The Life Sciences Voice The Georgia Bio Industry E-Newsletter GEORGIA BIO

Newsletter Issue: December 19, 2014

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Letter From the President

As Georgia Bio's 25th year comes to a close, we can reflect on significant progress with our strategic plan and goal to bring innovative life science products to the market. Our membership has grown in all sectors over the past two years, but most importantly, we have added many new Core members so that we can better represent the breadth of this industry.

Our primary goal for 2014 was to improve the value of your membership. I hope you feel that we have helped your organization, but there is always more to do. We increased participation in our discount purchasing programs and added new benefits to membership, and we plan to continue focus on those benefits in 2015. We convened top bioscience minds as panelists and keynote speakers at the rebranded

and refreshed Georgia Bio Innovation Summit; and featured several new and emerging Georgia companies. Georgia Bio hosted and partnered with over 30 events throughout the year, including industry tours, CEO leadership breakfasts and BioBash happy hours.

Our staff has grown to serve you better as well. We welcomed Angela King, first as a summer intern, and now as our Member Services Manager. Angela is here to help ensure that you are getting the most from your membership, so please drop her a line sometime to go over all of our features and benefits. The Georgia BioEd Institute welcomed Jennifer Kauffman as its new Development Director, helping to further grow our education and workforce initiatives with our Program Director, Melissa Nikolic. Of course, Maria, Norene and myself remain available to you as well and we look forward to working with you in the new year.

2015 will prove to be an even more exciting year for our association as we launch and reactivate several committees and networks, including the Industry Marketing Committee, MedTech Network and Health IT network. As the board and membership of the new angel network - the Bio/Med Investor Network - has been established, we expect to host our first company presentations meeting to investors in March or April.

As I mentioned earlier, there is always more to do, and we rely on your feedback and advice to continue advancing our organization and this important industry. Please join us on February 22nd for our annual awards dinner to help us celebrate the industry's 2014 achievements and welcome in 2015.

Have a wonderful holiday season and a Happy New Year!

Sincerely,
Russell Allen

A Modern Acropolis in Georgia

Life sciences entrepreneurs in Athens, home to the University of Georgia, shared their experiences with the city's vibrant and growing startup community in November at a networking event co-sponsored by Georgia Bio.

"Building the Modern Acropolis: Athens' Life Science Entrepreneurs," held at Hotel Indigo, featured a panel of pioneering Athens startup company founders who discussed their innovations and journey from academic research to commercial success.

The Athens entrepreneurs – Kausar Samli, CEO, Glycosensors & Diagnostics; Nic Chronos, CEO, ViCapsys; Tom Robertson, CEO, IS3D; and Steve Stice, chief scientific officer and chairman, ArunA Biomedical – talked candidly about getting started and finding funding, who to know and where to go to find the support new companies need.

They also talked about why so many companies are emerging from UGA research or relocating to Athens.

"Athens has many advantages of a university town — technology and talent and green spaces — but without the city costs and traffic congestion like Atlanta," said Stice, a Georgia Research Alliance Eminent Scholar in Animal Reproductive Physiology in the UGA College of Agricultural and Environmental Sciences, and director, UGA Regenerative Bioscience Center.

"The play-hard, work-hard lifestyle is so much better here. The people are friendly, and there's a real sense of community. Having a number of options for dining, arts, sports and entertainment – all within easy

walking distance – is a great draw for potential new hires," he said.

Stefan Schulze, GBBC associate director, noted the recent surge of entrepreneurial interest in recent years across UGA's campus. More than 130 companies, most of them life science companies, have been founded at UGA since 1972; 70 are still classified as active. While an average of three to four companies based on UGA research are founded each year, the number last year increased to eight.

"This has largely been driven by researcher's interest in maximizing the impact of their work on society," Schulze said. "They're looking to translate investments in research into better patient outcomes, higher living standards, and economic gains for our community."

Over 75 people attended the Athens Event.

Schulze noted that in addition to UGA faculty, staff, and students, the event was attended by industry service providers such as attorneys and accountants and people from the Athens local business community. The event was co-sponsored by Athens Clarke County Economic Development Department, which along with the state, has provided strong support for startup activity in Athens.

Georgia BioEd Institute: Partnerships & Beyond

By: Melissa Nikolic, Georgia BioEd Institute

It's been a busy first year for the Georgia BioEd Institute. Our first anniversary rolled around in August and we have continued to make our mark as the premiere partner organization to strengthen life science workforce in the state! Our program highlights include our **teacher trainings** where we not only educate teachers on biotechnology and industry opportunities, but we also distribute much needed laboratory supplies at no cost to educators. One training can reach up to 400 students and our aim is to be the best training for our phenomenal biotechnology teachers.

One area where we provide substantial value during our workshops is the industry speaker. Information on the opportunities in industry, directly from an industry representative, has value beyond measure to these dedicated educators. The rallying cry behind the efforts of our extraordinary teachers provides opportunities for their students. Without active participation by industry there would not be an opportunity for teachers to gain valuable insights into industry needs and translate that into meaningful instruction. Your participation is directly impacting classroom instruction today.

Through our newly developed **Equipment Loan Depot** we have begun to support classroom laboratory science and this is only made possible by our great supporters, thank you **VWR** and **UCB**! Our visiting scientist program is always looking for exciting scientists, and others, who work in the life sciences. For a one hour commitment you are able to touch the lives of students, inspiring them to consider the wonderful opportunities in this exciting and meaningful industry. You truly make a difference by answering the age old question, "Why are we learning this"? Help make biotechnology relevant for students in Georgia, volunteer today!

GEORGIA BIOED Institute

The impact of the Institute is also felt in the new partnerships that we are continually developing. We are proud to have been chosen by the **Lieutenant Governor's office** to work on their annual **Business and Education Summit**. This year's Summit, held November 13th at the Rockdale Career Academy, focused on the biosciences and health IT industries as areas of workforce growth in Georgia. It was a productive morning discussing biosciences legacy and growth with **UCB**, **Merial** and **Baxter** representatives on an

outstanding panel (see photo caption below). The success of the panel was felt by the numerous positive comments from audience members.

This is one important way that the Georgia BioEd Institute strives to make life sciences in Georgia an important conversation topic worthy of conferences and media attention. It is our pleasure to be able to tell the story of opportunity and impact that the Georgia life sciences industry provides. [*Photo: Biosciences panelists were, from left, Joseph Zorzoli, UCB Pharma; Georgia Lt. Gov. Casey Cagle; Melissa Nikolic, Georgia BioEd Institute; Ken Howerton, Baxter International Inc.; and Frank Milward, Merial. (Staff Photo: Wade Marbaugh) http://www.rockdalecitizen.com/news/2014/nov/13/rockdale-career-academy-hosts-lt-gov-casey/*]

Ensuring the Safety and Commercial Success of Biosimilars

By: Jim Greenwood,
Biotechnology Industry Organization (BIO)

The forthcoming arrival of biosimilars into the U.S has spurred debate over the approaches that the FDA and industry should take to ensure patient safety while promoting market competition and continued biomedical innovation.

We know that public policy isn't created overnight, even in cases where everyone wants the same outcome. We believe that sound science is the key to the debate on biosimilars. As such, we have developed a myth vs. fact sheet to provide clarity on many of the complex issues associated with biosimilars. You can access the myth vs. fact sheet here.

With concerted action by state legislatures across the country and continued guidance by the FDA, seriously ill patients will gain access to additional medical therapies to improve their health and reduce their costs and those of the health care industry. We will continue to work with the FDA and other stakeholders to ensure that patients are protected and science prevails.

The Era of Clinical Trials in Latin America has Begun

By: Abhita Batra
Advanced Biopharma Consulting, LLC

The perception of the hidden continent Latin America has been changing over the years due to improved healthcare. In the past, very few companies conducted their clinical trials in Latin America because the standards for the region's healthcare systems were not perceived as high as in North America and Europe.

It's time to unveil the curtain and reveal the strengths of the continent in research!

The government and regulatory bodies in the region have been working hard and proactively to bring a positive change. Regulations are aligned with ICH GCP Guidelines and in some countries certifications are in place for investigators, CRAs and Ethic's Committees (local versions of IRBs).

Additionally, FDA and EMA have been conducting clinical trial inspections in the region, and some of the regulatory authorities such as ANMAT and many Ethic's Committees regularly perform inspections and audits while the trial is ongoing. Most multinational companies established their own Latin American Hub for clinical research more than 15-20 years ago.

Latin America has 21 countries; 569 million people. There are major urban centers, with large populations. Disease prevalence is similar to the US or Europe and in several countries standards of care are similar too. This is an advantage also, when considering diseases with seasonal behavior, because inclusion of Latin America allows for continuous patient enrollment all year round due to opposite seasons with the northern hemisphere.

Some of the therapeutic areas and diseases that have accomplished the most significant developments in the region are: cardiovascular diseases, metabolic diseases

(such as diabetes), respiratory disease (COPD, asthma), oncology (lung, breast, and colon), infectology (HIV, HCV), oncohematology (leukemia, lymphomas) and rheumatology. In the region clinical research costs are usually 15-20 % below the ROW.

Regulatory enforcement bodies, quality investigators, ethics committees ensuring patient safety and respect for their rights, proactive Good Clinical Practice (GCP) policy development, and large research naïve populations have been cited as contributing to the explosive growth of clinical trial management in this region.

What are the Regulatory Challenges faced in Latin America?

In Brazil, the National Committee for Ethics in Research (CONEP) provides the main ethical approval for clinical trials with foreign cooperation. The designated lead research site submits the study protocol and informed consent to CONEP. In parallel, the sponsor submits the trial for review and approval by the Ministry of Health.

Argentina also requires that a study must obtain institutional approval and approval from ANMAT (Regulatory Authority dependent of the Ministry of Health). ANMAT has a rigorous process not only for the protocol evaluation, but also for authorizing clinical trial sites and Investigators. Sites must have infrastructure and staff that is sufficient and adequate for conducting the study, and also demonstrate access to emergency medical assistance for the patients involved in the research in case it is needed. The sanitary authorization of the site as a healthcare facility is also required.

The Investigator needs to present his medical degree and his specialization degree, GCP training certificates and also a medical license that is current.

In Chile, both the IRB and the Ministry of Health evaluate the information about clinical trials. Chile's approval timelines are among the most competitive in the region.

How to plan for better outcomes in Clinical Trials?

Recruitment in clinical trials is always a challenge.

First step, think about bringing your trials to Latin America. Explore the feasibility of your projects in the region with a local vendor who is experienced through several phases of clinical research, aware of the challenges, health system, investigator network, local practices and regulatory and import processes.

Although there are well established sites and investigators in the therapeutic areas mentioned before, there is space and willingness to grow outside of these areas. Ophthalmology, Gynecology, Dermatology are areas capturing more interest in the region.

Set time for a face to face meeting and be sure to address all of your fears and concerns straight-on with the local vendor. Being able to discuss openly any potential issues or concerns will help you to develop trust with your CRO which is crucial for a successful outcome. It is also important to become informed about the Key Opinion Leaders in the region.

Explore potential for partnership, either with the CRO or through it. There are several grants and funding available for research & development through partnerships with local companies and/or clinical research sites.

Proactively establish and maintain regular communications between the regulatory authorities and sponsors/investigational-sites.

How to ensure success in Clinical Trials

- Large Patient Population
- High prevalence disease areas
- Investigational teams (experience, training, KOL)
- Integrated Health System
- Armonized Standards of Care

How to find the right partner

Advanced Biopharma Consulting has been working with Latin American companies (Rev upto 800M) and is well-aware of the need and wants to partner with the right CRO for committed reliable partnership that produces the desired results. We have partnered with Research & Development RA SA for their strategic market entry in North America. R&D, through a partnership with a CRO in the US (Clindatrix) is able to make your clinical trial global.

With more than twenty years of experience as a partner in clinical research, Research & Development RA SA has the expertise and breadth of experience to help you carry out your Latin-American clinical research program in a cost-effective and timely manner. They can assist you in the regulatory approval of your clinical program, managing your clinical studies and submit your application to Latin American Authorities.

What are the steps performed by R&D?

- Protocol Development
- Trial Setup & Management
- Monitoring
- Data Management
- Safety Reporting
- Medical Writing
- Biostatistics & Reporting
- Regulatory Affairs
- Project Management

How does R&D manage safety data?

- Reporting of Serious Adverse Events (SAEs) in International Clinical Trials
- Processing and Reporting of Adverse Drug Reactions (ADRs)
- Writing Periodic Safety Update Reports (PSURs)
- Designing, Conducting, and Analyzing Safety and Pharmaco epidemiological Studies
- Generating Integrated Summaries of Safety (ISS)
- Consulting and System Analysis

How conducting trials leads to increase in Sales

Well conducted clinical trials are a source of strong medical evidence which will help you to support or improve your product's indication within the scientific community.

It also provides additional safety information which can further define the safety profile of your product, or even provide new information to modify the product's risk: benefit ratio.

Clinical trials also allow you to involve Key Opinion Leaders as investigators, which helps you build early on a network of renowned professionals with early hands-on experience with your product.

Also a trial provides data about the results of the drug in different geographical regions which is always an advantage when looking to expand and increase sales through product registrations in other markets.

The Atlanta Science Festival Wants You

The Atlanta Science Festival is a weeklong celebration of local science and technology held March 21-28, 2015. Scientists and educators from local universities, museums and companies will uncover mysteries and explain discoveries in hands-on activities, facility tours, stimulating presentations, and riveting performances for adults and children of all ages. More than 100 events will occur across the metro area culminating with the Exploration Expo, Atlanta's biggest interactive science event , to be held March 28 at Centennial Olympic Park. Curious? Watch a 60-second VIDEO.

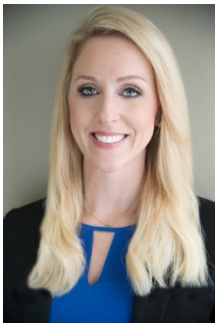
The Festival is seeking sponsors to support science literacy and economic development in our community, volunteers to help produce and promote the events, and STEM professionals to visit K-12

classrooms and inspire our youth. Sponsorship includes exhibit space at our March 28 Exploration Expo, which reached 16,000 people last year. We invite you to join the 30,000 people who attended last year's inaugural Festival to celebrate our region's STEM successes and opportunities.

Thinking of hosting a booth at the Expo? The deadline for Expo exhibit proposals is January 9 and space is filling up fast, so get your proposals in as soon as possible. For details on how to submit a proposal and tips on creating a successful booth, see the link above.

For more information visit www.AtlantaScienceFestival.org. Stay connected by subscribing to the newsletter or following on Facebook and Twitter to receive the latest updates on events and opportunities.

Georgia BioEd Welcomes New Development Director



Georgia Bio is excited to announce the hiring of Jennifer Kauffman as the Georgia BioEd Institute's, Development Director. Jennifer's primary focus is to build strong and lasting programmatic and philanthropic relationships with key stakeholders. Jennifer will play a key role in identifying, fostering and initiating successful relations with educational partners, life science companies, foundations and contributors.

Jennifer has worked in a variety of environments surrounding health promotion, public health, and marketing. This includes non-profit, for-profit, clinical, regulatory affairs, and event production. Most recently, Jennifer served as Development Associate for Grady Health Foundation. Prior to that, she served as the Program Coordinator for Quality Control & Regulatory Affairs at Resolutions, while seeking a degree from the University of Georgia. She was responsible for document control for client quality systems and medical device approvals submitted to the FDA. In order to earn her degree in Public Health, Jennifer completed three practicums for the following organizations: Athens Community Connections, Physician's Immediate Medicine and Athens Community Council on Aging.

Jennifer's commitment to healthcare and the community does not end there. She is an active member of the Associations of Fundraising Professionals and Healthcare Philanthropy, and the Atlanta Athletic Club. Jennifer has a strong passion for healthy living and stays active. She ranked 13th in the nation in Rowing and recently completed her first half marathon. Jennifer has been an integral part in the development of her father's restaurant, Ten Bistro; which was voted Best New Restaurant 2011 Inside Gwinnett Magazine.

Jennifer resides in Brookhaven where she supports the Brookhaven Chamber of Commerce by implementing the young professionals sector and serving on the board; she also is a supporter of MARTA, which she uses to travel to metro-Atlanta in support of the Clean Air Campaign.

According to Russell Allen, Georgia Bio President and CEO, the goal of hiring a Director now was to "take the wonderful K-12 and workforce development programs the Institute runs and sustain those efforts over the long term. We want the Institute to be here, helping Georgia's biotech and medtech industry as long as it's needed. Jennifer's experience will help the Institute expand development efforts, connect donors, partners, and increase community support."

New ShareVault Whitepaper: What's Hot & What's Not in Oncology Licensing

This white paper is based on a live web panel, hosted by ShareVault and the Biotechnology Industry Organization (BIO), discussing what's exciting in cancer drug development versus what is not popular in licensing, and why.

For the live event, biotech licensing and pharmaceutical business development consultant Linda Pullan was joined by three panelists who are business development experts from a global pharmaceutical company, a leading academic cancer center, and a top business development consulting firm. The panelists discussed theories of cancer, favorite targets and modalities, the impact of reimbursement, deal types, and more.

If you are developing a cancer drug or working toward in- or out-licensing of a cancer drug, you will want to read these perspectives.

To download a copy of the whitepaper, click here - http://bit.ly/1yZKIi0

ShareVault

Don't Go At It Alone- BIO BizLink and the Evolving R&D Marketplace

With companies in the biotechnology industry more frequently outsourcing R&D pipelines, selecting the right contract organization becomes more important. BIO, along with OnDeckBiotech, has recently launched a new online platform, BIO BizLink, that facilitates these relationships between biopharma companies and contract service providers.

BIO BizLink serves as a peer-rated database for contract manufacturing organizations (CMOs) and contract research organizations (CROs) and their specific capabilities, while additionally providing secure project management tools to help companies work seamlessly with their new business partners.

"BIO BizLink is designed to help emerging biotechs find strong partners for the research and development process," says Peter McHugh, Vice President of Business Operations at BIO. "With the speed at which products are being developed within the pipelines, companies want to make the best decisions to get things right the first time. BIO BizLink provides helpful functionality on the platform, such as a keyword search, confidential messaging, and a dashboard to manage secure documents, making this a unique and robust service for the industry."

BIO BizLink is free to use for biotechs, and service providers only pay a small fee on deals facilitated by the service. Signing up takes just a few seconds. Visit www.biobizlink.com to learn more.

This article is courtesy of the Biotechnology Industry Organization.

GaBio Welcomes Clean Harbors to the Purchasing Program

Georgia Bio and BIO are excited to announce it will be offering its members a program that can help your company save on Environmental & Waste Disposal costs through Clean Harbors Environmental Services, Inc. starting January 1, 2015.

BIO has partnered with Clean Harbors, one of the largest Environmental Services

companies in North America. Clean Harbors manages waste recycling and disposal for almost all waste streams, planned environmental and industrial services as well as Emergency Response Service with offices throughout the United States, Canada and Puerto Rico. Many companies today use third parties who own no disposal assets and offer no assistance related to compliance requirements, however with Clean Harbors, members eliminate significant liability and compliance potential issues dealing with end disposal facility direct, as well as economic gain. Learn more about the savings and to sign up click here.

Welcome to Our Newest Members

Aiye Biopharma, Inc.

Cresa

Expression Therapeutics LLC

General Genomics, LLC

OneCare

Science and Compliance, LLC

WSP Group

GaBio Career Center

Find the people and careers driving innovation.

Our Career Center is the resource for life science jobs in Georgia.

One of Georgia Bio's top priorities is to help recruit, retain and train the talent needed to grow life sciences in Georgia. We are driving to connect an innovative workforce to our emerging and dynamic organizations committed to better health solutions.

The GaBio Career Center offers simple and easy-to-use tools to make searching for career opportunities and finding qualified candidates fast, efficient and successful.

This job board is custom tailored for the Life Science industry, which means we attract the most qualified professionals in Georgia. Create an Employer Account and post your Life Science jobs today!

Click Here to visit the Career Center today to post a job or find your next job in the life sciences sector.

Upcoming Events

[Biotech Showcase™ 2015](#)
January 12-14, 2015

[Atlanta Center for Medical Research Industry Tour](#)
January 15, 2015

[Teacher Training Workshop: Using Molecular Modeling in High School Science Courses](#)
January 16, 2015

[A Starry Night: Georgia Bio Awards Dinner & Education Fundraiser](#)
January 22, 2015

Georgia Bio Day at the Capitol – *details coming soon*
January 28, 2015

[WIB-Atlanta Presents: Be Your Personal Best While Networking](#)
January 28, 2015

[Atlanta Science Festival 2015](#)
March 21-28, 2015

ATLANTA SCIENCE FESTIVAL

[Pharma/Biologic Reimbursement & Market Access Strategy Meeting](#)
March 24-25, 2015

[Southeast Medical Device Association (SEMDA) Conference-"Smart Devices + Smart Medicine"](#)
March 31 – April 1, 2015

SEMDA Medical devices. For life.

[BIO Legislative Day Fly-In](#)
April 14-15, 2015

[World Orphan Drug Congress USA 2015](#)
April 23-24, 2015

WORLD OrphanDrug Congress USA 2015

[Cell Culture World Congress USA 2015](#)
May 27-28, 2015

Cell Culture World Congress USA 2015

[World Biosimilar Congress USA 2015](#)
May 27-28, 2015

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