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**Georgia Bio Newsletter Credits**

Editor: JoAnna Pendergrass, DVM

Veterinary writer/editor at wikihow.com; Georgia Bio & ELN Newsletter Coordinator

Layout & Distribution: Maria Thacker, Georgia Bio

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## Letter from the President

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I hope you are having a terrific year. Can you believe that 2015 is half over? I would like to take a moment to highlight a handful of Georgia Bio's 2015 activities.

- A number of Georgia Bio member companies - EndoChoice, Clearside Biomedical, Celtaxsys, Femasys, and CorMatrix - have had a very successful year raising capital.
- Georgia Bio in partnership with BIO, PhRMA and other partners, successfully pushed through critical legislation to create a pathway for the substitution of interchangeable biologic medicines.
- The GeorgiaBioEd Institute launched a new website - [www.georgiabiomed.org](http://www.georgiabiomed.org) - where you can learn how your company can volunteer time, and donate equipment and funds for STEM initiatives throughout the state.
- We hosted several events, including programs on Telehealth, Growth and Investment in the Biosciences, 4 sold-out industry tours, 2 small dinners, the Academic & Industry Intersection Conference in conjunction with ACTSI, and a variety of workforce development webinars.
- One of our most popular events, BioBash, was held in May and welcomed over 80 attendees at The Painted Pin. The event was sponsored by Troutman Sanders. We look forward to seeing each of you at our next BioBash!
- Georgia Bio staff recently attended the Biotechnology Industry Organization (BIO) International Convention in Philadelphia, where the energy and excitement of the event was tremendous and served as a great reminder of what a fabulous industry this is.
- The Innovation Crescent Regional Partnership and Georgia Bio signed a Memorandum of Understanding, formally agreeing to collaborate in the promotion and support of the life science industry in Georgia.

- Our career center moved to the JobTarget platform the strongest career center platform and services model with the best recruitment and advertising sales force in the marketplace.
- The Emerging Leaders Network issued a 5-year strategic plan.

Be sure to check out our events calendar for more great 2015 programs! You don't want to miss any of the great events, or opportunities to network or to be a sponsor.

Our staff is hard at work preparing for the 2015 Georgia Bio Innovation Summit scheduled for November 2 at Cobb Galleria. Learn more at [www.gabio.org/summit2015](http://www.gabio.org/summit2015).

Stay tuned to additional events, news, and activities by following us at: [www.gabio.org](http://www.gabio.org) or connecting with us on Twitter, LinkedIn, and Facebook.

Sincerely,  
Russell Allen

## Omega Bioservices, Inc. is awarded two R&D contracts from the Environmental Protection Agency

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Omega Bioservices Inc., located in Norcross, is a recent addition to the growing cadre of biotechnology companies in Georgia. Omega Bioservices is led by Chief Executive Officer Ken Guo, who is the founder and CEO of its parent company, Omega Bio-tek. Omega Bio-tek has been a manufacturer of biotechnology reagents since 1998. Omega Bioservices focuses on providing a full suite of laboratory services to commercial, academic, and government clients with a primary focus on next-

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generation sequencing with their Illumina instruments, the MiSeq and HiSeq 2500.

In May 2015, Omega Bioservices competed for and won two R&D contracts from the Environmental Protection Agency to explore faster, more comprehensive, and more cost effective ways to use next-generation sequencing as a method to screen chemical compounds for potential human toxicity. The results of these studies will reveal if changes in gene expression in cultured human cells upon exposure to a specific chemical can be used as an indicator of toxicity. “These awards really highlight what we believe to be our competitive advantages in the business of next-generation sequencing service providers,” stated Chief Science Officer, Dr. Weining Tang. “We possess the expertise and capability to perform the full spectrum of lab work to include DNA/RNA extraction from any clinical or environmental sample types, as well as integrating processes onto our robotic platforms to develop customized and high throughput solutions for our customer’s needs.”

Omega Bioservices participated in the June 2015 BIO International Convention in Philadelphia as part of Georgia Innovation Crescent’s group of new small biotechnology businesses. “We were extremely pleased to be invited to be a part of that group. The business-to-business exposure that we received at that convention is critical to our growth,” said the Director of Business Development, Dr. Mike Farrell. “We only have six employees now, but we plan to hire more scientists in the near future as we become an integral piece of Atlanta’s burgeoning biotechnology hub.”

*Learn more about Omega Bioservices at*  
<http://omegabioservices.com/>.



## FDA/Sponsor Interactions During Drug Development- Preliminary Data

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BIO is conducting a first-of-its-kind survey on FDA/Sponsor Interactions During Drug Development. Earlier this year, BIO held an exclusive webinar to reveal the preliminary data from this survey. You can view select slides from the [webinar](#). Survey participants have full data access -- you can sign up to receive exclusive insights from our upcoming spring data pull by visiting [fdasurvey.bio.org](http://fdasurvey.bio.org). We have been able to glean some high-level insights from the preliminary data set presented during the webinar, but we need more participation for this survey to affect positive change at the FDA. In-depth company feedback will enable BIO to provide real-time information to the FDA and will inform BIO's policy priorities. Companies are encouraged to share their insights by [signing up](#). If you have any questions, please contact [Charles Crain](#).

## Innovation Crescent Sponsors Start-Ups at BIO International 2015

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*By: Michelle Oleson,*  
*Innovation Crescent Regional Partnership*

When it comes to launching new products or businesses, entrepreneurs will say there are a variety of keys to success. Although what works for some may not work for others, there is no doubt that the more access to financial and industry support a company has, the better.

That’s why Georgia’s Innovation Crescent sponsors 5 life science start-up companies each year to exhibit at the BIO International tradeshow, inside the Georgia USA pavilion. Attended in June 2015 by more than 15,000 people from more than 60 countries and all 50 states, the BIO Convention draws representatives from many life science sectors including therapeutics, medical devices, research, and government relations. The show provides

critical opportunities for networking, building business partnerships and keeping up-to-date on new industry trends and issues. This year, BIO was held in Philadelphia.

“There were some tangible benefits that occurred for us that absolutely would not have happened if the Innovation Crescent and State of Georgia hadn’t invested their time and money into making our attendance happen,” said Dale Sizemore, senior marketing consultant at Ennaid Therapeutics, one of the 5 sponsored companies in 2015. Sizemore said that in addition to the 100 visitors he met in the booth, Ennaid Therapeutics had first-hand discussions with 2 highly-qualified and interested investors, numerous meetings with international industry contacts, and even obtained leads for potential employees.

In addition to Ennaid Therapeutics, the Innovation Crescent sponsored Axion Biosystems, BioReactor Sciences, Glycosensors and Diagnostics, and Omega Bio-tek [not pictured] this year. The Innovation Crescent’s BIO sponsorship includes complimentary pedestal space and meeting space within the Georgia USA pavilion, exhibitor passes, company listing in the BIO Show Directory and the opportunity to promote products and services to national and international decision-makers in biotechnology.



“I was honored to help spread the word that Georgia indeed has a strong bio and life sciences message for the rest of the world,” said Sizemore. “I witnessed firsthand people wanting to know more about the companies in the Innovation Crescent. The word is getting out.”

The Innovation Crescent is both a geographic region and partnership of more than 15 counties and economic development entities in Georgia, all dedicated to the region’s life science and technology growth. For more information, visit [www.innovationcrescent.com](http://www.innovationcrescent.com) or call 678-849-7841.

## Executive Interview Series: Dr. Praveen Tyle, PhD, President and CEO, Osmotica Pharmaceutical

*By Ishaneka Williams, MBA*

*ELN Small Business Liaison*

***This is part 2 of a two part interview.***

***To view Part 1 Click here.***



Dr. Praveen Tyle has led an impressive career with a list of achievements and rewards paving his path. Dr. Tyle credits where he is to previous managers and mentors who believed in him—allowing for professional development opportunities and exposure

beyond his academic trainings.

Dr. Praveen Tyle is currently president, CEO and board member of Osmotica Pharmaceutical (OP), located in Marietta, GA. He is responsible for the financial management, operational oversight, and strategic direction of the company's worldwide operations. Dr. Tyle joined OP in August 2012 as executive vice president and Chief Scientific Officer (CSO) and managing director of Marietta site at OP.

Dr. Tyle has 30 years of diversified pharmaceutical industry experience with an impressive record of moving pharmaceuticals from pipeline development to commercial success. Prior

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to joining OP, he served as executive vice president and CSO for the United States Pharmacopeia. Dr. Tyle's broad experience in the pharmaceutical industry includes senior executive leadership positions in areas of research and development, manufacturing, supply chain, quality, business development, and operations.

Dr. Tyle earned his doctorate in pharmaceuticals and pharmaceutical chemistry from the Ohio State University and his bachelor of pharmacy degree (First Class with Honors) at the Indian Institute of Technology, Banaras Hindu University in India.

**Q: Can you describe some of the attributes that contribute to the success of Osmotica?**

*A: The attributes that are of utmost importance to Osmotica's success are a highly valuable delivery system technology and a highly talented team. Our technology is quite robust and tested in the market place with several products currently in the market. The success of Osmotica in technology is due to the high caliber talent and personnel recruited to the company. The company's small size requires us to be very efficient in our efforts and work smarter than our competitors and big pharma. We do not have the budgets of big pharma, and as a result we have to reduce the risks of development projects to increase the probability of success. We accomplish this goal through the talent at the company in Argentina, Hungary and in the United States.*

**Q: Are there any new developments that Osmotica is currently working on that you can share?**

*The Osmodex drug delivery technology is ideally suited for inclusion of multiple drug actives in a single drug delivery platform. Oncology, Cerebral Nervous System (CNS) and psychiatry treatments are therapeutic areas that commonly involve polypharmacy. We are evaluating multiple opportunities that are of high unmet medical need and have the potential to have significant health outcomes benefit. Osmotica is investing heavily in this area for future products. Osmotica realizes that innovation comes in different forms. By focusing on high unmet needs in terms of patients and the end consumer, we can innovate in the realm of dosages and safety.*

**Q: As a global organization, what challenges you are facing in industry? With respect to drug development? Do you anticipate changes in years to come?**

*Change is one of the few certainties in our industry. The challenge for drug development is to address areas of high unmet medical need that also provides value to payers and*

*healthcare authorities. The day of developing undifferentiated therapies without meeting the need of the patient, provider, and payer has ended.*

**Q: What opportunities do you see for GeorgiaBio and the life sciences industry locally?**

*The outlook for the life sciences in Georgia is very bright. With the multiple universities and innovation at those institutions, the opportunities are great to leverage the science and knowledge within the system. Attracting and retaining quality talent is a major concern for life science companies within Georgia.*

## Georgia Bio Announces New Member Benefit: Executive Liability Protection through Aon Risk Solutions

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As a leading life sciences organization it's your mission to drive innovation. As the world's leading risk advisor, it's our mission to empower your mission.

Regardless of your organization's size, location or status as a public or private company, the executive liabilities you face are on the rise. Traditional risks such as directors and officers, employment practices, product liability and clinical trial risk have been joined by new threats such as privacy breach and cyber-crime. At the same time, increased regulation adds a new level of complexity and risk, especially for life sciences companies.

As the largest insurance broker and risk management advisor in the world, Aon uses its significant expertise and market strength to develop distinctive solutions that meet all your executive liability needs.

BIO and Aon have partnered to bring comprehensive coverage for Executive Liability Insurance programs. Aon has undertaken an extensive request for proposal process to vet and select an elite group of insurers based on their ability to deliver distinctive value to life sciences clients. Through the BIO Executive Liability Protection Panel, Georgia Bio can access and benefit from competitive quotes, utilizing broad Aon-negotiated

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policy language, all designed to enhance program efficiency and effectiveness.

For more information including a complimentary policy review and audit, visit <http://bbs.bio.org/content/aon-risk-solutions>



## Congress Must Protect American Innovators

*By: John J. Castellani, PhRMA*

The U.S. patent system is the critical legal shield protecting medical innovations as they make their way from America's labs to the patients in every state who need, want, and deserve them.

Patents are one reason why U.S HIV/AIDS death rates are down 83 percent from their peak in the early 1990's. They're why cancer death rates are down 20 percent from their peak, and the five-year survival rate for people with all cancers has soared to 68 percent. They're why hepatitis C is now curable in more than 90 percent of treated patients.

Patents are our industry's lifeblood, and our reliance on them as an industry is unique. Because while your smartphone might be protected by hundreds or even thousands of patents, the innovative new medicine you or your loved one take for improved health is usually only protected by a handful of them.

That is why our industry is fighting to protect the integrity of the critical patent system, which will ensure patients can continue to benefit from biopharmaceutical innovation.

We clearly have work to do – and fast.

In Washington right now, Congress is debating new legislation intended to address abusive practices by so-called patent trolls. While its intent is good, certain

provisions in this legislation could have broad, unintended consequences that hurt legitimate patent holders.

These include provisions that would increase requirements imposed on patent owners beginning a patent infringement lawsuit. This change would increase the cost, time and effort required to begin a legitimate patent enforcement action. And it would hamper the ability of legitimate patent owners to stop infringement of their patents and it could undermine the value of patents and the incentives for innovation.

This bill also fails to remedy problems at the Patent and Trademark Office (PTO) relating to a new petition process intended to make it easier for people to challenge patents at the PTO. However, this process is being exploited by predatory hedge funds that short sell the stock of patent-holding companies; challenge those companies' legitimate patents at PTO to "spook" the stock market; then attempt to profit from a resulting dip in the patent-holding company's stock price.

Any patent legislation must stop these abusive practices. In fact, in a recent poll conducted by the Morning Consult, 61 percent of voters said patients with life threatening diseases will have fewer treatment options as a result of these actions. And more than 80 percent think Congress should act to stop them.

Our industry is not alone in its concerns. As of today, 145 American universities, hundreds of businesses and independent investors in innovation have joined in registering their concerns about the bill.

America was born from great inventions, but built on having the wisdom to protect and defend them through a strong patent system. Congress would do well to listen to the growing chorus of concerned American inventors and revise this legislation – now.

John Castellani is President and CEO of the Pharmaceutical Research and Manufacturers of America.



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# Is There a Benefit to Including Long Lists of Side Effects?

By: JoAnna Pendergrass, DVM

When we turn on the TV or read a magazine, we are often inundated with commercials and advertisements promoting a particular drug. Over the years, pharmaceutical companies have increasingly used direct-to-consumer (DTC) marketing to advertise their products to consumers. By now, we have all become very familiar with these commercials and advertisements; how many of us, though, really listen to the long list of adverse side effects in commercials or read the fine print describing a drug's safety profile? And if we do, do we understand the terminology enough to know if the side effects are something that could actually affect us?

To ensure that a drug's risks are disclosed in prescription drug advertising, the Food and Drug Administration (FDA) instituted regulations (21 CFR 202.1) requiring that a drug's side effects be listed included in these advertisements, whether in radio or on TV. This listing is known as the "major statement"—the long list of side effects often read quickly and in a lowered voice; on TV, this is commonly accompanied by a series of positive visual scenes in the background.

However, concerns have been continually raised over whether these side effects listings, which often contain complex medical terminology, are beneficial to the consumer. These mounting concerns led the FDA to begin a study in 2014 involving 1500 participants that evaluates how well consumers understand side effects mentioned in TV ads. At the time of the study announcement, FDA issued this [statement](#): "There is concern that, as currently implemented in DTC ads, the major statement is often too long, which may result in reduced consumer comprehension, minimization of important risk information and, potentially, therapeutic noncompliance due to fear of side effects. At the same time, there is concern that DTC TV ads do not include adequate risk information or leave out important information."

Shortly following the announcement, John Kamp, executive director of the Coalition on Healthcare Communication, [expressed support of the study](#), saying that "...frankly, it seems that consumers are either terrified of risks that may be rare or are no longer even paying attention to the risk disclosures because they have become 'white noise.'" Even more recently, Richard Pazdur, director of the office of hematology and oncology at the FDA, went so far as to mention the long list of side effects in prescription drug ads as "[a waste of time](#)."

Although the FDA has not yet announced when the study will be complete, it has suggested that perhaps only the most serious side effects should be listed in advertisements; the less serious effects would be broadly mentioned as 'potential harms.' With the billions of dollars spent by pharmaceutical companies on DTC marketing, the results of this study could have a major impact on how side effects are listed in prescription drug advertisements for consumers.

Until then, as the commercials often say, "Talk to your doctor."

## "How to Win at the Partnering Game" - An Overview of Biotech and Pharmaceutical Partnering with Facts, Fallacies, and Tips

Biotech companies know the importance of aligning with strategic partners to advance their drug candidates to the market. For the small biotech company, partnering successfully requires knowing how to play the partnering game, from deciding when you should partner, understanding the partnering process both from your perspective and the partner's, clearly defining what it is you want from a deal, having an understanding of alternatives, and then reaching out to a variety of partners in order to find one that best fits your needs.

In this white paper, Linda Pullan provides a review of the rules of the partnering game – from preclinical to late

clinical development – to provide an understanding of what to expect in moving from introductions to negotiations of a license or acquisition and how to win with a clear strategy.

Download the White Paper here: <http://bit.ly/1JE4jsc>



## Swings *fore* STEM - The 1st Annual Georgia BioEd Golf Outing Tuesday, October 20, 2015 Trophy Club of Atlanta

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The 1st Annual Georgia BioEd Institute Golf Tournament will be held at the Trophy Club of Atlanta on October 20<sup>th</sup>. We hope that you will support GaBioEd STEM Programming by coming out and networking with C-Level executives and partners while playing this award-winning course. There will be great food, contests, and an exceptional golf experience. This event will surely sell-out, so reserve your spot today! Details coming soon to [www.georgiabioed.org](http://www.georgiabioed.org) Questions? Contact Jennifer Kauffman, GaBioEd Development Director at [Jennifer.Kauffman@gabio.org](mailto:Jennifer.Kauffman@gabio.org).

## Getting Ahead in Biotech: 3 Skills for Success

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*By: Melissa Nikolic, Director of Programming, Georgia BioEd Institute*

It is important to continuously hone your skills, regardless of which career you find yourself in. Pertaining to the field of biotech, here are 3 skills (courtesy of [BioSpace](http://BioSpace)) that will give you a few more goals to work towards.

### 1) Excellent Communication Skills

To sum this skill up, be concise. As a professor, it's my job to dig into a subject and explain it to students with various learning styles. However, I have to turn that off at Georgia Bio. I need to summarize the issue under consideration and outline key next steps succinctly.

You can practice your verbal communication skills with the 30-second elevator pitch. If you can distill any project into 30 seconds, then you are good to go. Networking events are great ways to practice this skill and take notes on who does it well and who doesn't. You can simply ask people, "What do you do?" Some jobs are easy to describe, such as "I'm a patent lawyer." For jobs with quick descriptions, you can follow that up with, "Tell me about a cool patent that you recently worked on." That takes a little more effort.

The general rule of thumb is that the higher up in the organization an individual is, the more summarized their job description should be: 1 page for a manager, summary for an executive, and a cartoon for the president.

### 2) Flexibility

To say that biotech is dynamic is somewhat of an understatement. The reality is that there are big rewards in biotech, but those rewards are commensurate with the risks. You have to position yourself as the person who has the knowledge and skills to execute projects, and the ability to quickly adapt, amidst the uncertainty of a difficult regulatory environment; it is the nature of the game. For those who excel, they are able to combine a proactive personality with strong communication skills and adaptability to overcome those inevitable bumps in the road relatively unscathed.

You should be proactive in taking risks that present themselves in the biotech industry, but make sure that those risks are calculated; uncertainty is always at play, and it's possible that you will make mistakes when taking those risks. However, keeping chaos at bay and remaining flexible will always give you that edge to know when to make the right move.

Like with any other skill, flexibility can be learned. Do something, within limits, that makes you uncomfortable: speak up during a meeting;

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join Toastmasters International to improve your public speaking; volunteer in a new role at work. Pushing yourself is the key to flexibility.

### 3) Team Player

Without strong communication skills and flexibility, you may struggle with the reality that science is no longer a solitary activity. You will be working with your own team and likely a business unit representative, HR director and someone from marketing, not to mention your direct supervisor; this is just within your own company. Firms are becoming more focused around business imperatives that cross typical job functions. Silos beget individuals, but teams open up new possibilities and greater collaboration opportunities.

I recently read something very interesting about a company that was looking for employees: they valued competitive skills to the extent that they specifically asked for individuals who had played competitive sports or were in the military. I could only surmise by these requirements that those with the discipline to go for the win as a team, rather than as an individual, were the kind of employees that this company wanted.

Don't fret if you didn't play volleyball in high school. I'm sure you will be fine. Nonetheless, the take home message is that you will be expected to work as a team within your company.

Practice these 3 skills by joining the [Emerging Leaders Network](#) as a student or emerging professional; if you are a seasoned professional, you can volunteer with ELN.

## Georgia Bio's Purchasing Program: Enhanced Member Benefits, Saving Money and Time, Helping You Help Patients

Through [Georgia Bio's Purchasing Program](#), our members have access to programs and services negotiated by Georgia Bio and BIO, offered at favorable rates and terms to save your company money. Through our affiliation with BIO, Georgia Bio is part of the largest

cost-savings program for the life science industry with the purchasing power of over 2,800 biotech companies. Our group discounts are for members only and your membership is the gateway to this purchasing power to save your company critical resources.

For more information on how you can sign up for these member discounts and save your working capital, contact Angela King, Member Services Manager, at [angela.king@gabio.org](mailto:angela.king@gabio.org).



## Welcome to Our Newest Members

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[T3 Labs](#)

[Biogen](#)

[World Courier Inc.](#)

[UMBRA Global](#)

[EmergenceGMA, Inc.](#)

[Validation & Engineering Group USA, Inc.](#)

Randy Howard, LLC

Annular Biotechnology LLC

[Horizon Pharma](#)

[HERA Laboratory Planners](#)

Immeedx, LLC

[Silicon Valley Bank](#)

Conceptus Consulting, LLC

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## GaBio Lauches New Career Center with JobTarget!

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Georgia Bio is proud to launch the new Georgia Bio Career Center in partnership with JobTarget. Our hope is that this new resource will not only make a significant difference for our members as they navigate their career paths, but also eventually become the resource for life science jobs in Georgia.

Learn more at <http://jobs.gabio.org/home/>

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!



## Upcoming Events

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### [Small Dinner Series w/ Dr. Tom Barrows of Cell Constructs](#)

July 16, 2015

### [SEMDA Quarterly Meeting and Summer Social](#)

July 22, 2015

### [Biotech 101 – Applied STEM \(For high school science teachers.\)](#)

7/24/2015

### [Kauffman FastTrac® TechVenture™ Entrepreneur Training Course](#)

The course will be given in 6 full-day sessions (8:30am - 4:30pm) over 7 weeks. August 2015 (20th & 27th) / September 2015 (10th, 17th & 24th) / October 2015 (1st)

### [Collaborative Care Summit/ ACO West](#)

August 20-21, 2015

### [Stem Cells & Regenerative Medicine Congress USA](#)

September 2-3, 2015

### [Industry Tour: AKESOgen](#)

September 9, 2015

### [AdvaMed 2015](#)

October 5-7, 2015



### [Georgia Bio Innovation Summit 2015:](#)

### [Health Transformed](#)

November 2, 2015

### [2015 HIT Leadership Summit](#)

November 3, 2015

### [Southeast BIO Investor & Partnering Forum](#)

November 11-13, 2015



### [Biolatam® 2015](#)

November 16-17, 2015

### [2015 World Stem Cell Summit](#)

Atlanta, GA | December 10-12, 2015

### [2015 RegMed Capital Conference \(RMCC\)](#)

Atlanta, GA | December 10-12, 2015

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## Better CRO Connections and Improved CRO Relationship Management

### BENEFITS FOR BIOPHARMAS

Explore a network of strong service providers.

Quickly identify experts and organizations for upcoming projects.

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### SOURCE

### EVALUATE

### MANAGE

### BENEFITS FOR CONTRACT VENDORS

Raise awareness of your organization, services and expertise.

Be recognized for the quality and scope of your service offerings.

Eliminate administrative barriers and start more conversations with experts.

Come see us at the BIO membership booth in the Business Forum, or visit us online at [biobizlink.com](http://biobizlink.com)



12th Annual

# World Congress on Industrial Biotechnology

*linking biotechnology, chemistry + agriculture to create new value chains*

July 19-22, 2015  
Montréal





## Latin America Conference

October 14-16, 2015  
Rio de Janeiro, Brazil

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