Biolife Solutions®

Collection
Packaging
Storage
Cold Chain
Thawing

Class-defining solutions for bioproduction workflows

Solutions for downstream workflows

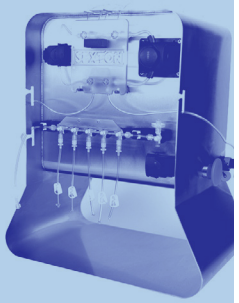
BioLife serves a wide range of bioproduction processes with class-defining tools and services to preserve and increase the viability of biologics.

01 Collection & Processing

Stabilize starting materials through expansion and cryopreservation

02 Fill & Packaging

Semi-automated filling and cryo-stable primary packaging



03 Storage Services

Sample management and off-site or hybrid storage services

04 Cold Chain Solutions

Smart Shippers for cold chain logistics and management

05 Thawing Solutions

Automate and control sample thaw rates with water-free solutions

Interview with Sean Werner, PhD

Sean Werner is the Chief Technology Officer – Cell Processing at BioLife Solutions, a leading provider of bioproduction tools and services to the cell and gene therapy and broader biopharma markets.

BioLife acquired Sexton Biotechnologies in 2021 where Sean was President of the company known for providing processing and handling solutions for the CGT industry. Sean received his PhD from Purdue University in Biology followed by post-doctoral positions at the Indiana University School of Medicine and Eli Lilly. Sean has previous experience filling various roles in the global regulatory and general management functions supporting medical devices, autologous cell therapy, and single use disposable development programs. In his 15 years working in the life science industry, he has guided pre-clinical and clinical testing and submission strategies leading to global commercialization of multiple medical devices and bioprocessing tools.

"We've created workflows showing how our tools work with other manufacturers' tools, such as bioreactors or filtration systems."

Sean Werner, PhD
Chief Technology Officer

Our time and energy are focused on living medicines

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Q: Your previous company, Sexton Biotechnologies, was recently purchased by BioLife Solutions. What most excites you about this new venture?

A: Our focus at Sexton Biotechnologies was to create tools to help users integrate across different unit operations in cell manufacturing, be it using automated or manual systems. Additionally, we focused on secure product storage solutions that were robust and met all the needs for closed processing. Now, as part of the BioLife Solutions product portfolio, we have a suite of tools that cover an entire workflow. That really builds upon what we were doing at Sexton. For example, BioLife cryopreservation media can be directly integrated into our formulation and processing tools like the Signata CT-5™ or CellSeal® vials. Further downstream, final cell products can be transferred in our evo shipping containers, and stored at any of our SciSafe locations, taking advantage of our sample management services. These tools were all developed separately and provide unique advantages, but when offered together, it solves a much bigger part of the manufacturing equation.

Q: Where can BioLife products make the biggest impact in the cell and gene therapy industry? What problems are you keen on solving?

A: There's an ever-growing number of challenges that the industry is trying to address. We provide and develop tools and manufacturing processes focused, in part, on risk mitigation. Many of our tools provide assurance of product stability, throughout the manufacturing process. We want to make sure that our customers' products maintain their critical quality attributes during some of the highest risk points of cell and gene therapy (CGT) manufacturing. The risks to stability and performance of final products in this industry are both high and difficult to detect. The BioLife portfolio was, until recently, focused on class-defining cryopreservation solutions. The new portfolio complements that original platform. We can support our customers with solutions to secure their precious products across the downstream and cold chain process. From fill and formulation to the final thaw. That's not to say that we don't have solutions for upstream aspects of CGT manufacturing, but the coverage at the downstream phases is unlike anyone else. Each platform brings unique attributes to help ensure the risks during downstream and cold chain process steps are well controlled.

Q: What differentiates BioLife from other CGT suppliers?

A: An aspect that is interesting and unique to me is our focus on the cell and gene therapy industry. Our time and energy are focused on living medicines as opposed to a broad range of adjacent industries, and that's relatively unique. I think this focus gives us the ability to have a strong internal team with expertise, backgrounds, and experiences relevant to the specific needs of this industry. There are unique concepts to understand when creating a therapy that is for a specific patient as opposed to a batch that treats thousands of patients. And these autologous therapies provide the foundation of future cell therapies that helps the industry continue to grow.

Q: How can suppliers work together to help continue the evolution of best manufacturing practices in CGT?

A: Collaborative communication in the pre-competitive space. One of the things that we worked on over the last couple of years was generating examples of how different pieces of equipment can be brought together for a successful manufacturing process. We've created workflows showing how our tools work with other manufacturers' tools, such as bioreactors or filtration systems. And as suppliers, we can embrace collaboration; there is space where we can build workflows and teach the industry how to think about using the tools that we as tech providers create to their fullest potential. That is one of the things that will be critical going forward as we hit an inflection point in the manufacturing concepts in cell and gene therapy. It's going to take suppliers and developers working together, recognizing where their strengths lie, to create those solutions that truly service the industry.

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BR-BLF-230697_R02