About Us

What We Do and Who We Are

Company

ProJect Pharmaceutics transforms all kinds of chemical and biological ingredients into pioneering drugs. We are experts in formulation science and pharmaceutical process development with special emphasis on recombinant proteins, ADCs / cytotoxics and live virus vaccines.

Adding value to our customers' bio-therapeutic products is our daily business. We design optimized pharmaceutical formulations and delivery systems that provide highest safety levels at maximum convenience.

We develop cost-effective fill and finish processes, tailor-made for the drug formulation and the delivery system of choice, and transfer them from our pilot lab to large-scale manufacturing. The ability to develop Antibody Drug Conjugates (ADCs) by combining protein formulation and process know-how with cytotoxic drug expertise puts ProJect Pharmaceutics in a unique position within the biopharmaceutical industry.

ProJect Pharmaceutics has its headquarter in the biotech cluster in Martinsried near Munich.

New safety facilities up to GMO S2 and BSL-2 classification in dedicated labs and a profound understanding of the challenges when formulating and processing live virus vaccines enables ProJect Pharmaceutics to provide specific solutions for this group of for this group of highly complex products.

Our pharmaceutical experts are well-trained in project and business management. The project manager assigned to your project will be your individual contact person and competent for all aspects of the project.

ProJect Pharmaceutics belongs to the JRS Pharma Family. For API management, Regulatory Services and Distribution, Lyomark Pharma is our trusted partner.

Management

Andreas Schütz

Dr. Schütz studied Pharmacy and received his PhD in Pharmaceutical Technology from the University of Erlangen in 1991.

He began his career in pharmaceutical development with Schwarz Pharma AG based in Monheim, Germany and last held the position of Head of Specialized Pharmaceutical Systems. Dr. Schütz joined Vetter Pharma, based in Ravensburg, Germany in 1998 as Head of Pharmaceutical Development and Senior Project Manager.

In 2001, Dr. Schütz joined Scil Technology based in Munich, Germany and last held the position of VP Pharmaceutical Development and Head of BioPharma Services. Together with Klaus Hellerbrand he founded ProJect Pharmaceutics in 2010.

Andreas Schütz is an inventor on numerous patents and patent applications. His key expertise is focused on Formulation Science, Drug Delivery Systems, Lyophilization Technology, Aseptic Processing, Project and Key Account Management.

Klaus Hellerbrand

Klaus Hellerbrand earned his degree of applied Science in Biotechnology from the University of Weihenstephan.

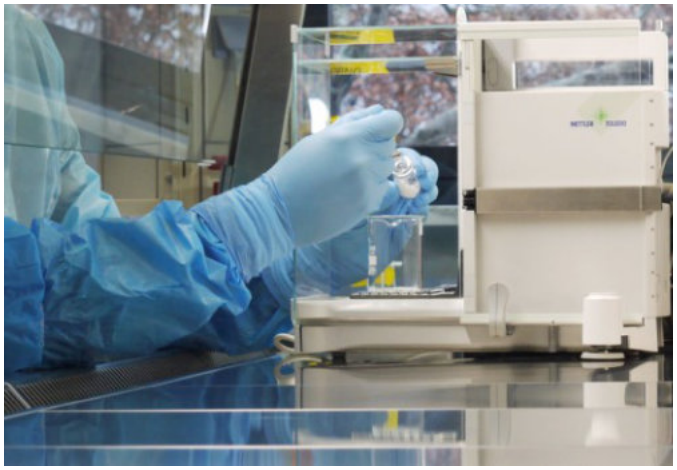
In 1995 he joined Boehringer Mannheim / Roche Diagnostics as a development engineer focused on down-stream processes for protein drugs and development of protein formulations. He joined Scil Technology in 1999 as protein formulation scientist.

Serving in positions of increasing responsibility, in 2003 he became Head of Pharmaceutical Technology, responsible for product formulation and protein drug supply. Together with Andreas Schütz he founded ProJect Pharmaceutics in 2010.

Klaus Hellerbrand is an inventor on numerous patents and patent applications. He is an expert in Protein Science, Protein Analytics, Downstream Processing, Process Technology, Coating Technology and Lyophilization Technology.

Drug Formulation Development

Drug formulation development for all kinds of recombinant proteins and protein conjugates.



Rational design of formulations and drug delivery systems for all kinds of biopharmaceutics inluding proteins, peptides ADCs and other cytotoxics.

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Protein drug formulation is particularly challenging due to structural complexity and instability. The biological activity of most recombinant proteins and protein conjugates emanates specifically from their complex 3-dimensional structure which needs to remain unaltered throughout the shelf-life of the product. However, cleavage, aggregation, or other post-translational modifications may not only reduce efficacy but also produce adverse immunologic effects.

We can look back at a wealth of experience from many successfully completed formulation developments, including highly concentrated monoclonal antibodies and antibody conjugates (ADCs), as well as cytokines, growth factors and peptides.

ProJect Pharmaceutics´ Predictive Formulation Analytics offers an innovative scientific approach for designing optimized protein formulations and reduces the need for extensive stability testing.

Plying state-of-the-art analytical methods to characterize the physicochemical state of proteins and analyze their response to certain excipients allows us to quickly and reliably identify promising formulation candidates.

A systematic algorithm based on design of experiments (DOE) is used to determine the most favorable composition for the native structure of a given protein with regard to its intra- and intermolecular physicochemical properties.

Rational design of formulations and drug delivery systems for all kinds of biopharmaceutics inluding proteins, peptides ADCs and other cytotoxics.

Beneficial effects resulting from pH value, ionic strength, ion types, detergents and other stabilizing agents can be identified and quantified without stability testing. Furthermore we explore the behavior of the protein under a variety of process relevant stress conditions such as freeze/thaw, temperature, light, oxygen, shear stress and surface interactions to identify mechanisms of degradation and define strategies for formulation and process technologies.

The data we obtain from Predictive Formulation Analytics provide the basis for a drug product composition that is tailored to the protein, its packaging system and its route of administration.

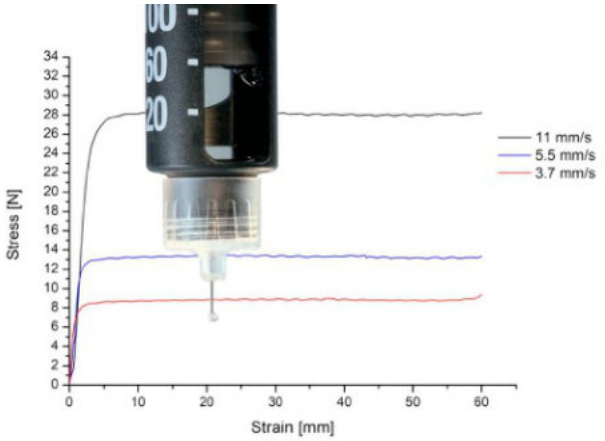
We explore all possible options to design a stable, liquid formulation of our client's drug and evaluate the maximally possible concentration of the API, if so required for the specific route of administration.

In case stability in aqueous solution is generally limited by the sensitivity of the API we develop freeze dried formulations selecting suitable excipients which stabilize the protein drug effectively within a defined amorphous matrix, and enable a straight forward and cost-effective lyophilization process.
A final stability test program, carried out on samples filled into the final packaging system under genuine pharmaceutical manufacturing conditions, serves to confirm the suitability and stability of the composition and provides trustworthy data for initiating clinical trials.

ProJect Pharmaceutics is a credited contract laboratory for Wyatt Technology in Europe.

High Protein Concentration Formulations

A science-based approach to develop best-in-class formulations for convenient use in pre-filles syringes and cartridges.



ProJect Pharmaceutics has specialized in this emerging field with a key expertise in development of stable, effective and syringe-able formulations together with their eligible processes.

Transforming therapeutic proteins into high-concentrated, stable and easy to use medications for subcutaneous self-injection can add up to a major challenge along their clinical development. A formulation's fundamental qualification, such as appropriate physico-chemical stability, container material compatibility and viscosity must be taken into account to support an acceptable in-syringe shelf-life, as well as convenience in regard to syringe-ability.

In order to address these various requirements and develop a pioneering new drug in a pre-filled syringe presentation, a great extent of knowledge, expertise and sophisticated analytics is needed that are sparingly found in this developing market to date.

ProJect Pharmaceutics has specialized in this emerging field with a key expertise in development of stable, effective and syringe-able formulations together with their eligible processes. Be it conformation of de-novo drug products towards a pre-filled syringe application or transfer of existing drug products into the like, ProJect Pharmaceutics features all the required key qualifications.

By applying an elaborate science-based approach to meet well-established critical quality attributes such as e.g. maximum effectiveness, high concentration for low injection volume, low aggregate content and low viscosity, ProJect Pharmaceutics offers profound guidance and support on the development of pioneering parenteral biologics.

Minimizing viscosity and aggregation by actively maximizing repulsive protein-protein interaction in solution is one of the key techniques applied. Additionally, shifting thermodynamic protein stability in solution to its maximum represents another key requisite to promote long-term stability of liquid formulations in pre-filled syringes.

Designed formulations' syringe-ability is measured directly in-system mimicking the typical administration procedure of the patient.

In case stability in aqueous solution is found to be limited by the biologic´s inherent sensitivity, freeze-drying clears the way forward. Innovative design of lyo-formulations and freeze-drying processes developed by ProJect Pharmaceutics reliably overcome the hurdles of reconstituting high-concentrated protein lyophilizates.

Supply of aseptic pre-clinical study material in pre-filled syringes at pilot scale complete ProJect Pharmaceutics' excellence as your pharmaceutical service provider in this exigent field of highly concentrated protein formulation development.

ADC / Cytotoxic Drug Development

Formulation and lyophilization process development for cytotoxic and other highly potent drugs, including Antibody Drug Conjugates (ADCs).

Introducing formulation and lyophilization process development for cytotoxic and other highly potent drugs, including cytotoxic drug immunoconjugates (antibody drug conjugates, ADCs).

We offer pharmaceutical development of ADCs and other cytotoxic drugs in our new safety laboratory with predictive analytical methods and high-end freeze drying capabilities implemented.

The ability to develop Antibody Drug Conjugates (ADCs) by combining protein formulation and process know how with cytotoxic drug expertise puts ProJect Pharmaceutics in a unique position within the biopharmaceutical industry. Our safety facilities in dedicated labs and a profound understanding of the challenges when processing highly potent drugs enable us to provide specific solutions for ADCs and other cytostatic agents.

Many pharmaceutical ingredients of this class show limited solubility in water and rapid degradation during compounding, filling and freeze-drying. ADCs in particular have a lower thermodynamic and colloidal stability due to the attachment of hydrophobic drug moieties leading to modified charge patterns and stronger hydrophobic interactions.

Reduced solubility and a pronounced tendency to aggregation and denaturation may be the consequences, in particular in case of higher drug antibody ratios (DARs).

PJP´s Predictive Formulation Analytics is the proven technology to quickly and reliably identify promising formulation candidates for ADCs and to overcome drug specific stability issues.

PJP's long lasting experience and comprehensive know-how of lyophilization from various kinds of solvent systems, as well as liposome encapsulation, enables our customers to follow new paths in formulation and process technology for modern cancer drugs.

Virus Therapeutics

Formulation and lyophilization process development for live virus vaccines.

ProJect Pharmaceutics expands its service portfolio to meet customer's increasing need for the development of GMO S2 and BSL-2 biological products like protective and therapeutic vaccines, as well as gene and cell therapy products.

New safety facilities in dedicated labs and a deep understanding of the challenges when processing virus vaccines enable ProJect Pharmaceutics to provide specific solutions for this group of highly complex products.

Smart formulations and manufacturing processes to safeguard the efficacy of the finished drug product are provided together with mandatory safety requirements up to GMO S2 and BSL-2 classification.

Maintaining the native quaternary structure of the virus capsid and avoiding virus aggregation is the key to maintain its full biological activity even under stress conditions like elevated temperature, freezing or freeze-drying.

Cutting-edge analytical high-throughput methods have been implemented in our biological safety lab in order to select the most effective combination of excipients for the final drug product.

Our biosafety lab is equipped with a dedicated pilot freeze dryer to design tailored lyophilization cycles both maximally robust and efficient in order to maintain virus activity during long term storage.

ProJect Pharmaceutics expands its service portfolio to meet customer's increasing need for the development of GMO S2 and BSL-2 biological products including live viruses.

Downstream Process Development

The rational design of cell harvest purification steps in biologics' drug substance manufacturing.

Predictive Formulation Analytics delivers the sound basis to define the best formulation conditions and process parameters for each single purification step in DSP of recombinant proteins.

Knowledge on the behavior of a candidate protein (colloidal, thermodynamic, chemical and interface stability) in particular at high concentrations, as occurs during elution or at the concentration/diafiltration membrane, is a mandatory prerequisite for initiating a focused DSP development:

The general evaluation and characterization of the protein´s basic physicochemical properties (basic profiling) within a DoE matrix using a high throughput dynamic light scattering (DLS) plate reader, composition gradient static light scattering (CG-MALS) and nanoDSC to identify potential stability issues or formulation challenges by applying these methods already at an early stage.

The information on how pH, ionic strength, buffer types and stabilizers affect the protein stability and solubility enables the design of an efficient DSP while avoiding pitfalls or bad surprises such as product loss through aggregation/precipitation or degradation. Clogging of membranes or chromatography columns can be circumvented.

Based on this knowledge the appropriate chromatographic steps can be selected, approved and optimized. This scientific DoE based approach is more expedient and less time consuming compared to the commonly applied trial and error approach.

Once the process design is established and verified at development scale, the process can easily be scaled up and transferred into GMP manufacture at significantly minimized risk.

In parallel, sufficient amounts of material can be generated from test runs to be used for further formulation development, e.g. forced degradation study, at an early stage.

The use of Predictive Formulation Analytics as a starting point of process development supports DSP- as well as formulation-development already from an early stage and ideally results in a common formulation for both API drug substance and drug product.

Lyophilization Process Development

The art of developing efficient and robust freeze drying cycles which also work under conditions of large scale manufacturing.

Pilot scale lyophilization cycle development adapted to GMP manufacturing of all kinds of freeze-dried drug products.

Lyophilization Cycle Development und Technology Transfer
We take new paths in lyo-cycle design to quickly and efficiently generate a dry and elegant lyophilizate without compromising process safety and stability of the product.

- ☑ Our experience in lyophilization process development covers freeze-drying of:
- ☑ formulations in vials, (dual chamber) syringes and bulk trays
- ☑ containers in nest&tub configuration
- ☑ formulations containing organic solvents
- ☑ formulations of highly concentrated proteins
- ☑ ADCs and other cytotoxic drugs
- ☑ live virus vaccines

Three high-end HOF pilot freeze dryers, adaptable to any specific conditions of large scale manufacturing, are implemented in dedicated labs for the rational design of reliable and cost-effective freeze-drying cycles. After physicochemical characterization of the final drug product formulation, we define the ideal freezing (including own technologies for controlled nucleation), sublimation and drying parameters and run an in-depth analysis of lyophilizates by own scanning electron microscopy (SEM).

We determine the critical lyophilization parameters and modulate those by means of robustness studies to explore the design space for the process (Quality-by-Design). Our goal is a technology transfer to clinical / commercial drug product manufacturing without defective batches.

Process Mock-up Studies and Aseptic Manufacturing of Preclinical Samples

Our pilot labs are equipped with all relevant process technologies which are also used in commercial aseptic manufacturing of final drug products. During pharmaceutical process development we take specific formulation characteristics into account like viscosity, surface incompatibilities, shear sensitivity and explore mixing, filtration, filling and freeze-drying operations under real conditions to define process specifications.

By aseptic manufacturing under clean bench conditions using sterile containers / equipment and sterile filtered drug solutions in combination with aseptic freeze drying, we can provide samples for stability and preclinical testing with a quality equaling that of the later clinical or commercial product.

Partners

ProJect Pharmaceutics uses pilot freezed dryers from Hof Sonderanlagenbau, technology leader and high quality manufacturer of freeze drying systems. Experts from both firms are in mutual exchange of experience to promote lyophilization technology.

ProJect Pharmaceutics uses Teclen Lyoprotect® systems to mitigate the contamination risk in freeze-drying.

ProJect Pharmaceutics and LYOCONTRACT teamed up to provide the pharmaceutical industry with high quality parenterals. LYOCONTRACT is a state-of-the-art pharmaceutical manufacturing site with the capabilities of producing liquid and freeze-dried parenteral drugs from clinical to large scale commercial scale.

Contact

Get in Touch. Please contact us by phone or email.

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