formulations for pioneering drugs

Name	› ProJect Pharmaceutics GmbH
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Email	› info@project-pharmaceutics.com
Website	› www.project-pharmaceutics.com
Social Media	› LinkedIn; Xing; ADC directory
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 period; slim and reliable timelines
Areas of Activity	› Analytical characterisation; pre-formulation screening; formulation development; process, lyophilisation 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. › Customized solutions for challenges in formulation, analysis or process and tailored solutions for unmet needs not yet supported by the industry.

ProJect Pharmaceutics is one of the leading independent European CRO service providers specialized in formulation and manufacturing process development for parenteral drug products mainly biologics (rec. proteins, antibodies, fusion proteins), cytotoxic small molecules and ADCs. 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. In about 850 m^2 we operate special safety laboratories for biologics and cytotoxics, each equipped with a dedicated industrial HOF pilot freeze dryer.

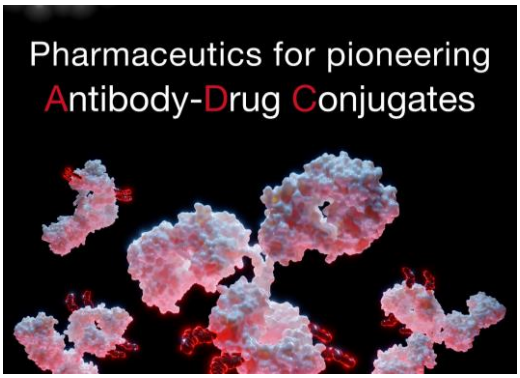
Pharmaceutics for pioneering antibody-drug conjugates

› Quality-by-design based formulation and lyophilization cycle development
› Predictive, high-throughput formulation analytics
› Rational design of efficient and robust lyophilization cycles tailored to the formulation
› Forced stress, in-use and accelerated stability studies
› Bulk lyophilization for intermediate process products
› Process robustness and design space evaluation
› Fill & finish process mock-up
› Aseptic pre-clinical pilot batch manufacturing
› Technology transfer into GMP

Since 2011 we have developed > 25 ADCs of every generation for international top players in the pharmaceutical industry. 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 and linker-payload bulk.

ProJect pharmaceutics

formulations for pioneering drugs



Pharmaceutics for process intermediate: antibody

› Accelerated formulation development by predictive formulation analytics (e.g. liquid frozen high-concentration)
› Concentration challenge testing
› UF/DF development
› Forced stress, in-use and accelerated stability studies

Pharmaceutics for process intermediate: linker-payload

› Solubility screening
› Bulk formulation development
› Bulk lyophilization development (solid or powder)
› Harvesting lyophilized bulk from bulk containers
› Technology transfer into GMP

ProJect Pharmaceutics is managed by experts with >30 years of experience in the pharmaceutical industry. The pharmaceutical development team includes a direct line to dedicated pharmaceutical development managers for each project (engineers that hold a MS in related field). The team will comprise profound expertise in analytical chemistry, formulation chemistry and process development with a key focus on and deep-niche knowledge and understanding in freeze-drying since many years. The combined expertise and complementary set of qualifications enables ProJect Pharmaceutics to deliver the high-tech pharmaceutical services that are in increased demand for the global biopharmaceutical industry on ADC development services.