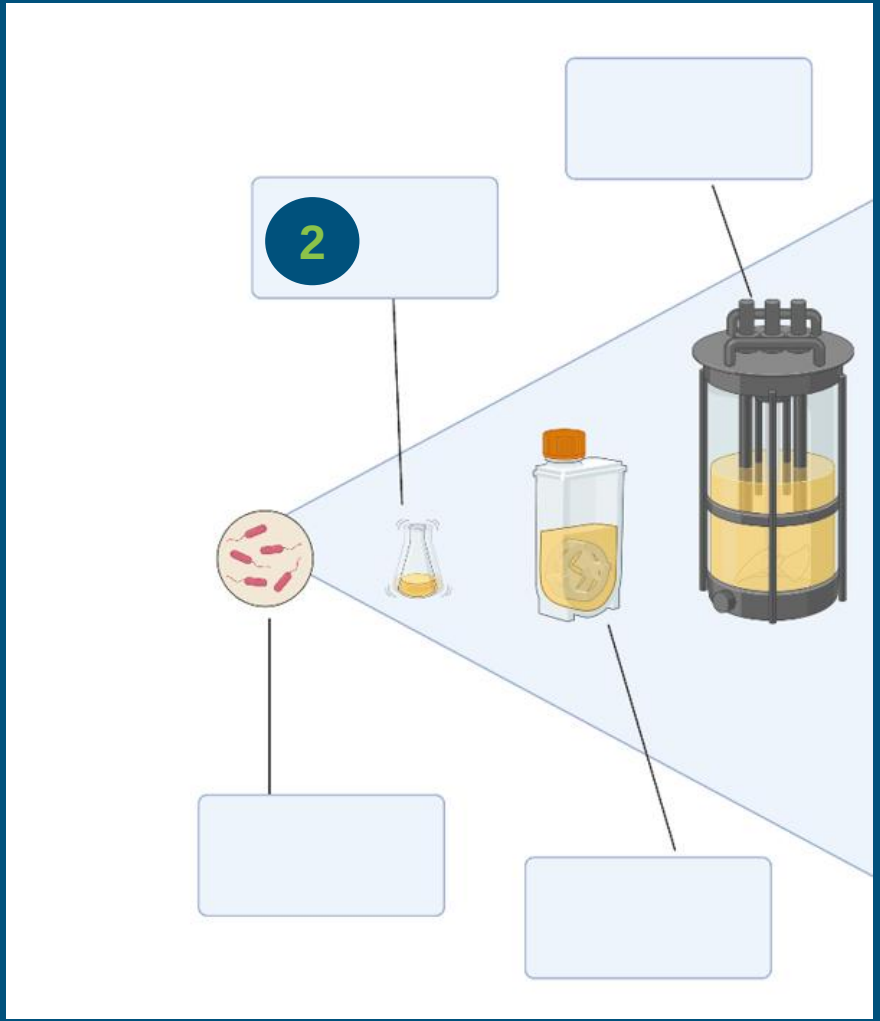
Upstream Process

1 - DNA encoding a bioengineered protein product is created in a lab. This DNA is put into cells so they produce a specific therapeutic product.



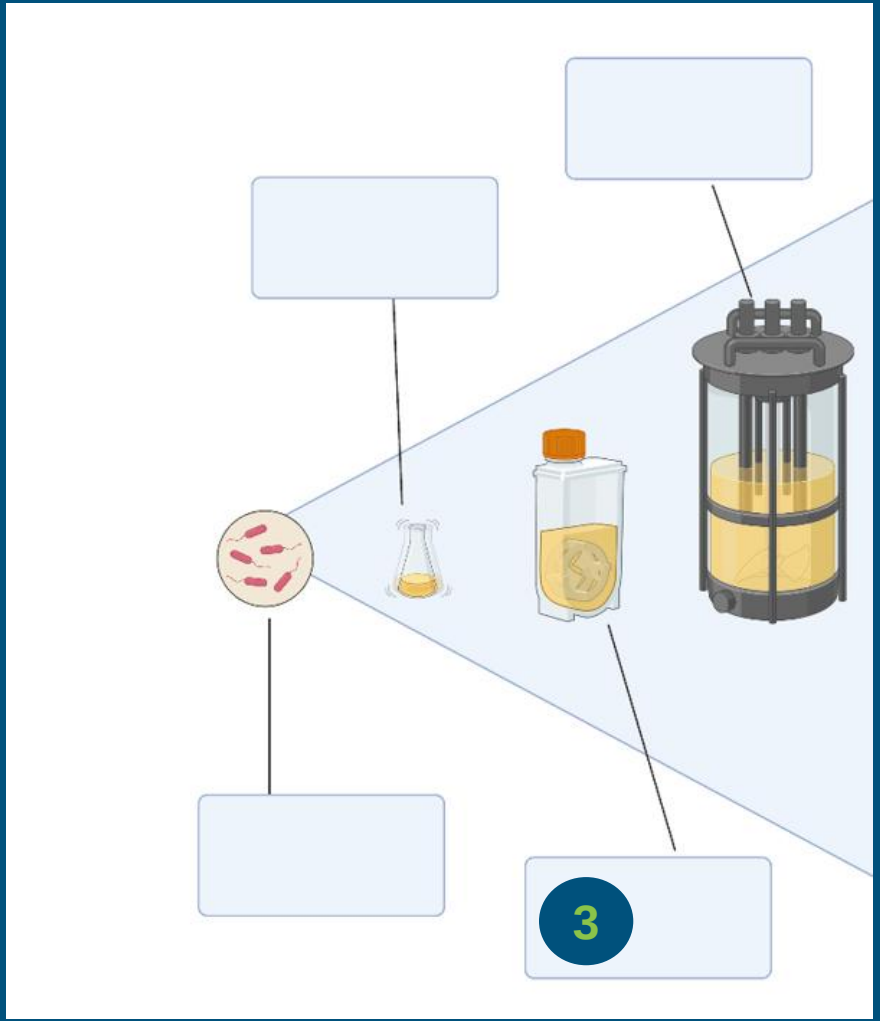
Upstream Process

2 - The seed stock (small amount of culture containing the recombinant cells) is grown in a shaker flask or bag



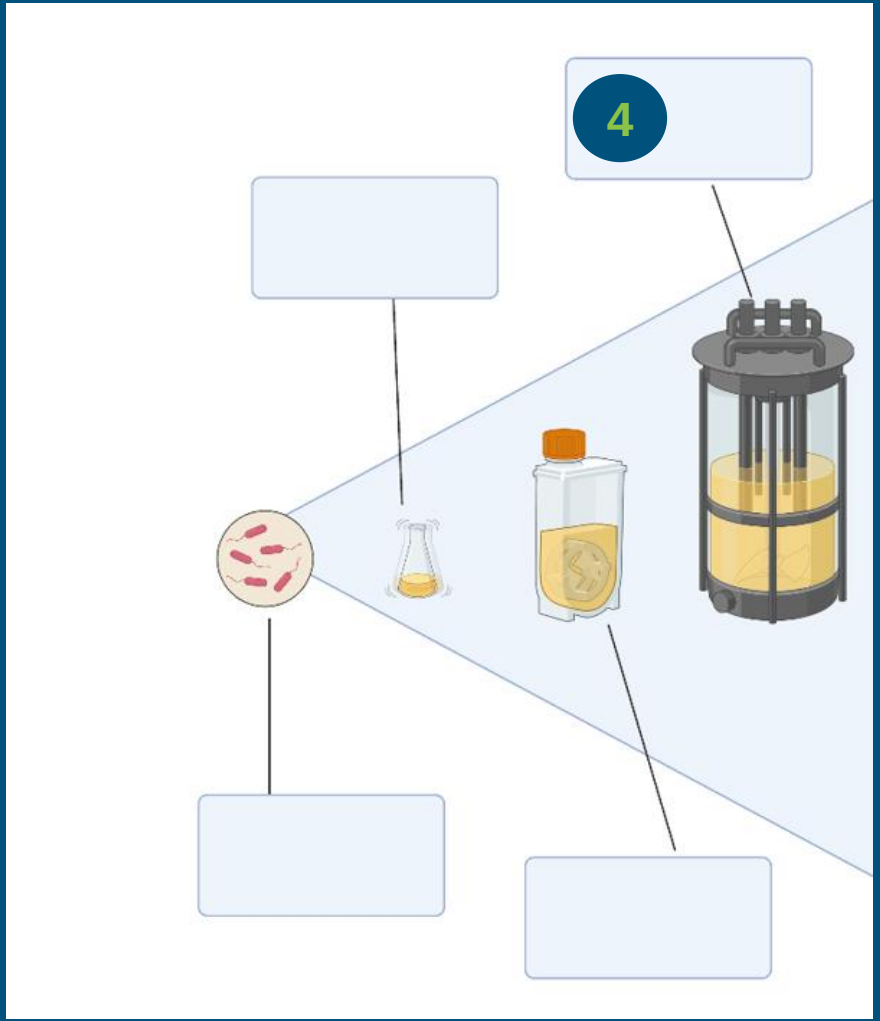
Upstream Process

3- Volumes are gradually scaled up by moving to larger and larger containers. Levels of nutrients and other conditions are carefully controlled.



Upstream Process

4 - The culture is moved to a **bioreactor**. Here, multiple liters (from tens to thousands) of cell culture are carefully monitored and controlled. The recombinant cells dutifully produce the protein they were designed to make



Downstream Process

When the culture in the bioreactor has produced the desired protein product, it must be harvested and separated from the other materials in the solution.

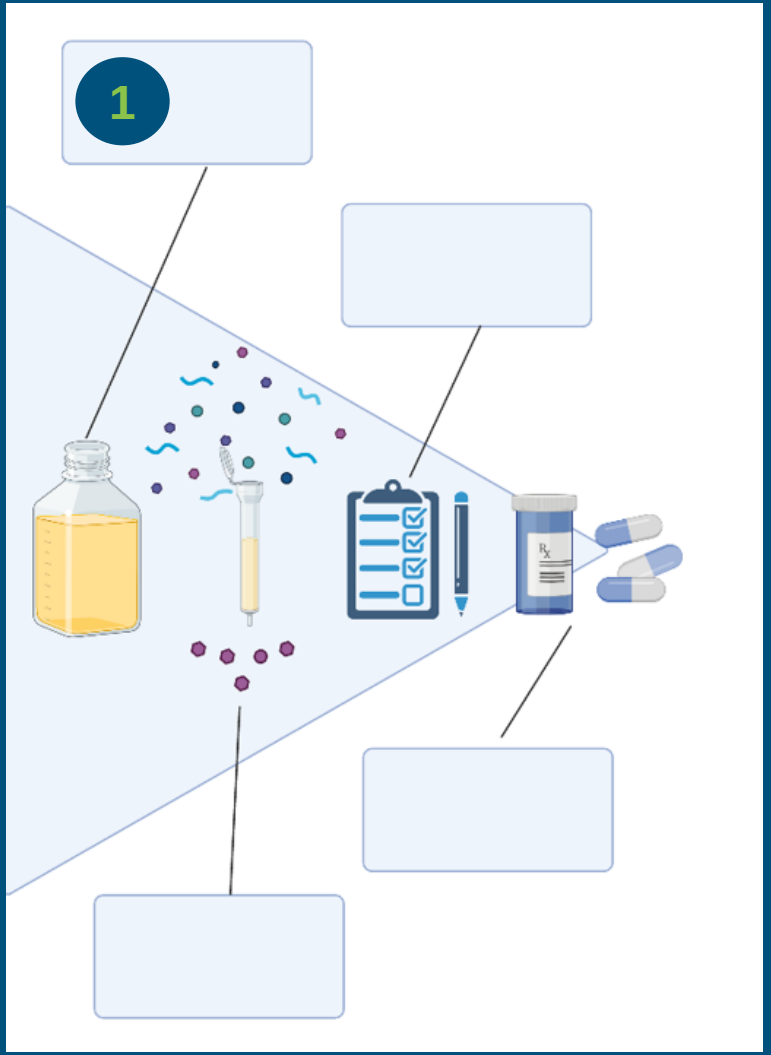
The processes of harvesting and purifying the product of interest is referred to as **downstream**.



Downstream Process

1 - The protein product often is secreted into the liquid media. In this case, the media (contain the protein of interest) needs to be separated from the cells.

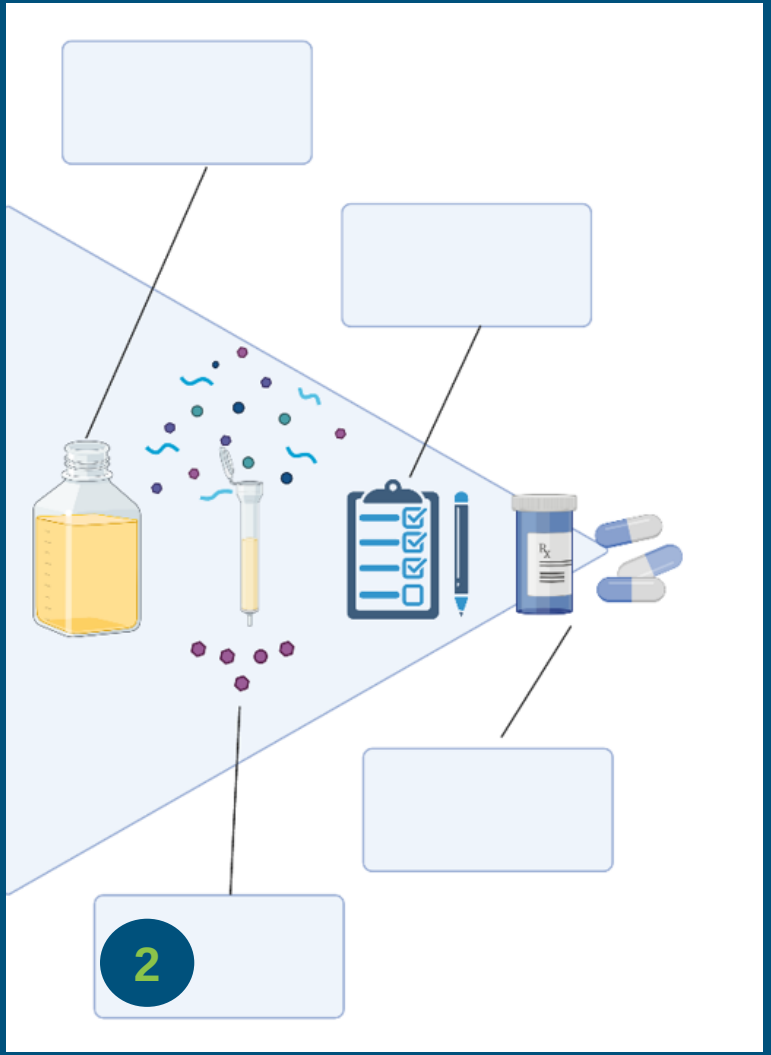
Other times, the proteins are inside the cells. In this case, the cells must be opened up, then separated.



Downstream Process

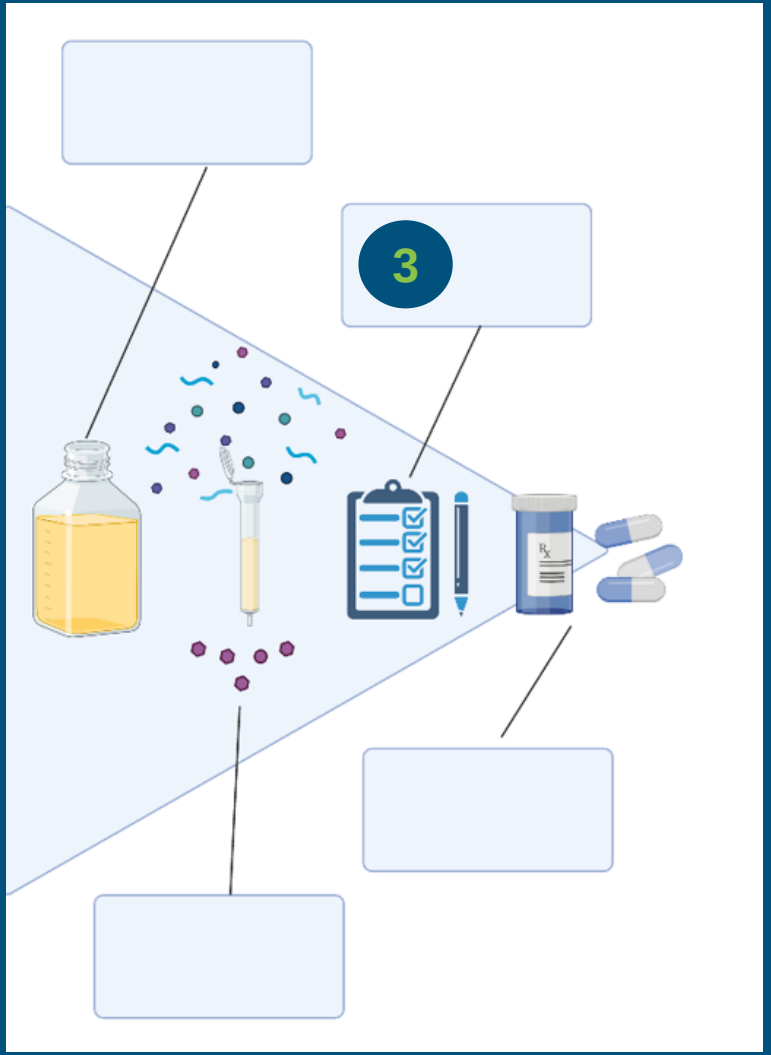
2 - The protein of interest is purified - separated from all the other proteins and molecules found in the solution.

A common method of purification is called **chromatography**.



Downstream Process

3 - Numerous checks and tests are performed to ensure the purity and quality of the protein.



Downstream Process

4 - The final therapeutic product includes the protein, along with different chemical substances. Combining these in the correct concentrations is termed **formulation**.

Bulk fill is the process of dispensing the therapeutic into bottles or vials.

