



BioAustin, Texas Medical Device Alliance & Austin Health Tech Newsletter

December 2017

I hope everyone enjoyed Thanksgiving and is ready for the holiday festivities! Please feel free to share events, information, or career opportunities with the Life Science community by emailing elisa@texmda.org or sarah@texmda.org so that we will include them in the monthly newsletter.

Here are the news and upcoming events:

INDUSTRY NEWS:

What is Human Factors Testing of Medical Devices? And Why Does the FDA Care About It? - TMDA November Meeting Summary

It is an exciting time for healthcare – medical providers and device manufacturers across the country are developing innovative approaches to age-old challenges at a rapid pace. Additionally, pharmaceutical companies are developing easier ways for patients and caregivers to deliver life-saving treatments. However, to ensure the safe and effective use of these new devices calls for the rigorous application of Human Factors methodologies throughout the design and development process. In fact, the FDA requires it!

As part of the overall 510(k) pre-market approval process, medical device designers and developers must demonstrate their due diligence in reducing all possible “use-related” hazards that new devices might pose to patients and caregivers. In his two-part session at the Q4 TMDA meeting this month, Joe McDonald, PhD, presented the Human Factors methodologies that the FDA is looking for when assessing the medical device evaluation process. In the second half of the session, TMDA members got the chance to try one of the methods for themselves, and discovered first-hand the challenges (and benefits) of designing medical devices that are not only effective for treatment, but safe for use by all who come in contact with them.

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Temple Health and Bioscience District (THBD)

The THBD team is excited to announce that our network will be expanding with the addition of an advisory committee. While details are still being determined, we are excited about this opportunity to include physicians and local entrepreneurs in our program. Read more updates from our latest board meeting in the [Temple Daily Telegram](#). If you are interested in applying to serve as an advisory committee board member, please contact Tami Annable, Interim Director, at tamia@templebioscience.org.

Women In Bio (WIB) -Texas Chapter Expanding

Women In Bio is an organization of professionals committed to promoting careers, leadership and entrepreneurship for women in the life sciences. The Texas chapter of WIB, founded in 2015, is expanding, and we are currently looking for volunteers and sponsors who can help us grow. We are looking for volunteers from all across Texas, from El-Paso to Dallas, San-Antonio, Austin, and Houston areas! Volunteering with WIB serves as a great way to meet new people, get involved with your local community and develop new skills.

If you are interested in joining a team of motivated and dynamic women and contributing to the growth of our chapter, [contact us](#) for more information. We are looking forward to an exciting 2018 program filled with social, networking, professional, and educational events! Join us!

*To take advantage of a free subscription to **WIB-Smartbrief**, a weekly newsletter that will keep you updated about women making a difference in biotech and life sciences, please [sign up here](#).*

UT's Cockrell School of Engineering Looking for Entrepreneurial Advisors (EAs)

The Innovation Center's Entrepreneurial Advisors program is designed to provide mentors, expert guidance and key connections to faculty and student teams on the path to commercialize their technology. EA's are unpaid volunteers with successful track records as entrepreneurs.

<http://www.engr.utexas.edu/innovation/entrepreneurial-advisors>

UT's Cockrell School of Engineering, Innovation Center Mission: "We aim to accelerate impacts of faculty and student discoveries and inventions using startups as vehicles of innovation, in short to help Austin be a better Silicon Valley."

For information on sponsorships, programs and events, contact Louise Epstein via email at louise.epstein@utexas.edu or by phone at 512-567-1849

SMALL BUSINESS AWARDS

Nominations Now Being Accepted - Deadline 1/9/2018. Winners disclosed during National Small Business Week, April 29 - May 5, 2018.

<https://www.sba.gov/offices/district/tx/san-antonio/resources/san-antonio-district-office-small-business-week-award-nominations-2018>

FDA News & Events - Medical Devices

Press releases, meetings, conferences, and other announcements to keep the public apprised of significant news and activities related to medical devices.

<https://www.fda.gov/MedicalDevices/NewsEvents/default.htm>

FDA News & Events - Biologics

Press releases, meetings, conferences, and other announcements to keep the public apprised of significant news and activities related to medical devices.

<https://www.fda.gov/BiologicsBloodVaccines/NewsEvents/default.htm>

UPCOMING EVENTS:

TUESDAY, December 5th

Deadline to apply to Mass Challenge Texas

Apply here: <http://texas.masschallenge.org/apply>

WEDNESDAY-FRIDAY, December 6th – 8th

Dell Medical School presents: Wilson Sonsini Goodrich & Rosati Healthcare Innovations Venture Investment Forum

[Register here](#)

Austin, TX

Investors participating in-person include: 5AM Ventures, AbbVie Biotech Ventures, Apple Tree Partners, Atlas Venture, ARCH Venture Partners, Bain Capital, Bay City Capital, Deerfield, Fortress Biotech, Gurnet Point Capital, HIG Capital, Illumina Ventures, Integra LifeSciences Holdings, J&J Innovations, Lilly Ventures, Merck Global Health Innovation Fund, NEA, Pfizer Investments, Novartis Institutes for Biomedical Research, Novo Ventures, Sailing Capital, Siemens Healthineers, Taiho Ventures, 3M

Ventures, 8VC, Accelerator Corp., Apex Landmark, Charles River Ventures, Hatteras Venture Partners, Live Oak Venture Partners, Mercury Fund, MP Healthcare Venture Management, S3 Ventures, Sante Ventures, Thiel Capital, Translink Capital Partners, Cartmell VC, and KdT Ventures.

WEDNESDAY, December 6th

Austin Cloudera User Group Featuring Ascension Health and StreamSets

<https://www.meetup.com/Austin-Cloudera-User-Group/events/245006886/>

THURSDAY, December 7th

Austin HIMSS December Social Hosted by Athena Health

<https://www.eventbrite.com/e/austin-himss-december-social-hosted-by-athena-health-tickets-39710004693?aff=es2>

FRIDAY-SUNDAY, December 8th-10th

Hack Austin - Exploring Data for Health and Safety Outcomes

<https://www.eventbrite.com/e/hack-austin-presented-by-the-city-of-austin-galvanize-tickets-39048292494>

TUESDAY, December 12th

Austin HIMSS Leadership Innovation Panel Hosted by Dell Medical School

<https://www.eventbrite.com/e/austin-himss-leadership-innovation-panel-hosted-by-the-dell-medical-school-tickets-40890718239?aff=es2>

WEDNESDAY, December 13th

7:45 AM – 9:30 AM CST

HealthTechAustin.com: CYBERSECURITY AND HIPAA

<https://www.eventbrite.com/e/cybersecurity-and-hipaa-tickets-40190355435>

WEDNESDAY, December 13th

5:30 PM - 7 PM

Healthcare Businesswomen's Association Austin Holiday Happy Hour

<https://my.hbanet.org/MyHBA/EventDetails.aspx?MeetingID=B38CA66A-8ED3-E711-9598-0050569C00A7>

SXSW Release It Pitch Competition

Apply here: <https://www.sxsw.com/awards/sxsw-release-it/>

CAREERS CORNER:

Merck

Multiple positions
Austin, TX

[Apply here](#)

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

Engineering Project Manager - Medical Device Automated Tooling
<https://arsenal-products.careerplug.com/jobs/718779/apps/new>

Automation Engineer - Mechanical Engineering
<https://arsenal-products.careerplug.com/jobs/664882/apps/new>

Principal Product Development Engineer - Medical Devices
<https://arsenal-products.careerplug.com/jobs/716624/apps/new>

Tevido BioDevices

TeVido BioDevices has a position for a highly motivated scientist or engineer to assist TeVido scientists and management in performing process work in the field of Cell and Tissue Engineering. TeVido is developing an autologous cell therapy-as-a-service platform to treat patients with skin pigmentation disorders such as vitiligo. The main roles of this position include process validation and quality engineering, including assisting in process validation, quality test development, and creation of proper documentation. The successful candidate will be expected to operate and maintain lab equipment, perform experiments, analyze results, and maintain accurate documentation. The position will be posted on the website shortly at <http://tevidobiodevices.com/>; otherwise, please contact Laura Bosworth at bosworth@tevidobiodevices.com

Looking for Position

My name is Cara Wessels and I am currently looking for employment in the Austin biotechnology industry. I recently graduated from Texas Tech University with a PhD in Animal Science with a concentration in Reproductive Physiology in August 2017. I began my research career in 2011 as an undergraduate research scholar in the Howard Hughes Medical Institute. This research allowed me to create a new, patent pending device to measure embryo quality and viability. In 2014, I began a doctoral program where I completed my dissertation research. As a graduate student, I published 5 papers in peer reviewed journals, presented my work in 27 national and regional presentations, instructed courses for undergraduates and was president and co-founder of two student organizations. My background is not limited to academics. In 2017, I became involved in entrepreneurship through the Texas Tech University Innovation Hub at Research Park. As I am passionate about my research, I wanted to be involved in the commercialization of the product. With the sponsorship of the TTU Innovation Hub, I participated in the National Science Foundation regional I-Corps (Innovation Corps) program, which was accepted for a \$50,000 grant for customer discovery. Additionally,

I am a co-founder of a start-up company called *Embryotics* with experience writing Small Business Innovation Research (SBIR) grants. While I am passionate about my company and research, I am looking for alternate employment in Austin. I have experience in research, statistics, entrepreneurship and commercialization of a biomedical device. I look forward to learning about any possible opportunities in the area!

Cara Wessels, PhD
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Warm regards,

Dana Abramovitz, Hilary Graham, Sarah Haverin, Ashley Lane, Elisa Maldonado-Holmertz, Tamiko Oguri, and on behalf of BioAustin, Texas Medical Device Alliance and Austin Health Tech