Liof Pharma

BIO FILL&FINISH

Your reliable partner for sterile biologics and drugs
From development to commercial manufacturing

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As a first-class European biotech CDMO partner in the field of pharmaceutical contract manufacturing of sterile drugs, specialised in fill and finish services of multiple formats of vials for injection and plastic bottles (eye drop type), we use our expertise in Pharmaceutical R&D, Aseptic Filling, Lyophilization of Biologics (including peptides and proteins, antibodies / mAB, RNA, adenovirus, etc.) and extensive knowledge of international requirements to enable your product to meet the most demanding quality standards and thus fulfil customer needs.

Our facilities, equipped with the latest technologies, are strategically located in a vibrant biopharmaceutical hub in the North of Spain, near prominent research institutions and other relevant partners which help to enhance our capabilities and resources.

We have experience and expertise in working with major regulatory authorities. Liof Pharma's own Quality Assurance (QA) system complies with international GMP standards. We undergo regular inspections as part of our commitment to quality and compliance, including successful Pre-Approval Inspections by the FDA. We are a flexible, experienced and customer focused team. We have implemented our own systems to continuously enhance processes and procedures.

Liof Pharma development services offers clinical manufacturing expertise from early-stage development to market launch. Our goal is to serve as your one-stop-shop biotech CDMO from clinical development to commercial manufacturing, covering all aspects from sterile processing to distribution. An experienced Project Manager will oversee every aspect of your project to ensure its success.

- Time to market oriented
- Flexiblity with methodology
- Reliable partner from clinical manufacturing to market approval
- Right first time

Process Development

Liof Pharma offers contract development and preclinical supply services including flexibility on the manufacturing of small batch size pilot lots of preclinical trials for efficacy, safety as well as other complementary studies for technology scale up.

We have extensive experience working with complex substances such as biologics, including monoclonal antibodies, peptides and other proteins, adenovirus, and small molecules. Lyophilization is one of our areas of expertise. Knowing how to design an appropriate manufacturing process is critical for both regulatory and efficiency purposes.

We also have a flexible manual filling area available, where we desing with our customers a product-specific manufacturing process that enables availability of product for testing and a smooth transfer later to commercial manufacturing. For lyophilized products, we develop lyophilization cycles and conduct transfer as well as initial upscaling trials.

Our services include feasibility studies, cycle optimization, engineering batches and stability, clinical and validation batches. We can provide all in-house validation support, from protocol desing to execution, manufacturing, packaging and related processes.

Small batch sizes flexibility available

We offer a perfect combination of purpose-built facilities and experienced scientists

We can provide all in-house validation support, from protocol design to execution, for cleaning, manufacturing, packaging and related processes

Clinical Manufacturing

Flexibility and efficiency were the key concepts for designing our State-of-the-art filling facilities and equipment. Our processes are specially designed for easy format changing resulting highly effective for small batches production.

We work with disposable equipment and have a flexible set up to handle multiple vial formats and to ensure fast and flexible technical transfers, without the need for extensive cleaning validations. Because of our size and flexible set-up, we have a low overhead structure, can start quickly, and offer very competitive pricing.

Clinical manufacturing (Preclinical, Phase I, Phase II, Phase III) service is offered using NoncGMP/cGMP automated filling processes matching all the customer needs. Manufacturing steps include sterile filtration, preparation of primary packaging materials (e.g., cleaning, sterilization), preparation of the formula and lyophilization if required – primarily biologics such as proteins and monoclonal antibodies.

We have the experience to provide regulatory recommendations to comply with the expectances for the CMC sections of the regulatory submissions.

Regulatory focus | Small batches manufacturing | We take special care of the regulatory compliance at this stage and offer flexible and efficient equipment for small batches production

Commercial Manufacturing

We have extensive knowledge manufacturing sensitive, high-value biologics and aseptic processing. Our aseptic filling technologies meeting the latest state-of-the-art are among the most advanced in the medicinal product contract manufacturing industry incorporating HVAC automatic control, continuous particle monitoring, automatic cleaning, sterilization and other automatic processes and testing.

Once the product is filled and finished, we perform 100% inspection of the drug product containers prior to labelling.

In-house Qualified Person

We also have the ability to confirm/certificate clinical and commercial batches for you (In house QP). QP has the ultimate responsibility to ensure the quality of medicines and fulfilment with the requirements in corresponding dossier.

Reliability | Quality | Efficiency | Based on effective technology transfers, we can guarantee a reliable, efficient and fully compliant supply

Analytics and Quality Control

Our analytical quality control capacities are focus on testing of raw materials, packaging materials, bulk solutions, in-process controls and finished products for lot release, according to Eur. Ph. or international Pharmacopoeias or Client specifications.

We offer a full range of techniques (microbiology, biochemistry, bioassay and physical chemistry) for the analysis and characterization of products.

We also offer the design and execution of stability studies (pre-register, register, in use, ongoing, forced degradation, etc.)

Our personnel, trained in the state-of-the-art analytical techniques, can handle the complete development, transfer, implementation and validation of analytical methods to comply with international guidelines.

Safety and product knowledge

We develop the most efficient methods for the product analysis from the development stage to production

Distribution

We also offer storage and distribution services to your clinical or commercial distributors. These services are designed for one goal: to be your one-stop supplier for everything related to aseptic fill/finish & lyophilization.

Cold chain expertise is also provided, offering a wide range of validated solutions.

Full-service concept

Our distribution capabilities specialized in cold chain management round off our full-service package

Sustainability

At Liof Pharma we regard sustained business as the combination of an intact environment, corporate success and social responsibility.

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