"Formulation matters"

RENTSCHLER BIOPHARMA/LEUKOCARE Back in February 2017, CDMO Rentschler Biopharma SE and formulation specialist Leukocare AG joined forces to give biologics and biosimilar makers a competitive edge through significantly stabilised end products. European Biotechnology spoke with Leukocare's CEO Michael Scholl about the impact of formulation on drug product performance.

EuroBiotech_ When Rentschler Biopharma joined Leukocare as exclusive partner back in February 2017, you and Rentschler Biopharma's CEO Frank Mathias said you hope to elevate the role of formulation strategy on the biopharmaceutical industry's agenda. Why?

Scholl_ We both figured out that formulation or, spoken more generally, drug product development, is underestimated in the schedule of biopharma development. Frank and I concluded that by elevating the awareness about the impact formulation has on the features of therapeutic proteins, we could provide a competitive advantage to Rentschler Biopharma's clients. Therefore, Rentschler Biopharma and Leukocare commissioned a just recently finished industry survey with the goal to gain strategic insights on the importance, expectations, common challenges and future directions of drug product formulation. Results will be published shortly.

EuroBiotech_ The industry has had a lot of discussion on, for example, protein aggregation or impurities associated with single-use equipment – so why is the topic still under the radar?

Scholl_ We can already see a change of attitude in the industry. But it's still in its beginning. Rentschler Biopharma and Leukocare thus see themselves at the forefront of drug optimisation through advanced formulation technologies.

EuroBiotech_ Could you please outline how Leukocare's SPS® (Stabilizing and Protecting Solutions) formulation technology works and how it differentiates from the platforms of competitors?

Scholl_ Basically, the SPS® technology platform consists of two major elements: an excipient library and the way we combine five to eight of these excipients to improve the quality of a biological product. We have approximately 100 well-characterised excipients in our library, which we specifically combine towards the degradation pathways, hot spots, and the product needs of our customers. We only use well-established and -approved excipients in order to prevent regulatory complexity. For identification of the optimal combination of excipients for a certain drug, we have a rational algorithm-supported development approach, which starts with a basic characterisation of the molecule and then reduces the design space by using deep learning algorithms before going into the lab. We are currently in the process of strengthening the use of artificial intelligence for automatic preselection of the optimal formulation components. As this approach currently is unique in the industry, it is a differentiator per se.

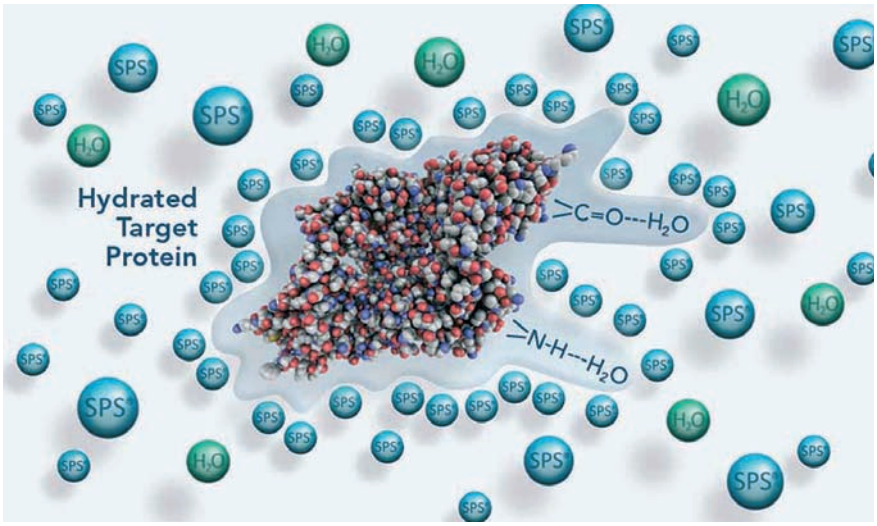
MICHAEL SCHOLL
is the Chief Executive Officer of Leukocare AG (Martinsried), where he heads the division's strategy, finance, corporate law, marketing and sales, and human resources. Before co-founding Leukocare in 2003 with Prof. Dr. Martin Scholz, the business engineer worked as a business consultant at Boston Consulting Group and led the foundation and business development of a range of technology and IT companies.

EuroBiotech_How can your technology help biologics and biosimilar developers to get an edge over their competitors?

Scholl_ There are multiple aspects. First, by increasing thermal stability of protein therapeutics, our technology prevents degradation and allows for room temperature storage in many cases, which is also very relevant for vaccines. Second, many biopharmaceuticals today have to be lyophylised for stability reasons. We can transfer lyophilised to liquid formulations, which reduces manufacturing costs, adds convenience in administration, and comes without any loss of drug

Picture: Leukocare AG

activity. We recently announced a collaboration with the Danish peptide anti-infectives developer Xellia, who will switch its lyophilised anti-infectives to liquid products using the SPS® platform. Third, our technology allows for subcutaneous, instead of intravenous formulations, which are mainly restricted by protein aggregation that occurs at high protein concentrations. Fourth, formulation can increase time-to market for biosimilar manufacturers such as Leukocare's partner Laboratorios Liomont. By providing freedom to operate towards originator formulation patents, their biosimilar candidate can reach the market two to three years earlier. Both examples – the case of Xellia and of Laboratorios Liomont – illustrate how advanced formulation technology can create competetive advantages.



Leukocare's SPS® technology helps stabilise proteins in liquid formulations. Water-protein interactions are stronger than SPS®excipient-protein interactions, resulting in a stabilised hydration of the protein. The hydration shell prevents interaction with co-solvents, resulting in lower free energy and thus increased protein stability.

Picture: Leukocare AG

EuroBiotech_Where do you see the strategic fit of the partnership with Rentschler Biopharma?

Scholl_ The partnership with Rentschler Biopharma allows us to integrate formulation into the broad range of CMC and CDMO offerings Rentschler Biopharma has to make, providing clients a three to six months acceleration in time-to-clinic and time-to-market and appropriate cost savings. As Leukocare, we benefit from the strong market position of Rentschler Biopharma. The alliance allows us to reposition formulation as a key success factor in biopharmaceutical development.

EuroBiotech_How was the feedback from the sector in the 18 months since the deal has been announced?

Scholl_ Of course, I cannot disclose exact figures but Leukocare and Rentschler Biopharma have started several new fully integrated projects, particularly with new clients from the US.

EuroBiotech_What are your next goals?

Scholl_ As the collaboration now is up and running, next we would like to learn more about the formulation needs of potential clients. Formulation is currently still an undeveloped market with some small players around. Our alliance, for the first time, has created some momentum to raise the awareness of formulation development in the drug product development. ■

t.gabrielczyk@biocom.eu