



**Texas Medical
Device Alliance**



BioAustin | Texas Medical Device Alliance | Austin Health Tech

NEWSLETTER

December 2020

The year is coming to a close and we're still pushing through.

Help us close out the year and start next year strong by joining our newsletter volunteer team. This roundup of new, meetings, conventions, & networking events in the life sciences and health technology community isn't possible without community support!

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....

How an Immunologist Pivoted to Tackle COVID-19

From mice to men. Read about his Akiko's Iwasaki's lab has transformed in order to tackle the pandemic. [Read the full story.](#)

LIFE SCIENCE INDUSTRY NEWS

Across the Pond....

New Expedited Timelines For Medical Device Registration Approvals In Mexico

New approval times and timelines for medical devices and pharmaceutical supplies have hit Mexico. [Learn and read more.](#)

INDUSTRY RESOURCES & FUNDING OPPORTUNITIES

Cisco Global Problem Solver Challenge

Calling All #TechForGood Startups. Check this opportunity for up to \$1 Million USD. [Learn more.](#)

The Kidney Innovation Accelerator (KidneyX)

Join the competition to accelerate artificial kidney development. The U.S. Department of Health and Human Services (HHS) and the American Society of Nephrology (ASN) have launched the KidneyX Artificial Kidney Prize, a competition to accelerate the development of artificial kidneys toward human clinical trials. This multiphase competition is KidneyX's first fully dedicated effort toward artificial kidney advancement, with initial phases offering up to \$10 million in prizes. To learn more, prospective entrants can join a [virtual information session on December 3.](#)

The Artificial Kidney Prize is open to both U.S. and international entrants, subject to eligibility requirements. The first phase seeks component or integrated prototype solutions that enable and advance the functionality, effectiveness, and/or reliability of artificial kidneys. Phase 1 submissions are due March 24, 2021.

[Learn more.](#)

WOMEN IN LIFE SCIENCE & WOMEN'S HEALTH

Pregnant Women Face Increased Risks From Covid-19

US Health officials added pregnancy to the list of conditions that put people at increased risk of death.

Full Story: [New York Times](#)

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/ygzr6jv>

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.

December 1 | Virtual

Canadian Field Evaluation Requirements for Medical Electrical Equipment and Systems

Speed up your time to market for your medical electrical equipment and systems.

[Learn more and register.](#)

December 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.](#)

December 2 | Virtual

A practical approach to restricted materials in MDR

This webinar will discuss effective approaches that meet the requirements of EU MDR.

[Learn more and register.](#)

December 3 | Virtual

Virtual Trivia Night and Discussion

Hosted by the Fort Worth Life Sciences Coalition. Since 2002, FWLSC has fulfilled its mission to educate in the life sciences, and to promote and support life sciences and life scientists. [Learn more and register.](#)

December 8 – 9 | Virtual

2021 State of Medical Device Virtual Summit

Free of charge! Understand strategies for regulatory and product development.

[Learn more and register.](#)

December 10 | Virtual.

Cobalt-60: The Heart of Radiation Sterilization

Richard Wiens, Director of Strategic supply at Nordion, will give insight into the workings of the global Cobalt-60 supply chain, and explain the impact of recent events.

[Learn more and register.](#)

December 14 – 17 | Virtual

American Association of Clinical Chemistry (AACC)

Connect with global leaders, learn cutting-edge technology and hear about vital research and important changes in the field.

[Learn more and register.](#)

CAREER CORNER

Regulatory Consultant (CDE/China FDA)

Seeking an experienced regulatory consultant that has regulatory experience with the regulatory authority in China (the CDE, Center for Drug Evaluation) to help provide strategic guidance and input for the client's phase III study of an immuno-oncology small molecule drug candidate. Contact Alex Magoon for additional details at 978.289.9741 or amagoon@blackdiamondnet.com.

Greenlight Guru, Multiple Positions

Check out positions in sales, marketing, product development, and more. [View on their website.](#)

Regulatory Affairs APAC Registrations consulting

This is a fully REMOTE, long-term contract and our client is looking to bring someone on ASAP. This person would be responsible for supporting product technical documentation, leading gap assessment and PTR Remediation. The ideal candidate would be fluent in Mandarin and would be able to interface with the notified bodies in china.

Please send your resume to kdoucette@alku.com or give her a call at 978-289-5825 if you are interested in hearing more about this project or opportunities for anyone with EU MDR/IVDR experience.

Association of Medical Diagnostics Manufacturers

Beaufort, LLC, a leading provider of regulatory, quality and clinical solutions for in vitro diagnostic companies is seeking an energetic, self-motivated individual who can fill the role of either Regulatory Affairs Manager or Senior Regulatory Affairs Specialist. The final title and salary will be commensurate

with demonstrated experience. This is a remote position. Click here to view job posting and learn more. [Click here to view job posting and learn more.](#)

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. <https://preview.tinyurl.com/Chamber-job-postings>

Nuclein Senior Scientist

Nuclein is an Austin-based company commercializing a disposable, hand-held PCR testing device for human pathogens. We are currently focused on developing a COVID-19 test. Our platform uses standard, real-time PCR, requires no technical expertise to operate, and delivers battery-powered, sample-to-answer results in under one hour, at the testing site. Please visit <https://nuclein.com/demo> for more details. We offer a fast-paced, dynamic, collegial environment, where individual contributions are highly valued while working on meaningful, exciting projects. Please visit <https://nuclein.com> or contact HR@nuclein.com for more information.

Position Summary: This individual will be integral to the development of next-generation molecular diagnostic devices. This scientist will report to the VP, R&D and develop diagnostic tests and reagents for the detection of various human diseases. The primary responsibility will be developing novel, multiplexed PCR assays for the amplification and detection of RNA and DNA from human pathogens.

The successful candidate will:

- Be experienced in developing robust, fast, and sensitive multiplexed quantitative nucleic acid assays
- Be experienced in the use of statistical methods and programs for optimizing amplification conditions
- Be experienced with systems and methods to minimize DNA contamination
- Have excellent written and verbal communication skills
- Be experienced in managing a small team
- Multitask with a high level of attention to detail and operate efficiently and independently with minimal supervision while working with a team

Qualifications:

- M.Sc. or Ph.D. in molecular biology or related field or equivalent applicable experience
- At least 5 years of experience developing quantitative, multiplexed nucleic acid (PCR) assays
- Primary contributor to developing at least 10 commercialized qPCR diagnostic assays
- Background in human infectious disease is preferred. [Click here if for the job posting.](#)

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-360271bo/>

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

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

Austin Health Tech Meetup

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

Health Technology Forum Meetup

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

Austin Technology Incubator (ATI)

<https://ati.utexas.edu>

Health Wildcatters, Dallas

www.healthwildcatters.com

BioAustin LinkedIn Group

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

Temple Health & Bioscience District (THBD)

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

BioHouston

<http://biohouston.org/>

Texas Biomedical Research Institute, San Antonio

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

BioMed San Antonio

<http://www.biomedsa.org>

Texas Biotech, Pharmaceutical & Life Sciences Companies

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

BioNorth

<https://bionorthtx.org/>

Texas Health Catalyst

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

Capital City Innovation (CCI)

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!



Health Tech Insight

Oriel
STAT A MATRIX

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)