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TECH OUTLOOK

EUROPE SPECIAL

VIROLOGY
EDITION



LIQUID DRUG
FORMULATION
BOLSTERED BY AI

Michael Scholl,
CEO

Leukocare AG



COVER STORY

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LIQUID DRUG FORMULATION BOLSTERED BY AI

By Stacey Smith

In the 1950s, an English microbiologist—Prof. Harry Smith—and his colleagues found that filtrates of serum extracted from animals infected with *Bacillus anthracis* were lethal for other animals. In contrast, extracts of culture fluid from the same organism grown in vitro were not. This discovery of the anthrax toxin via in vivo experiments was a significant breakthrough in the studies of the pathogenesis of infectious diseases. Although in vitro and in vivo drug developments have led to tremendous innovations in the past, these methods fail to help pharmaceutical companies maintain an exponential growth curve in the current industrial

climate. Thus, following early engineering simulation adopters such as the aeronautic, automotive and nuclear industries, biomedical and pharmaceutical companies have started to widely embrace computer modelling and simulation (also known as in silico methods) to accelerate their product development processes and reduce the enormous cost of bringing a new drug to market. Using big data for drug discovery-related databases and drug development and leveraging sophisticated computation theory for molecular design in silico drug discovery is becoming increasingly practical. Operating at the helm of the drug development landscape, Leukocare AG blends its leadership's expertise in biopharmaceutical formulation development with

the innovative potential of bioinformatics and AI algorithms to design formulations that are superior to traditional approaches.

Founded in 2003 by Prof. Martin Scholz and Michael Scholl, Leukocare was initially a pioneer in providing solutions for stabilising immobilised antibodies during manufacturing, terminal sterilisation, and storage. Over the years, the organisation has expanded its formulation technology to encompass large molecules such as peptides, antibodies, viral vectors, vaccines, ATMP, and more.

An Alternative Drug Formulation to Lyophilisation

In drug manufacturing, stability is a pivotal factor that determines the

efficacy and safety of the final product. In practice, the difference in complexity between small and large molecules creates several challenges in terms of stability and storage feasibility. The significantly more complex large molecule compounds are traditionally stored at refrigerated conditions, in some cases even in frozen state at -70°C , as seen with even a few COVID-19 vaccines recently. Understandably, this process is cost-inefficient and is challenging to sustain over extended storage periods. Even lyophilisation or freeze-drying of large molecules can make the drug manufacturing process more tedious and expensive while also deterring positive drug activity. Instead, Leukocare has engineered formulation techniques that allow large protein molecules such as vaccines and viral vectors to be stored in a liquid form at $2-8^{\circ}\text{C}$. This not only increases the convenience for physicians and patients but also eliminates the need for freezers or complicated drying processes. The liquid formulation allows products to be stored for up to two years.

Leukocare combines innovative biostatistics, artificial intelligence and vast formulation expertise with first-class analytics. This approach makes drug development more cost-effective and allows for a shorter time to market, giving a significant competitive edge to the final drug product. "We generate value for our clients by stabilising proteins in a convenient liquid form such that they do not require additional drying processes," says Michael Scholl, CEO of Leukocare.

Bioinformatics and Analytics for Precise Drug Product Development

Leukocare reinforces its innovative formulations with high-end analytics and bioinformatics technologies. The company provides tailored and best-in-class formulations for a client's specific vaccine/vector requisites with an extensive database and sophisticated algorithms. "Modern analytical capabilities are the technological backbone to every formulation development," adds Scholl. Understanding the difference between

different formulations regarding modifications and degradations under various stresses is key to developing a stabilised drug product to distinguish multiple formulations and seek out the one that best fits the demand. But while analytics is critical for drug development, what sets Leukocare ahead of the curve is the company's unique approach to formulation.

Leukocare's formulation platform consists of two significant elements: a library of approximately 100 regulatory well-known and pharmacopoeia-listed excipients and a rational development approach that uses statistical software and self-learning algorithms to combine these excipients towards advanced formulations targeting molecule-specific degradation pathways and hot spots. For identification of the optimal combination of excipients for a specific drug, Leukocare employs a database-driven and algorithm-based development approach. It starts with the definition of the target product profile (TPP), followed by an essential characterisation of the molecule. Further,



LEUKOCARE



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the company continually reduces the design space needed by using deep learning technologies to address hot spots specifically. “We leverage AI for automatic preselection and combination of optimal formulation components. This results in substantially higher stability along with making the entire drug development process faster, robust, and more reliable,” states Scholl.

Leukocare’s tools are used to develop liquid, lyophilised, or spray-dried formulations, select container closure systems, and conduct compatibility and stability tests. The company’s formulation technologies improve the quality of biological products by enhancing the thermal stability of therapeutic proteins, which prevent degradation and potentially allow for the storage of biologics at room temperatures—a feat seldom achieved in the pharmaceutical realm.

A Game-Changer in the World of Pharmaceuticals

Leukocare also collaborates with several eminent pharmaceutical firms to further innovate its formulation solutions. For example, the company’s ongoing collaboration with the Danish specialty pharmaceutical company focused on providing important anti-infective treatments against serious and often life-threatening infections, Xellia Pharmaceuticals, involves switching lyophilised anti-infective (antibiotic and anti-fungal) drugs to liquid products using Leukocare’s formulation technologies. Shifting away from lyophilisation to liquid formulation substantially improves a practitioner’s clinical routine. Physicians and nurses no longer have to spend time reconstituting the lyophilized product before administering the drug. Additionally, with Leukocare’s liquid formulations, Xellia also overcame its challenges in maintaining drug stability.

In the same vein, Leukocare has also played a crucial role in the battle against COVID-19. The pandemic reiterated the importance of collaborations for accelerated drug development, and Leukocare—wielding its virology expertise to develop vaccines—entered into a partnership with the Italian firm ReiThera for fast-tracked development of a single-dose adenoviral vaccine against COVID-19. Leukocare contributes to drug product development by rapidly developing highly stable liquid vaccine formulations based on its well-established technology platform for formulations of viruses and viral vectors.



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Expanding into Greater Horizons

Leukocare is currently working on 30 different projects for a variety of clients and another dozen of projects are about to be concluded. While the unique algorithm-based development approach and a vast library of excipients help the organisation serve its clients successfully, the company established an entity in the US. “Currently, most of our clients are based in Europe. Hence, our expansion to the US provides us with the biggest growth opportunity,” says Scholl. The organisation is currently establishing its foothold in the country and is poised to become a prominent name in the global healthcare ecosystem.

Rentschler Biopharma SE and Leukocare AG have been part of a very successful strategic alliance since 2017. This alliance is unique in the field because it combines best-in-class knowledge in the area of biopharmaceutical formulation development with best-in-class expertise in bioprocess development and cGMP manufacturing. Together, both partners have been working on manifold projects in the area of biopharmaceutical drug development, with the objective of delivering solutions tailored to the client’s e.g., drug product’s needs. This is facilitated by seamlessly

integrating Leukocare’s formulation services into every step of the biopharmaceutical value chain offered by Rentschler Biopharma. The alliance’s innovative approach offers clients significant competitive advantages, enabling them to optimize time-to-clinic and time-to-market as well as exploiting the full commercial potential of their products. In January 2021, the two partners extended their service offering with Leukocare AG joining Rentschler Biopharma at its U.S. site. Rentschler Biopharma and Leukocare AG very much look forward to serving clients on both sides of the Atlantic to provide best-fit solutions and customized services for every joint project.

Frank Mathias, CEO of Rentschler Biopharma, states, “Our strategic alliance with Leukocare is truly a great success for our two companies, and importantly, for our clients. Recognizing the industry’s need for a seamless partnership between formulation and process development in biomanufacturing, we bring a highly flexible offering to the table, addressing every client’s needs. We are partnering with the best-in-class to always deliver outstanding services to our clients and their patients – together!” 

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*The annual listing of 10 companies that are at the forefront
of providing Virology solutions and transforming businesses*