



BioAustin, Texas Medical Device Alliance & Austin Health Tech Newsletter

January 2018

Happy New Year! If one of your resolutions includes participating in more career events in the Austin area, then see the many events provided below. 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.

INDUSTRY NEWS:

A PROLONGED DESIGNATION PROCESS FOR EU NOTIFIED BODIES

The EU Notified Bodies Operations group has issued a new guide outlining a 20-month process for designating authorities upon initial application. Briefly, the initial application must be submitted to the designating authority 18 months in advance which will require an additional 2 months of processing to the final designation of the authority's confirmation (a detailed flow chart found can be found [here](#).) This new NBOG guide intends to provide guidance to the authorities responsible for notified bodies and joint assessment teams in the application process for medical devices and/or IVDs, and to create consistency among the different designating authorities. However, this all translates to allowing only 10 months for transitioning to the new MDR.

FDA MODERNIZES ITS REGULATORY FRAMEWORK TO EXPEDITE MEDICAL DEVICE APPROVAL

A newer "[Least Burdensome Provisions](#)" was just drafted by the FDA with the intent to expedite the total product life cycle of new medical devices. This draft outlines the reduction in review times by enhancing current safety tools and establishing a new pre- and post-market evaluation system (NEST) without sacrificing patient safety. An included provision will grant the FDA the ability to remove the 510(k) submission burden for devices posing lower risks such as items found in the fitness/wellness industry. Although the Commissioner of the FDA, Scott Gottlieb, M.D. has elaborated on the [many benefits](#) of this new program, it is not entirely clear how new medical devices will protect [patient data and privacy](#).

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 9th – 18th, 2018. It brings an international audience of startups, investors, and seasoned companies including those in the biotech and healthtech 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.

UPCOMING EVENTS:

THURSDAY, January 4

Austin Healthcare Think Tank luncheon

Listen to the inaugural Executive Director of Capital City Innovation, Christopher Laing discuss ideas to propel Austin's Innovation District forward as he incorporates his experience in innovation, entrepreneurship, and urban innovation district management. This luncheon is hosted by Strasburger & Price, LLP, so please email Linda Elliot at linda@ellitoconnection.com or call her at (210) 495-1733 for details to register for this event.

Austin, TX

MONDAY, January 8

Medical Device Webinars and Stakeholder Calls

[Register here](#)

The FDA will host multiple webinars in January (8th-16th) to provide guidance on the regulation of medical devices and provide an opportunity to interact directly with FDA officials.

Webcast

TUESDAY, January 8

Austin HIMSS Lunch and Learn

[Register here](#)

WEDNESDAY, January 10

Austin Forum on Technology & Society

Top tech trends for 2018 and beyond

[Register here](#)

WEDNESDAY, January 10

Signup to Maximize Your SXSW Badge Discount!

<http://bit.ly/BioAustinSXSW2018>

THURSDAY, January 11

Greater Austin STEM Networking Forum

[Register here](#)

Meet fellow STEM educators, organizations, and leaders at this quarterly interactive networking forum designed to strengthen the STEM community and facilitate collaborations. Hosted by Texas SARTBASE Austin at Camp Mabry with the goal to share resources and ideas.

Austin, TX

SATURDAY, January 13

SCICOMM SOUTH 2018-Communicating science in the South Central States

[Register here](#)

This event is designed to facilitate networking and collaboration among disparate scientists, students, PIOs, publishers, reporters, editors, freelancer, etc. scattered across the South Central States (Texas, New Mexico, Oklahoma, Arkansas, and Louisiana). David Biello, the Science Curator of the TED Conferences will be a keynote speaker to kick off this collaborative event.

Austin, TX

TUESDAY, January 16

Free Stop the Bleed Training sponsored by Dell Medical School

[Register here](#)

As a member of the medical and science community, why not add a life-saving skill under your belt? Attend this training session sponsored by Dell Medical School and learn how to stop uncontrolled bleeding, which is the leading cause of preventable death from injury.

Austin, TX

TUESDAY, January 23

Immigration Today: Impact on the Health of Our Community

[Register here](#)

Expand your cultural horizons by participating in the first of several community conversations hosted by the Dell Medical School's Department of Population Health and the Office of Diversity Equity and Inclusion. The event will begin with a screening of an HBO documentary meant to spark discussion and open community conversation centering around social identity and its impact on health in central Texas.

Austin, TX

TUESDAY and WEDNESDAY, January 30-31

Fostering Digital Health Innovation: Developing the Software Precertification Program

[Register here](#)

Join in person at the NIH or online for the public workshop hosted by the FDA to discuss the progress of the pilot precertification program about the ongoing development of the Software Precertification Program and details of the Digital Health Innovation Action Plan. To attend the webcast, registration is required before January 18, 2018.
Bethesda, MD or Webcast

WEDNESDAY, January 31

The Medical Device Summit

[Register here](#)

Health Tech Austin will host a medical device summit presented by Cooley. Check the website for more details that will be provided soon.
Austin, TX

THURSDAY, February 1

[Healthcare Informatics Framework Success Stories](#)

THURSDAY, February 15, 2-4 pm

Texas Medical Device Alliance (TMDA)

[Register here](#)

Marketing -Developing a Winning Strategy

More details to be provided shortly at www.texmda.org or check out LinkedIn
Norris Conference Center, Austin, TX

WIB: <http://www.womeninbio.org/wib-chapters/austin-area>: Check the link for future events!

CAREERS CORNER:

Merck

Multiple positions
Austin, TX

[Apply here](#)

Please feel free to notify us of any openings!

Warm regards,

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