



**T E X A S**  
Medical Device Alliance



BioAustin | Texas Medical Device Alliance | Austin Health Tech  
**NEWSLETTER**  
**APRIL 2018**

Greetings friends and colleagues! We're excited to share this month's news and updates with you, but first we want to **thank our readers and participants** as we enter the **seventh year of this collaborative newsletter effort**. Thanks to at least a dozen people who pitch in throughout the year, we have the privilege of **servicing over 1,300 recipients each month!** We are committed to informing—and making a difference to — the life sciences and health technology community in Austin and Central Texas.

And as always, if you have more news, job postings, or resources to share, please reach out to Elisa Maldonado-Holmertz ([elisa@texmda.org](mailto:elisa@texmda.org)).

## INDUSTRY NEWS

### **Capital City Innovation Is Delighted to Partner With Impact Hub Austin On Their Workforce Development Accelerator**

Capital City Innovation (CCI), the organization behind Austin's new Innovation District, is teaming with co-working innovator Impact Hub Austin to source solutions for workforce development. Impact Hub Austin's Workforce Development Accelerator is collaborative in its design and welcomes participation from government, tech companies, large employers, nonprofits, and any person or group who has a good idea for workforce development.

The Workforce Development Accelerator will hone in on three industries with projected significant job growth: healthcare, IT, and advanced manufacturing. The decision to focus on these industries is based on thousands of hours of research, which resulted in the Workforce Solutions Capital Area 10-year Workforce Master Plan.

The Accelerator is also gathering support from Austin's elected leadership, including the Mayor of Austin, Steve Adler. "Austin creates more middle-skill jobs than any other city in the country but we don't match the people living here to those jobs," said Mayor Adler. "This is a huge opportunity for Austin, and I love that Impact Hub Austin is creating platforms for collaborative work around solutions."

<http://campaign.r20.constantcontact.com/render?m=1102243211937&ca=58f44817-f1e9-412a-960a-86a08aa4ef67>

## **Health And Life Science Startup Affinity Group**

Austin Community College (ACC) Bioscience Incubator hosted its second Health and Life Science Startup Affinity Group meeting on February 13. The meeting included representatives from Austin Community College, Austin Technology Incubator, Dell Medical School Health CoLab, Drug Dynamics Institute at UT Austin, Texas Life Science Collaboration Center in Georgetown, and Texas State University's STAR Park. The group is currently focused on common messaging, collecting and sharing common metrics of performance, and representing one another at conferences and events.

There is a great deal of interest in forming a working group focused on international business attraction. Steve Frayser from STAR Park is taking the lead on the working group, which will work with the City Economic Development Office, the Austin Chamber of Commerce, and others.

<https://www.capitalcityinnovation.org/for-companies>

## **ACC Bioscience Incubator Partners With Macromoltek And Receives SBIR Grant**

Austin Community College (ACC) Bioscience Incubator and local biotech company Macromoltek were awarded a supplement grant through NSF's SBIR (Small Business Innovation Research) Program. The SBIR grant funds an ACC Bioscience Incubator lab bench for a Macromoltek scientist for 6 months, and also funds two ACC student interns to work with the scientist.

ACC Bioscience Incubator hopes to pursue SBIR funding with eligible companies in the future.

<http://sites.austincc.edu/incubator/acc-bioscience-incubator-partners-with-macromoltek-and-receives-sbir-grant/>

## **BioAustin Presents Awards at Austin Energy Regional Science Festival**

- First Place: **Megan Cantwell**  
Project: Social Skills in Adolescents with Cochlear Implants
- Second Place: **Xiao Zhou**  
Project: Multiple Sclerosis and Epilepsy: Insights Into a Potential Therapy Through the Role of Mutation T1244C of Theiler's Murine Encephalomyelitis Virus (TMEV) in Reducing Virulence
- Third Place: **Mohammed Oza**  
Project: Effect of Temperature on Stem Cell Regeneration

If you're interested in participating as a Science Festival judge in the future, please contact Scott Collins: [scott@bioaustin.com](mailto:scott@bioaustin.com)

## **AI's Marketing Problem: Inflated Claims, Outsized Expectations May Actually Be Slowing AI's Move Into Clinical Practice**

Pharma companies such as GlaxoSmithKline are using AI (Artificial Intelligence) technology to accelerate drug discovery, wearables startups are using AI to identify biometric warning signs, and a range of companies, Johnson & Johnson among them, are collecting and mining patient data to build more effective virtual coaching platforms.

These concrete applications are often lacking in discussions of AI's impact on the industry. Instead, AI technology is regularly painted in broad, forward-looking strokes. "I have no doubt that sophisticated learning and AI algorithms will find a place in health care over the coming years," data scientist Andy Schuetz recently told VentureBeat. "I don't know if it's two years or

ten — but it's coming.” AI is a powerful tool but not a “magical oracle that will solve all our problems,” he said. “A hammer won't build a house for us, but it's a heck of a lot easier to build a house with one than without.”

<https://tinyurl.com/ycp3say8>

### **FDA Considers Shift On Device Quality System Regulations**

Stephanie Caccamo, a press officer for the US Food and Drug Administration (FDA) told *Focus* that “With the publishing of the 13485:2016 revision, there has been industry evaluation of the regulatory requirement linkages to the standard. In the spirit of global harmonization of quality management systems, the FDA is considering an evaluation/mapping of the 13485 clauses to the appropriate U.S. regulatory requirements.” So when is this evaluation or mapping going to occur? Caccamo said, “We cannot speculate on timing.”

[https://www.raps.org/news-and-articles/news-articles/2018/2/fda-considers-a-shift-on-device-quality-system-reg?utm\\_source=Email&utm\\_medium=Informz&utm\\_campaign=Weekly-Update&zs=sNlxE1&zl=QgJK4](https://www.raps.org/news-and-articles/news-articles/2018/2/fda-considers-a-shift-on-device-quality-system-reg?utm_source=Email&utm_medium=Informz&utm_campaign=Weekly-Update&zs=sNlxE1&zl=QgJK4)

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## **UPCOMING EVENTS**

THURSDAY, March 29th, 3:00 - 4:30pm, Austin TX

### **Texas Health CoLab Monthly Learning Series**

Intellectual Property: More than patents, a foundation for an organization's value and security.

Guest speaker: Trevor Lind from Lee & Hayes (FREE)

<https://www.eventbrite.com/e/texas-health-colabs-monthly-learning-series-intellectual-property-tickets-44369818321>

THURSDAY, March 29th, 7:00-10:00pm, Austin TX

### **Healthcare Informatics Framework Success Stories**

<https://www.meetup.com/Healthcare-Predictive-Analytics-Meetup/events/237054017/>

WEDNESDAY, April 4th

### **DEADLINE: Growing Your Startup from the Ground Up Pitch Competition Application**

<https://events.r20.constantcontact.com/register/eventReg?oeidk=a07ef7y9eoz00d55403&oseq=&c=&ch=>

TUESDAY, April 10<sup>th</sup>, 7:30am – 9:30am, Round Rock, TX

WEDNESDAY, April 25<sup>th</sup>, 7:30am – 9:30am, Round Rock, TX

### **Payments Education - Interchange/Merchant Services Explained (FREE)**

EPMG Advisor's Payments Education for Small Business is an overview on the management of electronic payments (cards, ACH and the like) from the merchants' perspective and education on the industry. We briefly cover the fundamentals as well as innovations in payments. Over 1,000 merchants have attended our workshops - join them!

April 10<sup>th</sup> workshop:

<https://www.eventbrite.com/e/payments-education-interchangemerchant-services-explained-tickets-43859305363>

April 25<sup>th</sup> workshop:

<https://www.eventbrite.com/e/payments-education-implementing-a-security-awareness-program-for-small-businesses-tickets-43860279276>

WEDNESDAY, April 11, Houston, TX

**Healthcare Think Tank Meeting (FREE)**

Featured Speaker: James T Willerson, MD, President Emeritus, Texas Heart Institute.

<https://healthcarethinktank.org/members/meetings/>

WEDNESDAY, April 11, 8am – 4:15pm, Austin, TX

**Internet Marketing Course At Local University (TICKETED)**

Join this crash course in Internet Marketing to learn how your business can use the Internet to get more customers.

<https://localuaustrin.com/>

WEDNESDAY, April 18<sup>th</sup>, 7:45am – 9:30am, Austin, TX

**Health Tech Breakfast At The Capital Factory: “Blockchain Health Care” (FREE)**

Health Tech Austin (HTA) is a gathering of Health Tech Leaders and Influencers from Central Texas and beyond. HTA has monthly networking and educational events.

<https://www.capitalfactory.com/event/health-tech-breakfast-the-capital-factory-copy-2/2018-04-18/>

THURSDAY, April 19, 2-4 pm, Austin, TX

**Texas Medical Device Alliance (TMDA) Quarterly Meeting: Interoperable Medical Devices (FREE)**

The need for plug & play - the ability to easily make a medical device interconnected with other devices has attracted great attention. Interoperable devices with the ability to share information across systems and platforms can reduce errors and adverse events, and encourage innovation. The goal for this discussion is to shed light on what devices are affected, how the FDA views them, and what steps the manufacturer should take to safely and effectively exchange and use information.

<https://www.eventbrite.com/e/texas-medical-device-alliance-tmda-interoperable-medical-devices-tickets-44472349996?aff=es2>

MONDAY-WEDNESDAY, April 23-25, Austin, TX

**2018 Texas Life Science CEO Summit (TICKETED)**

The CEO Summit is THE must attend event for Life Science CEOs in the state of Texas. This is an intimate and exclusive two-day event with an agenda hand crafted by CEOs.

<https://www.eventbrite.com/e/2018-texas-life-science-ceo-summit-tickets-42202745548?aff=es2>

THURSDAY, April 26 7:00 - 10:00pm, Austin TX

**Health and Social Science 101**

<https://www.meetup.com/Healthcare-Informatics/events/244743129/>

THURSDAY, April 26, 3:00 - 4:30pm, Austin TX

**Texas Health CoLab Monthly Learning Series**

Convening to Strengthen the Health Innovation Pipeline.

Chris Laing, Executive Director of Capital City Innovation, and Yash Sabharwal, CEO of CherryCircle Software and NanoMedical Systems, will talk about applying for and managing SBIR grants. Dell Medical School, Health Discover Building, [1701 Trinity Street](#). For more information and future events go to <https://dellmed.utexas.edu/event-topics/texas-health-colab-learning-series>.

THURSDAY, May 3rd, 1pm – 3pm, Austin, TX

**Health Tech Austin: IBM Watson (FREE)**

See a demo of IBM Watson cognitive technology and tour IBMs “aging in place” lab and design thinking studio.

<http://www.healthtechaustin.com/>

FRIDAY, May 4, 7am – 3:45pm, Temple, TX

**Growing Your Startup From The Ground Up (FREE)**

Join Temple Health & Bioscience District's (THBD) annual medical technology conference and pitch competition,

<https://www.eventbrite.com/e/growing-your-startup-from-the-ground-up-annual-medtech-symposium-pitch-competition-tickets-44200548029>

MONDAY - WEDNESDAY, May 7 - 9, Houston, TX

**Japan-Texas Economic Summit by the U.S. - Japan Council (TICKETED)**

An event that will examine the historic trade ties between Japan and Texas and explore business development opportunities between Japanese and Texan businesses.

<https://www.jetro.go.jp/usa/topics/japan-texas-economic-summit-by-the-us-japan-council.html>

TUESDAY, May 8<sup>th</sup>, Austin, TX

**Texas-EU Business Summit (TICKETED)**

In its 7th year, the Texas-EU Business Summit is the premier event for Texas businesses, entrepreneurs and economic development professionals seeking to expand their footprint in Europe. The summit provides Texas businesses, entrepreneurs, policymakers, and target businesses with an overview of trade and expansion business opportunities in Europe, as well as information and connections to make the most of those opportunities.

[https://conferences.la.utexas.edu/texaseusummit/?mc\\_cid=2d743ffc20&mc\\_eid=f5ac326120](https://conferences.la.utexas.edu/texaseusummit/?mc_cid=2d743ffc20&mc_eid=f5ac326120)

SATURDAY, June 9-13, Burlington, VT

**Association of Food and Drug Officials: 122nd AFDO Annual Educational Conference (TICKETED)**

<http://burlington.afdo.org/>

AGENDA:[http://burlington.afdo.org/uploads/1/5/9/4/15948626/2018\\_afdo\\_conference\\_program\\_02.22.18.pdf](http://burlington.afdo.org/uploads/1/5/9/4/15948626/2018_afdo_conference_program_02.22.18.pdf)

THURSDAY-FRIDAY, August 8-9, Austin, TX

**Life Science Women's Conference (TICKETED)**

BioAustin members will be offered an exclusive discounted registration fee of \$995 (regular price is \$1250). Enter the coupon code "TMDA2018" on the website for this event.

<https://lifesciconf.com/>

MONDAY-TUESDAY, August 12-14, Philadelphia, PA

**7th Clinical Trials Inspection Readiness Summit (TICKETED)**

As clinical trials are conducted, inspections ensure quality and integrity of care, data, and drug performance. Clinical trials must be prepared for visits from countless stakeholders over their course. At the 7th Clinical Trials Inspection Readiness Summit, you will learn to improve inspection readiness and trial success through better documentation and operational standards.

<http://exlevents.com/clinical-trials-inspection-readiness-summit/>

TUESDAY, October 2, Austin, TX

**Innotech Austin (TICKETED)**

Speakers and sessions are still being organized, but events will include Women in Tech Summit, DevOps, IT Security Track, and many more. Keep track of this event on the link below.

<http://www.innotechconferences.com/austin/>

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## CAREER CORNER

### **Arsenal Products (Austin, TX)**

- Solidworks CAD Technician  
<https://arsenal-products.careerplug.com/jobs/725469/apps/new>
- Project - Medical Device Automated Tooling  
<https://arsenal-products.careerplug.com/jobs/718779/apps/new>
- Automation Engineer - Mechanical Engineering  
<https://arsenal-products.careerplug.com/jobs/664882/apps/new>
- Principal Product Development Engineer - Medical Devices  
<https://arsenal-products.careerplug.com/jobs/716624/apps/new>

### **Austin Healthcare Companies (Austin, TX)**

- Talent Search via Built in Austin  
<https://www.builtinaustin.com/guides/austin-healthcare-companies>

### **CSA Laboratory Solutions (Austin, TX)**

- Seeking a sales manager to lead sales operations, inbound/outbound lead generation and integrative marketing for life science and healthcare services.

Contact Joe Rettinger, VP, Laboratory Services CSA Laboratory Solutions, Email: [joe.retinger@csa-service.com](mailto:joe.retinger@csa-service.com), Office: 512.732.1210 ext 112, Mobile: 512.775.6754

### **FDAQRC (TX)**

- GCP/GMP Auditor
- GCP/PV Auditor
- Project Manager
- Resource Manager

[https://fdaqrc.com/careers/?utm\\_source=Friends+of+FDAQRC&utm\\_campaign=43300d82ee-EMAIL\\_CAMPAIGN\\_2018\\_03\\_19&utm\\_medium=email&utm\\_term=0\\_3f1bd5c5c0-43300d82ee-121156925](https://fdaqrc.com/careers/?utm_source=Friends+of+FDAQRC&utm_campaign=43300d82ee-EMAIL_CAMPAIGN_2018_03_19&utm_medium=email&utm_term=0_3f1bd5c5c0-43300d82ee-121156925)

### **Globiox (Austin, TX)**

- Regulatory Affairs/Quality Auditing Specialist

<https://www.indeed.com/viewjob?jk=9217d403b6fcb3c&from=myjobs&tk=1c79cu7uuao6k8r1>

### **HCB Health - Marketing Communications (Austin, TX)**

- Project Manager
- Senior Copywriter
- Copy Supervisor

Apply with [myra.bull@hcbhealth.com](mailto:myra.bull@hcbhealth.com)

### **LeadingReach (Austin, TX)**

A referral management and patient engagement platform for the entire healthcare ecosystem.

- Customer Success Specialist
- Market Development Representative
- Senior PHP or Full-Stack Developer

<https://www.builtinaustin.com/company/leadingreach-inc>

### **Medical Device Search Group (Austin, TX)**

Innovative recruiting services: <http://www.medicaldevicesearchgroup.com/home>

### **Medical Writing Contract Position (TX)**

- 12-month Medical Writing contract position with a Medical Device company. Person must be on site in any of the three following: Tennessee, Texas, or Massachusetts.

Email Dennis Kapsimalis (ALKU) at [dkapsimalis@alku.com](mailto:dkapsimalis@alku.com) or call 978-296-1888 to discuss further.

### **Merck (Austin, TX)**

- Twelve positions

<https://www.indeed.com/q-Merck-l-Austin,-TX-jobs.html>

### **Pharmatech Professionals, Senior Regulatory Affairs Specialist (Denver, CO)**

- Software experience is required for this opportunity to work on new technology with this medical device company. Relocation assistance is offered.

Email Mike Lambert at [mlambert@pharmatechpro.com](mailto:mlambert@pharmatechpro.com) with your resume and your available hours to talk.

### **Regulatory Affairs Manager (Dallas, TX)**

- Requires application of regulatory knowledge, technical/business understanding, and people management skills to lead a regulatory team with pre- and post-market responsibility. Serves as the Regulatory Affairs leader for the Communications Business Unit, interacting with other functional teams.

Contact: Andrew Brown, Medical Device Search Group, Inc. call 786-372-4343 or email Andrew at [abrown@medicaldevicesearchgroup.com](mailto:abrown@medicaldevicesearchgroup.com)

### **Regulatory Affairs Specialist International (Dallas, TX)**

- Regulatory Affairs Specialist to focus on Class II and Class III submissions to international regulatory agencies in countries like Brazil, China, Japan, EU, etc. This candidate should have experience advising teams and communicating prior deficiencies with past submissions.

Contact: Andrew Brown, Medical Device Search Group, Inc. call 786-372-4343 or email Andrew at [abrown@medicaldevicesearchgroup.com](mailto:abrown@medicaldevicesearchgroup.com)

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## **VOLUNTEER OPPORTUNITIES**

### **ATX Women in MedTech**

Looking for volunteers to support with community outreach, event management, PR, sponsorship and more. Email [womeninmedtech@gmail.com](mailto:womeninmedtech@gmail.com) for details.

### **BioAustin**

We are seeking volunteers to maintain our website. If interested, please reach out to Scott Collins at [scott@bioaustin.com](mailto:scott@bioaustin.com).

### **Judges Needed for the Austin Energy Regional Science Festival**

Science Fest is a competition for students from 23 school districts and 12 counties who are advancing from their local schools.

Because judging is competitive, subject matter experts are needed to evaluate the projects. About 7-8 projects are assigned to each group of judges (typically consisting of 3 people). After a group has interviewed their assigned students, group members discuss the merit of each project and jointly determine the ranking. It is a 2-4 hour commitment. Orientation sessions provided in the weeks leading up to the fair.

If you're interested in participating as a judge, please contact Scott Collins: [scott@bioaustin.com](mailto:scott@bioaustin.com)

### **TMDA Executive Director**

TMDA is looking for an Executive Director to replace Sarah Haverin who is stepping down. The vacancy is to be filled by an individual that has an interest in supporting the medtech/medical device/diagnostics industries. Texas Medical Device Alliance (TMDA) is a volunteer, sponsor based industry organization (<http://texmda.org/>). If you'd like to learn more, please contact Elisa at [elisa@texmda.org](mailto:elisa@texmda.org).

**Please notify us of any Careers or Volunteer opportunities!**

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## RESOURCES

### **ATX Women in MedTech**

[womeninmedtech@gmail.com](mailto:womeninmedtech@gmail.com)

### **Austin Health Tech Meetup**

<https://www.meetup.com/Austin-Health-Tech/>

### **BioAustin LinkedIn Group**

<https://www.linkedin.com/groups/6535301/profile>

### **Capital City Innovation**

<https://www.capitalcityinnovation.org/>

### **Health Technology Forum Meetup**

<https://www.meetup.com/HealthTechnologyForum-Austin/>

### **Texas Medical Device Alliance (TMDA) LinkedIn Group**

<https://www.linkedin.com/groups/6952028>

### **Top Austin-Area Medical Device Companies**

<https://www.bizjournals.com/austin/subscriber-only/2017/10/13/the-list-top-austin-area-medical-device.html>

### **Women in Bio**

<https://www.womeninbio.org/page/texas>) is partnered with SmartBrief to provide you quick up-to-date news affecting your field.

Subscribe for free at: <https://tinyurl.com/y9e7g9wx>

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## PRODUCTS & SERVICES SPOTLIGHT

### **doDOC**

doDoc allows several people to work on one document at the same time, with review and approve functionality on paragraph level. The software can measure the time spent writing a document, to benchmark projects and plan resources. For more info, contact Leif Masvar, Head of Sales and Customer Acquisition [leif.masvar@dodoc.com](mailto:leif.masvar@dodoc.com)

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## SPONSORS

Thanks to our TMDA sponsors!



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*Warm regards, Amy Dowell, Dan Greenfield, Dana Abramovitz, Diya Banerjee, Elisa Maldonado-Holmertz, Hilary Graham, and Tamiko Oguri on behalf of BioAustin, Texas Medical Device Alliance (TMDA), and Austin Health Tech (AHT)*