



**Texas Medical
Device Alliance**



BioAustin | Texas Medical Device Alliance | Austin Health Tech

NEWSLETTER

May 2020

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

TMDA 2020 Meeting Dates

May 5, 1-2pm – EHR & Medical Device Interoperability **Webinar**

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).

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LIFE SCIENCE INDUSTRY NEWS

In Our Neck Of The Woods....

Join Mask Challenge USA!

MedtoMarket is proud to have launched the Mask Challenge USA on Wednesday, April 15th with the goal of providing Personal Protective Equipment (PPE) to our frontline doctors, nurses and first responders. Through this campaign, the American public has the opportunity to purchase non-medical grade, 3-ply masks for their families and have them delivered to their homes quickly. The 3-ply masks help decrease the spread of COVID-19 by reminding individuals to not touch their face while also minimizing the spittle from talking, sneezing or coughing. We are also excited to announce that proceeds from this campaign will be used to buy much needed N95 and KN95 masks along with other medical-grade PPE items that will be delivered directly to the front lines across the United States. <https://maskchallengeusa.com/>

Gofundme: University of Texas Assisted Bag Breathing Unit: Providing a solution to the ventilator shortage

Responding to the urgent call for essential medical equipment in the fight against COVID-19, a team of faculty at the University of Texas at Austin and the University of Texas Health Science Center at San Antonio have developed and are currently testing a low-cost, reliable, effective medical ventilation unit to provide life support for patients with COVID-19 and other respiratory illnesses.

Solving the Ventilator Shortage with Windshield Wiper Parts

Researchers at The University of Texas at Austin are building a new type of ventilator made of cheap, widely available materials to help fill the demand created by the spread of COVID-19 for these critical devices that help patients breathe.

knowRx showcases its digital health solution as a first-line tool against COVID-19

knowRx, Inc proposes the use of its digital health solution, "Individual Health Insights," as a first-line tool to help empower patients, manage medical resources, and reduce the morbidity and mortality associated with COVID 19 disease.

Telemedicine Is Here to Stay

Some industry experts say that the rapid shift toward telemedicine in response to COVID-19 safety recommendations will stick long after the pandemic is over.

How Continuous Glucose Monitoring Systems Are Joining the COVID-19 Fight

Both Dexcom and Abbott diabetes systems are helping healthcare workers in hospitals minimize exposure to COVID-19 patients while also preserving the use of personal protective equipment.

Project Aether: an open-source, emergency ventilator for the COVID-19 pandemic

In response to anticipated needs for treating COVID-19 patients, a collective of companies and industry experts are working as one, carrying forward an open-source emergency ventilator design.

LIFE SCIENCE INDUSTRY NEWS

Across the Pond....

Parliament decides to postpone the MDR:

To prevent shortages or delays in getting key medical devices on the market, Parliament decided to postpone the application of the Medical Devices Regulation. European Parliament adopted the Commission proposal on Friday, by urgent procedure with 693 votes to 1 and 2 abstentions, allowing the application of the Medical Devices Regulation to be **postponed by one year until 26 May 2021**. The proposal now also has to be approved by the member states and published in the Official Journal **before it will enter into force**. This is expected at the latest by 26 May.

Link to EU Parliament: <https://tinyurl.com/yatycd3p>

The COVID-19 vaccine development landscape

The genetic sequence of SARS-CoV-2, the coronavirus that causes COVID-19, was published on 11 January 2020, triggering intense global R&D activity to develop a vaccine against the disease.

COVID-19 in Europe: Emergency market access for PPE, medical device and IVD manufacturers

European Union member states face similar crises as the US and other countries regarding shortages of medical devices and equipment needed to treat COVID-19 patients, driving the need for emergency access to European healthcare markets for these products at a faster rate than for the standard conformity assessment routes to obtain a CE Marking certification.

WHO launches global megatrial of the four most promising coronavirus treatments

A drug combo already used against HIV. A malaria treatment first tested during World War II. A new antiviral whose promise against Ebola fizzled last year. Could any of these drugs hold the key to saving coronavirus disease 2019 (COVID-19) patients from serious harm or death? On Friday, the World Health Organization (WHO) announced a large global trial, called SOLIDARITY, to find out whether any can treat infections with the new coronavirus for the dangerous respiratory disease.

Health Canada responds to COVID-19 emergency

Health Canada (HC) has issued a series of announcements of emergency measures and guidance documents since COVID-19 was declared to be a global pandemic.

INDUSTRY RESOURCES & FUNDING OPPORTUNITIES

Texas Health Catalyst is accepting applications!

We initiated a soft launch of the 2020 TXHC cycle that started in late February. We're running things a bit differently this year -- there is no application deadline, and not all of our program participants will be on identical timelines. Instead, we'll be continuously "open for business", ready to provide translational support for research teams at all stages of project development, whenever our support can best be used.

We will continue to support as many teams as possible with our consulting and advising services. We plan to provide funding support for a maximum of 10 teams per year, however, so we encourage you to send in your 250-word application soon! Application: <https://tinyurl.com/ya42jahv>

[**Austin Chamber of Commerce COVID-19 Resources**](#)

The Austin Chamber of Commerce page with resources for businesses that need assistance in developing staffing, continuity, and other plans in light of this situation. [Read more.](#)

[**COVID-19 News Central**](#)

QMed MD+DI's ongoing coverage of resources, regulatory support, and solutions for responding to the COVID-19 pandemic [Read more.](#)

[**How to Integrate Usability into your Medical Device**](#)

In this new episode of Global Medical Device Podcast, Jon Speer invites guest Isabella Schmidt to join the show to discuss the importance of usability for medical devices and best practices listeners can follow that are provenly effective for integrating usability into a medical device. [Listen to Podcast.](#)

[**Covid-19 impact on medical device industry: how to navigate the chaos and support public health**](#)

Learn about the impact of the coronavirus pandemic on the medical device industry, ways you can manage the disruptions, and what other companies are doing to respond to the global health crisis, so you can decide if you, too, are in a position to help. [Read more.](#)

[**10 Ways a Modern, Cloud-Based MDQMS Helps Remote Teams Stay Ahead**](#)

Read this helpful article designed to assist medical device companies in their transition to operating remotely that highlights ten provenly effective ways a cloud-based medical device quality management system (MDQMS) can help your team stay ahead while working remote. [Read blog.](#)

WOMEN IN LIFE SCIENCE & WOMEN'S HEALTH

[**The woman behind the most-trusted COVID-19 tracker**](#)

Lauren Gardner, co-director of the Center for Systems Science and Engineering at Johns Hopkins University, is behind the online dashboard that has become the most authoritative resource for tracking the COVID-19 pandemic. Gardner has done spatial modeling of measles and Zika virus epidemics, and she explains how her team collects data for the project.

[**Tango Therapeutics raises \\$60M amid COVID-19 pandemic**](#)

Boxer Capital, Cormorant Asset Management, and Casdin led a \$60 million Series B financing round for Tango Therapeutics, whose cancer drug discovery strategy is based on CRISPR and the concept of synthetic lethality to make tumors vulnerable. The funding came as the COVID-19 outbreak was reaching pandemic status, and CEO Barbara Weber says Tango was able to shift some research from and back to China.

[**Young Women In Bio announces launch of YWIB Ambassador Program**](#)

Young Women In Bio (YWIB) is excited to announce the launch of its YWIB Ambassador Program, a new initiative for high school girls interested in championing and supporting YWIB's efforts to create educational and leadership opportunities in STEM for young girls, both locally and nationally.

[IGI partners with UC Berkeley on rapid COVID-19 testing](#)

Julia Schaletzky, head of the Center for Emerging and Neglected Diseases at the University of California, Berkeley, was pushing the federal government to let academic research centers use the equipment they already have on hand to process COVID-19 tests at the same time CRISPR pioneer Jennifer Doudna was rallying her colleagues at Innovative Genomics Institute to take on the pandemic. IGI dismantled their lab, set up a COVID-19 testing lab, and established rapid-response research teams, and Berkeley's student health center extended its lab certification to a lab at IGI, which is scaling up to handle 3,000 tests a day.

[Women are stepping up in the coronavirus fight](#)

The majority of health workers on the front lines of the coronavirus fight are women, and female leaders must be included in efforts to identify, contain and treat the pandemic, write WomenLift Health Global Advisory Board members Geeta Rao Gupta and Jeremy Farrar. A number of talented women have already stepped up to the challenge, including Maria Van Kerkhove, the technical lead on the World Health Organization's COVID-19 team, CDC principal deputy director Anne Schuchat, and Sun Chunlan, who is leading containment efforts in China's Hubei province.

SPOTLIGHT

GALEN DATA - Cloud connectivity for medical devices

Galen Data provides a turn-key, configurable, scalable, and easy to use software platform allowing medical devices to centralize data and leverage cloud technologies. The Galen Cloud platform collects and securely stores data as well as provides tools to visualize and analyze both patient and device data. Galen Data maintains and secures the Galen Cloud, and ensures FDA and global regulatory compliance.

www.galendata.com

UPCOMING EVENTS

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

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.

May 5 | Webinar 1-2pm CDT

Texas Medical Device Alliance (TMDA) Webinar

Next Generation of EHR & Cloud Connected Medical Device Interoperability

Register for the TMDA webinar: <https://tinyurl.com/sgz7gub>

May 5 | Webinar 8:30-11am CDT

Health Tech Austin Hosts [The Coronavirus Summit](#)

[Click To Register](#)

June 8-11 | San Diego, CA (\$500-\$2400)

BIO International Convention

Join the world's largest, global biotech partnering event where 17,000 leaders from biotech & pharma will come together to network & discover cutting-edge innovations all week long. [Learn more & register](#)

June 9 – 11 | New York, NY

MD&M East 2020 | Medical Expo

Discover new technologies from 550+ companies, attend educational sessions and connect with peers. [Learn more and register](#)

June 14 – 18 | Washington, DC (\$250-\$2000)

DIA 2020 Global Annual Meeting

Join the largest global stage for life science professionals to connect and address healthcare problems. There will be 250+ educational sessions with 13 unique tracks of learning and engagement. [Learn more and register](#)

July 16, 2-4pm | Austin Norris Conference Center

Texas Medical Device Alliance (TMDA)

Design, Development & Design Transfer of a Medical Device

Register: <https://tinyurl.com/y9zs29tu>

August 12-14 | Bastrop, TX

Texas Life Science CEO Summit

Hyatt Regency Lost Pines Resort

Eventbrite link [here](#) or <https://tinyurl.com/t5nxbqw>

CAREER CORNER

Seeking Opportunity

I am an audio engineer and special events coordinator for the Texas Senate seeking a career change. While working full time, I decided to go back to school and obtained my biology degree with a focus on the health profession. As an undergrad I did research on alpha-2-macroglobulin, mainly focusing on isolation and point-of-care. I am an excellent communicator and adaptable to working in a variety of experiences. I am a quick learner, most recently focusing my personal time studying data science programming and healthcare policy. I would like to leverage my wide skill set and government experience to switch to a more fulfilling career in biotech.

Ty Liddell. 512-771-5078. Ty.liddell@gmail.com

Career Opportunities

Abbott

Multiple Positions

[View positions](#)

Aeglea Biotherapeutics

Multiple positions

[View positions](#)

ALKU

Multiple positions

[View positions](#)

Medical Device Regulatory Affairs Consultant

2mo, 10-15hrs/mo; possible extension

Urology 510(K) Strategy

Contact Recruiter dbere@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

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

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.

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

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. Contact Jeff at jeffl@advancedscanners.com

Remote Regulatory Specialist

Location: Remote Project

Start Date: Immediate

Duration: 3 weeks plus or minus

Title: Regulatory Affairs Specialist

Contact Alex Magoon, Life Sciences &

Technology Recruiter for Black Diamond

Networks at 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

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.

[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.

ATX Women in MedTech

Looking for volunteers to support community outreach, event management, PR, sponsorship and more. Email 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

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 mentees from the University of Texas at Austin who are very excited to meet women in STEM careers in Austin and receive your guidance. This is not a large time commitment for mentors.

RSVP to Margo Lee at awisaustin.president@yahoo.com

TEXAS LIFE SCIENCE ORGANIZATIONS

ATX Women in MedTech

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

Temple Health & Bioscience District (THBD)
<http://www.templebioscience.com/>

Texas Biomedical Research Institute, San Antonio
<https://www.txbiomed.org/>

THBI - Texas Healthcare and Bioscience Institute
<https://www.thbi.com/>

Texas Health Catalyst
<https://dellmed.utexas.edu/thc>

Texas Medical Device Alliance (TMDA)
<https://texmda.org/>

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!



Health Tech Insight

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)