Pharma&Biotech

Lonza

Cell Therapy Services

Your Product. Our Passion.

Complete Portfolio of Services for cGMP Manufacturing of Cell-based Products

Cell Therapy from Lonza

Lonza's commitment is to provide the highest quality service to support the rapid clinical development and commercial manufacturing of cellular therapeutics. Our global leadership in custom manufacturing for the pharmaceutical industry offers the ability to develop robust commercial manufacturing processes for cell therapy with our world-class current Good Manufacturing Practices (cGMP). Lonza has experience working with cell therapy developers at all stages of clinical development. A team of technical professionals will work diligently to help you source tissues, improve processes and test procedures, as well as implement cost-effective manufacturing technologies for autologous and allogeneic therapies. Through all phases of clinical development, the Lonza Team can address all aspects of cell therapy manufacturing in order to increase the likelihood of commercial success.

Service Offerings

Consulting Services

Tissue Acquisition

Development Services
- Analytical Development
- Media Development
- Allogeneic Development Services
- Autologous Development Services

cGMP-compliant Manufacturing
- Allogeneic and Autologous Cell Therapy Manufacturing
- World Class Quality Systems

Biopreservation/Fill & Finish
- Biopreservation
- Fill & Finish
- Storage and Distribution

Cell Therapy Manufacturing Sites

Consulting Services

Lonza has extensive experience manufacturing cell, viral and protein-based therapeutics. Leverage Lonza's experience for guidance on a variety of topics including:
- Regulatory Filing
- Facility Design
- cGMP Compliance
- Cost of Goods Optimization
- Assay Selection/Development
- Path to Commercialization

Tissue Acquisition

Let Lonza's Expert Team help you navigate the complexities of tissue sourcing logistics and regulatory hurdles. As an AATB (American Association of Tissue Banks) accredited, FDA-registered and state-licensed tissue bank, we provide the support you need. Our Team of experienced tissue banking professionals builds specific donor, tissue and cell programs to accommodate each client's unique plans. To assist clients in complying with current donor eligibility requirements, the Tissue Acquisition Team develops programs in accordance with 21 CFR Part 1271 (HCT/P) while ethically sourcing human tissues. Our clients may reference Lonza's Human Tissue and Cells Donor Programs Type V DMF in their regulatory submissions to the US FDA.

We Maintain the Following
- FDA-registered facility for human cells, tissues, and cellular and tissue-based products
- Licensed by the states of Maryland, New York and California
- AATB accredited

Our Staff
- Experience in designing donor programs to meet global regulatory requirements
- Comprised of a team of scientists, one of whom serves on the Standards Committee of the AATB, physicians with in-depth expertise in donor testing and eligibility criteria, and specialists who handle logistics, control, and documentation
- CITI-certified (Collaborative Institutional Training Initiative) in Protection of Human Research Subjects

Development Services

Lonza understands the unique needs of clients ranging from early stage clinical trials, all the way through to licensure. Each Lonza partner is assigned a team of scientists to work with you to transform your process into a closed-system, scalable process that is compliant with cGMPs. Your modified cell culturing process will be optimized to help ensure that your product maintains its critical quality attributes that will be validated by customized analytical testing.

Analytical Development

We have the knowledge and experience to qualify and validate your existing assays necessary for product release testing. Your designated team of scientists can also develop customized tests of your product, where necessary, which may be used for product characterization, formal comparability studies, and/or release testing. Additionally, our expertise in cell-based assays and in-depth knowledge of flow cytometry can be leveraged for the development of potency assays.

Media Development

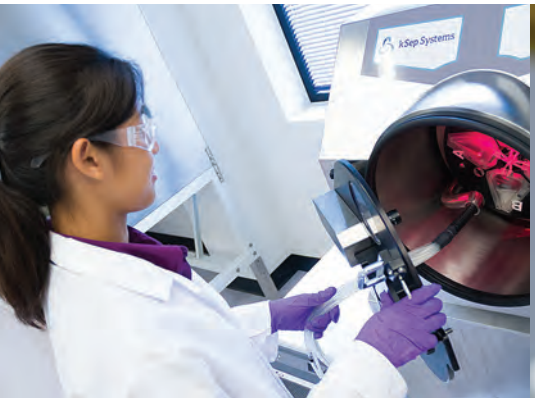
As a tools and service provider, Lonza is uniquely positioned to work with our partners to develop a custom medium that will maximize the yield and/or performance of your product cells. Optimization of Lonza Media early in clinical development minimizes the impact to product comparability. Lonza Custom Media are formulated to help ensure they are amenable to closed-system, scalable cell processing.

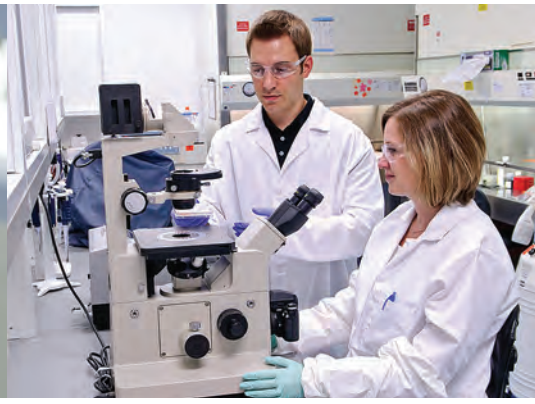
Allogeneic Development Services

Our scientists and engineers are innovators of tools and techniques that facilitate closed-system, large volume downstream processing that is gentle enough for cell-based products. The Lonza Team is poised to transition your process to a scalable, closed-system process while maintaining the comparable biological activities of your product and, at the same time, controlling the cost of goods for manufacturing your product. Lonza is globally recognized for our experience in allogeneic cell therapy manufacturing. Lonza scientists have extensive experience developing and executing large-scale, closed-system processing for universal donor cell-based products.

Autologous Development Services

Lonza is prepared to face the challenges presented by the manufacture of patient-specific products. Our process engineers can model each client process in order to best understand key cost drivers and processing bottlenecks. Once modeled, Lonza scientists work to develop a streamlined, closed-system process that maintains the critical quality attributes of your product. We have dedicated state-of-the-art autologous cell processing suites at all of our cell therapy manufacturing sites. Our autologous processing suites were designed with safeguards in place to help ensure lot segregation.



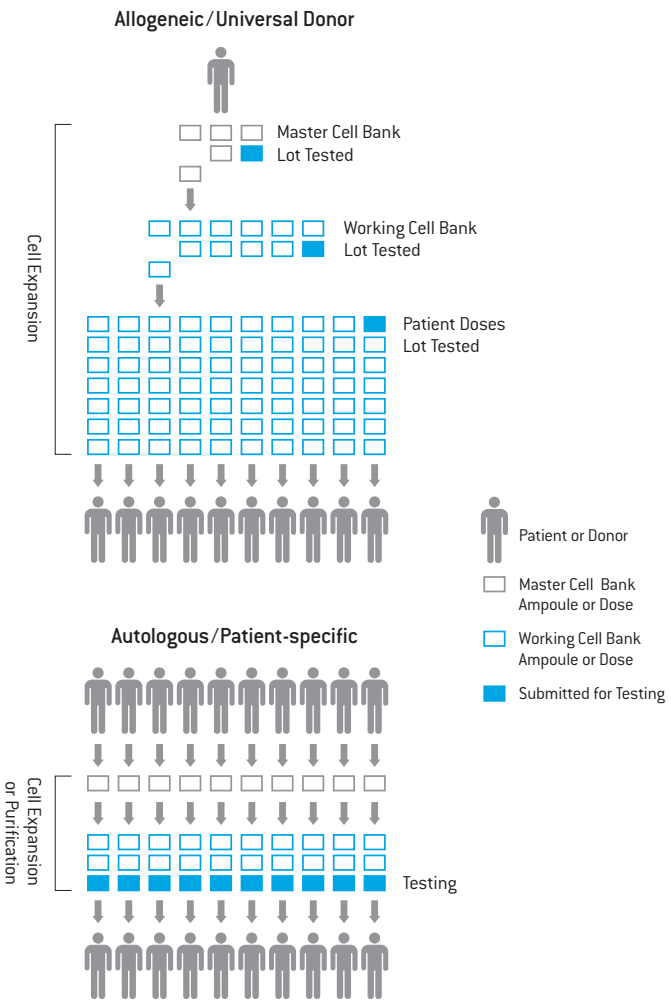



cGMP-compliant Manufacturing

At each of our Cell Therapy manufacturing sites, Lonza offers multiple suites of varying sizes and flexible design. Our suite design can be adapted to meet your needs. All sites offer specialized processing equipment for isolation, large-scale cell culture, and volume reduction. Our rigorous training program helps ensures that our staff is experienced with the procedures required to execute your manufacturing protocol.

Lonza has experience manufacturing allogeneic/universal donor products as well as autologous/patient-specific products, including gene-modified cellular immunotherapies.

Lonza's world-class quality systems help ensure global regulatory compliance of our Cell Therapy manufacturing processes and products. We source the highest-grade materials for the products we manufacture. Unidirectional material movement and personnel flow are available for your manufacturing technology needs in nearly all of our Cell Therapy manufacturing suites at Lonza's sites. Our paperless environmental monitoring helps ensure the quality of the manufacturing setting while streamlining batch record documentation. Our dedication to operational excellence allows for the establishment of efficient process protocols, which minimizes wasted time and reduces the number of manufacturing deviations. Furthermore, we can address your product labeling and document needs, prepare and approve all regulated documents prior to submission, and will gladly consult with the regulatory agencies during audits.



Universal donor and patient-specific products present unique manufacturing and testing challenges. Lonza has the experience and infrastructure to manufacture both types of products according to cGMPs, globally.

Biopreservation/Fill & Finish

Biopreservation

The Lonza Team has experience with the formulation and biopreservation of a wide range of product types. We have expertise optimizing the formulation of fresh (non-frozen), cell-based products in order to extend non-frozen shelf-life. Additionally, we can optimize cryopreservation formulation and freeze parameters to maximize viable cell recovery. Moreover, we optimize thawing protocols for clinical trials sites in order to minimize the risks of delayed onset cell death in your product.

Fill & Finish

Lonza offers the filling of closed vials for cell-based products that is scalable to thousands of vials/hour in a cGMP-compliant clean room setting. Additionally, we offer closed-system bag filling for both autologous products as well as low volume allogeneic products.

Storage and Distribution

Lonza is equipped to establish and maintain a cold chain for all of your cryostorage needs for both cell banks and product doses. All Cell Therapy manufacturing sites maintain a Dewar farm for the storage of cell-based products in vapor-phase liquid nitrogen. Our storage warehouse is equipped with redundant automated monitoring systems to help ensure the safety and security of all stored Master Cell Banks (MCBs)and products. Cell-based products can be distributed globally using dry shippers with temperature monitoring to help ensure even and consistent temperature for your product while in transit.



Cell Therapy Manufacturing Sites

Lonza Walkersville, MD USA

- Nine operational manufacturing suites
- State-of-the-art dedicated autologous suite (EU Grade B)
- Full US compliance with ISO 7 (Class 10,000) classification
- Four EU Grade B suites, compliant with European regulatory standards
- On-site manufacture of powder and liquid media
- On-site quality control testing and quality assurance specialists

Lonza Houston, Texas USA

- Two segregated manufacturing suites for autologous cell processing
- Designed to meet EU Grade B Standards
- 100% single pass air to support *ex-vivo* transduction utilizing viral vectors
- On-site manufacture of viral vectors
- On-site quality control testing and quality assurance specialists

Lonza Verviers, Belgium

- Four segregated cGMP certified (EU Grade B suites) manufacturing suites
- Inspected and approved by the Belgium Authorities
- On-site manufacture of powder and liquid media
- On-site quality control testing and quality assurance specialists

Lonza Tuas, Singapore

- Two state-of-the-art EU Grade B suites, with capacity to build out (commercial scale)
- Capacity to build a dedicated autologous suite (EU Grade B)
- On-site manufacture of liquid media
- On-site quality control testing and quality assurance specialists

Houston, TX (USA)
Cell and Viral-based Therapeutics
- Cell & Gene Immunotherapies
- Viral Vectors
- Autologous Cell Processing

Walkersville, MD (USA)
Cell Therapy
- Autologous & Allogeneic Cell
- Bioassays & Reagents
- Process R&D Services

Media
- Custom Media & Buffers
- Bioprocess Containers

Verviers (Belgium)
Cell Therapy
- Autologous & Allogeneic Cell
- Bioassays & Reagents
- Process R&D Services

Media
- Custom Media & Buffers
- Bioprocess Containers

Tuas (Singapore)
Cell Therapy
- Autologous & Allogeneic Cell
- Bioassays & Reagents
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