

Bioprocessing Equipment Solutions for the Pharmaceutical, Biotechnology & Food Industries

Bioprocessing Workflow



Contents

- Page 3: Why Biopharma Group?
- Page 4 & 5: Introduction to Bioprocessing
- Page 6: Bioprocessing Workflow
- Page 6 & 7 : What is Upstream?
- Page 8 - 11: Equipment summary:
 - Solvent Evaporators
 - Bioreactors
- Page 12 & 13: What is the Harvest stage?
- Pages 14 & 15: Equipment summary:
 - High Pressure Homogenisers
- Page 16 & 17: What is Downstream?
- Page 18 & 25: Equipment summary:
 - TFF
 - Fill/Finish Equipment
 - Freeze Dryers
- Page 26 & 27: Glossary of Capital equipment

Why Biopharma Group?



Expertise



Technical Services



Knowledge

Biopharma Group is a leading supplier of bioprocessing equipment to pharmaceutical, biotech, food, beverage and process industries in the UK, Ireland, and France. With years of expertise in the processing industries, our specialised range includes pharma & food production freeze dryers, centrifugal solvent evaporators, high pressure homogenisers, bioreactors and TFF systems, aseptic processing lines and fill-finish solutions. We are committed to meeting the needs of our customers and to work together to make every project a success.

Introduction to Bioprocessing

Bioprocess R&D and commercial manufacture has become a crucial workflow for the generation of many products in the pharmaceutical industry and food manufacture.

Whether the goal is to create an antibiotic following fungal fermentation, or to enhance nutrient availability in foods by fermentation; maximising efficiency of the bioprocess workflow is pivotal.

The bioprocessing journey starts in a **Bioreactor**, which is like a high-tech greenhouse for microscopic life, allowing for large-scale cultivation of cells or microorganisms in a controlled environment.

This is crucial for producing consistent, significant quantities of desired products, like:



Biopharmaceuticals

Bioreactors are essential for producing drugs, vaccines, and other therapeutic proteins created by living cells. They enable the consistent and reliable production of these life-saving medications



Industrial Enzymes

Many industries rely on enzymes for various processes. Bioreactors facilitate the large-scale production of these enzymes used from food processing to biofuels



Biofuels

Bioreactors can be used to cultivate microorganisms that produce biofuels, a potential alternative to fossil fuels

Once enough cells are grown, the **Tangential Flow Filtration (TFF)** system takes over. This technology acts like a molecular sieve, separating the product from the cell culture.

While bioreactors nurture the target cells/organisms upstream, downstream processing helps to refine the product. **High-pressure homogenizers (HPH)** can be needed to support the requirement of cell lysis to retrieve valuable material within the cells. This could be anything from proteins and enzymes to valuable nanoparticles. Without HPH's, these products would remain trapped, hindering yield and limiting research or production potential.

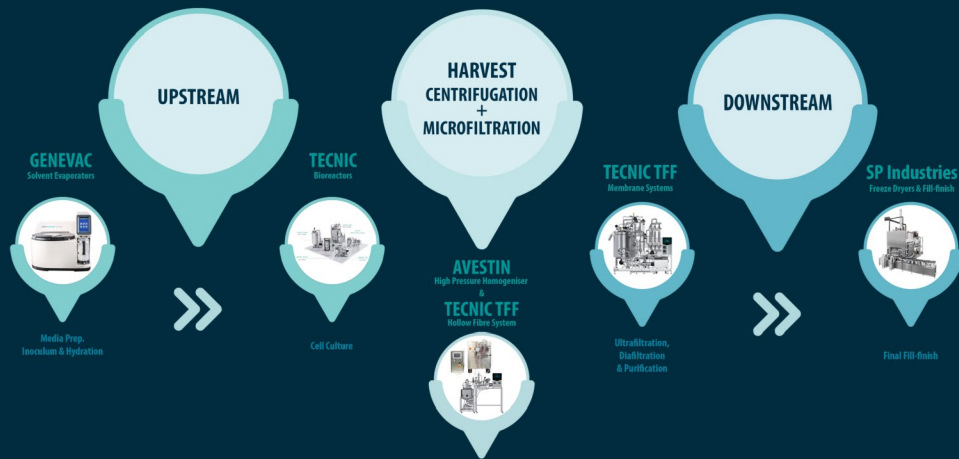
Freeze dryers can then be used to support the preservation of the product by removing water content through a process of freezing and sublimation, creating a stable and storable form at ambient temperatures.

Finally, the product is aseptically filled into vials or containers and packaged for distribution, using **Fill/Finish equipment**. This integrated workflow ensures the efficient production of high-quality biopharmaceuticals.

Bioprocessing Workflow: Upstream



The Bioprocess workflow image below shows each stage of the bioprocessing journey and the equipment solutions Biopharma Group can provide and advise on:



What is Upstream?

Upstream bioprocessing is the first stage of biomanufacturing, laying the groundwork for the creation of products like pharmaceuticals, enzymes, and biofuels. It focuses on cultivating and manipulating living cells, like bacteria, yeast, insect, or mammalian cells, to create the desired outcome.



The primary goal is to establish the optimal environment to stimulate target protein production by the cells.

It is a multi-step process with each stage playing a vital role:



Cell Line Development

Not all cells are created equal. This stage involves selecting or engineering a cell line that excels at producing the target molecule. Scientists might choose a naturally occurring cell line or use genetic engineering to create a custom champion



Media Preparation

Imagine a five-star restaurant for your cells. Here, scientists meticulously formulate a nutrient-rich growth medium containing sugars, amino acids, vitamins, and other essential ingredients to keep the cells happy and productive. Optimising this recipe is crucial, as the right balance fosters rapid cell growth and high product yield



Cell Culture

With the cell line chosen and the perfect 'broth' prepared, the cells can be introduced into large, controlled vessels called fermenters/bioreactors. These high-tech environments provide ideal conditions for cell growth, with precise control over temperature, pH, oxygen levels and other critical factors. Constant monitoring ensures optimal cell health and efficient product generation

Upstream Equipment Summary: Solvent Evaporators



Genevac's Solvent Evaporation Systems offer an industry leading solution via their innovative, efficient, and versatile technology.

Whether you are working on drug discovery, medicinal chemistry, HPLC fractions, Oligos, ADC's or natural products, our Genevac evaporator range have a solution for you.

- Additional freeze drying and crystallisation functions to reduce multiple unit requirements and reduce the risk of potential degradation of more sensitive materials during transport from one unit to another.
- Ranging from more basic MiVac systems up to the more complex HT and Automation-Friendly EZ-2 Bionic configurations



**HT Series 3i
for
High throughput**

**EZ-2 4.0 for
Parallel sample
evaporation**



**Rocket Synergy
& 4D for high-
speed
evaporation**

**miVac
Centrifugal
vacuum
concentrators**



**miVac
accessories for
use with miVac
sample
concentrators**



- DriPure®, designed to prevent the phenomenon of solvent bumping.
- Powerful vacuum pumps to aid evaporation speeds in an array of sample and solvent types and volumes; including those with high boiling points and strong acids like 6M HCL
- Auto-stop functionality to maintain sample integrity and therefore eliminate the need for constant monitoring

Upstream Equipment Summary: Bioreactors

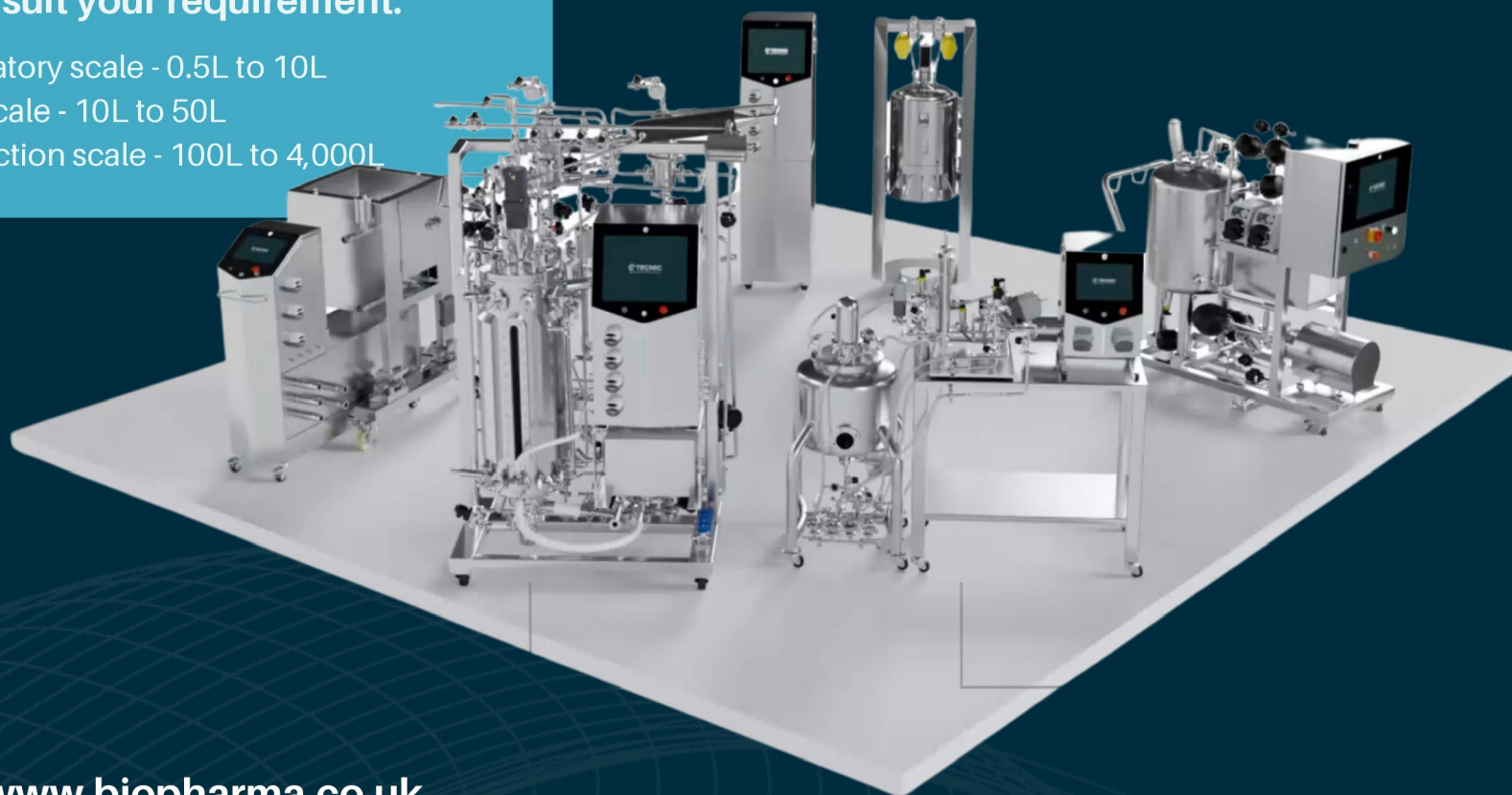


Designed to offer a high level of efficiency with an excellent level of flexibility, the Tecnic range of Bioreactors offer solutions to support smaller R+D projects through to full scale commercial production:

Scalable solutions to suit your requirement:

- Laboratory scale - 0.5L to 10L
- Pilot scale - 10L to 50L
- Production scale - 100L to 4,000L

- Unparalleled efficiency
- Easy scalability
- Advanced operating systems included across the range, for easy adjustment of settings
- Available in both multi-use (stainless steel) and single-use design
- Exclusively available from Biopharma Group in UK & Ireland



Bioprocessing Workflow:

Harvest

What is the Harvest stage?

The Harvest stage assumes the role of a bridge between the upstream world of growing cells and the downstream purification processes. A critical step where the valuable product, either the cells themselves or the biomolecule they produce, are separated from the surrounding culture broth.

This can be achieved through different cell separation techniques, such as:



Centrifugation

The culture broth is spun at high speeds, forcing the denser cells to settle at the bottom. The clarified supernatant containing the secreted product is then collected. Different types of centrifuges i.e. disc stack or tubular, cater to specific cell types and volumes



Filtration

This method is useful for harvesting broth containing very small cells or when the product itself is secreted into the broth. Specialised filters with appropriate pore sizes allow the broth to pass through while retaining the cells. Tangential flow filtration (TFF) is a common technique that uses pressure to achieve continuous filtration & has become a popular choice where preservation of shear-sensitive cells/products, high product concentration, or continuous biomanufacturing processes are needed



Flocculation

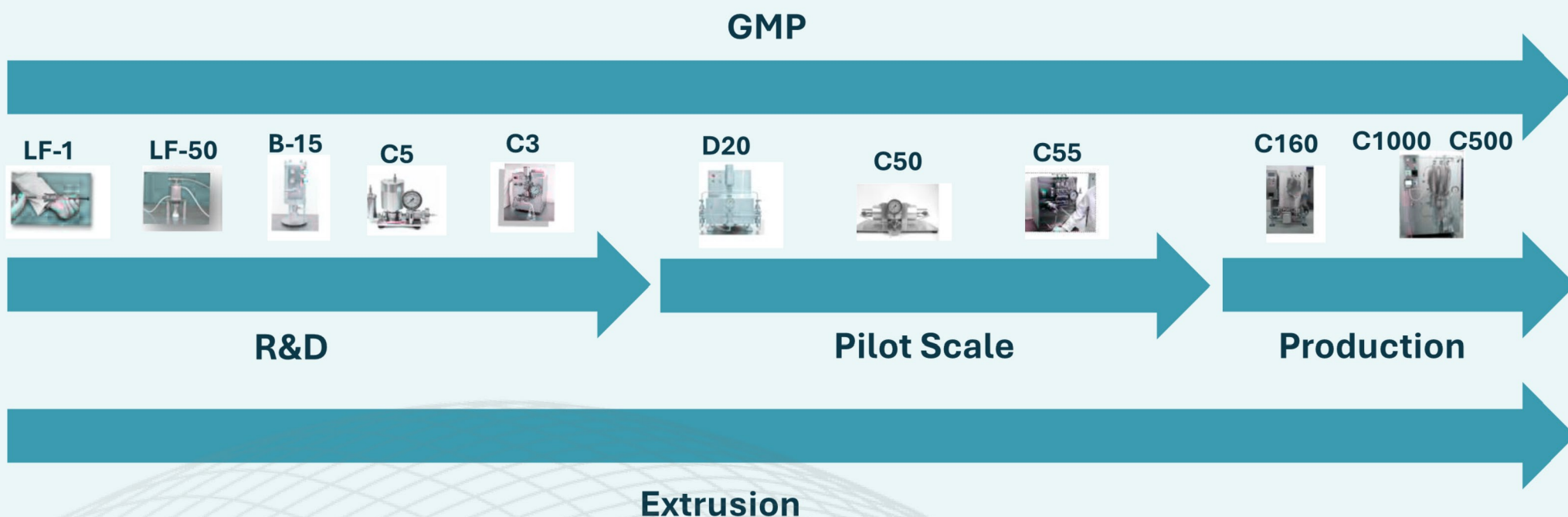
This technique involves adding specific chemicals that cause the cells to clump together, making them easier to separate through sedimentation or centrifugation. This is particularly useful for harvesting shear-sensitive cells that might be damaged by harsher techniques. Should the product still reside within the cells, the process of cell disruption would be needed to break open the cells to release the product. Using a high pressure homogeniser can lyse the cells in an efficient and scalable way.

Harvest Equipment Summary: High Pressure Homogenisers

AVESTIN

Avestin high pressure homogenisers, cell lysis & extruder systems are designed to deliver exceptional results whilst being user friendly and robust. Able to meet your requirements, regardless of production size, Avestin solutions are engineered to ensure reliable results every time.

Species	Pressure
Escherichia coli	10-15,000 psi (690 - 1030 bar)
Saccharomyces cerevisiae	25-29,000 psi (1700 - 2000 bar)
Pichia pastoris	23-27,000 psi (1500 - 1800 bar)



Bioprocessing Workflow: Downstream

What is Downstream?

This stage of the bioprocess workflow relates to 'downstream' bioprocessing after the successful cultivation and harvest of the desired product from living cells.

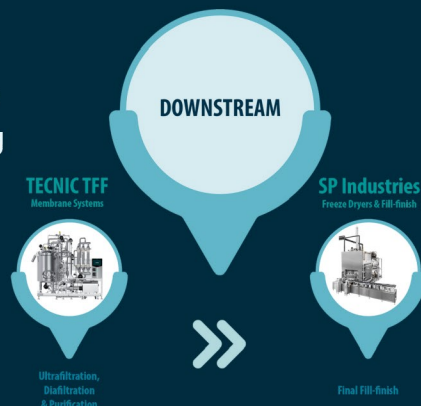
The purpose of the downstream phase is to isolate, purify, and concentrate the target molecule from the complex mixture it resides in, cell harvest or culture broth, transforming the crude product into a high-purity form meeting stringent quality and safety standards for pharmaceuticals, enzymes, or other bioproducts.

A distinctive downstream approach is:



Clarification

Following cell disruption/secreted products, clarification removes cell debris, unwanted proteins and other impurities from the harvest broth. This often involves filtration techniques such as tangential flow filtration (TFF)



Chromatography

This workhorse technique separates the target molecule based on its specific properties like size, charge, or affinity. Different chromatography methods exist, each offering unique separation capabilities



Concentration and Purification Polishing

Techniques like ultrafiltration or precipitation further concentrate the product and remove any remaining impurities. This stage ensures the final product meets purity specification capabilities



Formulation and Filling

The purified product is formulated with stabilisers and excipients (inactive ingredients) for stability and delivery. Finally, the product is filled in an aseptic manner into sterile containers like vials, RTU vials, syringes, tubes, ophthalmic 3-piece containers for storage and distribution

Typical Applications / Markets:

Cell and Gene Therapy - Antibodies / ADC's - Biosimilars
Vaccines - Industrial Enzymes - Bioplastics
Recombinant proteins - Alternative meat

Downstream Equipment Summary: Tangential Flow Filtration (TFF)

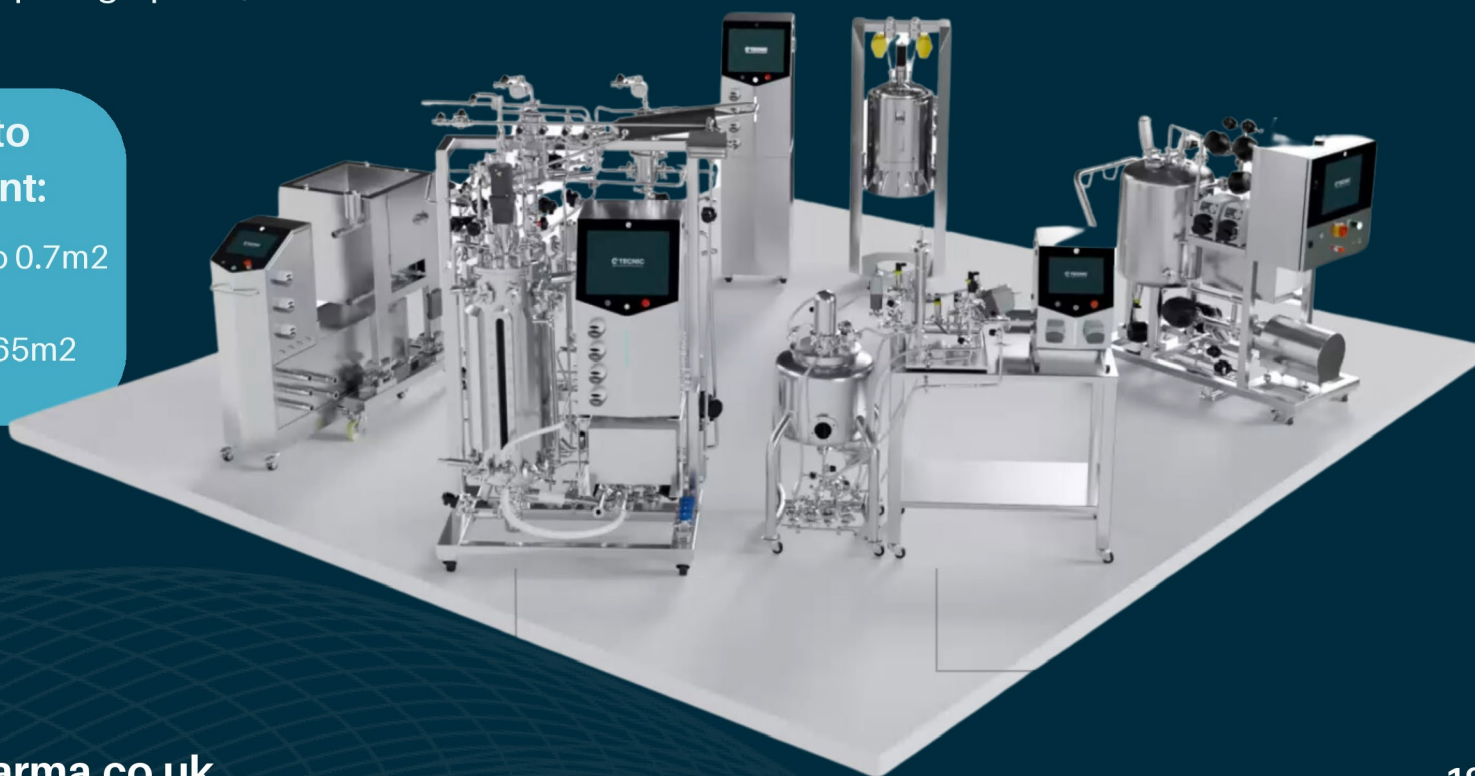


The TECNIC tangential flow filtration (TFF) systems are designed to enable the concentration or purification of liquids, including those involving proteins or antibodies, by passing them through a semi-permeable membrane. Our equipment solutions are available from laboratory scale to full production / commercial applications requiring up to 4,000L.

Scalable solutions to suit your requirement:

- Laboratory scale - 0.1m² to 0.7m²
- Pilot scale - up to 6.5m²
- Production scale - 7m² to 65m²

- High Performance: Achieving efficient concentration and purification with minimal clogging
- Sample Integrity: The system minimises shear stress, protecting delicate samples
- Simplified Workflow: Users can enjoy automated processes with minimal manual intervention
- Precise Control: Maintain complete control of specific flow rates for optimal results



Downstream Equipment Summary: Fill-Finish



Fill-finish solutions and aseptic processing lines offered by Biopharma Group are reliable, scalable, efficient and robust to get your biologics to market faster.

Features/Benefits:

- Complete automatic solutions with isolator/RABS
- No container-No fill technology
- Minimal Waste, maximum safety
- GMP compliant



Typical applications/Markets:

- Cell and gene therapy
- Antibodies/ADC's
- Biosimilars
- Vaccines
- Biologics
- Injectables
- Drug Manufacture
- Diagnostics
- Ophthalmic

- 100% check-weighing capability
- Modular and scalable: from standalone to fully automatic lines



Downstream Equipment Summary:

Freeze dryers



Whether laboratory, pilot, or full scale commercial GMP production for either sterile or non-sterile products Biopharma Group have the equipment configuration to meet those needs.

Typical applications/Markets:

- Tissue Engineering
- Wound Care
- PCR Diagnostics
- Biologics
- Vaccines
- Drug Development
- Drug Manufacture
- Injectables
- Liposomes / Exosomes

Benchtop Advantage Pro



LyoConstellation

Features/Benefits:

- Precise shelf temperature and vacuum control, supporting scale-up / down activities
- GMP Compatible
- CIP / SIP / VHP cleaning methods
- Clean room and isolator configuration
- Suite of PAT tools, including end point moisture determination
- AutoMTM/SMART
- Controlled nucleation
- TDLAS + Tempris
- Automated options
- Shelf area ranging from 0.3m² up to 100m² – catering for the complete range of needs

Genesis



Ultra Prime



Ultra

Downstream Equipment Summary:

Freeze Dryers



Biopharma Group are the exclusive UK and Ireland distributor of Gellert Freeze Dryers. Designed to be user friendly and robust, the Gellert freeze dryer range is precisely engineered, offering systems with cutting edge freeze dryer technology for food production.

Applications

- Production of dehydrated and powdered foods
- Laboratory sample preparation
- Formulation of powdered nutraceuticals and probiotics
- Preserving chemical compounds
- Production of high quality flavours and fragrances
- Fruit and seed preservations



Ranging from compact benchtop models to pilot and commercial scale machines, the equipment is scalable and highly customisable for a range of industries and applications.

Industries

- Food and beverage manufacture
- Agriculture and seeds
- Research and Development
- Cosmetics
- Healthcare
- Pet food
- Environmental sampling



Glossary: Capital Equipment

Genevac Solvent Evaporators	Pharma Freeze Dryers	Food Freeze Dryers	Fill/Finish Equipment	High Pressure Homogenizers	Bioreactors/ Fermenters TFF	UK & Ireland
<ul style="list-style-type: none"> • Medicinal chemistry • ADME • HPLC • Protac • Drug Discovery • Environmental Analysis • Flavours + Fragrances • Oligonucleotides • ADC's • Clinical Biochemistry • Natural Products • Cannabinoids 	<ul style="list-style-type: none"> • Tissue Engineering • Wound Care • PCR • Diagnostics • Biologics • Drug Development • Drug Manufacture • Injectables • Fill/Finish • Liposomes /Exosomes 	<ul style="list-style-type: none"> • Pet Food + Treats • Soft Fruits, i.e. Strawberries, blueberries and banana • Vegetables, i.e. pets, carrots, wasabi • Collagen Scaffolds • Dairy, i.e. whey proteins, lactoferrin, dried probiotics • Nutraceuticals • Human Food 	<ul style="list-style-type: none"> • Fill/Finish • Injectables • Vaccines • Commercial Manufacture • Sterile Liquid Filling • Diagnostic Liquid Filling • 3-piece Filling • GMP • Grade A - Isolators • Aseptic Freeze Drying/Lyo • Aseptic processing 	<ul style="list-style-type: none"> • Cell Lysis • Emulsions • Dispersions • Nanoparticles/ Liposomes/ Exsomes • Recombinant Proteins • Particle Size Reduction • Drug Delivery • Vaccines/Drug Discovery • Seaweed/ Algae 	<ul style="list-style-type: none"> • Probiotics • Vaccines • Antibodies • Therapeutic Proteins • ACD's • Biologics • Cell + Gene Therapy • Stem Cells • Biosimilars • Fermentation • Alternative Meats 	<ul style="list-style-type: none"> • BPS Capital Equipment sales are restricted to UK + Ireland only



www.biopharma.co.uk



+44 (0) 1962 84 1092



bps@biopharma.co.uk

**Biopharma House
Winnall Valley Road
Winchester
Hampshire
SO23 0LD
United Kingdom**