

FEATURE ARTICLE:







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.

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.





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"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."

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

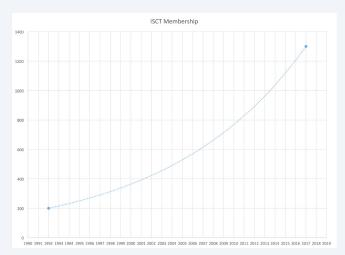


Figure 1. ISCT Membership Growth Over The Years

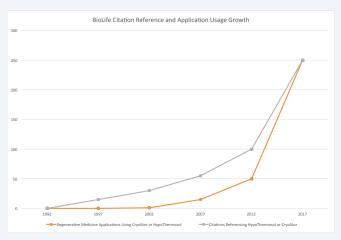


Figure 2 BioLife Citation Reference and Application Usage Growth

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.

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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.