

Cell Banking

Manufacturing • Testing • Characterization • Release

June 2024



advancedtherapies.com

Cell Banking

Accelerating Time to Market

WuXi Advanced Therapies is a Contract Testing, Development and Manufacturing Organization (CTDMO). We offer technology platforms and services that enable the discovery, development, testing, manufacturing, and commercialization of our clients pipeline. Our services and solutions accelerate time to market and support patients around the world.



Manufacturing Experience and Testing

Co-Located in a Single Organization

Regulatory agencies worldwide require a continuous and well-controlled supply of the specific cell lineage utilized in your manufacturing process.

WuXi Advanced Therapies' team of experienced cell culture and bioanalytical specialists will manufacture your bank and provide the testing results and documentation required to release it under industry recognized quality assurance standards.

Our team can manufacture your R&D, Master, Working, and End of Production Cell Banks and perform the necessary testing to prepare the required regulatory documentation.

We will collaborate with you on your process and work with you to optimize the final product in as short a time as possible.

Contact us for a quote today!

Robust Track Record





20+ Years of cGMP Cell Banking Experience

Our team has manufactured and released cell banks across a wide variety of cell types for products in all phases of production from pre-IND to commercial.

Integrated Testing and Characterization

We will help you demonstrate and document recovery viability, growth, biosafety and genetic characterization and provide a QA-approved Certificate of Analysis (COA).

From Research Grade to Commercial

Whether you need research, working, master or end of production cell banks, we can provide the guidance, manufacturing and testing support you need to meet regulatory guidelines.

Ability to Right-Size Production

Our team can work with you as needed to verify and optimize your cell growth and expansion plan and scale to produce anywhere from 10-1,200 vials.

Why Choose Us?





Integrated Testing & Characterization

Our team leverages our co-located testing and characterization services to confidently release your bank including cell line identification, viability and purity.

Please get in touch for a full list of all the assays and testing services available with associated sampling requirements, turnaround times (TAT) and pricing.



Proven Templated Approaches

You will have the opportunity to utilize pre-existing batch records for your cell bank.

By leveraging our batch records, you can shave weeks off your production timeline and capitalize on GMP ready documentation that has already been proven to result in successful production.

Cel Line Experience

Our team has experience with a wide array of cell lines.

Mammalian

- Embryonic Retina (PER-C6)
- Spleen
- Kidney (MRC-5)
- Neuroblastoma cells
- Embryonic Kidney (HEK 293)
- Umbilical cord

Murine

- Hybridoma
- Hybridoma Sp2/0
- Myeloma (NSO)

Monkey

- Africa Green Monkey (VERO)
- Rhesus Monkey (LLC MK2)



Our Capabilities

We have proven and robust quality systems which have been audited by numerous clients and the US FDA. Your cell bank(s) will be produced and tested under a single work order, saving you time and effort in contracting.

A dedicated project manager will coordinate all manufacturing and testing activities, saving you time and reducing risks related to communication issues.

Cell Culture Platforms

- T-Flasks
- Shaker Flasks
- Spinner Flasks
- Roller Bottles
- Cell Factories
- Hyperstacks





Cell Expansion & Harvest

- Capacity to manufacture 10-1,200 vials
- Campaign production approach
- Stringent raw materials release program
- Seed stock contamination acceptance screening
- Validated change-over and cleaning procedures

Batch Record Development

- Consultation to determine needs
- Clarify raw materials and process requirements
- Documentation of cell line history, growth profile and safety & characterization data





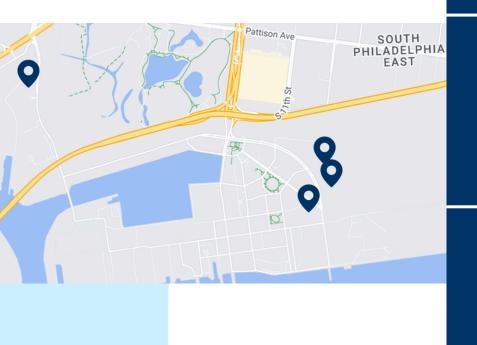
Visit the Philadelphia, PA Campus

Tour the Site

Our state-of-the-art campus at the Navy Yard in Philadelphia, Pennsylvania is home to all four of our U.S. facilities.

We invite you to come tour the facilties in person, or watch a video tour online.

Scan to watch video tour!



Late Phase/Commercial Viral Manufacturing and Testing

150,000 sq. ft Est. 2016

4701 League Island Blvd Philadelphia, PA 19112

State-of-the-Art
Integrated Testing
Laboratory

140,000 sq. ft Est. 2020

400 Rouse Blvd Philadelphia, PA 19112

Non-Viral Cell Therapy Manufacturing

55,000 sq. ft Est. 2020

4000 S 26th St Philadelphia, PA 19112

HQ/Early Phase
Clinical Manufacturing
and Testing

82,000 sq. ft Est. 2020

4751 League Island Blvd Philadelphia, PA 19112















