



THE LIFE SCIENCES VOICE

The Georgia Bio Industry E-Newsletter

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National Life Sciences Partners



Letter from the President



Can you hear it? There is a renewed buzz in the air around our industry in Georgia. I am encouraged to see public officials, support organizations and service providers all coming together to better serve life sciences in our state. I expect some significant announcements in the coming months that will boost our momentum, and I welcome you to join me in the effort by getting involved with our [committees](#), [networks](#) and [events](#). A few highlights:

Member Benefits

Your membership includes new benefits, such as our [discount purchasing agreements](#) with UPS, ALT refurbished laboratory equipment, and Illumina gene sequencing solutions. Our members are saving thousands of dollars on their everyday purchases and I hope you are taking advantage of these opportunities.

Policy & Advocacy

We completed this year's legislative session with strong interest from policymakers to help our growing companies. Join us in the conversation at our Policy & Advocacy Committee so we can encourage new legislation to fuel that growth. And we continue to push for strong funding at NIH and FDA to ensure our competitiveness in healthcare innovation.

Georgia Bio Innovation Summit

Our Summit Committee, led by Lee Herron at the Georgia Research Alliance, has some exciting new features to announce for this year's conference, including: **Executive Workshops** designed for discussion and networking around function-specific topics; Enhanced **CEO Chats** to bring you "From the Trenches" stories and advice for corporate growth & fundraising; [Company Investor Pitches](#) for early and mid-stage companies, including tailored mentoring in the months prior to the Summit; A more visible and enhanced **Innovation Stage** featuring discoveries with potential for commercialization and critiques from industry experts. Be on the lookout for keynote announcements and the launch of online registration.

Our [Call for Sessions](#) and [Investor Pitch Application](#) forms are open for another couple of weeks, so please do submit your ideas for content. And we are seeking additional sponsors and exhibitors, so [sign up](#) today to lock in your spot and maximize your visibility to the Summit audience. We look forward to your participation!

Have a great summer,

Russell



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Is Your App Considered a Medical Device?

Grace Powers, MS, MBA, RAC

There are more than two million apps available in the iTunes store. A few clicks on my computer show that there are thousands under the medical category. The top-paid app in this category is a fetal heartbeat monitor that finds the baby's heartbeat from the microphone feature on an iPhone. Another app is a vein finder that uses the flashlight and camera to find veins that would "otherwise be invisible to the naked eye." One of these apps notes that they are not intended for the diagnosis or treatment of disease.

Is your app considered a medical device in the United States? This is a hot topic among anyone with a medical-related app. The answer is not always clear, but it starts with the FDA's definition of a medical device. The applicable portion of the definition for a mobile application is:

An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease.

The question for apps is: Does the app diagnosis, cure, mitigate, treat, or prevent disease? In February 2015, the FDA posted a [44-page guidance document](#) with extensive information regarding this very topic. Per usual, the FDA starts with definitions regarding the guidance including mobile platforms, apps, and mobile medical apps. A mobile medical application is defined as:

a mobile app that is either is intended: to be used as an accessory to a regulated medical device; or to transform a mobile platform into a regulated medical device.

The document lists dozens of examples of apps and if they would be considered medical devices. An important section in the guidance is called "Subset of mobile apps that are the focus of the FDA's regulatory oversight." This section discusses apps that would be considered medical devices that include the following categories:

1. Mobile apps that are an extension of one or more medical devices by connecting to such device(s) for purposes of controlling the device(s) or for use in active patient monitoring or analyzing medical device data. An example is an app that provides the ability to control inflation and deflation of a blood pressure cuff.

2. Mobile apps that transform the mobile platform into a regulated medical device by using attachments, display screens, or sensors or by including functionalities similar to those of currently regulated medical devices. These apps are required to comply with the device classification associated with the transformed platform. An example is a mobile platform for creating an electronic stethoscope function that is considered to transform the mobile platform into an electronic stethoscope.

3. Mobile apps that become a regulated medical device (software) by performing patient-specific analysis and providing patient-specific diagnosis or treatment recommendations. These types of mobile medical apps are similar to or perform the same function as those types of software devices that have been previously cleared or approved. An example is an app that use patient-specific parameters and calculate dosage or create a dosage plan for radiation therapy.

Some of the medical apps that the FDA does not intend to enforce requirements include:

- Help patients (i.e., users) self-manage their disease or conditions without providing specific treatment or treatment suggestions;
- Provide patients with simple tools to organize and track their health information;
- Provide easy access to information related to patients' health conditions or treatments;
- Help patients document, show, or communicate potential medical conditions to health care providers;
- Automate simple tasks for health care providers;
- Personal Health Record (PHR) or Electronic Health Record (EHR) systems; or
- Intended to transfer, store, convert format, and display medical device data in its original format from a medical device (as defined by MDDS regulations).

In July 2016, the FDA published another guidance document that discusses [general wellness](#) devices that promote a healthy lifestyle. Some products that fall in this category are apps to track dietary intake, apps that play music to help reduce stress, apps to track heart rate for exercise, etc.

So, is your app a medical device? A common approach is to ensure that the app is completely clear of diagnosing any specific medical condition or disease. Understanding the guidance documents is also key. If there is uncertainty about your device status, one should check with a professional before marketing their product.

UGA Awarded Innovation Corps Site Status

Allyson Mann, University of Georgia

The University of Georgia has been named an Innovation Corps Site by the National Science Foundation, enhancing UGA's ability to turn ideas and research discoveries into commercially viable products or services by providing early evaluation of projects through a customer discovery process.

The I-Corps award will enable UGA to serve up to 30 new startup projects a year, adding to the university's rapidly growing entrepreneurial ecosystem and assisting the campus-wide collaboration focused on helping all entrepreneurial projects move to the marketplace.

Innovation Gateway, the university's arm for translating research discoveries into products and companies, will serve as the hub for I-Corps UGA, but collaborators will include UGA's Entrepreneurship Program, College of Engineering and numerous faculty and staff across campus.

"The hardest steps in creating a startup are at the beginning," said Ian Biggs, senior associate director of UGA's Innovation Gateway and the program's lead. "Becoming an I-Corps Site will allow us to provide more robust services, including financial resources. We'll be able to help anyone with an entrepreneurial idea that needs testing in the marketplace. This also builds on the recent \$500,000 award from the Department of Commerce to create a prototyping center focused on engineering and materials science."

UGA is one of 50-plus I-Corps Sites, programs that are based at academic institutions to catalyze the engagement of multiple local teams in technology transition and innovation. Ideas or projects supported by I-Corps Sites must be focused in an area of science, technology, engineering or mathematics, but can originate from faculty research, student work, industrial projects or ideas from the community.

The award provides funding that will help teams—of faculty, students, staff and others—better evaluate their ideas, improve risk assessment and define success earlier. Having access to NSF resources will allow the teams to conduct in-depth analyses, leading to more reliable outcomes, and will be particularly helpful to projects from the College of Engineering and the New Materials Institute.



Ian Biggs is the senior associate director of UGA's Innovation Gateway and the head of UGA's I-Corps Site. (Credit: Amy Ware)

The award provides up to \$100,000 annually for five years, enabling support for 30 teams working on commercialization projects that show potential for transition to the marketplace.

I-Corps Sites provide resources to individuals and teams in the form of space, seed funding, entrepreneurial mentoring, curriculum or other needed assets. For three months, the program contributes up to \$3,000 total per team that can be used to create a prototype or minimum viable product, travel to consult with potential clients or experts, and to seek training or education.

"The I-Corps award adds to the tools in UGA's expanding entrepreneurial landscape, which includes collaborations across campus and the region," said UGA Vice President for Research David Lee. "Teams of faculty and students will be able to explore their ideas from product development through customer discovery, learning about entrepreneurship and how to transit their ideas, devices, processes or other intellectual activities into the marketplace."

Since 1978, over 600 products and 150 startup companies have originated from UGA faculty and students. These entrepreneurial efforts, ranging from smart coatings to pharmaceuticals to peanuts, reflect the diversity of UGA's research engine. In the last year, Innovation Gateway has increased the number of startup projects in its pipeline by 40 percent.

According to the most recent data from the Association of University Technology Managers, UGA ranks among the top five U.S. universities for new products reaching the market for the third consecutive year; among the top 10 U.S. universities for total licenses, option agreements executed and active licenses for the ninth consecutive year; and among the top 20 U.S. public universities in licensing revenue for the 12th consecutive year.

Making Science Understandable to the Public

JoAnna Pendergrass, DVM



When you've spent a significant amount of time in the life sciences—in school and in the workplace—it can be easy to lose sight of just how complicated science can be, especially to someone without a scientific background. No matter how exciting a particular scientific research finding may be, that excitement could get lost in the shuffle of scientific and technical jargon.

The sheer volume of scientific information now available to the general public seems like a good thing. However, if that information is not written well, it could leave the reader confused and possibly even discouraged from continuing to read and learn about a particular scientific topic. When time is taken to craft well-written scientific content, though, a reader can feel not only more informed about scientific advancements, but also encouraged to learn more about how science applies to their daily lives.

So, who can fill this important role of making complex scientific topics more understandable and applicable to the general public? Medical writers!

Medical writers work in a wide variety of scientific arenas, including medical education and big pharma. News outlets also employ medical writers and task them with disseminating important health- and medicine-related news to the general public; these writers are often challenged with making science understandable without losing the 'spirit' or accuracy of the science. This is particularly important in the life sciences, where life-changing advancements in such areas as medical device development and drug development can be quite complex.

Many medical writers have scientific training and come from clinical or research backgrounds, enabling them to navigate across various scientific concepts with a relative amount of ease.

Overall, a medical writer is equipped with the scientific knowledge and writing skills to turn a complicated scientific concept into something that is informative, engaging, and easy to understand.

If your company has a need for a medical writer, visit the ['Employer Resources'](#) section of the American Medical

Writers Association website. If you are interested in becoming a medical writer, AMWA has a ['New Medical Writer Toolkit'](#) to help get you started.

Dr. JoAnna Pendergrass is the founder and owner of [JPen Communications](#), a medical communications company.

The 2016 Halo Report on Angel Investing Indicates Robust Angel Investment Activity in Southeast Region

Stephen MacDonald, Ph.D., MBA, Bio/Med Investor Network

Last month was the Angel Capital Association (ACA) annual meeting in San Francisco that attracted angel investors and managing directors from all over the world. It being my first ACA meeting, I was impressed by the attendance, the education and training, the networking and general community within the ACA and between its members. It is certainly a "must do" event for experienced or nascent angel investors at some point on their path. Additionally, each annual ACA meeting sees the release of "The Halo Report" prepared each year by the ACA's sister organization The Angel Resource Institute (ARI).

The Halo Report presents aggregate data on angel deal flow in the United States and presents the findings divided by region, industry and also demographic information on angel deal financing.

The Southeastern region, which includes the states south of Indiana and Ohio and east of Texas, took second place nationally, with 12% of angel-backed deals identified. (California stands alone in the study and took the number one spot with 30% of total deals surveyed). Syndication continues to be a tool used by angel groups to complete a round of financing. In the southeast, median angel group investment was approximately \$125,000 with a median round size of \$775,000 across all industries surveyed. These numbers are only slightly lower than the national average of \$127,000 and \$950,000 respectively. When broken down by industry, healthcare investment (which is the industry served by the Bio/Med Network) made up 16.2% of 2016 angel deals in the southeast region.

The report identified an interesting trend for the financing vehicle. In the southeast region specifically, 55% of 2016 deals were structured with preferred stock and 33% by convertible notes, which approximates national average. However, deals in California bucked the trend

with 36% of deals financed by preferred stock and 44% by convertible notes. The report indicates that convertible notes are being used more by angel investors on first-time investments in new portfolio companies and speculates that this increase is due to lower valuations or inability of investors and entrepreneurs to determine the right pre-money valuation of an opportunity.

As the Bio/Med Investor Network continues to attract new investors and companies through 2017, the national angel data will provide additional insight for Bio/Med Network activities that will be reported for the 2017 Halo Report to be released at the next ACA meeting in Boston in 2018.

The 2016 Halo Report can be downloaded at: <http://angelresourceinstitute.org/index.php>



GaBio Members Can Start Saving with Illumina Today!

We are excited to announce that Georgia Bio is now offering its members a program through Illumina for gene sequencing solutions that can offer substantial savings to first time Illumina customers. Illumina technology is responsible for generating more than 90%

illumina[®] of the world's sequencing data. Through collaborative innovation, Illumina is fueling groundbreaking advancements in oncology, reproductive health, genetic disease, microbiology, agriculture, forensic science, and beyond. This savings program, through BIO Business Solutions®, is the result of collaboration between Georgia Bio and the Biotechnology Innovation Organization (BIO), the world's largest biotechnology trade association.

For more information about the program and a full list of benefits, please visit www.bbs.bio.org/content/illumina.

Innovation from concept to Commercialization: Our SEMDA 2017 Takeaways

Jason Rupp, SEMDA

At this time last year we were in full 'go mode' for SEMDA 2016 in Nashville, the flagship event's first foray outside of metro Atlanta. Amazingly SEMDA 2017 is already in the rear view mirror. As we put the program and the people together, we knew we had something special and everyone delivered. We hope your experience at SEMDA 2017 was of high value and that you will continue to use us as a resource for connectivity within the Southeastern medtech ecosystem year round.

For those not able to attend here are a just a few of the event's many highlights: concept to commercialization.

The plenaries and keynotes

Aimee Copeland shared her inspiring story of surviving necrotizing fasciitis, a rare flesh-eating bacteria that took all four of her limbs – both arms below the elbow, her right leg below the knee, and her left leg almost to her hip. Her words struck a chord with every person in the room: physicians, innovators, investors and health-care professionals alike. She provided us a glimpse into the patient's point of view. Her story served as a vivid reminder as to why we continue to innovate- to better patients' experience and save lives. When learning how to tie her hair into a ponytail, Aimee shared, it took her over 200 tries. She attempted a different strategy on try 201 and she got it.

"If I would have given up when I was frustrated during my 100th try I would have never figured it out," Aimee said. "If I 'won't' do something, it's because I don't want to. If my will is fully in it, any goal is accomplishable. And if you don't get it, you probably didn't want it bad enough."

Regarding the patient experience, Aimee said, "People like to talk about themselves. All you have to do is ask them: in person, with no ego. Ask the about the experience, not the device. Bring the conversation down to everyday life for device improvement. Make it more open ended and you might [learn something] you didn't expect. If you ask something too specific you might miss out on something of high value."

Thank you, Aimee. We are grateful you shared your story with us.

Don Turner, Global Head, Commercialization, IBM Watson Health spoke during lunch on day one of SEMDA 2017. He focused on cognitive systems, their impact on the future of healthcare and how innovation must be a collaborative effort. Engineers and developers must

be creating and meeting clinical needs with the end user in mind- the physicians. He provided a valuable perspective on medtech innovation, especially for the early stage medical device companies, entrepreneurs, and physician innovators.

Dr. William E. "Billy" Cohn, VP for Johnson & Johnson Medical Devices Companies and the Director of the new Center for Device Innovation at the Texas Medical Center in Houston really blew us all away! I am not sure if anyone was expecting to receive a complete timeline of the development of the artificial heart, but that is exactly what he gave us. The point? Innovation is a process that can sometimes take decades and definitely takes a village. The first practical and total artificial heart is on the horizon after thousands of hours of research, hundreds of large animal studies, and all of the devices that have preceded current technologies in use and the continual advancements that follow on decades of innovation.

The politics of innovation

On day 2 of SEMDA, GCMI and T3 Labs CEO, Tiffany Wilson took the main stage to lead the panel "The Politics of Innovation." She curated a power packed panel featuring Craig Buerstatte, Director, Office of Innovation & Entrepreneurship for the US Department of Commerce, Russ Lipari, Founder & CEO of Health Connect South, and Ashley Wittorf, Executive Director & Sr. Vice President of AdvaMed Accel. The four discussed the current political landscape and how it influences investment in innovation in the US medtech industry.

The takeaways were many but to highlight a few...

- Cuts to NIH are not likely but other cuts may happen so get involved and engage the organizations that communicate to Congress to ensure innovation is funded.
- FDA operates on a pendulum- right now it is more collaborative. We hear often from the FDA "please come and talk to us."
- State representatives do not know what you need until you tell them. If they are going to advocate for you they need to know why. Make sure to be succinct with why what you do matters. Know your audience.

Insights from SEMDA breakout sessions led by industry leaders

- In the session "Immigration Compliance for Employers: Practical Advice for Uncertain Times" one piece of knowledge that definitely stood out was that over-compliance (having your employee provide more than the required identification documents) when submitting I-9 forms is actually not compliant.
- Startups and physician innovators, alike, received practical advice from Baker Hostetler and DePuy Synthes during the session "IP Protection Strategies for Emerging Medical Device Companies." The takeaways? Make sure you are aware of what you actually own with your IP and narrow your claims when filing patents- knowing that your claims can be amended and even added, provided of course the initial disclosure is broad enough to cover the added or amended claim. Expand your patent claims in the United States before investing in multiple international patents. For example, unless

you are manufacturing in Sri Lanka, then you shouldn't spend the dollars to obtain a patent there.

- Large companies are not immune to data security hacks and are in some cases more of a target than smaller firms. During the session "The Pacemaker Hack: Unpacking Risk Scenarios for Integrated Medical Devices" it was stressed that data breach is an issue for everyone- not just the IT team. The panel did point out, though, that the FDA has recently stepped up its efforts to combat the hacking of medical devices.
- During the session "Beyond the press release: Integrated marketing strategies for medtech and med device," we learned from each level of the organization that PR isn't something that you can just hand off to an agency- as a medical device company you need to stay hands on and be the eyes and ears of your product users, patients, and sponsors. For marketing efforts to prove successful there should be engagement from the C-suite through to the program directors.

So many thank yous

At the risk of missing someone, I would like to extend a heartfelt thank you to our outgoing Chair, Chris Lyons, Conference Chair Neely Carlton, Conference Programming Chair Kornelius Bankston, and Rob Natowitz for their conference program and PitchRounds Road Show leadership. A special thanks to Colette Inomata for her tireless work on behalf of the organization as a whole. Finally, thank you to all of our sponsors and producers without which none of this is possible.

Congratulations Patientory!

After scouring the Southeast during our six-stop PitchRounds Road Shows, 21 medtech startup and early growth stage companies met with investors and pitched their businesses to 19 investors, corporate development professionals, and industry experts at SEMDA 2017. When the dust settled, Chrissa McFarlane, founder and CEO of healthcare blockchain solution provider [Patientory](#), walked away with \$10,000 and a slot to present at AdvaMed 2017.

Congratulations Chrissa and crew! Good luck at AdvaMed!

Stay involved year round

SEMDA does not take a hiatus after the annual conference. Stay involved and learn more about the resources available to medical device innovators by engaging SEMDA. One thing is for sure, we are already counting down the days until #SEMDA2018 in Greenville, South Carolina! In the meantime, follow SEMDA on [LinkedIn](#) and [Twitter](#) for the latest.

What did you think? How was your SEMDA 2017 experience? What would you like to see more of? How can we increase the value of your experience in future editions? Email admin@semda.net



Upcoming Events

Bench to Business: Session 1
[June 16, 2017](#)

BIO International Convention
[June 19-22, 2017](#)

RESI San Diego 2017
[June 19, 2017](#)

Bench to Business: Session 2
[July 14, 2017](#)

KSU's 24-Hour Lab Safety Boot Camp
[August 7-10, 2017](#)

Bench to Business: Session 3
[August 11, 2017](#)

Bench to Business: Session 4
[September 8, 2017](#)

BioPharm America 2017
[September 26-27, 2017](#)

Bench to Business: Session 5
[September 29, 2017](#)

World Vaccine Congress
[October 10-12, 2017](#)

Georgia Bio Innovation Summit & Casino Night
[October 24, 2017](#)

BIO-Europe 2017
[November 6-8, 2017](#)

World Orphan Drug Congress Europe
[November 13-15, 2017](#)

SEBIO Investor & Partnering Forum
[November 14-16, 2017](#)

Featured New Member: **IHRC, Inc.**

IHRC, Inc. is an international consulting and professional services corporation, located in Atlanta, Georgia, USA. IHRC is a minority woman-owned small business and participates in the 8(a) business development program of the U.S. Small Business Administration. We assist our clients in accomplishing their missions and objectives in a timely and cost-effective manner, and we strive to exceed our clients' expectations.



Science comprises the core of IHRC, and the foundation upon which our broader capabilities are built. Our key executives have extensive experience in science and research, information management, program management, strategic planning, and other areas. Members of our executive management team were integral to the development and implementation of PulseNet, a global laboratory surveillance network dedicated to the rapid recognition of infectious disease outbreaks, now in its 20th year of operation.

IHRC's largest client is the US Centers for Disease Control and Prevention (CDC). We serve CDC's mission by providing expertise in areas including, but not limited to, bioinformatics, epidemiology, health communications, information management, laboratory science and research, mathematical modeling, and statistics.

[Learn more here.](#)

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