



## **BioAustin, Texas Medical Device Alliance & Austin Health Tech Newsletter**

**February 2018**

I hope all of you are off to a great 2018! As always, please feel free to share events, information, or career opportunities with the Life Science community by emailing [elisa@texmda.org](mailto:elisa@texmda.org) so that we will include them in the monthly newsletter.

### **INDUSTRY NEWS:**

#### **Texas Health Catalyst Accepting Applications/Letters of Interest**

Texas Health Catalyst - a UT Austin program housed at Dell Medical School & aimed at accelerating promising ideas (devices, digital health solutions, treatments, diagnostics) as they make their way to the clinic. Seed funding (\$5k - \$50k) available to select projects along with customized feedback, connections with strategic partners & networking opportunities. UT & Dell Med Faculty members and local innovators/companies eligible to apply. Grad students, residents & postdocs can also apply provided they have a UT/Dell Med Faculty PI. Info session on Feb 28th at 4pm. Submission deadline - March 23<sup>rd</sup>.

Program info and how to apply: <https://dellmed.utexas.edu/thc>

#### **Ultimate List of Medical Device Incubators & Accelerators**

For a new medical device company, getting space at a well-known incubator or accelerator program is one of the best ways to secure the funding and the support that you need to turn your medical device idea into a successful product. These programs offer financial support along with mentorship and other services that can help take your company to new levels of success.

Greenlight Guru has put together a master list of the best healthcare accelerators and incubators for new medical device companies [The Ultimate List of Medical Device Incubators and Accelerators](#)

## **FDA CDRH 2018-2020 Strategic Priorities**

FDA CDRH measure of success is that by December 31, 2020, more than 50 percent of manufacturers of novel technologies for the U.S. market intend to bring their devices to the U.S. first or in parallel with other major markets. FDA CDRH seeks to achieve this goal through the systematic application of the following three approaches:

- Employee Engagement, Opportunity, and Success
- Simplicity
- Collaborative Communities

In using these approaches FDA CDRH will continue to work and build on their 2016-2017 Strategic Priorities, such as establishing the National Evaluation System for health Technology (NEST) and partnering with patients. Along with the release of the FDA CDRH 2018-2020 Strategic Priorities, they are providing an update on their [2016-2017 Strategic Priorities](#), for which they have met or exceeded their goals. FDA CDRH is seeing the impact of investments in accomplishing these priorities. For example, in calendar year 2017, **CDRH approved the largest number of medical devices in the history of the program – 95** – continuing an almost annual increase in [novel device approvals since 2009](#).

## **2018 OUTLOOK FOR DRUGS AND MEDICAL DEVICES IN CHINA: REGULATORY REFORM FUELED BY INNOVATION**

The year 2017 ended with a central government directive to reform China's regulatory approval system for drugs and medical devices and a subsequent flood of changes and proposed changes to the system. Throughout 2018, we should see further regulatory reform as the Chinese government continues to encourage domestic innovation in this sector. Find out more about 2017's significant legal developments and the reforms to expect in China in 2018. By Ting Xiao and Published by DLA Piper LLP (US).

<https://www.dlapiper.com/en/us/insights/publications/2018/01/2018-outlook-for-drugs-and-medical-devices-in-china/>

## **2018 BIOAUSTIN SXSW DISCOUNTS**

We are pleased to extend a new benefit to you as part of your BioAustin membership. We've partnered with the team at SXSW and are offering paid members access to SXSW badges at a group rate substantially discounted from the current published prices. This discount will work for any kind of badge at the event.

SXSW will run from March 9<sup>th</sup> – 18<sup>th</sup>, 2018. It brings an international audience of startups, investors, and seasoned companies including those in the biotech and health tech area. If interest exists, we will have a lunch and learn to tell you how to take advantage of opportunities at SXSW early in the New Year. Please let me know if you are interested.

To receive discounted prices, you must fill out the form at <http://bit.ly/BioAustinSXSW2018> no later than 1/10/2018 for maximum discount. You will then be sent a unique registration

discount code allowing you to purchase the ticket. Pricing information can be found on this form. You may not resell or transfer these discount codes and you must be a paid member in good standing to qualify for this benefit. Membership information can be found at <http://bioaustin.com/benefits-dues/> Any questions should be directed to [sxsw@bioaustin.com](mailto:sxsw@bioaustin.com).



Austin Technology Council would like to announce

# WE'VE MOVED!

PLEASE NOTE OUR NEW ADDRESS

---

404 Rio Grande St.  
Unit #208  
Austin, TX 78701

*\*Please update our contact information  
for mailing, billing and Accounts Payable*



## UPCOMING EVENTS:

TUESDAY and WEDNESDAY, January 30-31, Bethesda, MD or Webcast

**Fostering Digital Health Innovation: Developing the Software Precertification Program hosted by FDA**

[Register here](#)

WEDNESDAY, January 31, Austin, TX

**The Medical Device Summit hosted by Health Tech Austin**

[Register here](#)

THURSDAY, February 1, College Station, TX

**Bill Nye: Science Guy Documentary Screening + Climate Science Q&A**

<https://www.eventbrite.com/e/bill-nye-science-guy-documentary-screening-climate-science-qa-tickets-39839041646?aff=es2>

TUESDAY, February 6, 6:30-8pm, Austin, TX

**Improving UX for Impact: Data and Design in Health Care**

[https://www.meetup.com/Austin-User-Experience-Professionals-Association/events/246839547/?gj=co2&rv=co2&\\_xtid=gatlbWFpbF9jbGlja9oAJGUxODBJNTE2LTE0OTgtNGY5Mi1hZjU1LWE0ZDJhZjc0NzA5Yg](https://www.meetup.com/Austin-User-Experience-Professionals-Association/events/246839547/?gj=co2&rv=co2&_xtid=gatlbWFpbF9jbGlja9oAJGUxODBJNTE2LTE0OTgtNGY5Mi1hZjU1LWE0ZDJhZjc0NzA5Yg)

WEDNESDAY, February 14, Plano, TX

**An Introduction to Design Controls**

<https://www.eventbrite.com/e/dfw-asq-biomed-dg-an-introduction-to-design-controls-tickets-42196538984?aff=es2>

WEDNESDAY – THURSDAY, February 14-15, Houston, TX

**Applied Statistics, with Emphasis on Verification, Validation, Sample Size, and Risk Management, in R&D, Manufacturing, and QA/QC**

<https://www.eventbrite.com/e/applied-statistics-verification-validation-sample-size-and-risk-management-ntz-a-tickets-41556784461?aff=es2>

THURSDAY, February 15, 2-4 pm, Austin, TX

**Texas Medical Device Alliance (TMDA) - Marketing - Developing a Winning Strategy**

<https://www.eventbrite.com/e/tmda-q1-2018-meeting-marketing-developing-a-winning-strategy-tickets-41844672542?aff=es2>

THURSDAY-FRIDAY, February 15-16, Irving, TX

**Tougher Import Rules for FDA Imports in 2018**

<https://www.eventbrite.com/e/tougher-import-rules-for-fda-imports-in-2018-ntz-tickets-38731199059?aff=es2>

THURSDAY-FRIDAY, February 15-16, Dallas, TX

**Risk Management Education Course | Medical Devices Industry 2018**

<https://www.eventbrite.com/e/risk-management-education-course-medical-devices-industry-2018-tickets-41002340103?aff=es2>

THURSDAY, February 15, Austin, TX

**The Invention Pathway: Invention. Higher Education and the Innovation Economy.**

<https://www.eventbrite.com/e/the-invention-pathway-invention-higher-ed-and-the-innovation-economy-tickets-42472560572?aff=es2#tickets>

SATURDAY, February 17, Austin, TX

**AAAS Family Science Days**

Bring your entire family into the world of science at this free interactive event sponsored by the American Association for the Advancement of Science. Explore exhibits, interact with scientists, and learn about various types of science jobs.

<http://meetings.aaas.org/family-science-days/>

WEDNESDAY, February 28, 4-5pm, Austin, TX

**Info Session - Texas Health Catalyst**

Anyone interested in the program is [welcome to attend an info session on Feb 28](#) at the [Health Discovery Building Auditorium](#), Dell Medical School.

FRIDAY – SUNDAY, March 9-11, Houston & Austin, TX

**SXSW 2018: Digital Health Tour**

<https://www.eventbrite.com/e/sxsw-2018-digital-health-tour-in-houston-austin-tickets-41062177077?aff=es2>

THURSDAY – FRIDAY, March 22-23, Houston, TX

**The New EU Medical Device regulation**

<https://www.eventbrite.com/e/the-new-eu-medical-device-regulation-ntz-tickets-42240656942?aff=es2>

MONDAY-WEDNESDAY, April 23-25, Austin, TX

**2018 Texas Life Science CEO Summit**

<https://www.eventbrite.com/e/2018-texas-life-science-ceo-summit-tickets-42202745548?aff=es2>

MONDAY-TUESDAY, August 13-14, TBD, TX

**7th Clinical Trials Inspection Readiness Summit**

<https://www.eventbrite.com/e/7th-clinical-trials-inspection-readiness-summit-exl-as-tickets-39250500303?aff=es2>

## CAREERS CORNER:

**Arsenal Products (Austin, TX)**

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

Solidworks CAD Technician

<https://arsenal-products.careerplug.com/jobs/725469/apps/new>

Project - 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>

**Merck (Austin, TX)**

Multiple positions

[Apply here](#)

**Medical Writing Contract Position (Texas)**

12-month Medical Writing contract position with a Medical Device company. Person must be on site in any of the three following: Tennessee, Texas, or Massachusetts. Email Dennis Kapsimalis (ALKU) at [dkapsimalis@alku.com](mailto:dkapsimalis@alku.com) or call 978-296-1888 to discuss further.

**Regulatory Affairs Manager (Dallas, Texas)**

Requires application of regulatory knowledge, technical/business understanding, and people management skills to lead a regulatory team with pre and post market responsibility. Serves as the Regulatory Affairs leader for the Communications Business Unit, interacting with other functional leaders and the General Manager. May serve as site Management Representative or deputy. Will interact with FDA, ISO, and other external regulatory agencies. Contact: Andrew Brown, Medical Device Search Group, Inc. call 786-372-4343 or email Andrew at [abrown@medicaldevicesearchgroup.com](mailto:abrown@medicaldevicesearchgroup.com)

**VOLUNTEER OPPORTUNITIES:****Judges Needed for the Austin Energy Regional Science Festival**

WEDNESDAY-SATURDAY, February 21-24, Austin, TX

Science Fest is a competition for students from 23 school districts and 12 counties who are advancing from their local schools.

Because judging is competitive, subject matter experts are needed to evaluate the projects. About 7-8 projects are assigned to each group of judges (typically consisting of 3 people). After a group has interviewed their assigned students, group members discuss the merit of each project and jointly determine the ranking. It is a 2-4 hour commitment. Orientation sessions provided in the weeks leading up to the fair.

**BioAustin** is giving a special award for the biotech/healthtech/health/life science category. If you would like to help judge this, please contact Scott at [scott@bioaustin.com](mailto:scott@bioaustin.com).

**BioAustin/AHT/TMDA**

We are seeking more volunteers to compile and write the newsletters or maintain our websites. If interested, please reach out to Scott Collins at [scott@bioaustin.com](mailto:scott@bioaustin.com) or Elisa Maldonado-Holmertz at [elisa@texmda.org](mailto:elisa@texmda.org).

Please notify us of any Careers or Volunteer opportunities!

Warm regards,

*Dana Abramovitz, Hilary Graham, Elisa Maldonado-Holmertz, and Tamiko Oguri on behalf of BioAustin, Texas Medical Device Alliance (TMDA), and Austin Health Technology (AHT)*