ProJect pharmaceutics

formulations for pioneering drugs

Name › **ProJect Pharmaceutics GmbH**

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Founded (year) › **2010**

Type of Laboratory › **Contract research and development (CRO); cytotoxic (≤OEL4); BSL-1; BSL-2; fee-for-service business model; 2-4 weeks start up time**

Areas of Activity › **Analytical characterisation; pre-formulation screening; formulation development; freeze drying cycle development; lyophilisation process and scale-up; pre-clinical batch manufacturing; technology transfer**

Biological Patents › **Several patents in freeze drying and formulation**

External Collaborations ›
- **Network for seamless development from pre-clinic to fill/finish and market.**
- **Formulation specialist for DS and DP CMOs worldwide.**
- **Process specialist for scalable drug products ensuring manufacturability.**
- **Cross-country competence hub with business partners in Asia.**
- **Credited laboratory for Wyatt Technology in Europe.**

Request for Further Collaborations ›
- **Small biotechnology/mid-size pharma companies, large top players in pharma/biotechnology.**
- **From DSP development to early and late drug product phases up to life cycle management.**
- **Customised solutions for challenges in formulation, analysis or process and tailored solutions for unmet needs not yet supported by the industry.**

ProJect Pharmaceutics is a leading independent European CRO specialised in formulation and manufacturing process development for injectables: biologics (rec. proteins, antibodies, fusion proteins), peptides, ADCs, cytotoxics, small molecules, generics, viral therapeutics, ATMPs, VLPs and other nanoparticular drug delivery systems. We apply innovative, quality-by-design based, rational concepts of pharmaceutical development according to ICHQ8 and other guidelines. We support our global customers in developing a consistently high-quality pharmaceutical product that is transferable, scalable and manufacturable under GMP conditions. ProJect Pharmaceutics is managed by experts with >30 years of experience in the pharmaceutical industry. In about 850 m^2 we operate special laboratories for biologics, cytotoxics and a BSL-2 unit, equipped with dedicated industrial HOF pilot freeze dryers.

Protein formulation

- Predictive formulation analytics: a QbD-based high-throughput approach for accelerated development
- Pre-formulation, early state & late phase formulation
- Liquid & lyophilised formulation (DoE-based)

High concentration protein formulation

- Low viscosity formulation for s.c. application
- UF/DF process development
- Syringeability evaluation

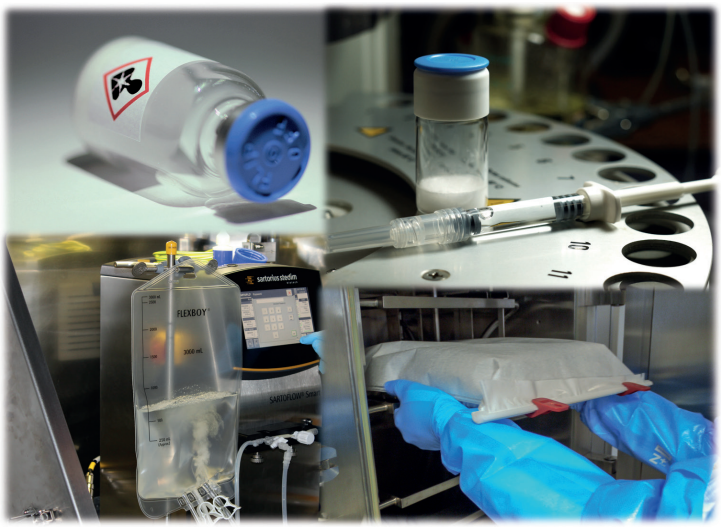
Cytotoxic small molecules

A deep understanding of the challenges when processing highly potent drugs, such as limited solubility in water and rapid degradation, paired with long-lasting experience and comprehensive know-how of lyophilisation from various organic solvents enables us to provide specific solutions for high potency & cytotoxic drugs.

Antibody-drug conjugates (ADCs)

- Predictive, high-throughput formulation development
- High-end freeze-drying technology

By combining protein formulation and process know-how with cytotoxic drug expertise the company holds unique assets to develop ADCs. On top we offer complementary formulation and process development of intermediate antibody & linker-payload bulk.



Peptide formulation

- Formulation and lyophilisation cycle development

Innovative liposome technology

- High encapsulation efficiency
- Hydrophilic & lipophilic APIs
- GMP-compatible manufacturability with standard equipment

Viral therapeutics

- Lyophilised formulation and cycle development

Downstream process

- Smart optimisation of UF/DF & purification steps
- Targeting a common BDS and DP formulation

Freeze drying

- In vials, dual chamber systems, syringes, cartridges, bulk trays or bags, containers in nest&tub configuration
- Out of organic solvents
- Rational cycle development (robust, collapse-safe, cost & time efficient, tailored to the formulation)
- Bulk lyophilisation (solid or powder)
- SEM structural analysis of lyo cake
- Time lapse video & IR thermal camera monitoring
- Aseptic pre-clinical batch manufacturing
- Robustness & design space evaluation
- Smooth technology transfer to GMP

Process development and manufacturing

- Container closure system compatibility
- Forced stress, in-use & accelerated stability studies
- Detergent & excipient quantification
- Sterile filtration study
- Manufacturability assessment
- Fill&finish process mock-up
- Aseptic pre-clinical batch manufacturing

Fill&finish

As state-of-the-art development experts we are teamed up with state-of-the-art contract manufacturing experts to provide high-quality parenterals from pre-clinical to clinical and commercial scale.