bpt BioPreservation Today®

Volume 7 - Issue 2 | Spring 2017

FEATURE ARTICLE:

BIOLIFE SOLUTIONS AND ISCT - CELEBRATING 25 YEARS OF ADVANCING CELL THERAPIES TOGETHER

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WEB RESOURCES

alliancerm.org | Alliance for Regenerative Medicine

aabb.org | American Association of Blood Banks

bestcollaborative.org | BEST Collaborative

bioinformant.com | BioInformant

biolifesolutions.com/evidence | BioLife Solutions Cryopreservation and Hypothermic Storage Evidence

celltherapysociety.org | International Society for Cellular Therapy

fiercebiotech.com | FierceBiotech

insights.bio | Cell & Gene Therapy Insights

ishrs.org | International Society of Hair Restoration Surgery

lifesciences.knect365.com | KNect365 Life Sciences

phacilitate.co.uk | Phacilitate

regmedfoundation.org | Regenerative Medicine Foundation

regmednet.com | RegMedNet

UPCOMING EVENTS

Cellular Therapies and Transfusion Medicine in Trauma and Critical Care 2017 (CTTACC)
May 17-19, San Francisco, CA

Future of Regenerative Medicine Congress (Perinatal Stem Cell Society)
May 17-19, 2017, Teaneck, NJ

International Cord Blood Symposium (Presented by AABB)
June 8-10, 2017, San Diego, CA

Cell Culture & Cell Therapy Bioprocessing Conference
June 26-27, 2017, Philadelphia, PA

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EDITOR'S CORNER

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

BOOTH #410

Greetings from the ISCT 2017 Annual Meeting in London – Silver Anniversary Edition.

Customers, suppliers, partners, and friends of BioLife; welcome to London and the International Society for Cellular Therapy's 25th Anniversary Annual Meeting. We're pleased and proud to support this key industry event as a Silver sponsor in several ways, including continued industry leadership by providing biopreservation expertise and best in class CryoStor® and HypoThermosol® clinical grade biopreservation media products; being a best practices resource; and supporting the increasingly critical cold chain. We are especially excited about this year's cold chain developments. Our partner SAVSU continues to innovate; please visit Booth #410 to see the new cloud-connected evo™ Dry Vapor Shipper (DVS) and Smart Cap™, the evo™ Smart Shippers operating at CRT, 2-8°C and -80°C with Dry Ice, and the latest software innovations of our cold chain SaaS for time and temperature sensitive biologic materials. Also while at the show, please browse our two poster sessions as we further best practices for biopreservation of cells, tissues, and organs:

- Abstract 2696094 – Transition to GMP, chemically-defined, xeno-free cryopreservation media increases post-thaw functionality of clinically-relevant cell banks (ID# 169)
- Abstract 2695771 – Cryopreservation and Transport of Jurkat T-cells Using Current and Optimized Practices: The Impact of Storage Duration and Temperature on Post-Thaw Recovery and Viability (ID# 149)

In the feature article of this issue BioPreservation Today™ Dr. Aby Mathew Ph.D., Senior Vice President and Chief Technology Officer, celebrates the 25-year anniversary of ISCT highlighting both the Society's and BioLife's growth in his article "BioLife Solutions and ISCT - Celebrating 25 Years of Advancing Cell Therapies Together."

Michael Weaver, Product Development Manager, then provides a collective update on what we have learned from our customers as they continue along the path toward commercialization in his article "Learnings from Customers Poised for Commercialization." Chances are we've seen many of the issues you are facing so please have a look to see how you can benefit from our collective knowledge and possibly improve your processes.

On a related note, Dr. Mathew explains how BioLife and our technical staff of Ph.D. scientists are available to answer any technical questions you may have specific to your organization, whether it is regarding biopreservation of your specific cell type, optimization of your methods, or integration with Good Manufacturing Practices (GMP). We are happy to remind you that collaboration and in-depth consultative services are available for our research and clinical partners. With the experience of 205+ customer Regenerative Medicine applications, 250+ scientific citations, and 500+ customers, it is our mission to support Biopreservation Best Practices.

Finally, Todd Berard, BioLife's Vice President of Marketing, pens an article explaining the "new media" industry resources that are evolving with our industry, including a collection of web resources, newsletters, and blog posts in his article "BioLife's BioInsights."

Thank you for your continued interest in BioLife Solutions. I hope you enjoy this issue of Biopreservation Today. We look forward to seeing you at our exhibit and during the conference.

Best regards,

Mike

ASK THE SCIENTISTS

Aby J. Mathew, PhD – Senior Vice President & Chief Technology Officer, BioLife Solutions Inc.

Biopreservation expertise has been a foundational hallmark of BioLife Solutions, Inc. In addition to the gold standards of the HypoThermosol® shipping/storage and CryoStor® cryopreservation media platforms that have been built from this expertise in biopreservation, our scientific team fields inquiries and provides consultation on a near-daily basis to customer questions from around the world. As our relationship with the evolving field of Regenerative Medicine has grown over the last three decades, the breadth of discussion topics has also evolved. In the 1990's, our discussions were more focused on basic science mechanisms, unraveling the modes of cell death that resulted from hypothermic and cryopreservation conditions, and introducing the concepts of intracellular-like biopreservation media and Delayed Onset Cell Death. Today, we still have many basic science cryobiology discussions, but also have many more discussions that focus on the Quality and Regulatory footprint of biopreservation media for customer clinical applications, as well as business discussions to ensure customers have long-term supply to this critical proprietary technology. We also frequently troubleshoot customer process development questions that may entail customized modifications in order to optimize their manufacturing and biopreservation workflow, and have also supported customer clinical applications with direct consulting communications with Regulatory authorities.

Internally, the questions may flow to us via a call to our Customer Care Team or an email to a Sales team member, in order for the customer (or prospective customer) to eventually ask their questions to the BioLife scientists. As we have received feedback from customers that this scientific dialogue

has proven to be a valuable resource for them, and that there has been interest expressed for a more direct channel to BioLife's scientific and technical expertise, BioLife Solutions is launching a new initiative called "Ask The Scientists". Ask The Scientists is intended to be a multi-channel resource that links avenues of print (BioPreservation Today), direct website link (BioLifeSolutions.com/Evidence), and direct email channel. We welcome questions and feedback from our customers and prospective customers, and value the unparalleled direct communications and relationships that have led to HypoThermosol and CryoStor being incorporated into several hundred customer clinical applications, articles/abstracts citations, and poster/data references.

For more information or if you have a question for the BioLife Solutions scientific team, please submit your questions at http://www.biolifesolutions.com/ask-the-scientists.

For this inaugural Ask The Scientists BioPreservation Today panel, an example of a topic frequently discussed would be: Can HypoThermosol or CryoStor be used in clinical applications? Our biopreservation media, CryoStor and HypoThermosol, are utilized by a number of cell therapy groups (currently approximately 250+ regenerative medicine applications). We have a number of clinical customers that also use the solutions as excipients without wash for patient application of their cell therapies. The media solutions are not classified as drugs or devices, and therefore do not carry specific therapeutic regulatory approvals. Within their classification as ancillary materials in a customer process (or excipient if utilized in this manner by a customer), they are reviewed within the context of the customer process. Each group certainly needs to appropriately qualify the ancillary or excipient usage within their specific cell product application, but we can provide you with some clinical supporting information for your review. For clinical applications, there are several models being utilized by customers relevant to CryoStor and HypoThermosol:

a. Thaw of cell product at bedside, and then infuse. The solution is the vehicle solution for the cell therapy product with no dilution.

b. Thaw of cell product in the lab or bedside, and then diluted with isotonic solution. There is no wash step so cells are not lost, and biopreservation media is diluted before administration.

c. Thaw of cell product in the lab, and then diluted (or washed and resuspended) in HypoThermosol – this is more of a model when one does not want the bedside thaw but needs to ship/hold the product for a significant number of hours where the cell product loses stability.

d. HypoThermosol for non-frozen stability of source material (apheresis, bone marrow, tissue biopsy) and/or final cell/tissue product at 2-8°C.

e. CryoStor for frozen stability of source material (apheresis, bone marrow, tissue biopsy).

BioLife Solutions has also consolidated information regarding the wide breadth of customer clinical applications. Within the Evidence Page on our website, there is a list of customer clinical applications using CryoStor and HypoThermosol, including if utilized as an excipient. Please visit us at http://www.biolifesolutions.com/evidence/ and click the "BioPreservation Media Products in Customer Clinical Trials" tab for the most current list. We look forward to hearing from you.

BIOLIFE SOLUTIONS AND ISCT - CELEBRATING 25 YEARS OF ADVANCING CELL THERAPIES TOGETHER

Aby J. Mathew, PhD – Senior Vice President & Chief Technology Officer, BioLife Solutions Inc.

As we come together to honor the 25-year anniversary of The International Society for Cellular Therapy (ISCT), we at BioLife Solutions, Inc. proudly appreciate our parallel growth and partnership hand-in-hand with ISCT and its membership.

Toward the latter part of 1991, it became apparent that the concept of bone marrow cell transplantation needed leadership to stimulate understanding of this area. There was a need to ensure that the patient understood the technology, that information was disseminated so that a sufficient number of donors would come forward, and a way to provide for the dissemination of information about various techniques and procedures. The co-founders, Adrian P. Gee, PhD., Nancy H. Collins, PhD, and Diana Worthington-White, formed the International Society of Hematotherapy and Graft Engineering (ISHAGE), in order to provide an educational forum for the therapeutic benefits of transplantation, to improve the quality of patient care and attract donors, to establish minimum laboratory standards, and to stimulate the exchange of ideas. The Society was officially incorporated in 1992, as the International Society of Hematotherapy and Graft Engineering (ISHAGE). The Society changed the name to International Society for Cellular Therapy (ISCT) in 2001.

Simultaneously in 1992, the emerging biopreservation and cryosurgery technology that would eventually lead to the formation of BioLife Solutions was being initiated and developed by Cryomedical Sciences, Inc. In 1998, BioLife Solutions was formed initially as an academic incubator subsidiary of Cryomedical Sciences. By 2002, ISHAGE had evolved into ISCT, and Cryomedical Sciences had evolved into BioLife Solutions, Inc.

I remember my first ISCT meeting - the 2004 Somatic Cell Therapy Symposium in Houston, TX. If I recall correctly, it was back-to-back with the old WilBio Cell & Tissue Bioprocessing meeting, also in Houston. Within several days of each other, we were able to tour John McMannis' lab at MD Anderson and Adrian Gee's lab at Baylor. I still have a business card from meeting poor Janet Macpherson, who was stuck sitting next to me on a conference bus taking us to the GMP lab tour, and was gracious enough to tolerate conversation with me. Most likely, I tried to give Janet the highlights of Delayed Onset Cell Death following cryopreservation and hypothermic storage, and all Janet probably heard was "Blah, blah, blah", while thinking "Who is this young whippersnapper?". Janet has sufficiently recovered from that experience to become the current ISCT Regional Vice-President for Australia & New Zealand.

Continued from page 5

"BioLife Solutions, Inc. Mission: We strive to be the leading provider of biopreservation tools for cells, tissues, and organs; to facilitate basic and applied research and commercialization of new therapies by maintaining the health and function of biologic source material and finished products during manufacturing, distribution, and clinical administration."

During this time period, BioLife Solutions was being pulled into the cell therapy arena, as a handful of early commercial cell therapy groups realized value in BioLife's novel intracellular-like biopreservation platforms, HypoThermosol® and CryoStor®. Our scientific idealism (naiveté?) had us thinking that we were going to raise the standards of non-frozen storage and cryopreservation, and isotonic (extracellular-like) home-brew cocktails for biopreservation would go the way of photographic slides and manual slide projectors. We were in store for quite the learning curve, however the seeds of Biopreservation Best Practices that were early concepts back then, have proven to bear fruit.

By 2006, our internal notes indicated that the 2006 ISCT Annual Meeting in Berlin was BioLife's "best conference ever". In 2007 BioLife Solutions started a relationship with ISCT as a corporate partner, facilitated at the time by ISCT President and BioLife Solutions founding Scientific Advisory Board member Shelly Heimfeld, that has continued to this day. BioLife Solutions also relocated cross-country from upstate New York to outside Seattle, WA. We are not saying that we moved to be geographically closer to ISCT Head Office in Vancouver, Canada, but we will just leave it that it was an added perk.

Along the way, the BioLife Solutions booth was a favorite at the 2011 Annual Meeting in Rotterdam. The popularity of our booth had less to do with our esteemed booth personnel, CEO Mike Rice and myself, and was mainly attributed to the couch we had in our booth that turned into a favorite gathering spot (mostly by folks who had no clue it was part of the BioLife booth space). The next year at the 2012 Annual Meeting in Seattle, BioLife Solutions was proud to be the Local Industry Host.

For me personally, ISCT has been an invaluable venue for networking, learning, and professional growth. I began participation with the old Commercialization Committee in 2008, way back when our favorite "recovering attorney", and former Executive Director of ISCT, Lee Buckler was leading it. BioLife Solutions embraced the Industry Community Patron membership since the first year of the Industry Community, and I have been a member of the current Commercialization Committee since 2011. For the 2014 Paris Annual Meeting program planning, I participated on the Strategies for Commercialization Track Subcommittee, and for the 2015 Las Vegas Annual Meeting, I served as the Strategies for Commercialization Track Subcommittee Chair and member of the conference Organizing Committee. Those opportunities to work on the planning of the scientific program certainly provided insight into all the hard work that the organization, the leadership, and the committee volunteers put into planning the meetings.

Both BioLife Solutions and ISCT have established Mission Statements as core values for each organization. Both organizations share common aspects of their respective missions, and that reinforces the synergies between BioLife and ISCT.

ISCT Mission: To drive the translation of all cellular therapies for the benefit of patients worldwide.

BioLife Solutions, Inc. Mission: We strive to be the leading provider of biopreservation tools for cells, tissues, and organs; to facilitate basic and applied research and commercialization of new therapies by maintaining the health and function of biologic source material and finished products during manufacturing, distribution, and clinical administration.

BioLife Solutions began with a scientific academic foundation. We subsequently pioneered a robust Quality/Regulatory footprint for our biopreservation technology, that has supported translation into hospital-based and commercial customer clinical applications.

As indicated in these graphs on page 7, there is parallel growth when one looks at how both ISCT and BioLife Solutions have evolved, and the growth of both organizations mirrors the growth of cellular therapies and Regenerative Medicine over the past 25 years. The ISCT Membership has grown from about 200 members in 1992 to over 1300 members today. BioLife Solutions has grown from a research novelty to having its enabling intracellular-like biopreservation platforms, HypoThermosol and CryoStor, incorporated into 250+ regenerative medicine applications, and cited in 250+ research and clinical citations. For both BioLife Solutions, Inc. and myself, it has been an honor and a privilege to grow alongside ISCT not as a vendor or exhibitor, but as an Industry Partner. We look forward to many more years of partnership with ISCT and its membership, while we all ride this adventurous and promising wave of Regenerative Medicine.

About the International Society for Cellular Therapy

Established in 1992, the International Society for Cellular Therapy (ISCT) is a global society of clinicians, regulators,

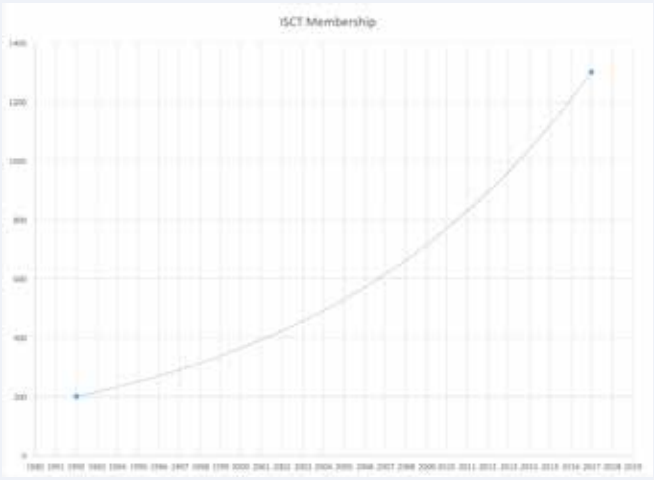


Figure 1. ISCT Membership Growth Over The Years

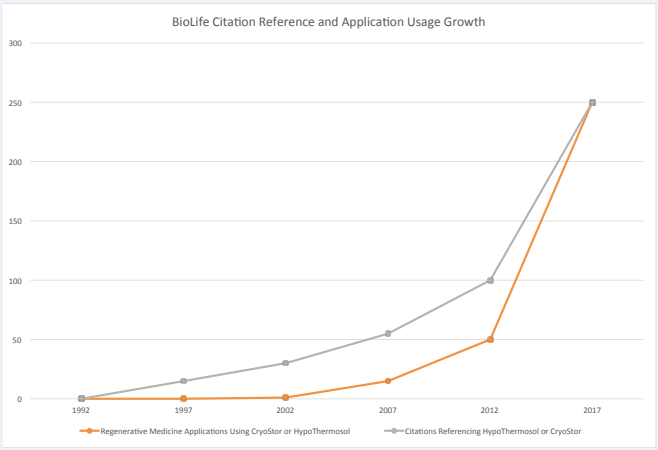


Figure 2 BioLife Citation Reference and Application Usage Growth

researchers, technologists and industry partners with a shared vision to translate cellular therapy into safe and effective therapies to improve patients' lives worldwide.

ISCT is the global leader focused on pre-clinical and translational aspects of developing cell-based therapeutics, thereby advancing scientific research into innovative treatments for patients. ISCT offers a unique collaborative environment that addresses three key areas of translation: Academia, Regulatory and Commercialization. Through strong relationships with global regulatory agencies, academic institutions and industry partners, ISCT drives the advancement of research into standard of care.

Comprised of over 1,300 cell therapy experts across five geographic regions and representation from over 50 countries, ISCT members are part of a global community of peers, thought leaders and organizations invested in cell therapy translation. For more information about the society, key initiatives and upcoming meetings, please visit: www.celltherapysociety.org.

Aby J. Mathew, PhD – Senior Vice President & Chief Technology Officer, BioLife Solutions Inc.

Dr. Mathew was part of the founding team of BioLife Solutions, Inc., and is a co-developer of BioLife's biopreservation media solutions. He is a co-inventor on multiple issued and pending patents related to methods, devices, and formulations for the preservation of cells, tissues, and organs. He holds a Ph.D. in Biological Sciences within the Biochemistry, Cell and Molecular Biology Program from Binghamton University and a B.S. in Microbiology from Cornell University. Dr. Mathew has been researching low temperature biopreservation since 1994, and his studies contributed to the development of BioLife's current commercial HypoThermosol® and CryoStor® product platforms and intellectual property foundation. Dr. Mathew was part of the scientific team that linked cell death via apoptosis (programmed cell death) to exposure to hypothermic and/or freezing temperatures. These discoveries were integral to the development of BioLife's intracellular-like biopreservation media, and also contributed to improvements in cryosurgical ablation of cancer. Dr. Mathew was BioLife's first Director of Manufacturing, established BioLife's initial Quality system, and has been Senior Vice President & Chief Technology Officer since February 2011. From January 2007 through February 2011, Dr. Mathew served as Senior Scientist, Director of Strategic Relations, and Senior Director of Strategic Relations. From June 2003 through January 2007, Dr. Mathew served as Director of Manufacturing. From September 2000 through June 2003, Dr. Mathew served as Clinical Accounts Manager and Director of Hypothermic Preservation for Cryomedical Sciences/BioLife Solutions. Dr. Mathew is currently active in, or previously a member of, AABB (formerly the American Association of Blood Banks), BEST (the Biomedical Excellence for Safer Transfusion collaborative), the International Society for Cell Therapy (ISCT), the Alliance for Regenerative Medicine (ARM), Tissue Engineering & Regenerative Medicine International Society (TERMIS), Society for Cryobiology, International Society for Biological and Environmental Repositories (ISBER), American Society for Cell Biology, and the Society for In Vitro Biology. Dr. Mathew is a member of, the Board of Directors, and Advisory Panel, of the Parent's Guide to Cord Blood Foundation, the Scientific Advisory Board of HemaCare Corporation, the founding Board of Directors of the Cord Blood Association, the NIST-AMTech National Cell Manufacturing Consortium, the California Institute for Regenerative Medicine (CIRM) Clinical Advisory Panel, and the Scientific Advisory Board of SAVSU Technologies. Dr. Mathew has obtained UCLA Corporate Governance Program Certification.

LEARNING FROM REGENERATIVE MEDICINE CUSTOMERS POISED FOR COMMERCIALIZATION

Michael Weaver, Product Development Manager, BioLife Solutions Inc.

One of the advantages of being a manufacturer within an industry as broad as Regenerative Medicine is a opportunity to discuss integration of biopreservation best practices with our customers. This includes process applications of BioLife's products with customers and prospective customers, from industry subsectors including biobanking, biomedical research and development, cell and gene therapy, drug discovery, and genetic engineering.

Biolife Customers Represent Virtually Every Segment Within Regenerative Medicine

As research, clinical and commercialization interests for the application of cellular therapeutics including genetically engineered cells continue to grow, BioLife estimates the company's biopreservation solutions CryoStor® and HypoThermosol® are embedded in more than 250 customer regenerative medicine applications representing virtually every segment within Regenerative Medicine.

Cell Therapy Advances Do Not Occur In A Vacuum

Our scientific team of biopreservation experts is uniquely positioned to listen to challenges customers face and respond with optimized solutions (literally) that meet and exceed customer expectations and requirements and improve the quality of customers' products. The reciprocal benefit is that we learn from every customer application and continually seek to add more value. Key messages that are outcomes of this breadth of collaborations with customers and adoptions of our products are an important tool that BioLife applies to expand our knowledge base, develop new applications for our solutions and drive new product development. Outcomes are evaluated, strengthened and recycled to contribute to improved applications of best practices in biopreservation industry-wide, from startup to scale up, providing further benefit to customers engaged in research and development, clinical development and commercialization.

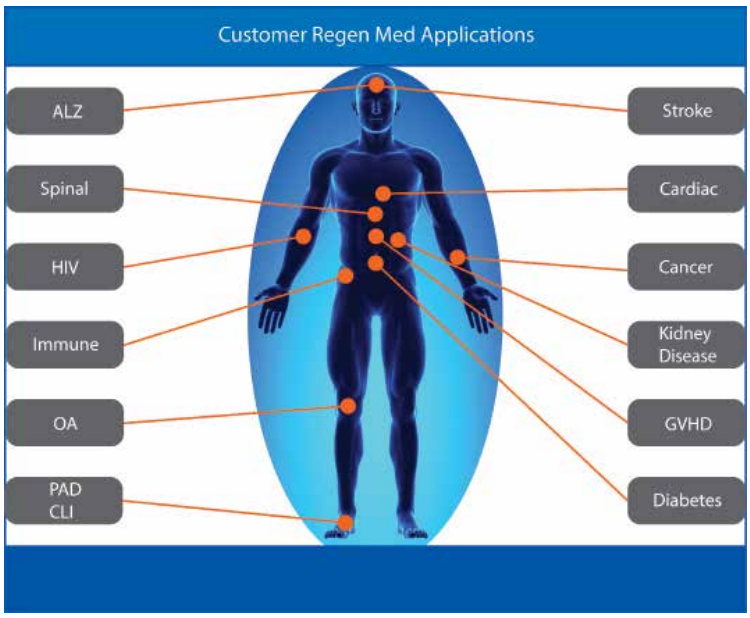
BioLife shares product-related literature in a knowledge base accessed on the corporate website (http://www.biolifesolutions.com/evidence) that includes references to BioLife products published in the literature (presentations, journal articles, abstracts and posters). Prospective customers often ask which product is suitable for their particular cell type and application. BioLife's searchable Evidence webpage is an excellent place to start to find preliminary information that can lead to conversations with our product application experts. (Please see the article on "Ask the Scientist" on page 4).

Cell Therapies Are Precious and Sensitive to Storage, Handling and Transportation. Each cell therapy is a unique product that requires individualized optimization. Consider best practices at the beginning of product development for:

- cell collection
- short term storage
- transport
- processing
- long term storage
- patient preparation
- cell therapy administration to the patient
- follow up

Cell Collection. BioLife has been awarded U.S. Patent US 8642255 B2 (Australia 2009228056; EP 2271209) for "materials and methods for hypothermic collection of whole blood, and components thereof, which can extend the holding time of blood beyond the current useable limit. Additionally, blood can be drawn directly into a hypothermic preservation solution without the addition of standard anticoagulants." A quick search using "human blood collection" as the search term on the Evidence tab on BioLife's home page identifies a poster titled "Human Blood-Derived Raw Material: Enabling Controlled, Consistent Collection" authored by HemaCare. The authors determined mononuclear cells derived from peripheral blood (MNCs) maintained higher viability out to 96 hours stored in HypoThermosol than MNCs stored at ambient temperature

"Our scientific team of biopreservation experts is uniquely positioned to listen to challenges customers face and respond with optimized solutions (literally) that meet and exceed customer expectations and requirements and improve the quality of customers' products. The reciprocal benefit is that we learn from every customer application and continually seek to add more value."



in phosphate buffered saline (PBS). Subpopulations that included CD4+ cells, CD14+ cells or CD8+ cells showed higher percent viability stored in HypoThermosol at 96 hours than MNC subpopulations stored at ambient temperature in PBS. The poster summary states, "Use of cGMP, serum-free, protein-free biopreservation media such as HypoThermosol shows great promise to enable worldwide shipment of fresh cellular products isolated from apheresis collection, extending shelf-life of cell therapy products, and delaying need for cryopreservation."

There are any number of variables associated with cell collection for different cell types. BioLife's cell preservation experts will be happy to discuss your unique cell collection and preservation requirements.

Short and Long Term Storage. The previously mentioned poster raises the question, "Which solution is appropriate given my cell type/process stage/application?" Entry of the search term "short term storage" into the Evidence tab on BioLife's home page identifies a number of selections including an article published in Bioprocess International titled "Hypothermic Storage and Cryopreservation: Successful Short- and Long-Term Preservation of Cells and Tissues." The authors acknowledge the technology involving sourcing cells, cell therapy manufacture, storage and distribution present challenges that require technologically advanced solutions. The authors present scenarios faced by companies advancing into clinical trials with cell therapies that have discrete product stage dependent short or long term storage requirements. The authors discuss issues involved with storage and maintaining cell viability and function, compare hypothermic storage to cryopreservation and demonstrate superior outcomes can be achieved using HypoThermosol and CryoStor compared to reagents that have been historically recognized as "gold standards."

BioLife's technical applications experts will be happy to help you optimize your cellular therapy's storage requirements.

Transportation. BioLife scientists collaborated with joint venture partner Savsu Technologies and Brooks Life Sciences Systems to examine procedures, products, storage and transportation practices that consequently affect the quality of cells. Study details were featured in a poster titled "Next Generation Technology Procedures and Products Facilitate Biopreservation Best Practices and Increased Viability for Cellular Therapy" presented at the ISCT Annual Meeting last year in Singapore. Succinctly, "quality in" equals "quality out" and if you have been having success using products/processes that are "gold standard" or status quo, consider that "quality improvements in" equal "improved product out." The poster's authors explained why shipping cells on dry ice is not a trivial undertaking. Best practices involving state-of-the-art CryoStor cryopreservation solution, evo® SMART shipper with embedded temperature and gps location tracking, cloud-based data storage and access to real time monitoring using an internet accessible web browser are superior compared to traditional "home brew" cryomedia, EPS shipping containers and drop-in-the-box data loggers. For the study, Jurkat T-cells cryopreserved in 95% fetal bovine serum/5% DMSO or CryoStor CS5 were initially stored in a high efficiency liquid nitrogen freezer equipped to minimize transient warming events during access (protection of innocents). Cryovials containing cells were removed for cross country

Continued from page 9

shipment frozen in dry ice in Cryo evo SMART shippers or standard EPS shippers. Upon return, sample analysis demonstrated that, similar to non-shipped controls, Jurkat T-cells had higher viability and more rapid recovery of function in the CryoStor/evo group compared to Jurkats in the DMSO/EPS group.

BioLife's cryopreservation and cold chain transportation experts will be happy to discuss further details presented in the poster.

Processing. To search for processes that incorporate CryoStor, entering the search term "processing CryoStor" identifies a total of thirteen references, among them, a poster from Stemedica titled "Scalability of Allogeneic Stem Cell Manufacturing." Stemedica examined scalability required for the manufacture of hMSCs to advance from Phase 2a to Phase 3 clinical trials. Stemedica's requirements included scalable, robust, cost-effective, user friendly clinical dose preparation and preferably off-the-shelf. Requirements for an optimal cryopreservation medium included extended in-process hold times, extended prepared dose storage times, and lowest DMSO concentration that retained efficacy. Stemedica compared 2% DMSO, 5% DMSO and 10% DMSO to CryoStor CS2, CS5 or CS10. The study reported 5% DMSO (CryoStor CS5) maintains viability of hMSCs between 2 – 5 hours. HMSCs frozen in CS5 or CS10 exhibited efficient post-thaw recovery, passed QC testing for identity and potency and supports hMSC viability during extended in-process hold times and dose preparation times.

To search for processes that incorporate HypoThermosol, entering the search term "processing HypoThermosol" identifies a poster titled "Developing Patient-specific Cell Therapy Manufacturing Processes: Reducing COGs While Maintaining Quality Parameters" from Lonza. The authors determined that in the event that T-cells need to be infused without a cryopreservation step, HypoThermosol maintains superior viability of ex vivo expanded T-cells stored out to 120 hours at 4°C compared to T-cells stored in Plasmalyte/HSA.

BioLife's GMP-manufactured CryoStor and HypoThermosol are delivered to you for use as off-the-shelf solutions, ready to incorporate into your cell preservation processes.

Patient Preparation/Administration. BioLife Chairman and CEO Mike Rice wrote an article titled "Clinical Adoption of HypoThermosol and CryoStor: Optimized Biopreservation Media for Regenerative Medicine Applications" for the Spring 2011 issue of "BioPreservation Today." Clinical customers have adopted our solutions for any number of different therapeutic cell types, indications and routes of administration. CryoStor and HypoThermosol are being used as ancillary reagents (removed from the final cell product prior to administration) or excipients (integral to the cell product for maintenance of viability and function throughout storage/transport/infusion/injection). Rice wrote in summary, "Hospital transplant centers and commercial companies should look to produce the highest quality cell or tissue- based therapy, taking into consideration the critical impact that optimized biopreservation media products can have on logistics, regulatory approval, system performance, and ultimately, clinical outcomes."

Follow Up. Off-the-shelf allogeneic cell therapies are routinely cryopreserved; however do not overlook possible use cases for cryopreserving autologous cells. Is your autologous cell therapy administered as a single dose, one time, or multiple doses at multiple time intervals? Ex vivo expanded cells administered over multiple time intervals frozen in CryoStor represent the most consistent option with the least dose-to-dose variability. Even if the cell therapy is single dose, are you archiving an aliquot of those genetically engineered cells at -196°C for reference or possible future use and expansion?

In summary. Determine what is necessary at each stage of the product cycle to know what to optimize. Cells cannot be bullied into viability. How you store and transport cells makes a difference. Brief but to the point, we have said it before and it bears repeating, dead cells do not cure cancer [or any other disease].

It Takes A Community To Commercialize A Cellular Therapy

Thank you ISCT for 25 years of collaboration, committees, and guidance. Thank you for establishing leadership overseeing policies under public and political scrutiny including the use of stem cells outside of established clinical trials, expeditious and evidence-based path to regulatory approval and the under-appreciated value of funding for scientific investigations in this era of executive budget cuts, health care cost reductions and government referendums. We are all racing toward the common goal to deliver the promising cures that cellular therapies may offer to patients around the world.

BIOTECHNOLOGY INDUSTRY GROWTH GIVES RISE TO A NEW GENERATION OF INDUSTRY RESOURCES

Todd Berard, Vice President of Marketing, BioLife Solutions, Inc.

"The field is rapidly advancing from basic research into translation and commercialization, however, there are still many complex challenges ahead. Thus the time is now for a truly multidisciplinary journal to provide a forum for debate and discussion by all stakeholders committed to progressing this field and converting scientific innovation into life-changing therapies"

Prof. Chris Mason, Senior Editor, Cell & Gene Therapy Insights

Cell & Gene Therapy Insights and other publications provide detailed research, clinical trial, commercialization, and other updates and metrics to the trade

The explosive growth of the regenerative medicine and cell therapy space has led to rapid and dynamic daily change for our industry - numerous companies being born, clinical trials being commenced, business partnerships being formed, and a host of other industry dynamics. As the sector continues to grow and evolve, a whole new generation of resources has arisen to keep track of the space and make sense of it all. In addition to the traditional core scientific journals, such as CytoTherapy, Blood, and Stem Cell Research, these new resources take the form of the new media - websites, white papers, twitter feeds, and blog posts. Examples of some of these resources include Cell & Gene Therapy Insights, RegMedNet, BioInformant, and Fierce Bio.

As the biopreservation experts and a trusted industry partner, BioLife is typically asked to produce articles or editorial content for many of these publications. One of our favorite resources is Cell & Gene Therapy Insights; and a good example of this collaboration is the biopreservation spotlight series they are doing for their May issue. The series contains an expert article from BioLife's own Dr. Aby Mathew PhD; highlighting the key role preservation plays in cell therapy manufacturing.

Cell & Gene Therapy Insights is an open access, peer-reviewed, online journal with a translational focus. Featuring a blend of articles and interviews, podcasts, webinars and videos, Cell & Gene Therapy Insights provides in-depth coverage of all the key issues facing the biotechnology, regenerative medicine, and cell therapy sectors. This includes:

- Advances and challenges in cell and gene therapy manufacturing; emerging technologies, techniques, reagents and bioprocesses
- Bench-to-bedside translation of cell, gene and tissue-engineered therapies: clinical challenges including dosages, safety, trial protocols and delivery mechanisms
- Novel methods of gene transfer, control and silencing, including use of cells as gene therapy vehicles; CAR T cells and engineered vectors
- Clinical trial design and outcomes
- Commercialization of cell and gene therapies
- Regulatory and reimbursement updates
- Ethical and legal perspectives

Like many of these "new media" resources, all Cell & Gene Therapy Insights content is available free of charge, including the current and upcoming special focus issues:

- Biopreservation (April) *Co-sponsored by BioLife Solutions, Inc.*
  - The latest advances in cryopreservation technology
  - Formulations to optimize freeze-thaw transition
  - Innovative and practical thawing techniques
  - Optimizing preservation processes to comply with latest regulatory guidelines
  - Future goals, including alternative approaches to preservation without cryopreservation
- Latest Advances in Cord Blood Applications & Commercialization (May)
- Scale-Out and Scale-Up Strategies for Cell Therapies and Vectors (August)
- Automation (September)
- Supply Chain Management – Storage, Handling & Thawing (October)
- Product Tracking & Data Management (November)

To sign up as a member, access all Cell & Gene Therapy Insights content free of charge, and receive their newsletter, visit http://insights.bio/cell-and-gene-therapy-insights/. For additional information on these resources, please also see the inside cover of this issue.

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 function.