

BioAustin | Texas Medical Device Alliance | Austin Health Tech

NEWSLETTER

February 2019

Happy February and looking forward to spring time weather!
 BioAustin and Texas Medical Device Alliance are both hosting events this month – join us!

FEBRUARY 1-3, Austin, TX (FREE Event) – BioAustin Life Science Hackathon

FEBRUARY 21, Austin, TX (FREE Event) - TMDA Quarterly Meeting: IP and Licensing

If you want to know what’s going on in biotech, medical 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

UT Researcher Wins the “Triple Crown” Of Diabetes Research Recognition

UT Southwestern’s Dr. Philipp Scherer has become the first scientist to win what could be called the “Triple Crown” of diabetes research recognition. Dr. Scherer, Director of the Touchstone Center for Diabetes Research, has been chosen to receive the 2018 Manpei Suzuki International Prize for Diabetes Research in recognition of his discovery of adiponectin, a hormone released by fat cells, and subsequent research into the hormone’s role in fending off diabetes. His research has “deepened and widened our understanding of diabetes, obesity and energy homeostasis,” according to the Manpei Suzuki Diabetes Foundation, which bestows the \$150,000 prize.

<https://www.utsouthwestern.edu/newsroom/articles/year-2019/diabetes-research-awards.html>

Across The Pond...

UK To Request ‘Responsible Person’ To Be Situated In The UK If There Is A ‘No-Deal’ Brexit

The recent no-deal Brexit notice from the UK government states that businesses retailing devices in the UK require a ‘responsible person’ to be actually situated in the UK and not just have an address there if the business is not based there. The UK Medicines and Healthcare products Regulatory Agency (MHRA) which published the guidance note says that 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.

<https://tinyurl.com/yaahwpm>

SPOTLIGHT

Texas Health Catalyst 2018 Program Highlights

Texas Health Catalyst supports the translation of promising ideas and discoveries into solutions that improve health outcomes and lower healthcare costs. Over the past 3 years, Texas Health Catalyst program awardees have received a total of \$600k in funding from the program and have gone on to raise \$12+ million in federal and private funding. Awardee projects have also resulted in the creation of 6 startups and a few more are underway. <https://dellmed.utexas.edu/thc>

- The 2018 THC cycle was launched in April where 80 proposals were received, 24 projects were invited to pitch, 13 were finalists, and 6 were funding awardees.
- THC finalists participated in customer discovery through a partnership with the NSF I-Corps program - <https://dellmed.utexas.edu/blog/teaming-up-for-the-innovation-roller-coaster>.
- Innovators unwrapped key insights during the consulting phase - <https://dellmed.utexas.edu/blog/innovators-unwrap-texas-health-catalyst-wraps-up>.
- THC closed out the cycle with Demo Day 2018 that brought innovators, clinicians & industry together to create synergies - <http://www.siliconhillsnews.com/2018/11/07/texas-health-catalyst-ut-austin-showcases-early-stage-projects-demo-day/>.
- A THC awardee from a previous cycle won accolades - <https://dellmedrethink.com/we-can-identify-cancer-in-just-10-seconds/>.
- A case study was published to showcase another THC awardee project and their journey through and beyond THC - <https://dellmed.utexas.edu/case-studies/translating-ideas-into-tools>.

INDUSTRY RESOURCES & FUNDING OPPORTUNITIES

European Commission Factsheets

The European Commission recently published a number of factsheets that are useful. The documents broach the issue of the MDR and IVDR and address specific questions that may come up in discussions with “third country” authorities, end clients, or distributors/importers.

https://ec.europa.eu/growth/sectors/medical-devices_en

JPM Recap: Must-Reads Of The Week, From FDA To IPO To M&A And More

If you missed the J.P. Morgan Healthcare Conference, check out the recap from Fierce Pharma.

<https://tinyurl.com/ygc278mu>

6 Questions On The Future Of Healthcare

The three key levers to improving healthcare value, straight from a professor of Healthcare Finance.

<https://tinyurl.com/y5z5rdh>

Startup Health Insights Global Digital Health Funding Report: 2018 Year End Review

Austin Ranked 7th Best for Digital Health Funding in the U.S.

<https://tinyurl.com/y748xu2e>

Top 10 Most Popular Greenlight Guru Posts Of 2018

Between Greenlight Guru’s blog, webinar, and podcast content, they published over 150+ actionable and educational posts in 2018! Topics ranged in everything from medical device quality to regulatory changes to product development and more. Check out Greenlight Guru’s most popular posts at

<https://tinyurl.com/ycrjv6mc>

11 Best Practices For Protecting Connected Medical Devices

The Department of Health and Human Services, working with more than 150 healthcare and cybersecurity experts, has released a report, “Health Industry Cybersecurity Practices,” to aid stakeholders in managing threats and protecting patients. The 36-page report includes a section on attacks against connected medical devices that may affect patient safety. In distilling the guidance of the experts, HHS recommends 11 best practices to safeguard this sensitive equipment.

<https://tinyurl.com/y8kdjjjv>

NAMSA Announces Acquisition Of Reimbursement Strategies, LLC, Expands Medical Device Development Portfolio

NAMSA®, the world’s only Medical Research Organization (MRO) that accelerates medical device development through integrated laboratory testing, clinical research and regulatory consulting services, is pleased to announce the acquisition of Reimbursement Strategies, LLC, a Minneapolis-based consultancy focused on reimbursement, health economics and market access for the international life science industry.

<https://tinyurl.com/ybuk37rv>

Best Practices For Effective Medical Device Design Reviews

Design Reviews are critical to the success of medical device product development. So much so that the famous design controls waterfall diagram shows a design review after every major design control stage.

<https://tinyurl.com/y9bzfdvx>

WOMEN IN SCIENCE & WOMEN'S HEALTH

Texas Beats California As No. 1 State For Female Entrepreneurs

Texas used to conjure images of cowboys in the Wild West, but it's becoming a startup hotspot with new business increasingly saddling up in the Lone Star State. Texas is hands-down one of the nation's top states due to its business-friendly legal and economic climate. Put aside having no corporate or income taxes and a high rate of startup growth; startups are flocking to Texas due to a high startup success rate. Plus, with a below average cost of living, you can quickly increase your living standards and improve your lifestyle for less.

<https://tinyurl.com/y8wszgp>

Female CEOs: Take Chances, Be Authentic

Embracing authenticity, taking risks and recovering from setbacks are among the steps necessary to achieve success, a group of female CEOs say. "The person who gets up faster and keeps moving forward wins," said Daina Trout, co-founder and CEO of Health-Ade Kombucha.

<https://www.forbes.com/sites/yolaroberti/2019/01/04/secretstosuccess/>

Women Account For 30% Of Health Care Executives, 13% Of CEOs

Women account for about 30% of health care executives and 13% of CEOs, even though most decision-makers in the health care workforce are women, according to an Oliver Wyman report. "How can the industry move toward becoming more consumer-oriented when it lacks a leadership team that reflects and relates to those making the most decisions?" said Terry Stone, Oliver Wyman's health and life sciences managing partner.

<https://www.fiercehealthcare.com/hospitals-health-systems/invisible-barriers-to-women-s-advancement-healthcare-c-suite>

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!

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

UPCOMING EVENTS

FEBRUARY EVENTS

FEBRUARY 1-3, Austin TX (FREE Event)

BioAustin BioHackathon

BioAustin is sponsoring a BioHackathon on February 1-3, 2019. Topics include: Interoperability - tracking of information among software; Genomic Big Data - dealing with large genomic data for implementation and analysis; Life Science Tools - software package tools for the life science community; BioEducation - educational tools for the life science community. More information can be found at <http://lifescihack.com/>

FEBRUARY 2-5, Austin TX

Orthopedic Research Society

The ORS Annual Meeting provides numerous opportunities for you to hear the latest research discoveries, learn about technology advances in the field, participate in career development programs, network and have fun with colleagues.

<https://www.ors.org/2019annualmeeting/>

FEBRUARY 5, Austin TX (FREE Event)

BioAustin Happy Hour

Join BioAustin at the Hyatt Regency Austin on Tuesday, February 5, 5:30 to 7:30 PM to catch up on life sciences news and make new connections. The hotel bar validates parking for 2 hours. Contact scott@bioaustin.com for more information.

FEBRUARY 5, Fort Worth TX (FREE Event)

BioNorthTX Coffee Meet Up

Starting in February, join BioNorthTX the first Tuesday of every other month from 7:30 AM – 9:00 AM for coffee and networking at our host location and community partner, TechFW (1120 South Freeway, Fort Worth, TX). A brief discussion on the benefits of the Purchasing Program for BioNorthTX Members. <https://tinyurl.com/y9z8rtv7>

FEBRUARY 7, Austin TX

The Founder Institute Texas

The Founder Institute Texas Fall 2018 Austin cohort has just completed a 3.5 month program to help them launch an enduring company and you're invited to celebrate their graduation! Mix and mingle with current and past FI grads, mentors, partners, and special guests. Expect exciting announcements and surprise guests from across the country to celebrate. <https://tinyurl.com/y9e2xurf>

FEBRUARY 11-12, Austin TX

6th Annual Texas Healthcare And Bioscience Summit And Luminary Dinner

Each year, THBI hosts the Summit and Luminary Dinner to educate policy leaders and bring together industry executives to highlight the world-class innovation taking place around the state. The Summit will include discussions on issues being reviewed during the 86th Legislative Session, health policy issues impacting patient access, research and development, and the future of the healthcare and life sciences industries in Texas. <https://tinyurl.com/ycqn72rw>

FEBRUARY 12, Austin, TX (FREE Event)

Austin Healthcare Founders Meetup: Lessons Learned

The "lessons learned" session will feature real-world experiences from healthcare startup founders. Austin based healthcare entrepreneurs will give a brief overview of their experiences as they have gone through their own startups. Following the "lessons-learned" session there will be a Startup Teardown with a panel of healthcare investors offering their feedback and insight of what goes into an investment. Start-up founders will have 3 minutes to present their Business Case, Go-to-Market Strategy, and Scaling Plan. Start-up founders can submit their application with a one-page executive summary addressing all three of their requirements at austinhealthcarefounders@gmail.com. Meetup 6:00 to 8:00 PM at the Capital Factory (701 Brazos St., Austin, TX). Register at <https://secure.meetup.com/register/?ctx=ref>

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/ybqqyk6z>

FEBRUARY 28, Austin, TX (FREE Event)

Texas Health CoLab Learning Series: Corporate Transactions For Early Stage MedTech Companies

The Texas Health CoLab Learning Series will host a panel discussion with practical information and perspective on considerations impacting corporate transaction planning, structuring, and execution – with a focus on planning and preparation by early stage companies. The panel will include corporate attorneys, a venture capitalist and a founder/member of senior management with recent experience selling their company. They will discuss planning for a future transaction or exit, common mistakes made by early stage companies, engaging with a potential investor or buyer, common due diligence issues in a transaction and important issues to address in letters of intent and sale documents.

<https://tinyurl.com/yc3rzxhk>

FEBRUARY 28, Austin, TX

Amplify Austin Day

Make a difference in our community by supporting local organizations on Amplify Austin Day! Amplify is Austin's day of giving that strives to meet the needs of our community by providing a digital marketplace to connect local donors to Austin area nonprofits. Check into volunteer opportunities and if your company is part of their corporate challenge.

www.amplifyatx.org

MARCH - JUNE EVENTS

MARCH 3, Austin, TX

SXSW Networking Happy Hour

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

<https://tinyurl.com/y9b7r7hd>

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

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.taftp.org/marketing/cfw>

APRIL 18, San Antonio, TX

The San Antonio Medical Foundation

Healthcare: Yesterday, Today and Tomorrow Luncheon featuring Dr. Vivek Murthy, past US Surgeon General.

Ticket purchase: <https://lnkd.in/dEbwdA>

JUNE 7, San Antonio, TX

Texas Family Medicine Symposium

The Texas Family Medicine Symposium offers engaging, high-quality continuing education, drawing more than 300 primary care physicians and other health care providers from across Texas.

<http://www.taftp.org/marketing/TFMS>

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

- Multiple Positions

https://3m.rec solu.com/job_boards/

Abbott

- Multiple Positions

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

Aeglea Biotherapeutics

- Multiple positions

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

ALKU

- Multiple positions

Contact Logan Blake, Regulatory & Scientific Recruiter at lblake@alku.com, (978) 296-6903

Arsenal Products

- Multiple positions

<https://arsenal-products.careerplug.com/account>

Asuragen

- 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)

- Compliance Specialist (Auditor IV)

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

FDAQRC (TX)

- Clinical Quality Assurance Project Manager
- GCP Auditor with GMP/PV Skills

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

Luminex (TX)

- Multiple Positions

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

Molecular Templates (Austin, TX)

- Multiple positions

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

Syneos Health

- Multiple positions

<https://tinyurl.com/yd77ku42>

Tek Resource

- Multiple positions

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

Director of Regulatory Affairs

- Washington D.C. Metro area (MD, D.C., VA).

Contact Andrew Brown, Medical Device Search Group, Inc., Tel (786)372-4343

abrown@medicaldevicesearchgroup.com

Oxford Life Sciences

We specialize in providing senior level consultants with mission critical skill sets and emerging industry-specific experience. To learn more about regulatory and compliance specialty areas and opportunities contact Ivy Smith, 561.277.2862 Direct, ivy_smith@oxfordcorp.com
www.oxfordcorp.com

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

TeVido BioDevices: Manufacturing Engineer

TeVido BioDevices is seeking a highly motivated individual to join our team as a Manufacturing Engineer. We are a small Austin, TX-based biotech company that is addressing unmet needs in reconstructive and cosmetic surgery. The company is launching the manufacturing of our first product, cellular grafts, to treat patients with skin pigmentation disorders such as vitiligo. The person in this role will be responsible for managing daily production operations, resolving quality issues, and owning manufacturing-related improvement projects. This individual should be adept at and interested in learning new skills. A bachelor's degree in biological sciences or engineering with 3-5+ years' experience in manufacturing, quality and/or supply chain support is required. This is a challenging and exciting opportunity to contribute to an innovative, fast paced startup in Austin, TX whose mission is to enhance a patients' quality of life using their own tissue.

Learn more <http://tevidobiodevices.com/mfg-engineer/>

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.

Additional Opportunities:

BITC 2487 Internship: Biotechnology Laboratory Technician:

<http://sites.austincc.edu/biotech/internship-and-career-resources/>

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

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 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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EMERGO

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)