BioPreservation Today®

Volume 4 - Issue 2 | Winter 2013

PHACILITATE'S 9TH ANNUAL
CELL & GENE THERAPY FORUM
WASHINGTON, DC

FEATURE ARTICLE
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GLOBAL FROZEN SHIPPING SOLUTION FOR LIFE SCIENCES

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WASHINGTON MONUMENT – COMPLETED IN 1884; 555 FEET

WEB RESOURCES

www.aabb.org | American Association of Blood Banks
www.celltherapy.org | International Society for Cellular Therapy
www.asbmt.org | American Society for Blood and Marrow Transplantation
www.ishrs.org | International Society of Hair Restoration Surgery
www.alliancerm.org | Allliance for Regenerative Medicine
www.bestcollaborative.org | BEST Collaborative
www.regenerativemedicinefoundation.org | Regenerative Medicine Foundation
www.phacilitate.co.uk/pages/cgtherapy/index.html | Phacilitate

UPCOMING EVENTS

Phacilitate Cell & Gene Therapy Forum 2013
January 21-23, 2013
Washington, DC

2013 BMT Tandem Meetings
February 13-17, 2013
Salt Lake City, Utah

8th Annual New York Stem Cell Summit 2013
February 19, 2013
New York, NY

Adult Stem Cell Regenerative Medicine Conference
April 11-13, 2013
The Vatican

ISCT
April 22-25, 2013
Auckland, New Zealand

EDITOR'S CORNER

Mike Rice, Chairman & CEO, BioLife Solutions, Inc.

Greetings from the Phacilitate Cell and Gene Therapy Forum 2013,

Customers, suppliers, partners, and friends of BioLife, welcome back to Washington, D.C. for what I'm sure will be another informative and productive regenerative medicine conference organized by the team at Phacilitate. We're pleased and proud to support this key industry event as a silver sponsor. In addition to our corporate exhibit, Dr. Aby J. Mathew, Ph.D., our Senior Vice President and Chief Technology Officer, will be a panelist at 2:30PM on Monday in a roundtable discussion of: ***Delivering key action points to minimize cost of goods and maximize efficiency of your operations.*** Following this discussion, Dr. Mathew will then present a lecture on ***Designing best practices for stability/biopreservation characterization of cell and tissue therapies.***

In this issue of BioPreservation Today® (BPT), I recap the growth of BioLife and our presence as a critical supplier of clinical grade biopreservation media products to the regenerative medicine field.

Also in this issue, Joe Annicchiarico, our Vice President of Manufacturing, offers some thoughts on the critical need that contract manufacturing service providers fulfill in the regenerative medicine industry. Joe also highlights BioLife's specific expertise and competence in contract aseptic formulation, fill, and finish services of liquid media products.

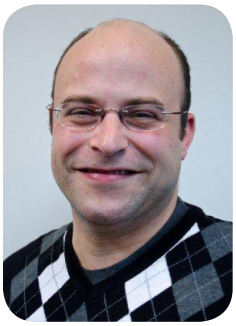
We're also pleased to invite our colleagues at CryoPort to contribute an overview of their innovative biopreservation tools and services.

Finally, as you know, during 2012 we greatly expanded our Bothell, Washington facilities with the build out and validation of our second multi-grade cGMP clean room suite, new warehouse space, and expanded administrative offices. You can read more about our growth in this issue of BPT.

Thank you for your continued interest in BioLife products. I hope you enjoy this issue of BioPreservation Today. We look forward to seeing you at our exhibit and corporate tutorial.

Best regards,

Mike



BIOLIFE SOLUTIONS CONTRACT MEDIA MANUFACTURING

Joe Annicchiarico, Vice President of Manufacturing, BioLife Solutions, Inc

Although transplant surgeries have occurred since at least the second century AD, only recently has regenerative medicine begun to attract the same regulatory scrutiny as its pharmaceutical and biotechnology cousins. BioLife Solutions, Inc. has expected this increased regulatory attention for the past few years and has structured its quality systems in anticipation of it. Combining ISO13485 Certification with experienced pharmaceutical professionals has enabled BioLife to jump ahead on the regulatory curve. BioLife now brings expertise in manufacturing its own serum-free protein free cell and tissue preservation solutions to the wider CMO market.

The FDA and other regulatory agencies have a long history of responding to public health emergencies by both issuing new and tougher rules and regulations and expanding their scope. Just as state-run com pounding pharmacies can expect changes to the law in light of the recent fungal meningitis outbreak allegedly due to contamination in a widely distributed sterile drug from a pharmacy in Massachusetts, the field of Regenerative Medicine is just a crisis away from its own reactionary legislation. Currently, cell and tissue preservation fluids are governed by a hodgepodge of standards which varies depending on the solution's clinical application (e.g., as an ancillary ingredient, excipient, or medical device). Still, many companies and research groups continue to use home-brew formulations manufactured using non-compendial ingredients under non-cGMP conditions, which leads to inconsistent results and frustrating, expensive delays.

BioLife Solutions manufactures all of their own and their contract manufacturing customer's products using the highest commercially available grade ingredients in an ISO 13485-certified EU Grade C (analogous to Class 10,000) cleanroom. Sterile filling at BioLife occurs in a Grade A (Class 100) vertical laminar flow hood situated within a Grade B (Class 1,000) modular cleanroom. All cleanroom personnel undergo gowning qualification upon hire and participate in three media fill validation lots prior to becoming fill line operators. BioLife designs media fill events to mimic actual worst-case process parameters by introducing various process interventions, which are called out in filling validation protocols written specifically for each media fill event. Operators, filling lines, and the Grade A/B areas are re-qualified every six months, and Grade C areas are requalified yearly by an accredited contract firm. Additionally, supervisors conduct frequent hands-on training with their staff members and every production team member completes both online and practical cGMP training courses.

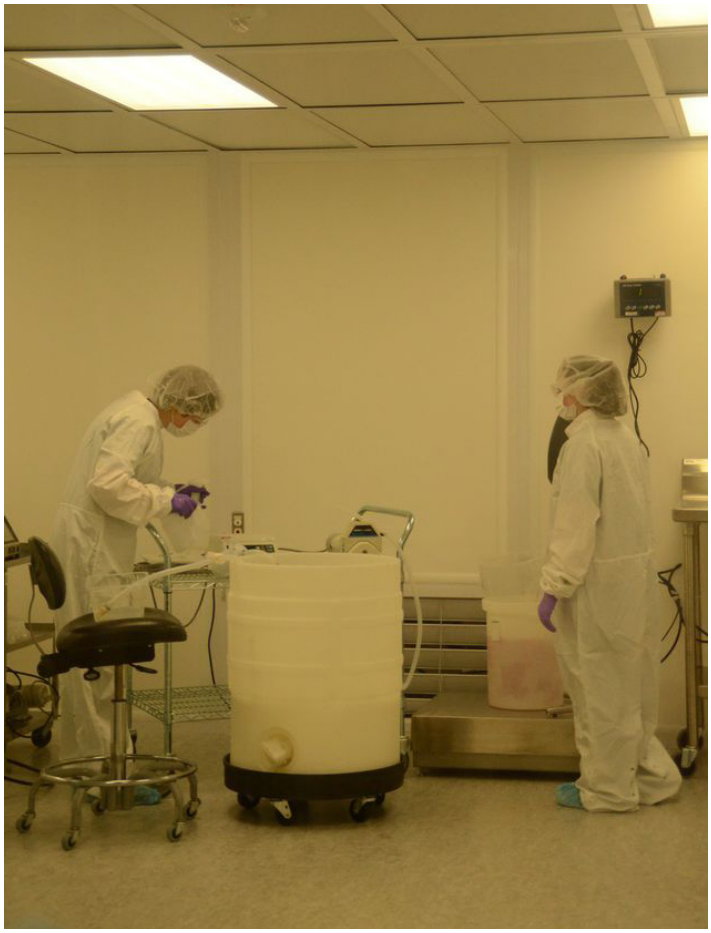
"BIOLIFE'S HYBRID QUALITY SYSTEM MEETS RELEVANT MEDICAL DEVICE AND DRUG STANDARDS AND GUIDANCES."

BioLife formulates and fills all of its and its customer's products using steam-sterilized or gamma-irradiated single-use disposable vessels and filling lines. Batch records and Standard Operating Procedures are written separately for all cGMP processes and equipment. This customization allows the BioLife team to consider material compatibility, utility, and extractables/leechables profiles when selecting

in-process and finished product contact materials, rather than a one-size-fits-all approach so common to many preservation systems. BioLife's solid working relationships with both large and small vendors allow the company to source any item to meet its customers' needs.

BioLife has recently completed a second cleanroom build out which effectively doubles its manufacturing capacity to over 140,000 Liters per year. This gives the company both redundant capacity during room qualification downtime and added space for new customers and products. Vessels ranging from lab scale (1L) to 500L batch size can accommodate almost every commercial need. Scale-up expertise help customers envision their products on a larger scale than ever before, and BioLife's onsite quality control laboratory can test a variety of product attributes at virtually any point in that formulation or filling process. Afterward, every product undergoes a 100% quality inspection both before and after onsite labeling; highly trained team members catch any visual particulates or other defects before the product leaves the facility, saving the time and expense of costly product recalls. Whether the customer requires experience filling bags, bottles, vials, or syringes, BioLife has the expertise and quality system to get the job done.

When translating a product from conception to reality, many areas of expertise are required. Scientific, regulatory, quality, process engineering, and design experts are prevalent in large companies but rarer in small ones. Often, a companies' product gets lost in the bureaucracy of their CMO. BioLife brings the best traits of a resourceful large company in a task-focused, small group of dedicated, experienced professionals.



The regulatory sheriff is headed for the Wild West of regenerative medicine; it's only a matter of time. BioLife can help ensure your products are safe and secure.

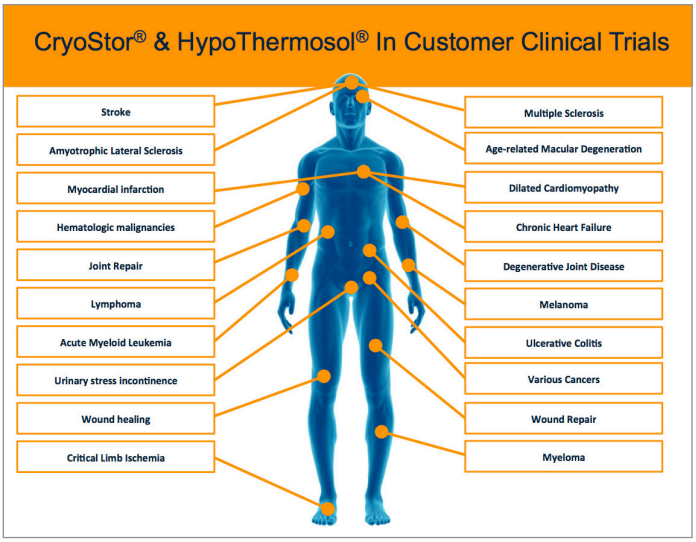
BIOLIFE PRODUCTS IN REGEN MED CLINICAL TRIALS

Mike Rice, Chairman & CEO, BioLife Solutions, Inc.

Company Overview

BioLife Solutions, a life sciences tools and services provider, develops, manufactures, and markets liquid biopreservation media products for cells, tissues, and organs. The company is based in a high-tech campus that was formerly a dairy farm in Bothell, Washington. Strategic markets and (end-users) include biobanking (umbilical cord blood and tissue banks, adult stem cell banks, hair restoration centers, biorepositories) drug discovery (pharmaceutical companies, cell suppliers, toxicology testing labs), and regenerative medicine (hospital based stem cell transplant centers, commercial companies developing cellular therapies and engineered tissue products). Since 2007, the Company has achieved compounded annual growth at over 30%. For several years, BioLife has been a corporate member and major supporter of ISCT. The Company's HypoThermosol® and CryoStor® products have been incorporated into more than fifty clinical trial stage regenerative medicine products and therapies.

Since the successful completion of small animal safety studies at the Fred Hutchinson Cancer Research Center in Seattle, and the submission of Drug Master Files to the US Food and Drug Administration, the adoption of BioLife's proprietary biopreservation media products has significantly increased. For some targeted diseases and disorders, several customers are using the products for the same clinical indication. Also, in many customer-validated applications in clinical trials, the products are used as excipient reagents, acting as the biopreservation medium and also the vehicle solution for introduction of cells into the patient. Routes of administration include IV, IM, and SubQ, intrathecal, intra-articular, sub-retinal, and intracranial.



Over the last five years, BioLife has built a very robust quality environment in which its products are developed, manufactured, tested, and distributed. In addition to certification to ISO13485 since 2009, the quality system adheres to 21 CFR Part 820 - Quality System Regulation for Good Manufacturing Practices (GMP) of medical devices, 21 CFR Parts 210 and 211 covering GMP for Aseptic Production, Volume 4, EU Guidelines, Annex 1 for the Manufacture of Sterile Medicinal Products, ISO 13408 for aseptic processing of healthcare products, and ISO 14644 for Clean Rooms and Associated Controlled Environments.

Leading Partner and Supplier to the Regenerative Medicine Field

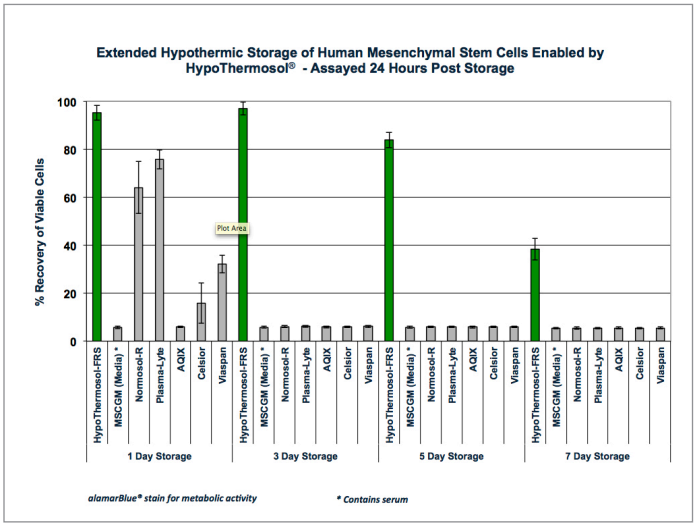
This focused attention on quality has resulted in product adoption by a multitude of commercial companies and hospital based stem cell transplant labs throughout the world. A small sample of customers in BioLife's strategic markets is illustrated in the graphic at the left. Many of the customers represented previously used traditional, home-brewed preservation media formulations, and experienced suboptimal post-preservation results. This was due to the non-optimized traditional formulas, which typically consist of culture media and serum, and in the case of freeze media, a cryoprotectant such as DMSO. Poor performance results from incorrect ionic concentrations for use at low temperature. Also, risk factors related to the use of home-brewed or traditional preservation media formulations include lower quality ingredients, animal derived components, manual formulation labor, limited release criteria, lot to lot variability, and often, a non-cGMP validated process.

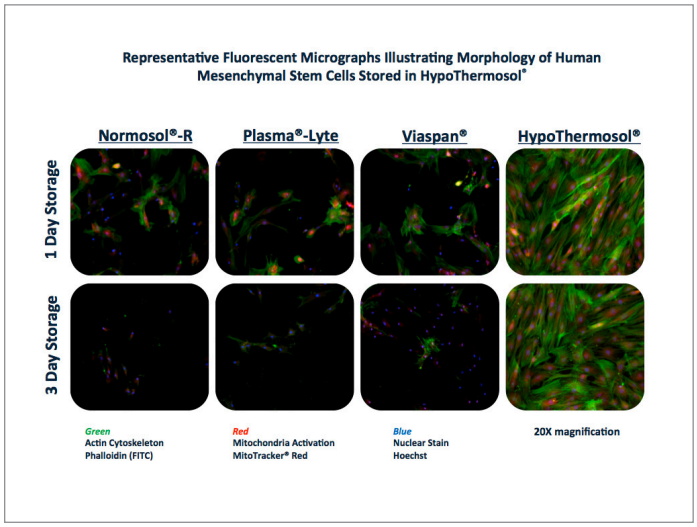
Innovation in Biopreservation Media Formulation

In contrast, BioLife's products are pre-formulated, manufactured under cGMP, serum-free, protein-free, and utilized USP/multi-compendial or highest available grade ingredients. Every production lot is subjected to a robust panel of release criteria including USP sterility and endotoxin, appearance, pH, particulates, and a metabolic cell based assay. The discoveries by BioLife scientists of several molecular mechanisms of preservation-induced cell damage and death enabled the formulation of a new class of intracellular-like preservation media products with ingredients that specifically mitigate preservation-related cellular stress pathways.

Product Performance Evidence

A growing library of customer-generated and internal data now supports the superior biopreservation efficacy of BioLife products, in extending shelf life/stability of relevant clinical cell types, and also in improving post-preservation viability, recovery, and function. In the hypothermic storage example at the left, Human mesenchymal stem cells isolated from bone marrow aspirates were stored for up to seven days in HypoThermosol and several other typically used storage media including leading organ





storage solutions. Cells stored in HypoThermosol were still viable at greater than the FDA minimum of 70% after 5 days in cold storage. By comparison, only one of the other storage solutions tested maintained cell viability for 24 hours. Companion flourorescent micrographs of the cells under test confirm the significant extension in shelf life effected by HypoThermosol. Cytoskeletal integrity, mitochondrial activity, and presence of intact nuclei are all visible in the graphic at the right. Conversely, nearly

no viable cells are visible after storage in the competing solutions. These findings clearly indicate the critical impact HypoThermosol can have on the commercialization potential of regenerative medicine products. Enabling a worldwide geographic clinical delivery footprint from a single manufacturing/distribution center has a tremendous positive impact on the cost of goods for cell and tissue-based products. In some cases, this may make the difference in post-regulatory approval success or failure for a commercial enterprise. Cryopreservation is a common mode of biopreservation applicable to a broad array of regenerative medicine therapeutics, due to longer storage time and advances in cold chain management tools. BioLife's product offering of cryopreservation freeze media products includes the BloodStor® family of products including BloodStor 55-5 DMSO/Dextran and BloodStor 100 DMSO, and the CryoStor family of CS2, CS5, and CS10, with the suffix indicating the DMSO concentration. These products are packaged in sterile, single-use vials, media bottles, and will soon be available in syringes and bulk storage bags. The following data graphs illustrate how serum-free CryoStor outperforms leading commercial competitors, and also home-brewed formulations, many of which include serum. In the graphic at the left, all CryoStor products outperformed traditional serum-containing home-brewed formulations, with CryoStor CS2, containing only 2% DMSO, roughly comparable. Again, the companion florurescent micrographs support the ability of CryoStor to render superior or similar post-thaw recovery of cells that were frozen in serum-containing freeze media formulations. The complete evidence library of comparable biopreservation efficacy data can be viewed on BioLife's website.

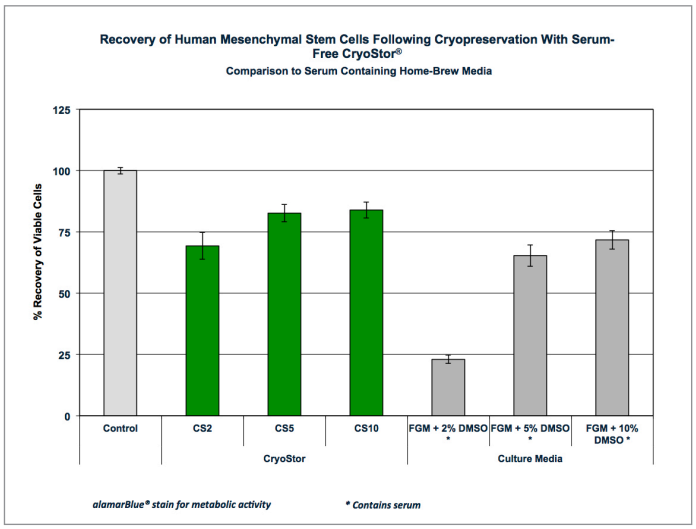
Contract Manufacturing

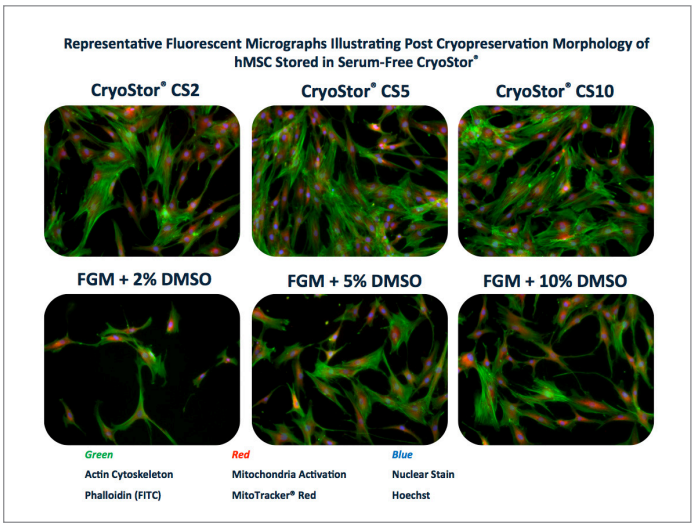
To further augment its product offering to the regenerative medicine field, BioLife also performs contracted aseptic media formulation, fill, and finish services. Customers in need of specialized media manufacturing, custom packaging, flexible batch sizes, and process optimization consulting rely on BioLife to fulfill these requirements. Two independent, multi-grade (EU Grade D - wash through Grade C formulation and Grade A - fill) clean room suites are validated and staffed by an experienced media formulation/fill team supported by a quality team with several years of combined experience.

"CRYOSTOR OUTPERFORMS LEADING COMMERCIAL COMPETITORS, AND ALSO HOME-BREWED FORMULATIONS, MANY OF WHICH INCLUDE SERUM."

Summary

BioLife management is committed to supporting the development and successful commercialization of cell and tissue-based products and therapies. The Company's scientific innovation, quality environment, and customer service focus are now recognized by the leaders in the regenerative medicine field. For more information please visit www.biolifesolutions.com





BIOLIFE SOLUTIONS COMPLETES VALIDATION OF 2ND CGMP CLEAN ROOM MANUFACTURING SUITE

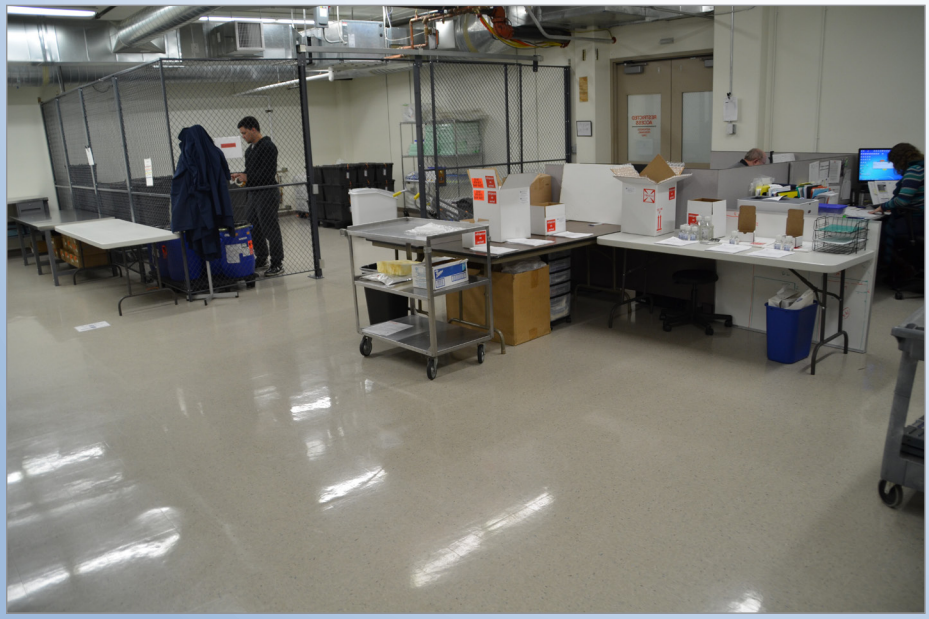
Company Also Increased Total Facilities Under Lease With Additional Warehouse Space to Improve Efficiency and Support Future Growth

BioLife Solutions, a leading developer, manufacturer and marketer of proprietary clinical grade hypothermic storage and cryopreservation freeze media for cells and tissues, and contract media manufacturer, recently completed the validation of its second current Good Manufacturing Practice (cGMP) clean room manufacturing suite. The Company also added 5,103 square feet to its warehouse facilities to improve efficiency and as an investment to support future growth. Total facilities under lease include 25,864 square feet.

Mike Rice, Chief Executive Officer, said, "We're pleased to announce completion of this milestone, which should better position BioLife to capture additional market share for biopreservation media products, as the biobanking, drug discovery, and in particular, the regenerative medicine market, segments continue to experience rapid growth over the next several years."

Certified to ISO 13485:2003 since 2009, the Company's manufacturing facility and quality systems adhere to 21 CFR Part 820 - Quality System Regulation for Good Manufacturing Practices (GMP) of medical devices, 21 CFR Parts 210 and 211 covering GMP for Aseptic Production, Volume 4, EU Guidelines, Annex 1 for the Manufacture of Sterile Medicinal Products, ISO 13408 for aseptic processing of healthcare products, and ISO 14644 for Clean Rooms and Associated Controlled Environments.

Rice continued, "We now have redundant capacity and manufacturing capabilities, which should give our current and future customers even more confidence about our ability to meet their demand for HypoThermosol® and CryoStor®. Our contract manufacturing customers can now also be assured that we can maintain our manufactured supply of their products to support their growth."



cryoport

GLOBAL FROZEN SHIPPING SOLUTION FOR LIFE SCIENCES

Cryoport delivers an innovative and complete outsourced frozen shipping solution for biological materials. The Cryoport solution replaces outdated dry ice and virtually eliminates the risk of cell degradation in frozen shipping. Cryoport combines the breakthrough technology of liquid nitrogen dry vapor shippers with the most advanced logistics management platform in the industry. When added with their logistics expertise, they provide a complete outsourced solution that advances deep-frozen shipping for the life science community.

PACKAGING

Liquid Nitrogen Dry Vapor Shippers

The Cryoportal™ Logistics Management Platform provides the most advanced web portal in the industry for managing all your frozen shipping logistics. From full carrier integration for up to the minute track and trace to managing the entire shipment - including ordering, document preparation, customs clearance, carrier management, shipment tracking, issue resolution, and delivery.

TECHNOLOGY

Proprietary Logistics Management Platform

The Cryoport Express® liquid nitrogen dry vapor shippers are validated to maintain a stable -150° C for ten plus day dynamic shipments. The custom built dry vapor shipper features a LN2 dry shipper for maximum stability, reliability and safe frozen shipping at cryogenic temperatures

DATA

Data Monitoring and Analytics

With complete data monitoring and tracking on every shipment, Cryoport not only delivers chain-of-custody but chain-of-condition on every shipment. This integrated solution eliminates costly temperature excursions, adds flexibility to your logistics system and confidence that you'll have the highest specimen integrity for your high-value frozen biological materials.

LOGISTICS

Expertise and System Support

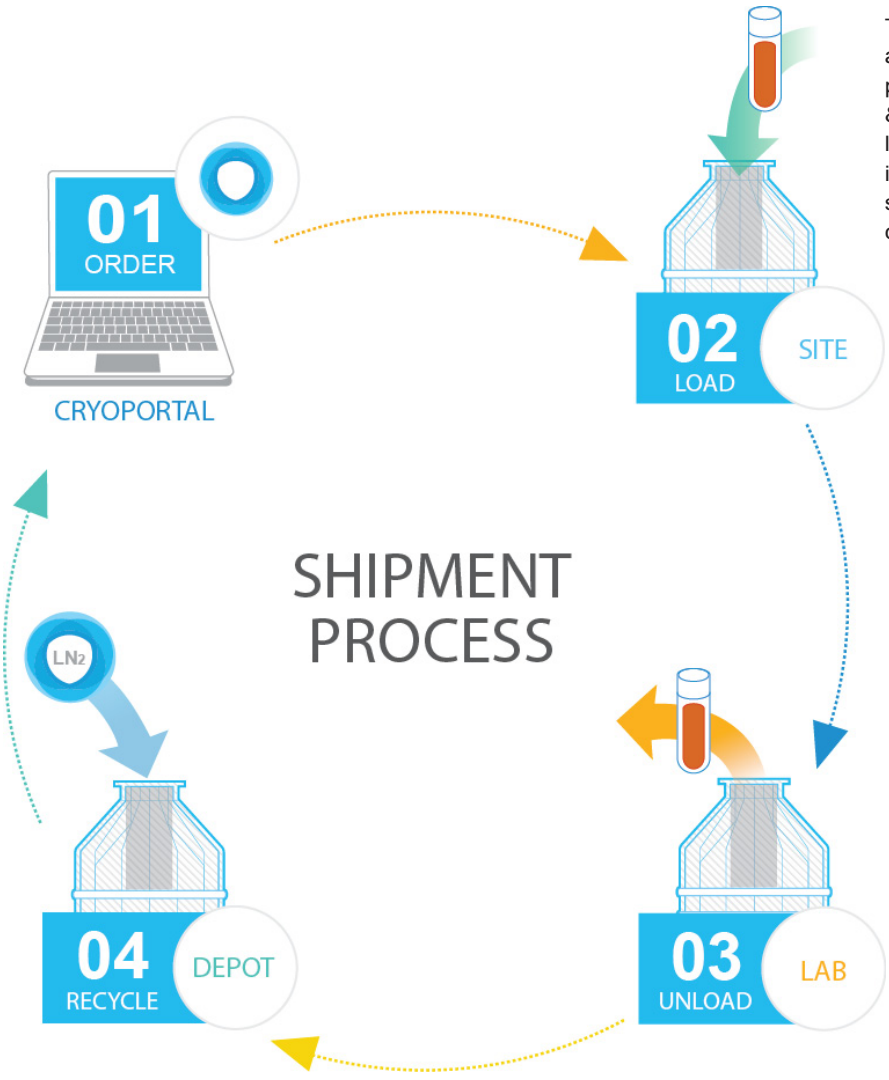
The Cryoport Logistics Team uses this same robust platform to manage your shipments and carriers, communicate with your team and to ensure seamless transportation of your shipments around the globe on a 24/7 basis.

Cryoport's total turnkey service management approach offers reliability, cost effectiveness, and convenience, while the use of recyclable and reusable components provides a "green" and environmentally friendly solution.

THE CRYOPORT PROCESS

Global Frozen Shipping Solution for the Life Sciences that Eliminate Dangerous Goods Shipping with Dry Ice

Enter order through the easy 5-step process on the most advanced web based portal. Cryoport then sends a charged shipper to the site.



The shipper arrives with all required paperwork & pre-printed documents & labels. The site then loads the biomaterials into the LN_2 dry vapor shipper for pre-arranged carrier pick-up.

The non-hazardous shipper is recharged and refurbished for future shipments.

The recipient unpacks the biomaterials & affixes the pre-printed documentation to return to Cryoport.

www.cryoport.com

WISHING YOU A PROSPEROUS 2013

THANK YOU FOR YOUR BUSINESS AND SUPPORT

BIOLIFE SOLUTIONS CUSTOMER SERVICE TEAM

BioLife Solutions develops and markets patented hypothermic storage/transport and cryopreservation media products for cells, tissues, and organs. BioLife's proprietary HypoThermosol®, CryoStor®, and BloodStor® platform of biopreservation media products are marketed to academic research institutions, hospitals, and commercial companies involved in cell therapy, tissue engineering, cord blood banking, drug discovery, and toxicology testing. BioLife products are serum-free and protein-free, fully defined, and formulated to reduce preservation-induced, delayed-onset cell damage and death. BioLife's enabling technology provides research and clinical organizations significant improvement in post-preservation cell and tissue and viability and function.

425.402.1400 | **www.biolifesolutions.com**

BioLife Solutions®
POWERING THE PRESERVATION SCIENCES