



Texas Medical Device Alliance



BioAustin | Texas Medical Device Alliance | Austin Health Tech

# NEWSLETTER

## February 2020

Happy 2020 and welcome to another year of exciting growth and development in the Life Sciences, BioPharma, Biologics, Med Tech, Health Tech and Medical Device industries.

We are committed to informing — and making a difference to — the life sciences and health technology community in the greater Austin area and Texas.

See you at the first **TMDA Meeting** of the year?! Join us on **February 20**  
**Conversation with Austin Medical Device Pioneers**

[Register today](#)

**BioAustin** welcomes **Committee Heads** to lead activities for Website, Membership, Events, etc. If interested in being a Committee Head, or interested in committee participation, please contact Scott Collins, [scott@bioaustin.com](mailto:scott@bioaustin.com)

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)).

### CONTENTS

<b>LIFE SCIENCE INDUSTRY NEWS</b>	<b>2</b>
<b>INDUSTRY RESOURCES &amp; FUNDING OPPORTUNITIES</b>	<b>3</b>
<b>WOMEN IN SCIENCE &amp; WOMEN'S HEALTH</b>	<b>4</b>
<b>SPOTLIGHT</b>	<b>4</b>
<b>UPCOMING EVENTS</b>	<b>5</b>
<b>CAREER CORNER</b>	<b>7</b>
<b>VOLUNTEER OPPORTUNITIES</b>	<b>9</b>
<b>Join the BioAustin/TMDA/AHT Teams!</b>	
<b>TEXAS LIFE SCIENCE ORGANIZATIONS</b>	<b>10</b>

## LIFE SCIENCE INDUSTRY NEWS

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

#### **Acquisitions, Relocations and Birth of New Industry Segments from BioNTX**

The big buzz in the North Texas life sciences community was the acquisition of Peloton Therapeutics by Merck & Co. for \$2.2 Billion just weeks after Peloton filed for an IPO. Unicorns are rare and the fact that North Texas has seen two in the past four years with at least two near unicorns in that same period speaks to the increasing presence of our life sciences community on the world stage. I imagine we are not far from at least one \$1B+ acquisition yearly, with a local company either acquiring or being acquired. Life sciences M&A activity in 2019 included:

- Medisource Partners acquired by Generex Biotechnology
- Aprima Medical (Dallas) acquired by eMDs Inc (Austin)
- eCore Software (Dallas) acquired by ESO (Austin)
- Peloton Therapeutics (Dallas) acquired by Merck \$2.2B
- Corepoint Health (Frisco) merged with Rhapsody (Boston)
- ThermiGen (Irving) acquired by Celling Biosciences (Austin)
- VitreosHealth (Plano) acquired by HMS Holdings (Irving) \$36.5M
- Vivify Health (Plano) acquired by Optum, a division of UnitedHealth Group
- Emergent Cold (Dallas) acquired by Lineage Logistics (Michigan) \$900M

<https://bionorthtx.org/acquisitions-relocations-and-birth-of-new-industry-segments/>

#### **Device warning letters plunged nearly 90% over 5 years. An FDA official predicts a rebound**

MCRA extracted key points from the MedTech Dive article: [Click here](#)

- FDA warning letters to medical device manufacturers slid by nearly 90% between 2015 and 2019, but may be set to rebound upward in 2020
- Now that FDA employees are more familiar with the new structure of CDRH's so-called super office, warning letters are expected to pick back up
- "We've been actively clearing our backlog of inspection reports to review and evaluate so we can focus on things as they come in the door and meet them in their timeframes. We're more confident that we will get back to issuing warning letters when they are appropriate because we will make timelines." – Erin Keith, Associate Director for Compliance and Quality

#### **Medical Device Development: 2019 Overview**

2019 FDA device regulations overview:

- Update on the new medical device provisions of the 21st Century Cures Act and the Food and Drug Administration Reauthorization Act of 2017.
- New statutory provisions and guidance documents related to regulation of software as a medical device, cybersecurity, general wellness products, real-world evidence, use of benefit risk information for both premarket and post-market processes, and when post-clearance changes require submission of a new 510(k) notice.
- Update on the new TPLC organizational structure of CDRH.
- Updates to the pre-submission process, including new MDUFA IV goals for meetings and feedback.

- Updates to FDA’s “refusal to accept” and review policies relating to 510(k)s, PMAs, and pre-submissions.
- Update on the investigational device exemption process including new guidance documents and policies related to clinical trials, including IDE benefit-risk considerations, new Good Clinical Practices (GCPs) guidance and policy for use of foreign data, policies regarding ClinicalTrials.gov registration, as well as guidance documents on adaptive design, leveraging data for pediatric use, and demographic factors in clinical studies.
- Changes to the premarket approval application process including FDA guidance on distinguishing between 30-Day Notice PMA Supplements and Site Change PMA Supplements.
- New policies and guidance documents concerning in vitro diagnostic products, including updates on research and investigational use and laboratory developed tests.
- Update on device compliance issues, including the 2016 medical device reporting guidance.
- New guidance documents and cases relating to combination products incorporating medical devices.
- New changes to FDA’s review of requests for issuance of certificates to foreign governments.
- FDA policy regarding the regulation of third party reproducers.

### **Enhancing Patient Engagement Through eClinical Technology**

Study sponsors and clinical research organizations (CROs) should take advantage of the latest tools to ensure that patients’ involvement meets their expectations and fits into their daily lives, while complying with data privacy concerns in the way we collect, store, and transmit their data. <https://www.pharmavoices.com/?p=459899>

### **Across the Ponds....**

#### **How to Select the Proper EU Notified Body for Your Medical Device Organization**

The objective of this White Paper is to provide information to manufacturers who intend to market medical devices in the European Union (EU) and/or Canada with guidance on identifying, selecting and approving accredited EU Notified Bodies in accordance with the regulatory requirements of current medical device directives. <https://tinyurl.com/umlhzw2>

## **INDUSTRY RESOURCES & FUNDING OPPORTUNITIES**

#### **Austin Inno's 2020 Tech Madness Competition**

The Tech Madness Competition is designed to raise awareness and excitement for local ecosystems, Tech Madness is an annual bracket-style competition for venture-backed and growth-stage startups, generating over 500,000 votes across the network each year. Every March, Austin Inno will unveil the brackets and matchups, and ask the community to vote for the companies they would invest in. **Deadline is February 21.** Submit your nomination [here](#).

#### **Medical Device Product Development and Quality Management Report 2020, Greenlight Guru**

This free original research report shares the results of more than 500 survey responses from medical device professionals across the globe representing company sizes that range from premarket startups with less than 20 employees to large, multinational enterprises.

[State of Medical Device Product Development and Quality Management 2020 Report »](#)

### **Quality and Regulatory Content Toolkit from Greenlight Guru**

Access your free resources by [clicking here](#).

#### **Gardner Law list recently held programs:**

General Data Protection Regulation (GDPR).

EU Medical Device Regulation (MDR).

General Data Protection Regulation (GDPR).

EU Medical Device Regulation (MDR).

EU Health Care Compliance.

US Health Care Compliance

Access the presentations and event recordings:

<https://gardner.law/2019/11/november-2019-regulatory-update-from-both-sides-of-the-pond/>

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

### **The Female Founded Club**

The Female Founded Club wants to help exceptional female founded startups get noticed and ultimately get VC funding. If your company is selected to be in the Female Founded Club, the application will become part of a public database that showcases excellent female founded startups that are raising venture capital. Interested ladies can apply [here](#).

### **Now accepting Boardroom Ready applications for 2020**

Are you a female executive who's ready to serve on corporate boards for life science companies? Executive Women In Bio's Boardroom Ready network can help. [Apply for the 2020 program today](#).

### **February 11 is the International Day of Women and Girls in Science.**

Kamana Misra, PhD, AWIS NJ Chapter president and CEO/Founder, ContraRx speaks at the Royal Academy of Science International Trust's conference at United Nations HQ.

<https://womeninscienceday.org/2020programagenda.html>

## **SPOTLIGHT**

### **Financial Community Sees Climate Risk as Investment Risk**

Risk management is an inherent part of the medical device life cycle. Businesses experiencing rapid growth and changing markets face new risks and challenges. Anticipating and planning for new risks, potentially disruptive changes and investor concerns is critical to organizational resilience.

Recent events in the news about climate sustainability and environment, social and governance (ESG) risks highlight what may be a significant change from business as usual. You may have seen the [letter from Blackrock](#) (<https://tinyurl.com/ycluszll>) stating that they will make "...sustainability integral to portfolio construction and risk management ... (and) exit investments that present a high sustainability-related risk." And the statement from Bank of America CEO that Bank of America clients have invested

\$25 billion in environment, social and governance funds and investor interest in ESG will continue to grow.

### What has changed?

The most rapid change may be in the seriousness placed upon the climate issue by the finance community - investors and insurers have come to the conclusion that “**climate risk is investment risk.**” Climate change is being recast as a business imperative by investors and expectations include preparation for potential future climate impacts.

### What does this mean for you?

You may already be accounting and reporting your Greenhouse Gas (GHG) emissions as some States require under air permitting rules or voluntarily reporting your emissions under standards like the Global Reporting Initiative (GRI) or the Sustainability Accounting Standards Board (SASB). Or you may just be starting on that journey. Be aware that climate impacts range from physical infrastructure damage, to increased costs of supply chain disruptions, to regulatory requirements or customer and employee attitudes.

### What can you do?

BSI's Sustainability Practice recommends these steps you can take to minimize risk:

1. **Broaden sustainability efforts** - implement or leverage existing management systems such as ISO 14001 (<https://tinyurl.com/qkp2p2a>) and ISO 50001 (<https://tinyurl.com/w9lo3f6>).
2. **Improve/establish your GHG program** - compare current greenhouse gas accounting and reporting against SASB standard for your sector (HC.4 Medical Technology).
3. **Manage risk in your supply chain** - implement monitoring tools or 2nd party supplier audits
4. **Identify and assess potential ESG issues** – assess risk in areas like climate action, responsible consumption and production, labor and human rights and anti-bribery.
5. **Scenario planning** - establish a consistent practice of scenario planning.
6. **Educate your organization** - train staff on the climate impact of business processes and waste.

### How can BSI help you?

BSI's highly-skilled consultants can support your climate risk adaptation programs, including:

- Gap assessments related to environmental risk and management systems
- Tools to help identify risk with your own sites and those of your suppliers
- Technical expertise related to greenhouse gas management, business continuity, scenario modeling, supply chain risk management

For more information visit [bsigroup.com/ehs](https://bsigroup.com/ehs) or contact [sally.pawsat@bsigroup.com](mailto:sally.pawsat@bsigroup.com). 512.797.5643.

## UPCOMING EVENTS

Capital City Innovation has compiled partner and community events relevant to innovation in health and life sciences. [Check out the calendar!](#)

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

Plan your 2020 conference calendar from east to west coast.

February 4, 2020 | Austin Central Library | 6:00pm Free

**Health Tech: How Technology, and Austin, Will Help You Live Longer & Better**

As we enter 2020, we can credibly picture a not-too-distant future in which precision medicine will end death from disease (if not disease itself), that nanotechnology and robotics will enable precision surgery to yield total recovery in nearly 100% of all cases, and that artificial limbs and organs will replace original ones with equal or greater capabilities and durability. <http://bit.ly/BioAF2020>

February 4 | Free Webinar 10-11am CT

**Measuring Success of a Quality Risk Management Approach**

<https://tinyurl.com/r7h2fes>

February 10 | Austin

**[Re]Verse Pitch 2020**

Entrepreneurs, are you looking for inspiration? The [\[Re\]Verse Pitch](#) Competition is awarding \$\$\$ to the best repurposing business ideas. Come to Opening Night on Feb. 10 to learn about the products, meet the material suppliers, and network with fellow entrepreneurs. [Learn More and RSVP Here.](#)

February 11 – 13 | Anaheim, CA

**MD&M West 2020 | Medical Expo**

<https://mdmwest.mddionline.com/>

February 13 | College Station, TX

**French American Innovation Day 2020**

[Register today](#)

February 18-20, 2020 | San Antonio, TX

**SWRI Presents: Tolerance Stack Analysis Training**

[Register today](#)

February 19 | Free Webinar 10-11am CT

**4 Pillars of IVDR - Integrating Post-Market Surveillance, Risk Managements, QMS and Performance Evaluation**

[Register Today!](#)

February 19-20 | Tampa, FL (\$338)

**2020 Life Science Women's Conference- Save the date!**

An unparalleled opportunity for women to accelerate their careers in the life science field through mentoring, networking, and education. [Learn more & RSVP.](#)

February 20 | Austin, TX

**Texas Medical Device Alliance Q1 | Conversation with Austin Medical Device Pioneers**

Join the first TMDA meeting of the year to be held at MedtoMarket! [Register today.](#)

February 26 | Austin, TX

**Blockchain and Digital Transformation in Health 2020 conference**

[Learn more & register.](#) Use code M2MVIP1 for 10% off your ticket.

March 5 | Free Webinar 9am Texas Time

**The Secret to Getting Packaging Content Right First Time**

<https://tinyurl.com/sa4x7sy>

April 7-8 | Dallas, TX

**Breaking Down Barriers: Addressing Challenging Research and Regulations**

Office for Human Research Protections (OHRP) Research Community Forum (RCF) hosted by the University of Texas Southwestern Medical Center. To include an educational workshop with interactive sessions about interpreting and applying the revised Common Rule as well as a full day conference with sessions on a variety of topics including emergency research, community consultation, return of individual results, community engagement, and more! More information and registration at:

<https://web.cvent.com/event/7f17d4de-c91b-4812-b50c-dfedoc4663c1/summary>

April 23 | Houston, TX (\$150-\$349 non-members/\$75-\$275 AWIS members)

**Innovation & Inclusion Summit & Awards Dinner - Save the date!**

The Association for Women in Science (AWIS) Summit is an impactful opportunity to further conversation, build networks and celebrate women in STEM while learning from thought-leaders and decision makers from industry to academia including panels with leaders from Los Alamos National Laboratory and NASA's Johnson Space Center. [Learn more & register.](#)

June 9 – 11 | New York, NY

**MD&M East 2020 | Medical Expo**

<https://advancedmanufacturingnewyork.com/mdm-east>

September 18 – 11 | Temple, TX

**Temple Health & Bioscience District Annual Medtech Startup Symposium & Pitch Competition**

THBD invites medtech startups, entrepreneurs and professionals to convene for a day-long conference featuring keynotes and workshops by industry leaders and innovators. <https://tinyurl.com/v62cyp3>

## 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](#)

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

Multiple position

Contact: Mallori Groh;

[mgroh@qaconsultinginc.com](mailto:mgroh@qaconsultinginc.com)

<https://qaconsultinginc.com/careers/>

### **Skills Alliance**

Multiple positions

[View positions](#) or 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](#) or Contact Recruiter, Alex

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

### **Quantitative Radiology Solutions**

Medical Image Analysis Intern/Co-op

[View position](#)

### **Manager, Clinical Quality Assurance, Kelly Scientific, Ft. Worth, Texas**

The Clinical QA Manager responsible for assuring the quality of clinical development systems, processes and related activities in the USA. This position does not manage personnel but manages the Quality Program. Looking for someone with a passion for QA experience in clinical development, and CRO experience.

Must have performed audits, report results of audits, and good communication.

Please send resumes to

[jason.ines@kellyscientific.com](mailto:jason.ines@kellyscientific.com)

### **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)

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.](#)

### **Director of National Sales - pharmaceutical company focused on animal health**

work alongside the VP of Sales and Marketing and create strategic vision, metrics, targets, and ensure they are met. The ideal candidate will have managed both inside and outside sales teams and of course has a passion for animals and pets.

Contact: Christine Erickson

[christine.erickson@skillsalliance.com](mailto:christine.erickson@skillsalliance.com)

**RA Specialist-IVDR** project in Sparks, MD to support BD to achieve MDR/ IVDR compliance for products within the Integrated Diagnostic Solution's Specimen Management business unit.

Contact: Matthew Wray

[mwray@maetrics.com](mailto:mwray@maetrics.com)

## VOLUNTEER OPPORTUNITIES

### **Passionate about research, education and advancing STEM in Central Texas? Become a THBD Scholars Program Mentor!**

The THBD Scholars Program partners elite college students with local professionals in Temple, Texas to offer hands-on experience, ranging from 20-40 hours per week. The 2020 internship program will take place from June 1 to July 31, 2020. Email [Tami Annable by February 15, 2020](mailto:TamiAnnable@templebioscience.org) to become a THBD Scholars Program Mentor, [tamia@templebioscience.org](mailto:tamia@templebioscience.org).

### **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](#)

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

We are mapping the 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 maintain our website. 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. We are announcing the formation of a mentoring circle for the 2020-2021 year. There is a pool of 31 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 ORGANIZATION

### ATX Women in MedTech

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

### Austin Health Tech Meetup

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

### Austin Technology Incubator (ATI)

<https://ati.utexas.edu>

### BioAustin LinkedIn Group

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

### BioHouston

<http://biohouston.org/>

### BioMed San Antonio

<http://www.biomedsa.org>

### BioNorth

<https://bionorthtx.org/>

### Capital City Innovation (CCI)

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

### Health Technology Forum Meetup

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

### 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 Healthcare & Bioscience Institute

[thbi.com](http://thbi.com)

### 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!



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)