



Texas Medical Device Alliance



BioAustin | Texas Medical Device Alliance | Austin Health Tech

# NEWSLETTER

## March 2020

Check out the news, meetings, conventions, & networking events in the life sciences and health technology community in this March newsletter!

### TMDA 2020 Meeting Dates

Apr 16, 2-4pm

Jul 16, 2-4pm

Oct 15, 2-4pm

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

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## LIFE SCIENCE INDUSTRY NEWS

### In Our Neck Of The Woods....

#### **UT Health Austin Pediatric Neurosciences at Dell Children's Welcomes the Comprehensive Pediatric Epilepsy Center** <https://tinyurl.com/shdp7z2>

UT Health has created a multidisciplinary team for multifaceted disorder of epilepsy to holistically understand and pediatric epilepsy. The goal is to be able to treat the child all in the same place, improving access and removing potential obstacles to bring the best care to patients.

#### **UT Southwestern Nearly Double Lifespan of Mice with Brain Cancer**

Cellular NanoPorotation Chips spawn a better form of drug delivery for gene therapy and has increased survival of mice with glioblastoma, one of the deadliest forms of human brain cancer.

#### **Accenture Sees Big Health Roles for AI and Emerging Technologies**

Discussion of impact of AI, blockchain, extended reality and quantum computing in health IT.

#### **FDA Takes Significant Step in Coronavirus Response**

FDA issues emergency use authorization for the first coronavirus diagnostic. It has been tested in CDC labs and has been authorized for patients meeting CDC criteria for the 2019-nCoV testing.

#### **iBio Partners with Beijing CC-Pharming Ltd to Develop Coronavirus Vaccine**

Texas biotech company working with Beijing CC-Pharming Ltd to develop and test a coronavirus vaccine making it one of dozens of drug makers working on vaccines or antivirals for treatment and prevention of the illness.

### Across the Ponds....

#### **Japanese Regulators Approve Non-Invasive Angiography Technology**

CathWorks FFRangio System transforms angiogram images into color-coded 3D renderings of blood flow in coronary arteries helping doctors optimize coronary artery disease decision making regarding stents. It is commercially available in the US and Europe.

## INDUSTRY RESOURCES & FUNDING OPPORTUNITIES

#### **Understanding Post-Market Surveillance Requirements for Medical Devices**

Review the key requirements for post-market surveillance and mandatory compliance procedures in the US & Europe. Learn how to improve customer safety and product efficacy. [Read the blog post.](#)

#### **5 Tips for Hiring Medical Device Advisors**

Dive into good and bad practices to keep in mind when looking for and hiring advisors during all stages of medical device companies in this episode of Global Medical Device Podcast. [Listen to the podcast.](#)

#### **The Art of Defining Design Inputs & Outputs**

Dive into how to define design inputs and outputs as they are the foundation of the device that can make product development easier to bring your medical device to life. [Read the blog post.](#)

### **10 Reasons Why Health Care Startups Fail**

Developing medical advancements is a time- and labor-intensive process. Making the wrong call can mean long delays and escalating costs. But just because many companies make mistakes doesn't mean yours has to. [Read more.](#)

### **7 FDA Pathways to Bring Your Medical Device to Market**

Revisit all 7, major pathways to bring a device to market and key details of each pathway to illuminate pros and cons of each to lead to the best choice for your regulatory strategy. [Read the blog.](#)

### **4 Parts to Interviewing Candidates for Medical Device Roles**

In this episode of Global Medical Device Podcast, learn about the pros and cons of 4 distinct parts of candidate interview process while hiring new professionals into the medical device world. [Listen here.](#)

### **EU MDR & IVDR Planning**

Navigate the European Union's new Medical Device Regulation (MDR) coming May 2020 and In Vitro Diagnostic Regulation (IVDR) coming May 2022. [Explore the planning resources from NAMSA.](#)

### **Help with FDA Submission**

Learn more about important 2019 FDA documents and reach out to Gardner Law for any help with an FDA submission. [Learn more & contact Gardner Law.](#)

## **WOMEN IN SCIENCE & WOMEN'S HEALTH**

### **[Solving Biotech's Missing Women Problem](#)**

Many millennial women are leaders at top biotech leading companies. These women are working at private companies, not only universities along with many emerging women founders in the biotech world.

### **[Conference Aims to Interest Girls in STEM Careers](#)**

The American Association of University Women's Celebrating Women in Mathematics and Science conference was held for its 14th year Friday at Victor Valley College.

### **[Medicare to Cover Genetic Sequencing for Breast, Ovarian Cancers](#)**

CMS proposes paying for genetic screening tests to detect certain ovarian and breast cancer possibly caused by hereditary factors. These next-generation sequencing tests are key to advancing precision medicine, focusing on an individual's DNA and genes to personalize disease prevention and treatment.

## **SPOTLIGHT**

### **Austin Chamber of Commerce**

The Austin Chamber of Commerce's Talent Ambassador Program is a free program where local businesses let us know how they would like to help grow a strong regional talent pipeline by indicating the various ways in which they would like to engage with the community. As educational institutions reach out to us, we can then match these businesses to the specific engagement requested, such as internships, mentorships, teacher externships (job shadowing), career speaker or site visits. Businesses can also let us know how they would like or are already engaging populations facing barriers to employment such as veterans, persons with disabilities or criminal backgrounds, foster youth and mothers returning to work.

The Austin Chamber also spotlights local employers who give back to the community through this program and here are stories from the [Hilton Austin](#) and [Encotech](#). If interested contact Kwee Lan Teo, [kteo@austinchamber.com](mailto:kteo@austinchamber.com), the Austin Chamber VP Talent Development & Acquisition. [Learn more about the Talent Ambassador Program here.](#)

### **Austin Chamber: Opportunity Austin Survey**

The Chamber is partnering with local school districts to connect your business with regional opportunities to make sure our school curriculum teaches the right skills, includes industry-based certifications that pay a good wage, and helps our working-age populations earn while they learn. Please complete this three-minute survey so that the Chamber may connect your company with the right opportunities and recognize your company as a **TALENT AMBASSADOR**. For questions, please email Kwee Lan Teo, VP of Talent/Workforce at [kteo@austinchamber.com](mailto:kteo@austinchamber.com). [Complete Survey Here](#)

## **UPCOMING EVENTS**

**NOTE: All events are now posted on Capital City Innovation's calendar.**

### **Capital City Innovation**

CCI has compiled partner and community events relevant to innovation in health and life sciences. [Check out the calendar!](#)  
<https://tinyurl.com/vurbb8o>

### **[Checkout 40+ Medical Device Conferences Happening in 2020](#)**

Plan your 2020 conference calendar from east to west coast.

## **CAREER CORNER**

### **Abbott**

Multiple Positions  
[View positions](#)

### **Aeglea Biotherapeutics**

Multiple positions  
[View positions](#)

### **ALKU**

Multiple positions  
[View positions](#)  
Contact Logan Blake, Regulatory & Scientific Recruiter at [lblake@alku.com](mailto:lblake@alku.com)

### **Asuragen**

Multiple Positions  
[View positions](#)

### **Babylon Health**

Multiple Positions

[View positions](#)

### **Luminex**

Multiple Positions  
[View positions](#)

### **Molecular Templates**

Multiple positions  
[View positions](#)

### **Syneos Health**

Multiple positions  
[View positions](#)

### **Molecular Templates**

[View positions](#)

### **QA Consulting, Inc.**

Multiple positions  
[View positions](#)

Contact: Mallori Groh; mgroh@qaconsultinginc.com

### Skills Alliance

Multiple positions

[View positions](#)

Contact [sarah.fletcher@skillsalliance.com](mailto:sarah.fletcher@skillsalliance.com)

### FDA Quality and Regulatory Consultants (FDAQRC)

Stay up to date with job openings at FDA Quality + Regulatory Consultants

[Join the FDAQRC CAREER NETWORK](#)

### Life Sciences & Technology Black Diamond Networks

Multiple positions

[View positions](#)

Contact Recruiter, Alex Magoon

[Amagoon@blackdiamondnet.com](mailto:Amagoon@blackdiamondnet.com)

### Quantitative Radiology Solutions

Medical Image Analysis Intern/Co-op

[View position](#)

### Director of Business Development

Looking in a confidential search with an international pioneering biopharmaceutical client in the process of developing one of the most diverse and rapidly growing biosimilars portfolios.

Their mission and company purpose is centered around making high quality biologic medicines accessible to more people, faster and cheaper. After a successful launch in the EU & UK, they are now in the process of establishing in the US (Greater Boston Area, MA) and assembling their leadership team for this high-profile launch scheduled for Q2 of 2020.

They are looking for a Business Development Leader to forge strategic partnerships with top biopharmaceutical companies, define key contract terms and negotiation strategy, and lead scientific and commercial due diligence. Please contact [christine.erickson@skillsalliance.com](mailto:christine.erickson@skillsalliance.com) if you are interested in the position.

### Software Developers/Engineers – full-time and part-time, perm and temp

**Advanced Scanners** is looking for software developers to continue development on their Optical Machine Vision System for neurosurgeons. Ideally an experienced C++ and python developer; 3D modeling and imaging is a plus. Contact Jeff at [jeffl@advancedscanners.com](mailto:jeffl@advancedscanners.com)

### Remote Regulatory Specialist

Location: Remote Project

Start Date: Immediate

Duration: 3 weeks plus or minus

Title: Regulatory Affairs Specialist

The client is looking for an experienced regulatory affairs specialist that is well versed in the FDA's requirements for medical device, drug and combination products to prepare a high-level overview of the registration/regulatory process and a timeline and budgetary/cost estimate for registration of the product. The client is having supply chain related issues with the current manufacturer of an ophthalmic product and wishes to develop a second source for a functionally identical product. The client has identified a manufacturer and wants to have this report/overview completed to further their discussions with the manufacturer and understand the parties involved responsibilities. Initially, the client is considering the FDA monograph for OTC ophthalmic demulcent (PART 349).

Contact Alex Magoon, Life Sciences & Technology Recruiter for Black Diamond Networks at [amagoon@blackdiamondnet.com](mailto:amagoon@blackdiamondnet.com).

CAI is seeking a pharmaceutical PM, commissioning and qualification engineer, and automation project manager. See links attached to CAI's Careers Page.

Pharmaceutical Project Manager (Dallas, TX) [Read job description here.](#)

Commissioning & Qualification Engineer (Dallas, TX) [Read job description here.](#)

Automation Project Manager (Coppell, TX) [Read job description here.](#)

## VOLUNTEER OPPORTUNITIES

### **BioAustin/TMDA/AHT/CCI/TX Health Catalyst/Capital Factory/ Health Tech Austin**

We are mapping Austin's landscape in healthcare/life sciences/biotech/MedTech. Anyone interested in volunteering to collect/compile this information as a team? If you are, please contact Scott Collins at [scott@bioaustin.com](mailto:scott@bioaustin.com).

### **ATX Women in MedTech**

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

### **BioAustin**

We are seeking volunteers to lead as committee heads (Financial, Membership, Marketing, Partnerships, PR, Fundraising, BioBash). If interested, please reach out to Scott Collins at [scott@bioaustin.com](mailto:scott@bioaustin.com)

### **AWIS**

AWIS Austin is growing quickly, and there is a need for women mentors to meet and connect with other women in STEM that are early in their careers in a relaxed, fun setting. There is a pool of mentees from the University of Texas at Austin who are very excited to meet women in STEM careers in Austin and receive your guidance.

Mentors and mentees will initially attend events to connect with one another and establish mutually beneficial partnerships. Following the establishment of mentor/mentee pairs, which we will help facilitate, pairs will be expected to meet monthly on their own. Mentors will offer their advice, tips, and knowledge gained through experience. This is not a large time commitment for mentors, just a nice way to share your knowledge in a fun setting and help another lady in STEM to succeed.

**RSVP to Margo Lee at [awisaustin.president@yahoo.com](mailto:awisaustin.president@yahoo.com)**

## TEXAS LIFE SCIENCE ORGANIZATIONS

### **ATX Women in MedTech**

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

### **BioMed San Antonio**

<http://www.biomedsa.org>

### **Austin Health Tech Meetup**

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

### **BioNorth**

<https://bionorthtx.org/>

### **Austin Technology Incubator (ATI)**

<https://ati.utexas.edu>

### **Capital City Innovation (CCI)**

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

### **BioAustin LinkedIn Group**

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

### **Health Technology Forum Meetup**

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

### **BioHouston**

<http://biohouston.org/>

### **Health Wildcatters, Dallas**

[www.healthwildcatters.com](http://www.healthwildcatters.com)

**Temple Health & Bioscience District  
(THBD)**

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

**Texas Biomedical Research Institute, San  
Antonio**

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

**Texas Health Catalyst**

<https://dellmed.utexas.edu/thc>

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

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

**The Health Cell, San Antonio**

<http://thehealthcell.org>

**TMCX/TMCX+, Houston**

<http://www.tmc.edu/innovation/innovation-programs/tmcx-plus/>

**Top Austin-Area Medical Device Companies**

<https://tinyurl.com/ya9v2s5u>

**Velocity Texas, San Antonio**

<https://velocitytx.org/>

**Women in Bio-Texas (WIB-TX, Austin &  
Houston)**

<https://www.womeninbio.org/page/t>

## THANKS TO OUR TMDA SPONSORS!



 **NORTON ROSE FULBRIGHT**



Health Tech Insight

With warm regards,

Christine Scheve, Dana Abramovitz, Elisa Maldonado-Holmertz, Madeline Spencer, and Victoria O'Dell  
on behalf of BioAustin, Texas Medical Device Alliance (TMDA), and Austin Health Technology (AHT)