



**Texas Medical
Device Alliance**

BioAustin | Texas Medical Device Alliance | Austin HealthTech

NEWSLETTER

January 2019

While celebrating the holidays, don't forget to jingle all the way through this month's newsletter to check out the sleigh-full amount of conferences, workshops, career events, and webinars going on! Happy New Year!

On behalf of the board of directors of Texas Medical Device Alliance, BioAustin and Austin Health Tech, we would like to thank the volunteers who have contributed to the past monthly newsletters. **Interested in joining the Newsletter Team?** Content is provided, and work is shared. Contact **Elisa Maldonado-Holmertz** for details (operations@texmda.org), and if you have news job postings, or other resources to share. Thanks for supporting BioAustin/TMDA/AHT!

If you want to know what's going on in biotech, med devices, life sciences and the future of healthcare in Texas, this is the source.

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LIFE SCIENCE INDUSTRY NEWS

In Our Neck of the Woods....

Apple expands its campus in North Austin

Apple recently announced its plans to build another campus in Robinson Ranch to initially employ 5,000 employees with the capacity to expand up to 15,000 employees. As the Silicon Hills expand, the growth of the life science and medtech sectors are bound to follow. For more information on this news release, click: <https://tinyurl.com/ycfg6kws>

CapitalCity innovation survey

Austin is a growing biotechnology community, and would like some feedback on how engaged the health innovation district is. Please, take a short (less than 5 minute) survey, to help us grow and plan our events for next year at <https://capital-city-innovation.typeform.com/to/WmFUPa>

Bill passed by the house prevents drug companies from overcharging Medicaid

Drug companies have been misclassifying brand-name drugs as generics in order to benefit from the Medicaid Drug Rebate program. The new bipartisan bill grants the Department of Health and Human Services new authority to reclassify a drug when manufacturers try to cheat the system to pay lower rebates. <https://tinyurl.com/y9hhyxsp>

Startups showcase their projects at Dell Med's demo day

13 early-stage ventures consisting of UT Austin and Dell Med faculty and students presented a five-minute pitch of their projects to the Texas Health Catalysts. These startups introduce devices, diagnostics, and therapeutics that address an unmet need. Texas Health Catalysts have received hundreds of applications and have already issued \$590,000 in funding for several projects. For more information of the presenters at Demo Day, click <https://tinyurl.com/yas3nzgv>. To apply to Texas Health Catalyst award, submit your innovation here: <https://tinyurl.com/y8z5gnz9>

The FDA to release new draft of the computer system & software in 2019

The current FDA regulations of computer systems have remained unchanged for over 20 years, and will finally evolve to catch up with the pace of current technology. The validation process has been so burdensome that the majority of medical device companies still rely mostly on paper for documentation. Details on how the FDA proposes to decrease the time and cost of current computer system validation can be found here: <https://tinyurl.com/yaypra4k>

Across the Pond...

As Brexit negotiation continues, the UK prepares for 'worst-case' medical supply plan

Although the draft withdrawal agreement was accepted by the Prime Minister's cabinet in mid-November, the Parliament and the remaining 27 EU member states need to sign off on the this deal; details include market goods, people, medicine regulation, and intellectual property. Such uncertainty surrounding these plans has prompted the UK government to create a stockpile of medical supplies to circumvent delays, if such a 'no deal' scenario occurs. <https://tinyurl.com/ygvzrzus> and <https://tinyurl.com/ybswnrnb>

The EU General Data Protection Regulation reminder to outside companies

The GDPR, which took effect earlier this year, can be broken down into three major categories: Data Subject Rights, Controller and Processor Responsibilities, and Transfer of Personal Data. The language of these guidelines is broad and unclear, but measures must be taken to for companies protect themselves when engaging in business with any person or company residing in an EEA country. To learn more, visit <https://tinyurl.com/yc6f4s8o> and <https://tinyurl.com/create.php>

Identifying opportunities in Asia for Medtech's digital revolution

The global digital market is a multibillion-dollar industry with vast potential to apply to the largest aging populations in Asia. The various areas of digital application have split into three distinct strategic paths: business process improvement, product-service innovation, and disruption with digital. Since a lack of clinicians and current infrastructure may provide barriers for rapid development and growth of the digital revolution, leaders are urged to innovate strategies to cope with these issues. <https://tinyurl.com/ycldtjbo>

INDUSTRY RESOURCES & FUNDING OPPORTUNITIES

Private BSL II Lab Suite Available

A private BSL II lab suite is available at STAR Park at Texas State University (San Marcos, TX). This state-of-the-art, 800-square-foot lab suite is part of a 36,000-square-foot technology incubator. The suite includes: two laminar flow hoods, work bench, DI water, nitrogen, chemical/hazmat waste management, dedicated independent HVAC units, lab air, and a standby generator support for critical systems. Clients have use of conference rooms, break rooms, and collaboration areas. Assistance is provided in recruitment of student workers, interns, access to graduates, and making connections with collaborating faculty. Companies at STARK Park are given university pricing when using specialized instrumentation/equipment. For more information or to arrange a tour, contact Stephen Frayser, Executive Director at s_f75@txstate.edu or 512-245-6434.

How to Drive Executive Engagement with Quality Systems (and Actually Get Them Excited About It)

Have you ever noticed the unspoken dissonance that exists between QA/RA and management in medical device companies? In this guest-contributed blog, discover the ways in which these two departments can align through one common language, resulting in executive engagement, support, and even excitement about your quality system by visiting <https://tinyurl.com/ycc5df77>

Ultimate Guide to ISO 13485:2016 Quality Management Systems (QMS) for Medical Devices

This guide, by Jon Speer, 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 the true quality vs. only compliance. Jon is the founder and VP of QA/RA at Greenlight Guru (quality management software exclusively for medical device companies) & a medical device guru with nearly 20 years industry experience. Jon knows the best medical device companies in the world use quality as an accelerator. To access the guide, visit <https://tinyurl.com/yawcnvc3>

Top 20 Medical Device Venture Capital Firms

Do you have a great idea for a new medical device? Have you already launched your own device company and are looking for the financial resources to take the company to the next level? If so, you're likely in the process of exploring options to secure funding for the growth of your business. To help

connect you with the top funding resources who cater to and understand the medical device industry, using CB Insights' data, we've compiled the 20 most active Medical Device VS firms since 2013. Check it out here: <https://tinyurl.com/ycucgjn>

British Standards Institute (BSI)- 10% off training courses

BSI provides assessment courses, software training, and advisory services to offer businesses multiple resources and solutions to promote excellence. BSI is offering a 10% discount when you register for any of the training courses found at <https://page.bsigroup.com/1/73472/2018-10-03/fk2vc>

NAMSA Biocompatibility Strategy Navigator

To simplify the process of identifying biological endpoint tests required for your medical device regulatory submission pathway, NAMSA provides the Biocompatibility Strategy Navigator, an online tool with open access, instant recommendations and email delivery options. This no-cost, easy-to-use resource identifies required testing strategies based on your intended regulatory pathway, utilizes the most up-to-date regulatory requirements to determine strategic recommendations, and digitizes and interprets the maze of biological endpoint matrices in one location.

<https://www.namsa.com/biocompatibility-strategy-navigator/>

NAMSA White Paper: Reducing Medical Device Development Timelines And Creating Value Through Biological Risk Assessments And Chemical Characterization

This NAMSA white paper provides details on how conducting the correct tests from the start can help streamline development timelines and reduce costs. <https://tinyurl.com/yqj6nzn>

Medical Devices Group Online

Access archived questions and answers, accessible webinars (replays, slides, transcripts), weekly industry announcements and a new full calendar of upcoming medical device events. The jobs board is now updated with several listings. Search the database for questions and answers, share posts on LinkedIn, Twitter, and email, ask questions directly to our Medical Devices Group Advisors, consult a "promotions" tab for member offers, conduct a poll, and more at www.medicaldevicesgroup.net

Capital City Innovation Startup Assistance Pilot Program

Capital City Innovation is running a pilot program to provide assistance to startup companies that are interested in applying for an SBIR or STTR grant from the National Institutes of Health or the National Science Foundation. Details of the pilot program and application at <https://tinyurl.com/y9mm5gub>

BIO International Presents: BIO Business Solutions

BIO International is offering corporate members of BioAustin the opportunity to participate in the BIO Business Solutions cost-savings purchasing program. Help your business grow by benefitting from 50-70% discounts on laboratory supplies, office products, shipping services, and more at

<https://tinyurl.com/ybdsb785> For additional details contact Steven Keeler, BIO Regional Business Development Manager, at skeeler@bio.org

WOMEN IN SCIENCE & WOMEN'S HEALTH

Research Triangle Park Companies Push For Diversity

Companies such as Lenovo, GlaxoSmithKline, and PrecisionHawk at RTP, the largest research park in the United States, have committed to increasing representation of women and minorities on boards currently comprising less 9% of such high level positions. Such initiatives include meeting minimal

representation quotas, providing certification programs, and increasing paid leave for caregivers to support families. <https://tinyurl.com/y84anhr8>

A Randomized Study at West Point Shows that Women Help Each other Advance

A study of women and peer groups at West Point revealed that women were more likely to stay and progress through the academy when in the presence of other women without affecting the progress of their male counterparts. This study provides possible evidence that women underrepresented in male-dominated careers such as advanced STEM fields are likely to succeed and progress with the support of female colleagues and mentors. Although these results may not apply to college or the workplace, such studies add to the increasing awareness and solution to the challenges that women face.

<https://tinyurl.com/yaxcecyg>

Women in Biotech accepting applications for Founders Professional Scholarship

WIB is accepting applications for the Women in Bio Founders Scholarship awarding three \$1,000 scholarships. The scholarship was established to advance the educational development of women in the life sciences industry by encouraging and supporting education on the business aspects of life science. Candidates must be a current WIB member and currently working in the life sciences. The 2018 awardees and more information are provided here: <https://tinyurl.com/ycbeemf3>

UPCOMING EVENTS

JANUARY 9, San Francisco, CA

Johnson & Johnson Innovation is Launching a Quick Pitch Event

In an effort to unearth the unseen and brightest innovations in healthcare, Johnson & Johnson Innovation is launching a Quick Pitch event where innovators can apply to present to Johnson & Johnson Innovation's leadership during the week of the 37th Annual JP Morgan Healthcare Conference in San Francisco, CA. If you are selected, you will have an opportunity to present for 5 minutes followed by a 5 minute Q&A session with Johnson & Johnson Innovation's leadership. Apply for an open spot at the Johnson & Johnson Innovation Quick Pitch event to be held on Wednesday, January 9th from 9-11am. Limited spots available. Application must be submitted by Friday December 7th. For more information and to apply, visit <https://tinyurl.com/yd7oa93p>

JANUARY 11, Austin, TX

Zoho One US Tour

Zoho is hosting a free, educational seminar on their complete business suite, Zoho One, in Austin. Register at https://one-seminars.zohosites.com/?utm_source=ATC

JANUARY 16, Austin, TX

Austin Technology Council: Leadership Dinner

Network with industry leaders at Z'Tejas to openly discuss emerging trends and market opportunities. Listen to a discussion-style event featuring best practices, problem solving, and thought leadership sponsored by Crown Castle. For information and to register, visit <https://tinyurl.com/ya478rkl>

JANUARY 14-16, Horseshoe Bay, TX

TAMSET 2019 Annual Conference: Neuroscience and Brain Health

Join us as we convene some of the top minds in Texas and the nation to explore the groundbreaking research that could lead to advances in neuroscience and better brain health. We'll investigate topics such as neurodegeneration, addiction and the opioid crisis, neurological disease prevention,

technological advances in mapping the brain, and neuroscience research priorities and challenges that lie ahead. The TAMEST Annual Conference is open to all in the research community. For more information and to register, visit <https://tinyurl.com/ycutuvvg7>

JANUARY 31, Austin, TX

Health, Design & Business: Design Thinking for Health Innovation

Join health entrepreneurs from across Central Texas as José Colucci, of the Design Institute for Health, talks about the business impact of design in health. This seminar is part of the Monthly Learning Series presented by the Texas Health CoLab @ Dell Medical School. Register at <https://design-thinking-health-innovation-txhealthcolab.eventbrite.com>

FEBRUARY 1-3, Austin, TX (FREE Event)

LifeSciHack



LifeSci Hack

BioAustin, Experimental Civics and CapChem are putting on the first life science hackathon in Austin. Topics include Interoperability, Big Data Analytics in Life Sciences, Life Science Software Tools and BioEducation. We are looking for life science professionals, programmers, hackers and other interested participants. Come learn more about how big data, data architecture, machine learning and life sciences can work together to make the world a better place. For more information, visit www.lifescihack.com or contact scott@bioaustin.com. Be part of history as we bring together these complimentary fields.

FEBRUARY 21, Austin, TX (FREE Event)

TMDA Quarterly Meeting - IP and Licensing

Join a fascinating discussion about legal issues that can make or break a company moderated by K. Lance Anderson, JD, Practice Group Chair for Pharma & Biotech at Dickinson Wright PLLC. This presentation will focus on the following topics: patent eligible subject matter, avoiding divided infringement, geographic development of your portfolio in a cost effective way, securing new IP, and acquisition complexities when university/government have contractual obligations.

<https://tinyurl.com/ybq9yk6z>

MARCH 3, Austin, TX

Networking Happy Hour

Save the date to join next spring's networking event during SXSW. For details, type in your email at

<https://tinyurl.com/y9b7r7hd>

CAREER CORNER

3M

- Advanced Application Development Engineer
- Regional Distribution Leader
- Multiple Positions

https://3m.recsolu.com/job_boards/

Abbott

- Medical Science Advisor
- Senior Product Manager
- Multiple Positions

<https://www.jobs.abbott/us/en/search-results?keywords=austin>

Aeglea Biotherapeutics

- Associate Scientist Protein Biochemistry
- Sr. Medical Writer
- Multiple positions

<http://www.aegleabio.com/biotechnonology-careers/#career-opportunities>

ALKU

- Medical Writing Regulatory Affairs – Remote contract positions.
- Contact Logan Blake, Regulatory & Scientific Recruiter at lblake@alku.com, (978) 296-6903

Arsenal Products

- Director of Engineering <https://tinyurl.com/yckjcbfq>
- CNC Machinist <https://tinyurl.com/y86cupv3>

Asuragen

- Field Application Scientist
- Scientist I – Product Development
- Multiple Positions

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

Austin Healthcare Companies

Talent Search via Built in Austin

<https://www.builtinaustin.com/guides/austin-healthcare-companies>

Cancer Prevention Research Institute of Texas, CPRIT (TX)

- Chief Product Development Officer

<http://www.cprit.state.tx.us/about-cprit/cprit-employment-opportunities/>

FDAQRC (TX)

- Clinical Quality Assurance Project Manager
- GCP Auditor with GMP

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

Luminex (TX)

- Flow Cytometry Sales Specialist
- Manufacturing Assembly Associate I
- Multiple Positions

<https://www.luminexcorp.com/about-luminex/careers/open-positions/>

Molecular Templates (Austin, TX)

- Director, Financial Planning & Analysis
- Scientist, Quality Control
- Multiple positions

<http://mtem.com/careers/>

Syneos Health

- Clinical US Home Based Positions <https://tinyurl.com/yagozuuj>
- Commercial Texas positions: <https://tinyurl.com/yd77ku42>

Tek Resource

- Help Desk Analyst
- Software Architect
- Multiple positions

<http://tekresource.com/jobs/>

Speragen, Research Assistant or Early-Stage Scientist

Speragen is a young start-up drug discovery company based in Austin and it has a great opportunity for a self-motivated Research Assistant or Early-Stage Scientist with mammalian tissue histochemistry, cell culture, and gene expression (qPCR) experience. This is an SBIR grant-funded, part-time position expected to begin early December 2018 and will continue through summer of 2019.

For more information and to apply send a single-page CV and contact information to:

james.hill@speragen.com

Skills Alliance, Market Access and Contracting Professional

Skills Alliance, a global life sciences recruitment agency specializing in placements across the Pharma, Biotech and Medical Device Industries has a great opportunity for a Market Access and Contracting professional specializing in US managed markets. This position will be with a prominent Market Access consultancy in NY, and will be reporting to the Head of US Market Access. The essential functions of the role will be to work closely with existing and new clients to help formulate payer and reimbursements strategies, and execute contracts with payers. This position will be responsible for overseeing multiple accounts simultaneously, and leading ground floor initiatives. You must have at least a Bachelors' degree, Market Access/Managed Markets experience, consulting experience, at least 5 years of payer and reimbursement formulated strategy experience, and previous project management experience. Ideal experience will include working directly with payers to execute contracts and implement strategies. Send inquiries and resume to sarah.fletcher@skillsalliance.com

Well-Qualified Interns From Austin Community College Biotechnology Program Looking For Positions!

Contact Dr. Linnea Fletcher, Department Chair (linneaf@austincc.edu or call 512 -223-5912), or Steven Spurlock (sspulock@austincc.edu or call 512 223-5915), Administrative Assistant for more information. For more information about the program visit Austin Community College Biotechnology Program at <http://sites.austincc.edu/biotech/>

VOLUNTEER OPPORTUNITIES

BioAustin | Texas Medical Device Alliance | Austin Health Tech Newsletter

Interested in joining the Newsletter Team? Content is provided, and work is shared. Contact **Elisa Maldonado-Holmertz** for details (operations@texmda.org).

ATX Women in MedTech

Looking for volunteers to support community outreach, event management, PR, sponsorship and more. Email womeninmedtech@gmail.com for details.

Austin Chapter, Women in Bio -Texas (WIB-ATX)

We are seeking volunteers to help with building chapter membership, chapter communications, obtaining sponsorships, event planning and organization, and Young Women in Bio mentoring

programs. We welcome any level of time commitment and involvement. Learn more about WIB-ATX at <https://www.womeninbio.org/>. Email Texas@womeninbio.org to enquire about volunteering.

BioAustin

We are seeking volunteers to maintain our website. If interested, please reach out to Scott Collins at scott@bioaustin.com. Also, if you are interested in joining the Newsletter Team, contact Elisa Maldonado-Holmertz at operations@texmda.org

BioAustin Science Fair Award Presentation

If you are interested in facilitating award presentations to Science Fair winners at BioBash, please contact Scott Collins: 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

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

Health Technology Forum Meetup

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

Health Wildcatters, Dallas

www.healthwildcatters.com

Temple Health & Bioscience District

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

Texas Biomedical Research Institute, San Antonio

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

TX Health Catalyst, Austin

<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/texas>

THANKS TO OUR TMDA SPONSORS!



With warm regards,

Amy Dowell, Dana Abramovitz, Diya Banerjee, Elisa Maldonado-Holmertz, Tamiko Oguri, and Melissa Hilgendorf on behalf of BioAustin, Texas Medical Device Alliance (TMDA), and Austin HealthTech (AHT)