Life Sciences Review

LIFESCIENCESREVIEW.COM
ISSN 2831-8331

BIOTECH STARTUPS EDITION

Leukocare

A Specialist in Bioinformatics based Stabilization of All kinds of Biological Molecules

Drug stability, therapeutic efficacy, and bioavailability are the three fundamental prerequisites that make or break efficient drug formulation and development. Addressing these prerequisites, however, necessitates mastery over chemistry, manufacturing, and control (CMC) functions, alongside a thorough comprehension of necessary formulations, resources, and time-dependant factors within a developmental setup. Safe to say, drug formulation and development is a multifaceted endeavour, one that demands an interdisciplinary team for the dynamic exchange of knowledge, expertise and skills within the clinical value chain. Leukocare, with its expertise in formulation development, is home to such a team, which strives to help clients 'accelerate formulation development by design,'

Leukocare stepped into the biopharmaceutical sector as a product development company almost 20 years ago. It pioneered the development of a coating for filter membrane, employing an antibody to reduce the activity of neutrophil granulocytes. In this undertaking, the company had to tackle the issue of stabilizing a functional molecule on the membrane. They saw that the stablization of the formulation was key for the drug product development. The company took the expertise gained and shifted its focus to offer services for drug product development. Over the last 5 years, they have focused on improving drug product development by combining innovative bioinformatics, biostatistics, artificial intelligence and first-class analytics. "We are highly specialized in stabilizing all kinds of biological molecules. And we have a very strong bioinformatics based approach, which we apply to different projects. This allows us to come up with superior formulations quickly," states Michael Scholl, CEO of Leukocare.

The company's formulation development approach consists of two key elements: the first features a library of up to 100 different regulatory, well-established and employed excipients, and the second is a rational development approach that employs statistical software and self-learning algorithms as well as state of the art design of experiment (DoE) matrices. With the help of pioneering bioinformatics and biostatistic models, Leukocare combines excipients for stabilized formulations that are tailored to a specific target product profile, expedited by a broader design space than conventional approaches to reach optimal formulations in less time and at lower costs.

Typically, many biotech companies start considering formulation too late in the product development life cycle, which adds risk to the clinical program; researchers would not know if the proposed formulation could have any adverse effects on the clinical outcome of the trial. Eventually, they spend millions of dollars on clinical trials while risking the degradation of product quality.

Leukocare addresses such issues through its robust technologies and vast expertise in the formulation development of biopharmaceuticals and viral vectors in combination with innovative bioinformatics. In an instance demonstrating the same, Leukocare developed a formulation for one of the clients developing a viral vector-based product to transfer the RNA into the target cells. To achieve the desired stability or shelf life, the viral vector-based product had to be stored in a frozen-liquid formulation at minus 70 degrees Celsius. To address this requirement, Leukocare was able to develop two stable formulations. One was in lyophilized form, stable at two to eight degrees for 24 months, without any titer drop. The other one was liquid form. They achieved very high stability in liquid, which is the most convenient form for physicians and patients, as they would not need to resolve and resuspend the product before administration, and avoid the burden of cold chain logistics.

Leukocare is continuously improving its technologies to add value to the customers by pushing boundaries when it comes to AI-based approaches in order to shift from in-vitro to in-silico processes. Leukocare has also incorporated a fully-fledged protein Analytical Lab and formulation development team in the Boston area in Milford. During the pandemic, the company has worked round the clock to add new modalities and is planning to work in the field of exosomes in the near future. LS

Michael Scholl