



**Texas Medical
Device Alliance**

BioAustin | Texas Medical Device Alliance | Austin Health Tech

NEWSLETTER

March 2019

Spring is near! Don't forget to take advantage of this month's newsletter content regarding conferences, workshops, career events, and webinars!

On behalf of the Board of Directors of Texas Medical Device Alliance, BioAustin and Austin Health Tech, we welcome volunteers to join the monthly newsletter team.

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.

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 Wood

Texas Joins The Top 10 Medical Device States

Although California, Minnesota, and Massachusetts still lead the U.S. medical device industry, several states also contribute significantly to medtech. With over \$47M in medical device VC investments in 2017, Texas snags 3rd place in Forbes Best State for Business. A significant contribution to the ranking comes from Houston boasting the largest medical complex in the world, the Texas Medical Center, and from Plano headquartering the largest medical device contract manufacturer in the world, Integer. Compare and contrast with the other states here: <https://tinyurl.com/y5h7zden>

The Growth YEAR

Dell Medical School marks their 3rd year in operation by recognizing that their first 50 students have now experienced “one year of classroom fundamentals, and spent another

year in clinical clerkships (one year sooner than at most medical schools).” They are calling this year their Growth Year as students start specializing their paths and embark on becoming the medical field leaders.

<https://tinyurl.com/yxrmxfgh>

The FDA Announced Another Record Year Of Novel Device Approvals

Despite increased regulations and stringent plans placed to protect and promote public health, the FDA shared data showing a steady progression of novel device approvals year after year since 2009. This provides some evidence that innovation and business enterprise are not stifled by higher patient safety standards imposed over the recent years. A statement released from FDA Commissioner Scott Gottlieb reveals several examples and details at:

<https://tinyurl.com/yy9z29qw>

Across The Pond...

Biofuels Are Making Global Progress

The Finnish Parliament approves 30% biofuel mandate for 2030, and Canada is investing up to \$7 million in a biomass research to grow their bioeconomy. Details can be found

<https://tinyurl.com/y3gtua9x>,

<https://tinyurl.com/y38frpjw>, and

<https://tinyurl.com/yyg2abru>

Exploring The ‘No-Deal’ Brexit Scenario

Britain is scheduled to leave the EU on March 29, 2019, so obviously almost every aspect of the British citizen’s life from driver’s licenses, pet rules, mobile phones, and travel restrictions are affected (details are listed here:

<https://tinyurl.com/y3om6p7a>). However, for the rest of the world, the links to Britain’s

energy, banking, and healthcare industries could face serious disruptions. The MedTech industry will be reminded again to consult The UK Medicines and Healthcare products Regulatory Agency (MHRA) that notes where a device manufacturer is not based in the UK, the registration of a product with the MHRA must be taken on by a ‘Responsible Person’ recognized in the UK and having a UK registered address who will be accountable for the product in the UK. Again, business addresses in the UK without physical presence is not acceptable. Details of this ripple effect can be found here:

<https://www.compelo.com/implications-of-no-deal-brexit/>

SPOTLIGHT

Temple Health And Biosciences District (THBD) Spreads The Love To Startups, Researchers, And Students Across Central Texas

Sending a heart-felt thank you to everyone who came to our Open House and Website Preview Party on January 31. The support of our local and biotech community continues to impress and inspire us. We appreciate your role in helping us spread the word about the ample resources available at the District for startups, researchers, physicians, and students. We hope you enjoyed the event! Feel free to reach out with any questions about the facility and remember to check the new website for upcoming events, latest news and information about the office and laboratory facility. <http://www.templebioscience.org/>

Last but not least, thank you to KWTX (CBS), KCEN (NBC), and KXXV (ABC), for attending and covering the event in Temple! If you missed out on the event, check out the coverage below including interviews with our Executive Director Tami Annable:

VIDEO: Facility provides home for bioscience startups

<https://www.kwtx.com/video?vid=505149282>

VIDEO: District pushes to make Temple center of bioscience

<https://www.kwtx.com/video?vid=505135462>

Cutting-edge biotech startups get a helping hand

<http://www.kxxv.com/story/39888623/cutting-edge-biotech-startups-get-a-helping-hand>

Temple Health & Bioscience District to host open house for biotechnology community

<https://tinyurl.com/y6btnkgo>

INDUSTRY RESOURCES & FUNDING OPPORTUNITIES

Texas A&M New Ventures Competition - Submission Deadline March 3, 2019

This is open to all Texas-based companies seeking to bring a new or enhanced technology to the marketplace. Participant companies must be technology- or science-focused independent ventures in the pre-seed/seed, start-up or early growth stages. All applicants are strongly encouraged to read the TNVC Rules and Guidelines to ensure they meet all eligibility requirements. <https://texasnvc.org/>

Thomas Jefferson Fund – Proposal Deadline March 5, 2019

This 2019 Call for Proposals is launched by the Embassy of France in the United States and the FACE Foundation, and aims to encourage and

support cooperation among the most promising young French and American researchers, and foster forward-looking collaborative research projects. Register here:

<https://tinyurl.com/y6agsx4y>

Alibaba Texas Midnight Pitch Event - Applications Close March 27, 2019

If you are ready to grow your sales and find new customers, we are seeking Austin's best consumer products. Register here:

<https://tinyurl.com/y2jubucp>

Medical Device Reimbursement Strategy: How To Plan For Successful Market Commercialization

Partially due to the Patient Protection and Affordable Care Act (PPACA) of 2010, companies have had to change strategies to successfully commercialize their products. Sign up to receive this White paper to further understand the impact of Value-Based Purchasing, Alternative Payment Models and hospital and physician incentives in order to position technologies for market success.

<https://tinyurl.com/yybnc8y9>

Brush Up On The 5 Most Common CAPA Process Problems

Explore the details with Greenlight Guru involving the most common problems in CAPA: Lack of Cross-Functionality, Reactive instead of Proactive, Overuse vs. Underuse, Poor Root Cause Determination, Poor Definition of a CAPA Process by visiting

<https://tinyurl.com/y5jxtwok>

Prepare For A QSIT Inspection

Visit Greenlight Guru's blog to review the QSIT method, inspection process, the closing meeting of the inspection, and what to do after a QSIT Inspection. <https://tinyurl.com/y6crhote>

Top 35+ Medical Device Conferences To Attend In 2019

Attending the right conferences can be crucial for those in the medical device industry by establishing a new partnership, making valuable new connections, and bringing important new knowledge of regulatory and other industry trends back to your company. Here is a list of top conferences for 2019:

<https://tinyurl.com/y4vo4hc5>

Are You Ready For The New EU Medical Device Regulation (MDR)?

In order to find all gaps within a company a complete gap analysis is required. This is exactly where my Excel based gap analysis tool will be of great support and will find all gaps immediately. <https://www.mdrtool.com/>

WOMEN IN SCIENCE & WOMEN'S HEALTH

Lifetime Achievement Award Presented To Lynn Meyer

The IntegReview IRB is a woman-owned business and independent institutional review board that provides ethical review globally to approve and conduct periodic review of biomedical, medical device, social, educational and behavioral research. While celebrating its 20th year in operation, IntegReview IRB thanks its founder and current Managing Partner, Lynn Meyer, for her dedication, visionary guidance, and outstanding leadership. Lynn will continue to lead this company with credo "success is a clear reflection of the effort, pride and passion with which a person lives."

<https://integreview.com/>

Equal Pay For Women Bill Was Introduced In Congress

Although women account for almost half of the United States workforce and more than half of earned college degrees per year than men, women still earn an average of 80.5 cents for every dollar earned by a man. When accounting for race, this disparity is even more exaggerated. To help end the wage gap cycle, this bill would also prevent employers from asking candidates about prior salaries. In addition, employees would not be able to fire or retaliate against employees who discuss pay.

<http://news.trust.org/item/20190130183805-wxae6>

Calling For More Women In Clinical Studies To Help Fill The Scientific Data Gap

A group of Illinois researchers led by the director of Northwestern's Women's Health Research Institute, Teresa Woodruff, are urging more women to participate in clinical studies by signing up themselves. Part of this effort includes the creation of the Illinois Women's Health Registry, an online, smartphone-compatible tool that allows women to access information about clinical studies, which should provide researchers with a broadened pool of female study participants. Including more women in clinical studies will provide the hormonal variables that most current clinical data lack. The initial goal is to have 10,000 women sign up on this state-wide tool.

<https://www.chicagotribune.com/lifestyles/ct-life-women-medical-research-illinois-registry-20190207-story.html>

Society Of Toxicology Honors 2 Women For Their Efforts To Spare Animals In Science

The Enhancement of Animal Welfare Award was received by FDA scientist Suzanne Fitzpatrick for her work in developing alternatives to animals in toxicology experiments. Also, Society of Toxicology recognized a National Toxicology Program scientist Nicole Kleinstreuer as the winner of this year's Achievement Award. Her computational toxicology modeling research reduces the need for animals in toxicology testing. <https://factor.niehs.nih.gov/2019/2/awards-recognition/sot-awards/index.htm>

Executive Women In Bio Boardroom Ready Platform: Accepting Applicants

Are you a female executive who's ready to serve on corporate boards for life science companies? Executive Women In Bio's Boardroom Ready network can help -- apply for the 2019 program today! The deadline to apply is March 15th! <https://www.womeninbio.org/page/BoardroomReady>

UPCOMING EVENTS

MARCH 1-3, Fort Worth, TX

Techstars Startup Weekend

Techstars Startup Weekend is the place to look for a team, create a prototype of your idea, validate your business idea, and receive feedback from experienced entrepreneurs, all in one weekend.

<https://tinyurl.com/y3rvtwx7>

MARCH 4, Austin TX

Tech^Map March Meetup: Building A Network In The Startup World

Join Colt Moncla (Business Consultant, Allan Chiulli (Founder, Author, and Speaker), Douglas Wengell (Co-Founder of ImaginLand), and CJ Finley (Brand Consultant) in a panel discussion on building a network in the Startup landscape. Monday, March 4, 6.30 PM to 9.00 PM at the Capital Factory, 701 Brazos St., Austin TX. Tickets via TechMap site (link below) are \$12, via MeetUp.com are \$15, and \$20 at the door.

Registration and tickets at <https://tinyurl.com/y4oy2exk>

MARCH 7, Houston, TX

French-American Innovation Day

An event that brings together prominent French and American experts to discuss innovation topics in order to foster transatlantic connections in research and innovation. Organized at the Texas Medical Center Innovation Institute by the Office for Science & Technology of the French Embassy, the 2019

FAID conference will focus on the two following themes: Computer-Assisted Surgery & 3D Visualization Tools, and AI & Machine-Learning in Medical Imagery and Healthcare.

http://faid-houston.france-science.org/?mc_cid=69d91c6460&mc_eid=4899d1f6a5

MARCH 8, Austin, TX

Providing for Providers: Future of Healthcare UX Meet Up

Review the near and longer term impacts of technology advancement, dramatic increases in provider demand, and explosion of care models that will effectively allow physicians to choose when and how they practice. Join others who are affecting this vision of the future to discuss the implications of improvements in healthcare technology and service design on caregiving and the clinician lifestyle.

<https://schedule.sxsw.com/2019/events/PP90098>

MARCH 8, Austin, TX

Energizing Health House

During SXSW, focus on creating opportunities for community advocates, entrepreneurs, venture capital, health organizations, industry and philanthropy to innovate, collaborate and activate initiatives aimed at eliminating systemic barriers and building healthier communities.

<https://www.capitalcityinnovation.org/events/2019-energizing-health-house>

MARCH 9, Austin, TX

'Must-Have' Capabilities for Tomorrow's Health Care Leaders

Join the American Hospital Association and Dell Medical School to explore how the health care field can improve health care value by fostering leaders who embrace a patient-centric, value-focused and empathetic approach to health and health care.

<https://dellmed.utexas.edu/events/must-have-capabilities-for-tomorrows-health-care-leaders>

MARCH 11, Austin TX (Free Event)

Capital City Innovation & Affinity Partners Invites You To The Central Texas Health Innovation Social

This is the second year that Capital City Innovation and partners will be hosting a social in March. Come out and socialize with local and global innovators, investors, and leaders in the health, tech, and life sciences space, and hear about opportunities to collaborate with key organizations in the Central Texas area. Monday, March 11, 4 PM to 7 PM at the Austin Central Library, 710 W Cesar Chavez St, Austin, TX. SXSW badge NOT required!

Register at <https://tinyurl.com/y5gaqrzr>

MARCH 13, Austin, TX

Exploring Life Science Collaboration Opportunities Between Texas and Denmark

The Consulate General of Denmark in Houston, in collaboration with Texas Medical Center, have the pleasure of inviting you to welcome HRH Crown Princess Mary of Denmark. To attend, please contact Christina Brinch Clark, Senior Commercial Advisor, Health & Life Sciences, Consulate General of Denmark, Houston, chrcla@um.dk or +1 832-660-6496

APRIL 5, Austin, TX

C. Frank Webber Lectureship

Texas Academy of Family Physicians' 2019. Join primary care physicians from across the state to learn, network, and explore the latest in techniques, products, and services.

<http://www.tafp.org/marketing/cfw>

APRIL 11, Waco, TX

Baylor University Science & Health Career Fair

On Thursday, April 11th from 3:00-6:00pm, Baylor University's Career & Professional Development Center is hosting a Science & Health Career Fair. The event will be held in the Baylor Sciences Building atrium, and they are seeking companies looking to hire undergraduate science students for full-time entry level, research, and internship opportunities. All employers must register online through Handshake at the following link: [Spring 2019 Science & Health Career Fair](#). The registration deadline is April 4th at 5:00pm CT. Contact Desiree Foley, Employer Relations Specialist, at CPDEmployerRelations@baylor.edu to learn more information about this event and get instructions on how to create a Handshake account for registration.

APRIL 18, Austin, TX (Free Event)

Texas Medical Device Alliance (TMDA) - Smart Medical Devices

Watches, fridges and phones aren't the only products to go smart, as the Internet of Medical Things (IoMT) market is estimated to be \$158B by 2022 (Deloitte). Connected medical devices generate, collect, analyze and transmit data. The data, along with the devices themselves, are creating the IoMT – a connected infrastructure of medical devices, software applications and health systems and services. Learn how to get digital transformation right – whether through adapting their existing business models, inventing new ones or both at the next Texas Medical Device Meeting. Speakers TBD. Register at <https://www.eventbrite.com/e/tmda-meeting-smart-medical-devices-tickets-57431532259?aff=ebdssbdestsearch>

APRIL 18, Austin, TX

Baylor University Career Trek

A Career Trek is where the Career & Professional Development Center takes a select group of students on a day-long trip to visit companies in Texas and learn about their career opportunities. A typical visit is 1.5-2 hours and includes a tour of the facility, a presentation about job/internship opportunities, and Q&A time with employees. If you are a biotech/life science company in Austin who is willing to host a group of 20 students, please contact Desiree Foley, Employer Relations Specialist at CPDEmployerRelations@baylor.edu to find out how to sign up.

APRIL 18, San Antonio, TX

The San Antonio Medical Foundation Annual Education Luncheon

Healthcare: Yesterday, Today and Tomorrow Luncheon featuring Dr. Vivek Murthy, immediate past US Surgeon General. Ticket purchase at: <https://www.samedfoundation.org/>

APRIL 24, Washington, D.C.

AWIS 2019 Innovation & Inclusion Annual Summit and Awards Dinner

The Association for Women in Science (AWIS) will present an innovative lineup of industry and academic leaders. Over 250 of the most influential leaders in science and technology will attend to further conversation, connect powerful ideas, recognize our awardees' accomplishments, and celebrate women in STEM. Ticket purchase here: <https://www.innovation-summit.org/>

JUNE 17-18, Las Vegas, NV

Medical Device R&D Summit

The Summit will highlight the current challenges and opportunities through visionary conference sessions and keynote presentations delivered by the most esteemed experts and thought leaders from North America's leading corporations. <https://events.marcusevans-events.com/meddevice-19/>

CAREER CORNER

3M

- Plant Engineering Technician
 - Dental Practice Sales Specialist
 - Multiple Positions
- https://3m.recsolu.com/job_boards/

Abbott

- Clinical Specialist I
 - Strategic Planning Director
 - 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/biotechnology-careers/#career-opportunities>

ALKU

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

Arsenal Products

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

Asuragen

- Lead Software Verification & Validation Engineer
 - Production Scientist II
 - Senior Net Developer
 - Multiple Positions
- <https://asuragen.com/careers/>

Oxford Life Sciences

OLS specializes in providing senior level consultants with mission critical skill sets and emerging industry-specific experience. To learn more about our regulatory and compliance specialty areas, visit

www.oxfordcorp.com

Contact Ivy Smith, 561.277.2862 Direct, ivy_smith@oxfordcorp.com

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)

- Field Application Specialist
 - Manufacturing Technician I
 - Senior Director, Research and Development
 - Multiple Positions
- <https://www.luminexcorp.com/about-luminex/careers/open-positions/>

Molecular Templates (Austin, TX)

- Project Manager/Sr. Project Manager, Biopharmaceutical Development
 - GMP Supervisor-Downstream
 - 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
 - Unreal Engine Developer
 - Multiple positions
- <http://tekresource.com/jobs/>

Speragen: Research Assistant or Early-Stage Scientists

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. 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

Join the BioAustin/TMDA/AHT Newsletter Team!

Content is provided (but we welcome new sources and original content too), and the work of compiling, editing and web publishing is shared.

Contact Elisa Maldonado-Holmertz at operations@texmda.org to learn more.

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 Medical Device Alliance (TMDA)

We are seeking volunteers to maintain our website. If interested, please reach out to Elisa Maldonado-Holmertz at operations@texmda.org

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/te>

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ELEMENT**

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With warm regards,
Dana Abramovitz, Diya Banerjee, Elisa Maldonado-Holmertz, and Tamiko Oguri on behalf of BioAustin, Texas Medical Device Alliance (TMDA), and Austin HealthTech (AHT)