



Texas Medical
Device Alliance



BioAustin | Texas Medical Device Alliance | Austin Health Tech

NEWSLETTER

November 2020

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

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....

Dell Children's Performed Historic First Pediatric Heart Transplant

In a first for Dell Children's Medical Center and The University of Texas at Austin, a team of pediatric heart transplant surgeons — all Dell Med faculty — successfully implanted a donor heart in an 18-year-old patient. [Read the full story here.](#)

The Morning Fix by 510k Cafe

Local med tech marketers [Amy Shepherd](#) and [Julie Dye](#) recently launched the podcast series, called The Morning Fix, by 510k Café. This series will examine current med tech trends, issues, and best practices as it relates to marketing and PR.

To subscribe and listen, please find the links to iTunes, Spotify, Stitcher and Touch Point Media: [Subscribe and listen here.](#)

LIFE SCIENCE INDUSTRY NEWS

Across the Pond....

Simplify Your Access to Brazilian Market with Current ANVISA Certifications

UL provides both test reports that meet Brazilian and other countries' requirements with experts to predict and interpret changes in legislation & requirements.

<https://connect.ul.com/index.php/email/emailWebview>

INDUSTRY RESOURCES & FUNDING OPPORTUNITIES

BioGlobal Accelerator

The BioGlobal Accelerator is a highly competitive, 16-week (8 weeks virtual & 8 weeks in-person) collaborative accelerator program that helps bioscience companies scale with velocity. Through coaching by entrepreneurs in residence, mentoring from industry experts, and interactive technical sessions, this unique program provides the resources entrepreneurs need to succeed. We connect high-potential companies with custom growth strategies, talent, investors, and a prominent bioscience ecosystem.

Applications September 2, 2020 – November 20, 2020

Companies will be selected on December 14, 2020

Program begins February 22, 2021

<https://velocitytx.org/what-we-do/accelerator/>

FDA Regulations for Electronic Documentation and Electronic Signatures

21 CFR Part 11 is a widely misunderstood regulation, and this confusion causes some medical device companies to resist moving to electronic systems when they know it's the right move. Read the complete guide [here!](#)

FDA Resumes Domestic Inspections: Are you Ready?

As recently reported, the FDA has resumed routine domestic inspections. This Gardner Law Regulatory Alert offers tips on how you and your team can get prepared for a visit from the Agency. This time, we are looking at a step-by-step process that, if done well, should help any company to get a good result from their CAPA process. Here are some [FDA inspection prep tips](#).

FDAQRC Press Release

For further information, please contact Marketing Coordinator, Kate Pfahl at k.pfahl@fdaqrc.com

(Cedar Park, Texas) – October 9, 2020 – FDA Quality and Regulatory Consultants announces a brand refresh as part of its 2020 anniversary celebration.

While things may look different, FDAQRC's commitment to its clients and consultants remains.

“We took the opportunity during 2020 to refresh our brand and create a simplified, clean logo. We believe the refresh is a wonderful wrap up to a somewhat difficult year for all of us. We used our downtime in COVID to streamline processes, reconnect with clients and refresh our brand. Overall, it's been a year of reconnections and we will wrap up 2020 with a continued attitude of commitment to our clients and consultants,” said company president, Chris Rush. “

As part of the brand refresh, FDAQRC has updated its iconic orange logo to a clean and more modern look. The new branding standards and logo was spearheaded by company president, Chris Rush and Marketing Coordinator, Kate Pfahl.

“Kate understood our product, company values and mission and embraced the challenge to create a new design,” Rush explained. “We believe this new look is a refreshing end to 2020 and will help us kick off an outstanding 4th quarter for our company.”

“The logo was carefully designed to reflect modernization, growth and uniqueness – all characteristics that help define the evolution of FDAQRC. With the help of bright colors and one-of-a-kind typeface, our new logo will be a staple in our brand recognition and corporate personality,” Pfahl stated.

FDAQRC was founded in 2009 by Rush. He incorporated the business in 2012. FDAQRC offers specialized Quality and Regulatory Consulting for pharmaceutical, medical device and biotech companies. The company employees 14 employees. The company headquarters is in Cedar Park, Texas.

WOMEN IN LIFE SCIENCE & WOMEN'S HEALTH

Garijo Named Next CEO of Merck KGaA

Belen Garijo will become CEO and executive board chair at Merck KGaA in May, replacing Stefan Oschmann. Garijo has been with the company for nine years, starting as chief operating officer of the biopharma unit before being appointed president and CEO of its health care unit.

Full Story: [Endpoints News](#)

Dress Code Exposes Gender Equality in Science

A dress-code policy barring passengers from wearing tight or revealing clothing aboard the Akademik Fedorov icebreaker, which was on an Arctic research mission led by Germany's Alfred Wegener Institute for Polar and Marine Research, sparked outrage and renewed concerns about sexism and gender discrimination in science. Full Story: [Read here](#).

SPOTLIGHT

Avomeen: CRO/CDMO Service and Expertise

Avomeen is an accredited, independent contract research organization (CRO) and contract development and manufacturing organization (CDMO), bringing chemists and scientists together to tackle scientific product-development challenges in the biopharmaceutical and medical device industries, as well as across other industries and applications. The company's unique approach is singularly focused on applying its expertise and working closely with clients to help transform their biggest goals into real solutions. Throughout each step of product development, Avomeen's scientists and experts work within a rigorous quality system to ensure products comply with regulatory requirements and consumer expectations.

Avomeen's facility is FDA-Registered and DEA-Licensed (schedules 1-5), and its laboratories are also GLP/GMP-compliant, ISO 17025 accredited, and QP authorized for clinical trial material in the EU. Avomeen offers complete, comprehensive scientific solutions that support the entire product development lifecycle, with a focus on growing strategic partnerships. For a complete overview of service offerings and areas of expertise, please visit www.avomeen.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.

November 5-6 | Virtual

Bio North Texas 2020 iC3® Life Sciences Summit

[Register here.](#)

November 5 | Virtual

FDA Emergency Use Authorization (EUA) and MDR. Case Studies

[Register here.](#)

November 12-13 | Virtual

Southwest Research Institute (SWRI)

ISO 9001 Internal Auditor training

[Click here to register](#)

November 17 | Virtual

FDA Public Meeting

Communications About the Safety of Medical Devices

[Register.](#)

November 17 | Virtual

Networking in a COVID-19 World: Harness Your Virtual Strengths

Join Temple Health and Bioscience District for the final E-Learning Series Webinar of 2020, and learn to optimize your virtual network.

[Register here.](#)

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.](#)

CAREER CORNER

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-360271ub0/>

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

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/>

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!



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)