

Company Showcase

CONQUERING COMPLEXITY WITH LIFECORE INJECTABLES



Figure 1: Lifecore is a go-to partner for complex injectables programmes.

“WHEN UNEXPECTED ISSUES ARISE, SUCCESS DEPENDS ON A HIGHLY TECHNICAL TEAM THAT IS ACCUSTOMED TO ADAPTING QUICKLY, KEEPING PROGRAMMES ON TRACK DESPITE EVOLVING COMPLEXITIES.”

Injectable drug products can vary significantly in complexity, and even seemingly straightforward formulations can present hidden challenges. For example, some formulations can be relatively easy to fill but require special handling due to oxygen or light sensitivity; other programmes demand extremely precise process control, where conjugation or other chemical reaction steps need to be controlled within seconds or risk the product’s physical form changing, leading to the product not meeting release specifications.

These challenges are not always apparent at the outset of a development programme – injectables are inherently

complex. When unexpected issues arise, success depends on a highly technical team that is accustomed to adapting quickly, keeping programmes on track despite evolving complexities.

A CAN-DO CULTURE BUILT ON DIFFICULT FORMULATIONS

As a US-based injectables CDMO, Lifecore Injectables has built a reputation for embracing complex process development and manufacturing challenges that others avoid (Figure 1). This mindset is rooted in the company’s legacy as a manufacturer of sodium hyaluronate, a highly viscous material known for being difficult to filter and fill. Developing expertise in such demanding formulations early on laid the foundation for Lifecore’s distinct technical capabilities.

Since initiating aseptic filling operations in 1989, Lifecore has accumulated decades of experience working with highly viscous and sensitive compounds. This history has fostered a culture defined by technical confidence and a willingness to tackle complexity head-on.

UNIQUE CAPABILITIES BACKED BY PROVEN QUALITY

No matter the challenge, Lifecore’s work is supported by a robust quality management system (QMS). The effectiveness of this system has been demonstrated through

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successful drug product, medical device and combination product submissions across all stages of development.

With hundreds of millions of commercial units distributed worldwide and more than 40 years of quality and compliance experience, Lifecore has established a strong regulatory track record (Figure 2). The company’s QMS continues to evolve through close engagement with global regulatory bodies and extensive oversight, including more than 60 audit days per year conducted by regulators and customers.

SOLVING THE PROBLEMS OTHERS CANNOT

Lifecore is frequently engaged by customers encountering manufacturing hurdles that cannot be resolved elsewhere. In one example, a customer approached Lifecore to fill and finish a polymer-based formulation so viscous that it was nearly solid at room temperature. The original equipment manufacturer deemed the product impossible to fill.

“LIFECORE IS FREQUENTLY ENGAGED BY CUSTOMERS ENCOUNTERING MANUFACTURING HURDLES THAT CANNOT BE RESOLVED ELSEWHERE.”



Figure 2: Lifecore has a global quality and compliance track record of over 40 years.

Lifecore’s team developed a solution by designing custom equipment to heat the product, enabling it to flow consistently throughout the manufacturing process. Filling machines were retrofitted with heating capabilities to ensure reliable flow through the narrow internal diameters of the filling needles.

Among Lifecore’s sterile filtration solutions, a proven high-pressure sterile filtration skid enables aseptic filtration of high-viscosity formulations (up to 100,000 cP). This capability addresses a critical need for products that cannot be terminally sterilised and has been validated for use in a variety of applications.

Viscosity-related challenges can also impact device performance. Increased

injection pressure in high-viscosity formulations may cause syringe needles to detach at the Luer. To mitigate this risk, Lifecore has collaborated with customers to implement custom assembly and packaging solutions that incorporate needle retention devices. While seemingly straightforward, successfully scaling these solutions required the design of custom automated machinery capable of meeting commercial production demands.

READY WHEN IT MATTERS MOST

Has Lifecore encountered every challenge imaginable? No. But with confidence grounded in decades of experience, a proven record of technical problem-solving and a culture that embraces complexity and has a quality system to back it up, Lifecore is prepared for the future challenges that will inevitably arise (Figure 3). At Lifecore, conquering complexity is not an exception – it is at the core of the company’s ethos and how it supports its customers when it matters most.

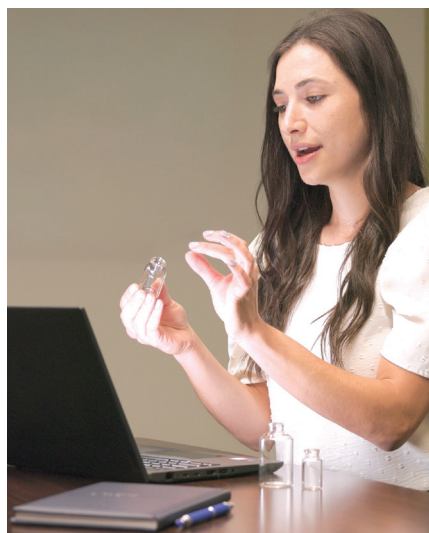


Figure 3: Lifecore can support a range of vial, syringe and cartridge options.

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