

BioLife Solutions Achieves ISO 13485 Quality Management Systems Certification Product Adoption Growing in Clinical Cell Therapy & Regenerative Medicine Markets

PRNewswire-FirstCall
BOTHELL, Wash.

BioLife Solutions, Inc. (BULLETIN BOARD: BLFS) , a leading developer, manufacturer, and marketer of biopreservation tools for cells, tissues, and organs, today announced that it has successfully completed audits of its quality systems and GMP production facility in Bothell, Washington by BSI Group and has been issued a certification to ISO 13485:2003, an international standard for quality systems supporting the design, development, and manufacture of medical devices.

(Logo: <http://www.newscom.com/cgi-bin/prnh/20090814/BIOLIFELOGO>)

Mike Rice, BioLife's chairman and CEO, noted, "This achievement is a strategic quality milestone for BioLife. Our growing clinical customer base expects us to set a high bar for the production of our GMP biopreservation media products, since many customer applications include the use of our products as a combined preservative/injection delivery solution for cell-based therapies used to treat cancer, heart failure, and a host of other diseases. We're continuing to enhance the quality footprint of our proprietary, best-in-class HypoThermosol® and CryoStor™ biopreservation media products with this certification and updates to our FDA Master Files. Furthermore, we expect to achieve CE Mark conformity for our products in 2010."

In addition to certification to ISO 13485, BioLife'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 also successfully completed quality audits of our new GMP production facility and quality systems by several strategic customers and continue to build our profile as the first choice for clinical grade preservation, transport, freezing, and injection media solutions for cell-based products. We're pleased that a growing number of clinical customers have selected our products over commercial competitors or internal formulation of preservation media, often made using lower quality components in sub-optimal processes. We're also very pleased to support our customers with custom packaging and custom formulations of our serum-free, protein-free, pre-formulated biopreservation media products."

About BioLife Solutions

BioLife Solutions develops, manufactures, and markets patented hypothermic storage/transport and cryopreservation media products for cells, tissues, and organs. The Company's proprietary HypoThermosol® and CryoStor™ 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's GMP products are serum-free and protein-free, fully defined, and pre-formulated to reduce preservation-induced, delayed-onset cell damage and death. Comprehensive small animal intravenous safety studies have been completed on

HypoThermosol and CryoStor, and both products are supported by US FDA Master Files. BioLife's enabling technology provides research and clinical organizations significantly enhanced post-preservation cell and tissue viability and function. BioLife Solutions is certified to ISO 13485:2003. For more information please visit www.biolifesolutions.com.

This news release contains forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. These forward-looking statements include any statements that relate to the intent, belief, plans or expectations of the Company or its management, or that are not a statement of historical fact. Any forward-looking statements in this news release are based on current expectations and beliefs and are subject to numerous risks and uncertainties that could cause actual results to differ materially. Some of the specific factors that could cause BioLife Solutions' actual results to differ materially are discussed in the Company's recent filings with the Securities and Exchange Commission. BioLife Solutions disclaims any obligation to update any forward-looking statements as a result of developments occurring after the date of this press release.

Media Relations:
Len Hall
Allen & Caron Inc
(949) 474-4300
len@allencaron.com

Investor Relations:
Matt Clawson
Allen & Caron Inc
(949) 474-4300
matt@allencaron.com

First Call Analyst:
FCMN Contact:

Photo: <http://www.newscom.com/cgi-bin/prnh/20090814/BIOLIFELOGO>
AP Archive: <http://photoarchive.ap.org/>
PRN Photo Desk photodesk@prnewswire.com

SOURCE: BioLife Solutions, Inc.

CONTACT: Media, Len Hall, len@allencaron.com, or Investors, Matt Clawson, matt@allencaron.com, both of Allen & Caron Inc, +1-949-474-4300, for BioLife Solutions, Inc.

Web Site: <http://www.biolifesolutions.com/>

<https://investors.biolifesolutions.com/2009-12-23-BioLife-Solutions-Achieves-ISO-13485-Quality-Management-Systems-Certification>