



Texas Medical Device Alliance



BioAustin | Texas Medical Device Alliance | Austin Health Tech

NEWSLETTER

September 2020

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

TMDA 2020 Save the Date
Sales and Commercialization Strategies for Medical Devices
Oct 15, 2-3:30pm
<https://tinyurl.com/yvznhj3>

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....

Bioscience Startup Develops Test to Detect Coronavirus in Wastewater and on Surfaces

[Temple Health and Bioscience District](#) (THBD) startup tenant [Industrial Genetics](#) was featured on news outlets locally and nationwide for their progressive approach to COVID-19 testing.

While many other developers and manufacturers focus on diagnostic testing to identify the virus in patients, Industrial Genetics has developed a way to identify the virus that causes COVID-19 (SARS-CoV-2) in wastewater and on surfaces. This advancement allows businesses and organizations to obtain more information on COVID-19 risks in high-traffic areas, which is particularly important as schools prepare to reopen this fall. Learn more in this [FOX 44 interview](#) with Industrial Genetics Founder Dr. David Sprague.

Texas Global Health Security Innovation Consortium (TEXGHS)

The Texas Global Health Security Innovation Consortium (TEXGHS) is a unique consortium between academia and public and private sector partners to coordinate efforts to support innovators and innovations fighting COVID-19 and future pandemics. Organized by the Austin Technology Incubator (ATI) at The University of Texas at Austin, TEXGHS is leading the creation and long-term success of a health security innovation ecosystem in Texas where equitable, inclusive solutions launch locally and grow globally.

TEXGHS will guide coordinated efforts among consortium members that will include company participation across incubator and accelerator programs; direct corporate/development; investment; cross institutional research collaboration; cooperation across existing networks of global health security experts; representation to local, state, and federal governments; resource mapping across the innovation ecosystem; prototyping, engineering, and legal and regulatory support. The consortium will coordinate efforts to mitigate the effects of COVID-19 and future pandemics by supporting innovators working toward pandemic readiness, response, recover and resiliency. [Get Involved! Contact TEXGHS at \[info@texghs.org\]\(mailto:info@texghs.org\) or visit \[www.texghs.org\]\(http://www.texghs.org\)](#)

Battling “Maskne” During COVID-19

UT Health Austin dermatologist Adewole Adamson, MD, shares tips on how you can protect your skin from developing "maskne" when wearing your mask for extended periods of time to help curb the spread of COVID-19. [Read more here.](#)

SVB's CipherBio Q2 Accelerator Insights Reveals that MedTech Innovator is the Largest Medical Device Accelerator in the World

Silicon Valley Bank's CipherBio released its Q2 Insights which tracked data across the leading life science incubators and accelerators. Their data revealed that MedTech Innovator ranks #1 for the number of medical device startups. [Read more here.](#)

15 Top MedTech Startups Selected for 2020 Pediatric Accelerator

MedTech Innovator and The National Capital Consortium for Pediatric Device Innovation (NCC-PDI) announced the 15 companies selected to participate in the MedTech Innovator Pediatric Accelerator program. [Read more here.](#)

Pfizer's coronavirus vaccine performs well in early study

Pfizer's Judith Absalon led an early stage clinical trial of BNT162b1, a SARS-CoV-2 vaccine candidate based on messenger RNA that induced a strong immune response that increased with higher doses. [Read more here.](#)

LIFE SCIENCE INDUSTRY NEWS

Across the Pond....

Changes in the medical device market and regulations in Mexico (part II)

In recent months, due to the global pandemic, there have been several changes in medical devices market and its regulation in Mexico. In this article, we describe the most relevant changes that any regulatory affairs professional in the industry shall consider. [Read more here.](#)

EU Commission published two new MDCG documents

MDCG 2020-13: Clinical evaluation assessment report template - [Link to document](#)

MDCG 2020-14: Guidance for notified bodies on the use of MDSAP audit reports in the context of surveillance audits carried out under the Medical Devices Regulation (MDR)/In Vitro Diagnostic medical devices Regulation (IVDR) - [Link to document](#)

INDUSTRY RESOURCES & FUNDING OPPORTUNITIES

NAMSA White Paper - Navigating Clinical Trials in the Era of COVID-19: An Assessment of Short-Term and Long-Term Strategies

The current COVID-19 Pandemic has affected the conduct and management of clinical studies with the potential to impact future studies. The medical device and IVD clinical research communities, including Sponsors, CROs, study sites, Investigators and IRBs, have been required to flex from their normal study operations and quickly plan and execute clinical studies to avoid any negative bearing on subject safety and integrity. [Read more here.](#)

5 Tips for Registering your Medical Device across Global Markets

Read to learn about the top global regulatory frameworks for medical device registrations and five tips for streamlining the registration process to gain access to your target markets for your medical device. [Read more here.](#)

From the Experts: Best Practices to Ensure Device Success

Read this featured article published by Medical Product Outsourcing where Jon Speer offers practical tips for manufacturers to ensure success for their medical devices. [Read more here.](#)

Regulatory Globe: Regulatory Intelligence Paper - August 2020 Edition

The Regulatory Intelligence Paper informs you about all upcoming regulations, guidances and standards from the last month with focus on all MDSAP countries + EU, UK and Switzerland - [Read more here.](#)

The Ultimate Guide to ISO 13485:2016 Quality Management Systems for Medical Devices

This guide offers step-by-step best practices for every aspect of your QMS, acting as a blueprint to help you design a well built, interconnected system--a quality system that allows you to focus on true quality vs. only compliance. [Read more here.](#)

WOMEN IN LIFE SCIENCE & WOMEN'S HEALTH

Birmingham scientist tapped for \$30M grant selection committee

Local biological scientist Dr. Adrienne Starks has been selected to serve on a committee that will award \$30 million to expand the power and influence of women in the United States by 2030. [Read more here.](#)

Investors put \$73M into Alpa Seth's new startup

Alpa Seth set up Biogen's European biosimilars business, served as chief operating officer of Vir, and now leads Nura Bio, which recently brought in \$73 million in a Series A round for preclinical work on axonal degeneration inhibitors. [Read more here.](#)

Screening for pancreatic cancer using artificial intelligence

Dr. Ananya Malhotra speaks to News-Medical about her latest research into pancreatic cancer, and how its prognosis could be improved by using artificial intelligence. [Read more here.](#)

SPOTLIGHT



Your Innovation. Our Expertise

Based in Austin and celebrating 20 years, QA Consulting is your trusted partner for innovative quality assurance, regulatory affairs, and microbiology services throughout the product lifecycle. Lean into our quality and compliance know-how to bring your medical devices to market and beyond.

From start-ups to multinational corporations, discerning medical device manufacturers of all sizes rely on our real-world knowledge, expert documentation, and mastery of industry protocols and procedures to navigate today's constantly evolving environment.

We design pragmatic solutions that ensure our clients exceed the highest industry standards to help them avoid regulatory roadblocks and guide them along a path to future success.

Medical device consulting with integrity. Lean into quality with medical device systems everyone can trust.

For more information, visit us at qaconsultinginc.com

Austin, Texas | 512.348.9404 | info@qaconsultinginc.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!](#)

Check out Austin Technology Council Calendar of Events

<https://tinyurl.com/ygzzr6jv>

Check out Texas States Small Business Development Center Network Calendar of Events

<https://tinyurl.com/ybf68aom>

Check out Women in Business Virtual Calendar of Events

Women In Bio welcomes you to attend any of the fantastic virtual events our dedicated chapters are holding, even if you don't live near those chapters. We offer a variety of networking and learning opportunities that will engage, educate, and empower. [View the full list of virtual events.](#)

Check out Temple Health & BioScience District's (THBD's) E-Learning Series Webinars Library

<https://www.templebioscience.org/elearning/>

Check out NAMSA's Podcasts Calendar of Events

Join NAMSA for a first-of-its-type podcast series, "BiocompCHATibility," as each episode features leading industry experts and discussion on how to proactively address specific medical device evaluation scenarios and challenges. Experts will also share real world examples and experiences focused on solutions proven to be successful.

<https://namsa.com/resources/podcasts/biocompchatibility-podcast/>

Check out MedTech Innovator Live Weekly Webinar Series

<https://www.youtube.com/channel/UCza4pwHPN-GQYTbi6FuE4rw>

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

Plan your 2020 conference calendar from east to west coast.

Sept 8 - Oct 23 | Virtual

The Virtual MedTech Conference powered by AdvaMed

[Learn more and register.](#)

Sept 10, 2020 | Virtual

HyperGiant AI Ethics A Two-Part Webinar Series

ATI is proud to partner with HyperGiant to bring you this free two-part series on the ethical implications of AI. [Learn more here and register.](#)

September 13-16 | Virtual 1-2pm CDT

RAPS Convergence 2020

[Click here to learn more.](#)

September 15 | Virtual

UL-Cybersecurity in Medical Devices, Change in Interoperability with Temporary & Field Medicine

<https://tinyurl.com/y533oafk>

September 29 | Virtual 12-1pm CDT

Temple Health and Bioscience District

The COVID-19 Pandemic: One Lawyer's Viewpoint

Event link: bit.ly/THBD92920

October 15 | Virtual 2-3:30pm CDT

Texas Medical Device Alliance (TMDA)

Sales and Commercialization Strategies for Medical Devices

<https://tinyurl.com/yvznhj3>

Nov 12-13/ Virtual

Southwest Research Institute (SWRI)

ISO 9001 Internal Auditor training

[Click here to register](#)

Dec 1 – 3 | Philadelphia, PA

MD&M East 2020 | Medical Expo

Discover new technologies from 550+ companies, attend educational sessions and connect with peers.

[Learn more and register.](#)

CAREER CORNER

Austin Chamber Talent Spotlight & Jobs Report

The monthly job market report is designed to provide insight into current employer demands, skills and occupations in the Austin MSA. [Read more here.](#)

Local Internship Opportunity

Having an accurate report of the Life Science ecosystem in Austin is imperative to its growth and to ensuring that workforce needs are met. ACC Bioscience Incubator is looking for a student intern to help compile a comprehensive and accurate list of the Biotech companies currently in Austin. For more information: <https://drive.google.com/file/d/ijwVIY4EkSBeWh9RcBEfpZwgHdjJUPvI/view>. Send resume to: Nancy.lyon@austincc.edu

Local Candidates Seeking Opportunities

Satyam Rajput | Master of Science | Biomedical Engineering | Texas A&M

I completed my Master's thesis on 3D printing of tissue engineering scaffolds and hydrogel based microfluidic devices with Dr. Akhilesh Gaharwar at Texas A&M and graduated in May 2020. I have also worked with Dr. Ellen Roche on various mechanical and chemical aspects of a cardiac septal wall closure device at Massachusetts Institute of Technology (MIT) at her startup, Holistick Medical. I have been fascinated to work in the healthcare industry as the solutions directly impact and improve people's lives. This has led me to pursue internships and research projects in the biomedical, biomechanical, and

biomaterials fields. I have sound technical expertise in computer aided design and engineering (CAD/CAE), prototyping, subtractive and additive manufacturing techniques, polymer and nanomaterial synthesis and characterization techniques. I have good technical writing experience as well. I am currently looking for a career in R&D, product development, process development, mechanical engineering, design and development, manufacturing/production/quality engineering roles in the medical device/healthcare sector. I would love to talk to you if you are hiring for any similar roles for your company.

Contact: srajput@tamu.edu | 979-422-2185 | www.linkedin.com/in/satyam-rajput/

Thomas Bates | Biology – to graduate 2023 | Trinity University

My name is Thomas Bates I am a rising sophomore at Trinity University. Due to the pandemic sending classes online I am currently looking for a way to take a gap year but still further myself academically and in my career goals. I am extremely interested in Immunology, and alternatives to antibiotics such as phage therapy, CRISPER, and Ecology. <https://www.linkedin.com/in/thomas-bates-360271b0/>

Career Opportunities

QA CONSULTING, INC. - Quality and Regulatory Consultant

The primary responsibility is to advise on and implement quality systems for medical device manufacturers with an added emphasis on regulatory processes. This position requires utilization of Quality Management System methods, including but not limited to: quality system implementation, project management, design controls, validation (design, process, and/or software), risk management, design verification, post-market activities, and regulatory strategies/submissions/correspondence. Must interact with consultants, clients, suppliers, and experts outside QA Consulting in order to communicate and implement QA Consulting's objectives. Contact Mallori Groh at 512-328-9404 office or mgroh@qaconsultinginc.com www.qaconsultinginc.com

Abbott

[View positions](#)

FDA Quality & Regulatory Consultants

[Join the FDAQRC CAREER NETWORK](#)

Aeglea Biotherapeutics

[View positions](#)

Luminex

[View positions](#)

ALKU

[View positions](#)

Molecular Templates

[View positions](#)

Babylon Health

[View positions](#)

QA Consulting, Inc.

[View positions](#)

Black Diamond Network

[Website](#)

Skills Alliance

[View positions](#)

Commissioning Agents (CAI)

<https://cagents.com/careers>

Smith+Nephew

<https://www.smith-nephew.com/careers/job-vacancies/>

Everlywell

[View positions](#)

Syneos Health

[View positions](#)

VOLUNTEER OPPORTUNITIES

Vitality Volunteers

Our mission is to help connect volunteers to organizations to improve the health of the community and increase awareness of diseases. We want to help the health and wellness-related organizations in our communities to promote their cause. Doing so will allow these organizations to make more of an impact and ensure that their message is heard. [Sign up for opportunities to volunteer virtually!](#)

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

TEXAS LIFE SCIENCE ORGANIZATIONS

ATX Women in MedTech
womeninmedtech@gmail.com

<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/>
BioMed San Antonio

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/>

Texas Biotech, Pharmaceutical & Life Sciences Companies

<https://biopharmguy.com/links/state-tx-all-geo.php>

Texas Health Catalyst

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

Texas Medical Device Alliance (TMDA)

<https://texmda.org/>

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

THBI - Texas Healthcare and Bioscience Institute

<https://www.thbi.com/>

The Health Cell, San Antonio

<http://thehealthcell.org>

TMCX/TMCX+, Houston

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

List: Top biomedical companies in the Austin area (2019)

<https://tinyurl.com/ybr7jjnm>

List: Leading medical device companies in the Austin area (2018)

<https://tinyurl.com/yb3bprtm>

Velocity Texas, San Antonio

<https://velocitytx.org/>

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

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



THANKS TO OUR TMDA SPONSORS!

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)