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Editorial

Unmet Needs in Protein Formulation Science

This special issue of the European Journal of Pharmaceutics and Biopharmaceutics focuses on unmet needs in protein formulation. On the occasion of the annual meeting of the LTS Academy held in fall 2010 on the Petersberg near Bonn/Germany, several speakers have been invited to submit their contribution for publication. This special issue includes these invited publications and selected manuscripts submitted to EJPB on the subject.

Over the last decades, the importance of biopharmaceuticals, specifically recombinant proteins, has grown tremendously. Biopharmaceuticals have exceeded 15% of the pharma market sales and are an important part of research pipelines all over the world. Consequently, formulation and manufacturing of proteins have gained much attention. Substantial progress has been made in understanding protein instability and aggregation, behavior upon lyophilization, and the hurdles in controlled release formulations, but many questions are still unanswered.

We have collected views from the industry and academia on the unmet needs and challenges of protein formulation technologies. The contributions range from the manufacturing of recombinant proteins in kg-ton quantities using animal cells in bioreactors to

a new method to produce equine antirabies immunoglobulin F(ab')₂ fragments from crude plasma. Protein stability is an important aspect and was approached from different angles. The development of high concentration protein formulations based on a platform technology is very important for big pharma development groups. Novel approaches to advance protein formulation science are also presented. Furthermore, contributions address specific challenges of freeze-drying and interaction of proteins with the vial surface. Several manuscripts approach the analysis of specific instabilities of different protein drug molecules. With this selection, we hope to inspire our readers to new thoughts and activities to identify and tackle other unmet needs in protein formulation science.

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