



BioPreservation Today[®]

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Vision Loss

Hair Loss

Cardiac Disease

Neurological Disorders

Cancer

Organ Regeneration



Buckler



Weber



Burger



Cardwell



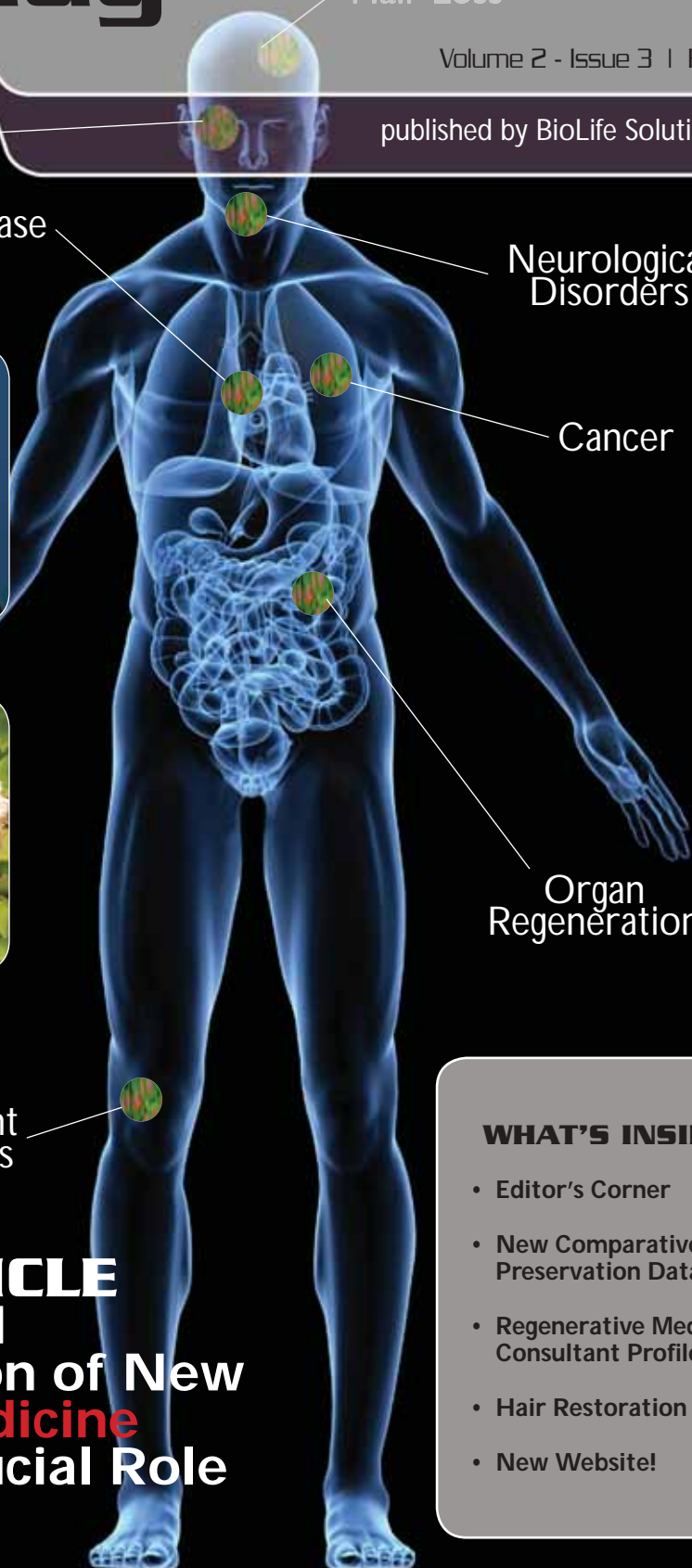
Driscoll

Movement Disorders

FEATURE ARTICLE
Development and Commercialization of New **Regenerative Medicine** Products; the Crucial Role of Consultants

WHAT'S INSIDE:

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- New Website!



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CHECK IT OUT!

BioLife Solutions has a new website and online resources.

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*

UPCOMING EVENTS

Cell Therapy Industry Summit 2010
www.celltherapyindustrysummit.eventbrite.com

Carlsbad, CA

Nov 3-5, 2010

Phacilitate Cell & Gene Therapy Forum
www.phacilitate.co.uk/pages/cgtherapy/index.html

Washington, DC

Jan 24-26, 2011

ASBMT 2011 BMT Tandem Meetings
www.asbmt.org

Honolulu, HI

Feb 17-21, 2011





EDITOR'S CORNER

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

Greeting from the ISHRS 18th Annual Scientific Meeting in Boston!

Biopreservation, the science and practice of maintaining the stability and viability of biologic source material, intermediate products, and finished cell and tissue-based products, is increasingly being recognized as a crucial determinant of the eventual successful commercialization of regenerative medicine products and therapies.

This issue of BioPreservation Today® includes corporate profiles of several leading regenerative medicine consultant groups. It's clear now more than ever that due to the dynamic quality, regulatory, and reimbursement climate, development stage regenerative medicine companies and hospital-based centers can benefit greatly from the advice and expertise of Biologics Consulting Group, Cell and Gene Therapy, LLC, Cell Therapy Group, DCi Biotech, and Quality Consulting, LLC. The names Darin Weber, Scott Burger, Lee Buckler, Dawn Driscoll, and Liz Cardwell are well known in the regenerative medicine space and we encourage organizations faced with safety, efficacy, cost, quality, and commercialization challenges to take advantage of the vast successful experience of these respected consultants.

Also in this issue, Dominic Clarke, Ph.D., our Director of Research & Development, reports the results of internally conducted comparative data of leading 'home-brew' and commercial hypothermic storage and freeze media products in an evaluation of preservation efficacy criteria of extended stability and post-preservation viability.

Finally, Dr. Clarke also reports the results of internally conducted research on the use of HypoThermosol® as an improved hair follicle holding solution, with extended ex-vivo stability clearly demonstrated. Several physicians are currently collecting independent clinical data of post-transplant growth rate and quality. Use of HypoThermosol by leading hair transplant clinicians is increasing and this new data may promote expanded adoption in this market, where over 250,000 procedures are performed annually.

For those readers attending the ISHRS 18th Annual Scientific Meeting in Boston this year, please stop by our corporate exhibit in space 55. Also, please visit our newly updated website at www.biolifesolutions.com. Thank you for your interest in our products.

Best regards,

Mike



NEW COMPARATIVE PRESERVATION EFFICACY DATA

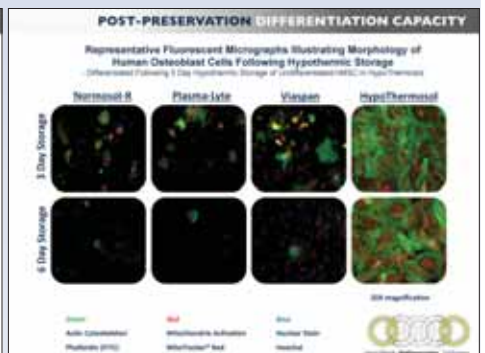
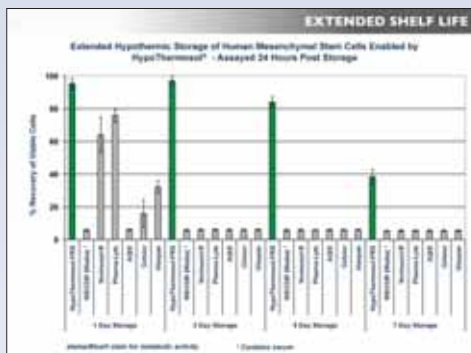
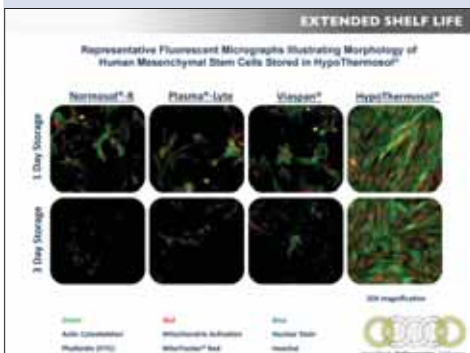
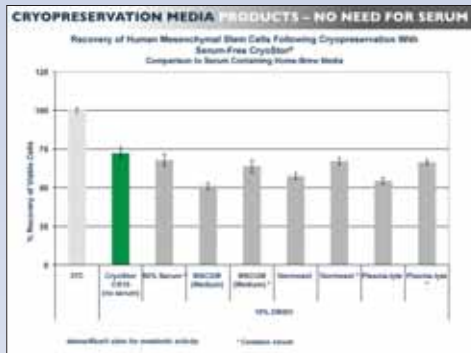
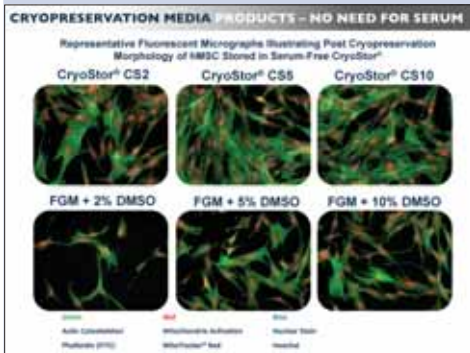
by Dominic Clarke, Ph.D., Director of Research & Development, BioLife Solutions, Inc.

Many traditional commercial and home-brew preservation formulations were designed nearly 50 years ago, without the understanding and discoveries of modern day molecular biology related to preservation-induced stress pathways. These alternative formulations have remained relatively unchanged, and tend to focus solely on the incorporation of DMSO for ice management, in a non-optimized carrier solution that often includes serum and protein components.

A growing body of independently published, peer-reviewed journal articles and internal research reports have demonstrated significant improvement in shelf life/stability extension and post-preservation

viability in a broad range of biologics through the use of our HypoThermosol® and CryoStor® biopreservation media products. A list of publication citations can be found here: <http://www.biolifesolutions.com/index.php/technology-education/research/>.

Our research team recently completed a series of comparative experiments with leading 'home-brew' and commercial hypothermic storage and freeze media formulations to assess preservation efficacy including extended stability and post-preservation viability. The complete data presentations can be found on our website here: www.biolifesolutions.com/index.php/2010/08/20/review-the-latest/. Selected data are presented below.





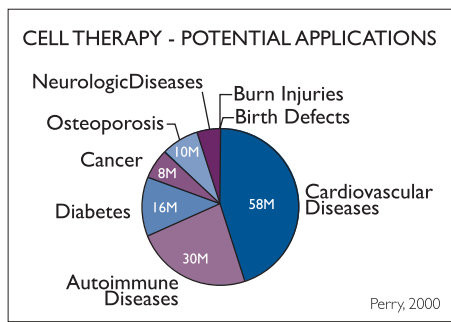
ADVANCED CELL AND GENE THERAPY

by Scott R. Burger, Principal, Advanced Cell and Gene Therapy

Regenerative Medicine Consultant Profile

Regenerative medicine offers unprecedented opportunities, with a remarkable range of potential applications in disorders affecting over 150 million patients in the United States alone. Targets for cell therapies, gene therapies, and tissue-engineered products include cardiovascular, orthopedic, neurologic and ocular disorders, diabetes and other metabolic disorders, soft tissue injury, autoimmune diseases, and cancer. Market estimates for cell therapy, gene therapy, and tissue-engineered products are in the range of \$200-400 million, with projected annual growth of 10-15%.

	Biotechnology	Cell Therapy
Product	Cells generate product	Living cells <u>are</u> product
Raw Material	Seed cell lines	Often unique, primary tissue
Variability, Heterogeneity	Limited	Often substantial
Product Definition	Well-defined, definable products	Product <u>defined through trials</u>
Process, Testing	Established early	<u>Evolve through trials</u>
Process Scale	Bulk processes predominate	Patient-specific products common



Promising as these novel biologic products are, commercialization presents unique challenges throughout the development pathway. Pharma- and biotechnology-based assumptions and practices do not always translate directly to living biologic products. Specialized expertise is essential, from initial due diligence, to planning preclinical studies, developing scalable, cost-effective manufacturing, and navigating the regulatory pathway.

Advanced Cell & Gene Therapy, LLC is a consulting firm specializing in

development and commercialization of cell therapy, gene therapy, and tissue-engineered products. We serve pharma and biotechnology companies, clinical laboratories, and investors, bringing extensive industry and academic experience and expertise to bear, and offering practical solutions and advice in key problem areas. We provide assistance with due diligence and strategic partnerships, GMP/GTP manufacturing process development, product characterization and comparability, quality systems and regulatory affairs. Our services include:

Strategic Analysis

- Due diligence
 - Evaluation of technical expertise, and resource sufficiency
 - Scientific and technical advice
- Strategic partnership, business development
 - Identification of potential partners
 - Diligence preparation

- Market analysis
- Potential for commercial-scale manufacturing
- Product development pathway
- Product delivery issues, costs

Manufacturing

- Technology transfer
- Product, process specifications
- Characterization testing, potency assay development
- Materials and technology sourcing, qualification
- Manufacturing process analysis, optimization, qualification
 - Cost-effective, controlled manufacturing
 - Scalability: high-throughput closed-systems, automation
- Contract manufacturer evaluation, qualification
- Manufacturing facility design, operations

Continued on page 12.



DCI-BIOTECH

CELL THERAPY BUSINESS STRATEGIES/ TECHNICAL OPERATIONS/LOGISTICS SUPPORT

by Dawn Driscoll MBA PhD, Principal, DCi-Biotech, Inc.

Regenerative Medicine Consultant Profile

Do you need experienced regenerative medicine business development experts who focus exclusively on clinical, regulatory, and market strategies to bring cell and gene therapies into routine medical practice? At DCi we are experienced specialists who firmly believe in the tremendous clinical and financial potential of regenerative medicines, and understand that achieving this promise means conquering highly technical, regulatory, and market barriers. We work closely with clients like you who are pursuing approval of regenerative medicines. Call or visit our website to find out more about our services:

Strategic Business Plans and Business Models

DCi generates long-term strategic development and commercialization plans tailored to your product's Regulatory requirements. Plans can be made for all development phases from pre-clinical through to life cycle/portfolio management planning.

DCi also works closely with you to develop multiple viable business model scenarios, based on your product's attributes (e.g. autologous or allogeneic, cryopreserved or fresh), the manufacturing options available you (e.g. the GMP Manufacturing options in multiple geographies or with multiple CMOs), the manufacturing capacity needed based on the clinical trial requirements and commercial sales projections, and the logistical constraints of both the patients and the product.

Primary Market Research and Advisory Boards

We design and conduct primary market research, in multiple regulated regions (US, EU, Australia, Asia-Pacific) with MDs, PhD, Regulators, and other key stakeholders.

Our experienced consultants understand that gaining input from the end users of your product at every step of the development process is critical. In order to answer key business questions, DCi manages all aspects of medical and scientific advisory board meetings, from development of questionnaires and agendas, to the selection of the best participants and Chairs. We then conduct and analyze the meetings, and make useful business recommendations based on the outcomes.

Clinical Development Plans

Our clinical development plans address Pre-IND and IND issues, development of clinical programs designed to achieve a BLA or equivalent, and inclusion of endpoints designed to help achieve optimal reimbursement. Plans are designed around your product's Regulatory requirements and around the competitive landscape.



Due Diligence and Business Development

DCi participates in business development and due diligence exercises representing clients with potential partners. We also will work with you to develop investor presentations and roadshows.

Integrated Sales, Market, and Manufacturing Capacity Forecasting

DCi develops quantitative market projections and product sales forecasts, and GMP manufacturing capacity forecasts based on clinical trial needs, and longer term commercial projections.

We integrate manufacturing, sales and business models together for long term commercial planning and business modeling.

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BIOLOGICS CONSULTING GROUP, INC.

by Darin Weber, Ph.D., Senior Consultant, Biologics Consulting Group, Inc.

Regenerative Medicine Consultant Profile

Founded in 1993 and based in Alexandria, Virginia, Biologics Consulting Group, Inc. (BCG) is an international consulting firm whose consultants provide national and international regulatory and product development advice on the development and commercial production of biological, drug, and device products. Our staff consists of experts in regulatory affairs, product manufacturing and testing, pharmacology/toxicology, facility inspections, statistics, program management, and clinical trial design and evaluation. Many of our consultants are former CBER, CDER, and CDRH reviewers, certified FDA inspectors, and senior scientists from the biotechnology industry. Because of our familiarity with FDA expectations we have an excellent reputation at the Agency for filing high-quality, easily reviewable applications.

BCG was founded on the realization that the regulatory process for biological products differs significantly from that for drugs and medical devices, and requires specific expertise based on the unique biochemical nature of the products. While the FDA and ICH regulatory guidance documents provide a necessary framework for biotechnology product development strategies, practical regulatory and operations experience is a vital part of successful licensure and post-market support.

Today, Biologics Consulting Group, Inc. specializes not only in the preparation and review of CBER regulatory applications (INDs and BLAs) as well as the inspection/audit of biologics manufacturing facilities, but also in similar regulatory activities for drugs, devices and combination products.

We provide expertise in the following areas:

Regulatory Affairs

Explanation of FDA regulations/expectations, advice on regulatory and development strategy, FDA regulatory submission preparation/review of IND, BLA, NDA, IDE, 510(k), PMA, CTD, MF, RAC submissions, Orphan Drug Designation, Fast Track Designation Request, Request For Designation (Combination Products), Electronic Submissions, and Preparation for FDA meetings and Advisory meetings. We can also support your Non-US regulatory submission in Australia, Canada, EU, and in Japan, as well as provide due diligence review of regulatory files.

Compliance

To assist your compliance activities, we can assist your organization in preparation of responses to FDA 483 citations and warning letters, import/export issues, injunction/seizure/consent decree issues, promotional labeling and advertising issues, and assist in FDA dispute resolution processes.

Audits and Inspections

We can perform realistic FDA "Mock" Inspections for compliance with GMP, GLP, GTP, and GCP and also conduct due diligence audits and assessments, facility design evaluation, and assess Pre-Approval Inspection (PAI) readiness.

Quality Assurance

We can provide quality assurance oversight of contract services, manufacturing, testing, toxicology, document system development/review, quality system evaluation/development, computer systems, data integrity/electronic records and signatures, and Good Automated Manufacturing Practices (GAMP).

Manufacturing and Quality Control

Let us strengthen the development/review of the CMC section of your regulatory submissions. We can assist with process development/technology transfer, manufacturing operations, and management validation/qualification/optimization. We can also assess the quality of your Overall Validation Program Assessment, Validation Master Plans, manufacturing processes, facilities, equipment, OTS Software with equipment, and analytical assay development assistance/assessment of Identity, Purity, and Potency.

Let us review and improve your stability testing, reference standard characterization test method Qualification/Validation/Tech Transfer, and provide advice and evaluation of your viral clearance studies, cell banking, Process / Product Comparability Protocols and Identification/Oversight of CMOs.

Preclinical Safety Testing

We have specific expertise in the development/review of pharmacology/toxicology sections of regulatory submissions, specifically

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COMPLIANCE CONSULTING

by Lizabeth Cardwell MT(ASCP), MBA, RAC, Principle, Compliance Consulting

Regenerative Medicine Consultant Profile

Compliance Consulting specializes in providing appropriate solutions to meet FDA GXP requirements. Working with a variety of companies and technologies and departments in FDA regulated industry provides Compliance Consulting with a broad scope. Compliance Consulting has implemented GXP solutions in cell therapy and gene therapy companies, biotechnology (rDNA and monoclonal antibody) companies, small molecule drug and combination product companies. GXP programs have been implemented in companies in various stages of clinical trials as well as in those with commercial products. Over twenty-five years in FDA regulated industry provides Compliance Consulting with a sound approach for implementing cGXPs in numerous business and technical environments. Expertise in GXP implementation has also been acquired by observations and audits of other FDA regulated companies for cGMP, Good Tissue Practices, Good Laboratory Practices, and Good Clinical Practices.

In quality and operations management, we are looking for the most effective, reliable and reproducible means to meet the essential regulatory requirements but still meet the customer and business needs. Identifying the essential regulatory requirements for the particular business and

putting together quality systems (e.g., documents systems, production documents, training, etc.) as appropriate to meet these needs takes cross-functional experience. In many cases, start-up companies have only a very basic understanding that they must be compliant with the regulations but they may not have the resources or experience to establish a com-

pliant quality system. Just reading the regulations doesn't impart this understanding. Just purchasing a 'off-the-shelf' quality system is not adequate for any specific application. The quality system must apply to the clinical trial program or regulated industry situation. Compliance Consulting helps companies establish and upgrade quality systems applicable to their particular business and technology.

Experience teaches us how to interpret the various regulations into adequate Standard Operating Procedures (SOP), batch records and forms to get the job done.

For example, a controlled document system must be established that meets industry and regulatory standards to identify, track, justify and implement document changes. The inexperienced person may not understand that a controlled document can be any written paper from an SOP to a master work plan or a master batch record to testing and in-

specion forms for quality control. Industry beginners to regulated industry may not know what records of operations related to manufacturing the product are required and need to be retained, and what for specific times. No one can know every aspect of all the pertinent regulations by experience teaches us where to look for the information.

Specific experience is helpful and necessary when establishing the systems required to assure sterility in products or intermediates that cannot be terminally sterilized. Leveraging my experience in implementing aseptic processes can mean the difference between

Just purchasing a 'off-the-shelf' quality system is not adequate for any specific application. The quality system must apply to the clinical trial program or regulated industry situation.



having an IND allowed to proceed versus being put on clinical hold. This wisdom is practical whether the company intends to manufacture their own products or to contract the production. There are expectations established by guidance documents and other references for building and inspecting cleanrooms and cleanroom operations. I've been involved in many such programs from planning from the ground up to performing audits after the cleanrooms have been built and validated. I've drafted and reviewed numerous validation plans for aseptic processing laboratories. I've used these experiences to help others plan, build and implement aseptic processing in their own establishments.

It is important and critical to note that none of the work that I've done for clients has been performed in a vacuum. The implementation of systems that work for a particular company require the commitment and accountability of the various teams at the client company. I've enjoyed working with a tremendous network of dedicated and smart individuals. My experience is enriched by each contract.

I feel truly lucky to have had such a wide variety of experience across a variety of industries. Working with start-up biotechnology and cell therapy companies has been exciting. Being part of the expanding realm of new technologies is intellectually

stimulating and rewarding. There is always another challenge to be met and another regulatory requirement to be implemented. It is very satisfactory to see newly established systems operated effectively in the complex regulated cross-functional environments of the client company.

COMPLIANCE CONSULTING

Lizabeth Cardwell MT(ASCP),
RAC, MBA, Principle Consultant
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Continued from **BIOLOGICS CONSULTING GROUP**, page 7.

program development/planning/assessment, study protocol development/assessment, due diligence assessment of new products, review and assessment of study results, pharmacokinetics and biodistribution study analysis/review/assessment, and identification/oversight of Contract Testing Organizations (CTOs).

Project Management

Our consultants have specific expertise to assist strategic planning and business development, development of timelines, budgets, and personnel requirements for tech transfer selection, costing and placement of manufacturing/research equipment and vendor management.

Biostatistics

We offer a detailed explanation of FDA expectations, statistical evaluation of clinical trial design, statistical issues for assay design, and preparation of integrated statistical and clinical reports.

Clinical

We can assist the development/review of the clinical section

of regulatory submissions including clinical program development strategy, protocol development/review, clinical trial design, product development plans, clinical trial report preparation/review, post marketing requirements, accelerated approval, surrogate endpoints, comprehensive "FDA" style review of safety and efficacy data, medical monitoring assist with the conduct of clinical trials, and also consultation regarding clinical and public health issues as they pertain to the development of new products and clinical trials.



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CELL THERAPY GROUP

BUILDING THE FIRST FULL-SERVICE CONSULTING FIRM IN REGENERATIVE MEDICINE

by Lee Buckler, Principal, Cell Therapy Group

Regenerative Medicine Consultant Profile

I launched Cell Therapy Group (CTG) in mid-2008 with the thought that what the industry clearly lacked was a consulting firm with a broad spectrum of talents available to offer a wide range of services.

Cell Therapy Group, the trade name for CTG Consulting, Co. (a Washington state corporation), is still wholly owned by myself but has now expanded well beyond my own skill set to include an expanding roster of expertise and experience capable of providing a wide range of scientific, technical, and commercial services to companies in or interested in the regenerative medicine industry.

My rather limited potential value to clients has always been and largely still remains based on two basic things. First is my unusually broad understanding and knowledge about the industry as a whole. Most people necessarily have to focus on a relatively narrow field of specialty, so few people have the luxury of being able to see, monitor, and analyze the industry as a whole like I have been afforded the opportunity to do. I refer to this as my "who-is-doing-what, with-what, for-what, at-what-stage, and with-whom" database. This is a proprietary database built and maintained over the past decade but there's an awful lot of human intel behind it as well.

Secondly, I make it my business to know or have some touch point with as many people in those companies as possible. This, it turns out, is more useful than just ensuring you always have someone to buy a beer for at conferences.

My clientele started out largely as companies with something to sell into the space, but increasingly it is also comprised of companies looking for intelligence either in terms of better understanding of the sector, certain companies or products in it, and/or for information that might lead them to identify technical solutions they had not come across, commercial opportunities that meet their specifications, and/or collaborations that further their business goals.

Driven to provide the regenerative medicine industry the kind of full-service consulting and project management company that it lacks, I began expanding the "Group" to something beyond myself after a year of consulting on my own. After formalizing the company's legal structure on both the Canadian and U.S. sides of the border, we announced a first wave of expansion with the addition of several "dedicated" consultants in late 2009.

CTG now has two tiers of consultants. The 'dedicated' consultants listed on our website have committed to helping grow CTG and are therefore exclusively available for consulting through CTG.

The second tier referenced on the website represents people with other jobs or consulting companies, but have a specific skill set. They are brought in on projects as appropriate. These consultants are under non-exclusive master services and confidentiality agreements with CTG so they can be brought in on projects without delay.

Finally, CTG has a large network of other consultants or other consulting

companies with which it works – some of whom are also profiled in this publication – as projects require, clients request, or capacity dictates.

Cell Therapy Group has worked with large pharma, mid-sized biotech, and startup ventures, companies with products to sell, companies on the buy and sell side of M&A, companies developing therapeutics or tools, investors, and even academic institutes looking to tech-transfer something out into or to a company.

Our group has expertise in R&D, technical operations, devices, clinical translation, manufacturing programs, business development, marketing, valuations, technical assessments, etc. CTG has worked on cell therapy product development, designing and implementing stem cell drug discovery or toxicity programs, cell therapy devices/equipment platforms, commercial, scientific, technical and market assessments, developing strategic investment roadmaps, identifying businesses/assets/partners for clients on the buy side, identifying investors/partners for clients on the sell side, building market profile and penetration, etc.

We're excited about the regenerative medicine industry and we're particularly excited with what we're building with this company. CTG is now the driving force behind a growing roster and network of consultants serving the regenerative medicine industry.

It is our belief that as this industry matures and scales up, its needs for consultants, project managers, and other term workers are going to become



more complex and demanding – certainly beyond what any sole proprietor consultant will be able to handle. We believe that our clients’ needs will best be met by a shop that can assign a team of people to a project such that each team member will contribute to different components of the project from their own sweet spot of particular expertise. A project manager ensures

this runs smoothly and results in an integrated product.

Our focus is making every attempt to ensure the client receives advice from the best possible person available however we can involve them on the project. That is why, for instance, we don’t have regulatory consultants of our own. The best out there already belong to other

firms so we just bring them in on projects as needed. Not only do we believe this leads to a higher quality product, we believe it can also be more cost effective.



www.celltherapygroup.com
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HYPOTHERMOSOL® ADOPTION IN HAIR TRANSPLANTATION

BioLife Solutions’ HypoThermosol® is increasingly being used by leading hair transplant physicians as an optimized ex-vivo holding solution for both the explanted tissue strip and dissected hair follicles. The formulation of HypoThermosol® has been shown to extend the ex-vivo storage interval for these biologics, while maintaining viability and in some cases, promoting faster engraftment of transplanted follicles. A series of comparative experiments on HypoThermosol® and the standard saline solution were conducted by the research team at BioLife Solutions. Figure 1 below includes representative fluorescent micrographs (A, B) and brightfield images (C, D) illustrating the morphology of hair follicles stored in HypoThermosol® or saline. Figure 2 is a graph of follicle viability after extended ex-vivo storage and extended culture conditions in either storage solution. Figure 3 illustrates six month hair re-growth for follicles stored in either solution (different follicles used in Figures 1 and 3, Figure 3 image provided by William Parsley, M.D.).

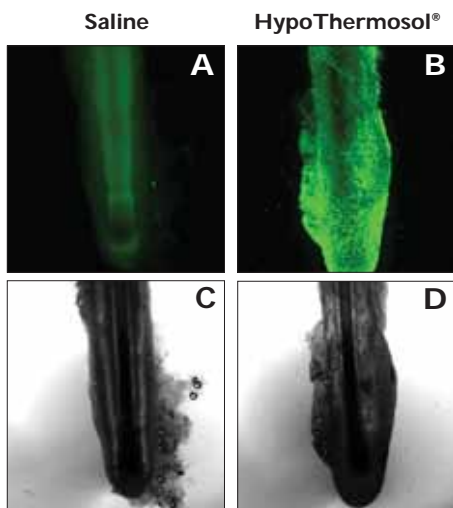
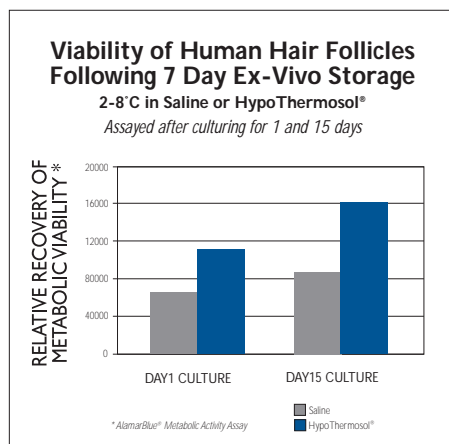


Figure 1



Saline product = PLASMA-LYTE® A (Baxter)

Figure 2



Figure 3

“The most significant limitation to hair transplantations is that there is a fixed and limited amount of good genetic hair that can be transferred to the balding area. Considering this limitation, physicians should use techniques and technologies that ensure the highest percent of grafts survive and grow. This is why I use HypoThermosol as the holding solution for the grafts. HypoThermosol reduces the harmful effects of “tissue-reperfusion injury” by:

- scavenging free radicals
- preventing gradient formation that causes shrinking and swelling in response to temperature changes
- minimizing apoptosis and necrosis by maintaining proper pH, structural integrity, and ionic balance inside and outside the cell membrane”

Paul J. McAndrews, MD, Senior Medical Advisor, The International Alliance of Hair Restoration Surgeons (IAHRS)

Continued from **ADVANCED CELL AND GENE THERAPY**, page 5.

Regulatory Affairs, Quality Systems

- Regulatory requirements and standards, regulatory strategy
 - US FDA, EMEA, national regulatory agencies (worldwide)
- Regulatory submissions - guidance and review
- Audits and gap analyses
- Quality systems, GMP/GTP infrastructure
- Personnel training

 **ADVANCED CELL & GENE THERAPY, LLC**

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www.ac-gt.com

Continued from **DCi-BIOTECH: Cell Therapy Business Strategies/Technical Operations/Logistics Support**, page 6.

Technical Operations and Logistics Support

DCi has expertise in managing operational logistics for GMP manufacturing facilities and GLP laboratories, technology transfer, new facility setup and outsourced services (contract manufacturing organization, raw material suppliers, bioanalytical testing laboratory and maintenance service vendors).

We also provide product and process improvement insights to achieve better product quality and operational efficiency.

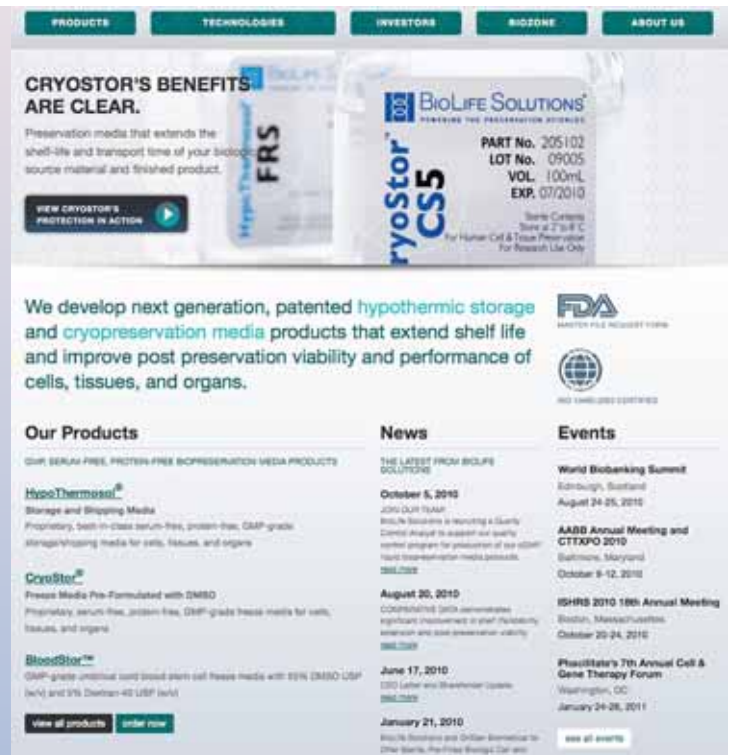


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CHECK IT OUT! BIOLIFE HAS A NEW WEBSITE

BioLife Solutions' corporate website was recently upgraded to improve navigation, include information on new products and scientific data, and enhance the overall visitor experience. The site features a simple and fast Master File cross reference request electronic form, new comparative scientific data comparing BioLife preservation media products to traditional 'home-brew' and commercial formulations, and an educational animation of the cell cryopreservation process. Future enhancements will include a searchable database of clinical and scientific articles that cite the use of HypoThermosol®, CryoStor®, and BloodStor®.



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.