Pharma&Biotech

Lonza

Drug Product Services

Our Industry-leading Experience and One-Stop-Shop Offering Makes Lonza Your Comprehensive Partner for Drug Products

Development of parenteral dosage forms can be a major challenge due to the increasing complexity of biopharmaceuticals. Adding to the challenge are the constantly changing regulatory expectations, which may also vary from country to country. To address these challenges, Lonza created its Drug Product Services offering that can help to differentiate a product and support lifecycle management. We provide a fully integrated approach to drug product design and development addressing formulation, process, and primary packaging across drug substance and drug product services.

Led by a team with more than 35 years of large pharma, strategy and regulatory experience, the Drug Product Services team works closely with the Drug Substance sites across the Lonza network. This enables an integrated and high quality One-Stop-Shop approach that delivers accelerated development timelines for early clinical candidates through marketed products. In addition, our One-Stop-Shop service reduces supply chain complexity by allowing our customers to work with one strategic partner from discovery through clinical supply. This provides a more in-depth knowledge of the product and addresses the current challenges of parenteral drug product development.

Our Drug Product Services are integrated across Lonza's technologies in mammalian, microbial, chemistry, conjugates, cell and viral therapy. All services are available as a complete package or as standalone offerings.

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Drug Product Services

Lonza's Drug Product Services team is highly skilled in the development of biopharmaceuticals including standard monoclonal antibodies, recombinant proteins, fusion proteins, antibody drug conjugates and vaccines, as well as viral- and cell-based therapies.

Formulation Development

Formulation development services are available for liquid and lyophilized drug product dosage forms and are performed integrating relevant container closure systems such as vials, stoppers and caps or syringes and appropriate drug product process manufacturing designs.

- Pre-formulation, developability, and candidate-selection support
- Early and late-stage formulation and process development
- Container-closure system selection, qualification and integrity testing
- Rapid automated high-throughput formulation screening
- Manufacture of pre-clinical GLP drug product (e.g. toxicology testing)
- In-use stability (simulated administration testing)
- Long-term and accelerated drug product stability studies according to ICH guidelines
- Drug product manufacturing process setup and design
- Technical transfer and scale-up support for clinical and commercial drug product manufacture
- Regulatory support for drug product documentation (e.g. IND/IMPD, BLA/MAA)

Visit Lonza's Drug Product Showcase Page on LinkedIn:
www.linkedin.com/company/lonza-drug-product-services
For more information, contact us at: **drugproduct@lonza.com**
www.lonza.com/drugproduct

Analytical Development and Quality Control

The analytical development and QC team offers specialized contract laboratory services including:

Drug Product non-GMP (R&D) and GMP (QC) Release and Stability Testing

- Analytical method development
- cGMP Drug Product stability testing
- Development of drug product control strategy for IND/IMPD or BLA/MAA submission
- Support QbD and Breakthrough therapy submission

Forensic Chemistry

- Fast-track particle root cause investigation in drug product processing and manufacturing
- Extractable and leachable characterization
- Excipient degradant characterization (e.g. Polysorbate degradation)
- Container closure system requirements, design and qualification and CCI testing

Particle characterization

- Complementary submicron and subvisible particle characterization
- Development of a particle control strategy