PharmaBiotech

Lonza

Viral Therapy
Contract Manufacturing Services
Relevant Industry Experience

Services for cGMP Manufacturing
of Virus-based Products

Process Development

Lonza's Houston site holds several proprietary production, purification and formulation processes for the development and manufacturing of gene therapy and viral vaccine products. In addition, our viral facility maintains access to the PerC6® cell line and the newly formulated Permexcis® cell culture medium for optimal virus production.

Streamlined technology transfer and successful scale-up are critical factors in early- and mid-phase production. The Lonza Viral Team understands the manufacturing challenges and has capabilities that are designed to help you navigate the development bottlenecks and accelerate your product development cycle. By engaging Lonza at an early stage, we will help ensure that the decisions regarding cell lines and the manufacturing process are suitable for later-stage products, thereby saving you time and money as your product progresses through clinical development. From process development and optimization to process scale-up and characterization, Lonza can offer you solutions to help you advance to the next level. Our development services are suitable for preclinical programs as well as for programs approaching commercial approval.

Viral Process Development Capabilities:

- Access to fully characterized production cell lines (adherent and suspension)
- Process development and optimization
- Process scale-up and production of preclinical study materials
- Process technology transfer
- Process characterization and validation
- Formulation development
- Cell line optimization
- Cell culture medium optimization
- Assay development
- Assay transfer

Commercial Manufacturing

Wherever you are in your process, Lonza has been there too. Currently we operate multiple BL-2 cGMP suites that utilize the latest single-use disposable technologies supporting up to 2 000 L production scale and meet both EU and US regulatory compliance standards. In addition, Lonza operates BL2 laboratory space for both process development and Quality Control (QC) testing.

Lonza offers industry-leading experience for viral-based products from Investigational New Drug (IND) to BLA. Few CMOs have the late-stage product development experience offered by the Lonza team, and we understand the complexities and the high level of scrutiny associated with viral-based therapy products from a regulatory standpoint. We provide cGMP manufacturing services from cell and virus banking, to bulk drug substance production and final drug product fill and finish. Our experience in regulatory submissions includes INDs, BLAs (USFDA), and MAAs (European Medicines Agency). Our clients may also reference Lonza's Type V DMF in their regulatory submissions to the USFDA.

cGMP Production:

- Viral bulk drug substance
- Viral final drug product
- Cell banking
- Virus banking
- Viral-modified immunocellular therapies (autologous and allogeneic)
- Adherent and suspension cell culture systems
- Single-use bioreactor technologies with capacity up to 2 000 L
- Depth filtration
- Large-scale ultra/diafiltration
- Large-scale chromatographic purification
- Ultracentrifugation
- Product storage and distribution

Aseptic Fill and Finish

The Lonza Viral team has nearly two decades of experience filling viral products for Phase I through Phase III clinical trials. We offer both EU- and US-compliant fill and finish services. Our current batch sizes range from 100 to approximately 8 000 vials per lot, and we are able to fill large volumes, up to 2 000 L. In addition, we offer flexible scheduling to accommodate your project needs.

Product Types Filled:

- Adeno-Associated Viral (AAV) vectors
- Adenoviral vectors
- Lentiviral vectors
- Retroviral vectors
- Live viruses
- Attenuated viruses

Quality Control and Regulatory Support

Understanding the complexity and high level of scrutiny associated with viral-based products is one of our core competencies. Lonza's clients value our industry experience and look to us to guide them through the hurdles of regulatory submission.

We offer a full range of product characterization and release testing for viral vectors, viral vaccines and viral-modified cell therapies. Our QC Team has experience in developing and validating a variety of assay types, and we understand the importance of running reference standards in all assays. Our Team, through its predecessor company, produced the Adenovirus Type 5 Reference Material (ARM) as a member of the ARM Working Group and is continuing to support its stability testing programs.

In addition to batch release testing services, we design and perform International Conference on Harmonization (ICH)-compliant stability studies to monitor product integrity over time and/or at multiple storage conditions.

QC and Stability Testing Capabilities:

- Assay validation (in accordance with ICH)
- Analytical and cell-based methods
  - Identity
  - Purity
  - Potency
- Cell and virus bank characterization
- Raw material release testing
- Product release testing
- Long-term and short-term stability testing
- Bedside stability testing

Regulatory Support Services:

- IND submissions
- Chemistry Manufacturing and Control (CMC)-related filings – BLA submissions

www.lonza.com
www.lonza.com/viraltherapy

Viral Therapy
Contract Manufacturing Services

Lonza's Viral-based Therapeutics specializes in the development and cGMP production of viral vaccine, viral vector biologics, and viral immunotherapies. Our experienced team has been involved in the manufacture and release of Phase 1 through Phase 3 clinical trial materials for use in the United States, Europe and Asia for nearly two decades. We offer turn-key services ranging from viral vectors and live viral vaccines manufacturing, viral-modified cellular therapeutics production to high volume fill/finish in our state-of-the-art multi-product Biosafety Level 2 (BSL-2) manufacturing facilities in Houston, Texas USA. Our team has a unique perspective in that its scientific and regulatory personnel have both contract manufacturing and relevant product development experience through Biologics License Applications (BLA) and Marketing Authorization Applications (MAA). Our extensive industry experience in process development, cGMP manufacturing, product characterization, release and regulatory submission represents a competitive advantage for our clients as we support programs from preclinical, Phase I to Phase III clinical trials through commercialization. Lonza's global reach, high-quality facilities, and technical capabilities allow us to be a trusted partner for your viral vaccine and viral gene therapy drug pipeline advancement.

Lonza is committed to working closely with our customers to provide cost-effective and time-efficient solutions for their development and manufacturing needs. We offer a complete service including process development, GMP manufacturing of drug substances, aseptic fill/finish of drug product, product release testing, regulatory support and cGMP storage and distribution. Lonza is your trusted development partner; together turning promising discoveries into viable products.

For more information about Viral-based Therapeutics, please contact your Lonza Sales Representative or visit us on the web at **www.lonza.com/viraltherapy**

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BR-VTMS 01/13 CT-BR003