



**Texas Medical  
Device Alliance**

BioAustin | Texas Medical Device Alliance | Austin Health Tech

## **NEWSLETTER**

### **MAY 2019**

Spring has sprung in Austin, so enjoy the gorgeous roadside sea of colors! Also, check out the colorful bouquet of life science news, meetings, seminars, and networking events in the May newsletter!

**WE WELCOME VOLUNTEERS TO JOIN THE MONTHLY NEWSLETTER TEAM** (details page 10)

As always, if you have news, job postings, or other resources to share, please reach out to **Elisa Maldonado-Holmertz** ([operations@texmda.org](mailto:operations@texmda.org))

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## LIFE SCIENCE INDUSTRY NEWS

### In Our Neck Of The Woods...

#### **International Space Station National Laboratory Comes To Austin**

In April, Austin Community College Highland hosted NASA Astronaut and UT Austin alumnus Stephanie D. Wilson and her NASA colleagues for a discussion about research onboard the International Space Station U.S. National Laboratory.

For more than 17 years, humans have lived and worked continuously onboard the International Space Station, advancing scientific knowledge and demonstrating new technologies, making research breakthroughs not possible on Earth that will enable long-duration exploration into deep space and benefit life here on our planet.

A global endeavor, more than 230 people from 18 countries have visited the unique microgravity laboratory that has hosted more than 2,400 research investigations from researchers in more than 103 countries.

Earth benefits from spaceflight R&D span the biomedical, biotechnology, and agricultural industries. To learn more: <https://www.issnationallab.org/about/about-the-iss-national-lab/>  
This event was sponsored by ACC Bioscience Incubator and BioAustin.

#### **FDA Explores Total Product Lifecycle Approach To Regulating Artificial Intelligence And Machine Learning Software As A Medical Device**

The FDA announced that it is exploring a framework that would allow for modifications to artificial intelligence and machine learning algorithms to be made from real-world learning and adaptation, while still ensuring that the safety and effectiveness of the software as a medical device is maintained. The FDA's ideas are the foundational first step to developing a total product lifecycle approach to regulating these algorithms that use real-world data to adapt and improve.

Read the Discussion Paper and FDA Request for Feedback: <https://tinyurl.com/y3zflumk>

#### **The Changing Landscape Of Marijuana Regulation For Medicinal Purposes**

In recent years there have been many changes, both in the regulations related to, and the acceptance of marijuana and CBD products. In the United States, marijuana has become legal for medicinal purposes in 33 states, and for recreational purposes in 10 states.

In 2018, the FDA approved the first drug comprised of an active ingredient derived from marijuana to treat a rare form of epilepsy (<https://tinyurl.com/y5cmhsch>).

Some of the key common questions in clinical research forums center on whether marijuana is considered a concomitant medication in a trial, whether it should be exclusionary in a clinical protocol, and how to accurately record dosage and levels of active ingredients in different marijuana strains.

Read about these questions and other challenges of regulating the medical use of marijuana in the FDAQRC Blog: <https://tinyurl.com/yyy2dggw>

### Across The Pond...

#### **European Commission Update On Medical Device Regulation (MDR) And In Vitro Diagnostic Regulation (IVDR)**

As the MDR/ IVDR transition period continues, the European Commission keeps publishing documents including an updated rolling plan and a number of smaller guidance documents. The Medical Devices Coordination Group (MDCG) recently published a new guidance document that limits the maximum

number of characters in the Basic UDI-DI to 25. Moreover, the MDCG announced that a decision has been made with regards to the nomenclature system to be used in Eudamed: Economic Operators will have to use the Italian CNL nomenclature, which will be mapped to the GMDN nomenclature. You may want to bookmark the website on the MDR/ IVDR regulatory framework published by the European Commission. The website has been recently revamped and includes the most important facts and guidance reference:

[https://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework\\_e](https://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework_e)

## INDUSTRY RESOURCES & FUNDING OPPORTUNITIES

### **TMCx Medical Device Accelerator Applications Open**

The TMCx Medical Device Accelerator application is now open! Our program provides medical device startups with shared workspace, a curriculum tailored to the needs of health care entrepreneurs and the guidance of more than 250 advisors from the front lines of the industry. Companies have access to the world's largest medical center, all without membership fees or equity sharing.

<https://gust.com/programs/tmcx-accelerator-medical-device-2019>

### **Applications For The First MassChallenge Texas In Houston Program Closes May 8, 2019**

MassChallenge Texas in Houston is opening an office in Downtown Houston with plans to support up to 25 startups during their first Houston-based program. The 6-week bootcamp will give startups access to MassChallenge's global ecosystems, 6-months of FREE office space at GreenStreet, focused mentor opportunities, intense curriculum bootcamps, and more. All for no equity.

**Startups!** Take the first steps in your MCTX in Houston application today and create your profile.

<https://accelerate.masschallenge.org/accounts/register/entrepreneur/>

### **Greenlight Guru: Understanding The Med Device Industry's Tsunami Of Regulatory Changes**

The medical device industry is being inundated with regulatory changes on a global scale. With ISO 13485:2016, the MDSAP audit process, and the extensive requirements changes in the new MDR and IVDR, manufacturers, consultants and suppliers need a robust quality system with an emphasis on risk management. Edwin Bills, ASQ Fellow, RAC, helps us better understand how these regulatory changes are concurrently affecting the medical device industry and how to best prepare for what is still yet to come.

<https://www.greenlight.guru/blog/medical-device-quality-system-regulatory-conundrums>

### **Greenlight Guru: Top 50 Medical Device Design & Development Companies**

One of the most important aspects to a successful launch is having the right design and development partner. We put together a list of the top 50 design and development firms from around the world to help you get started. <https://tinyurl.com/y5trwbz>

### **Webinar: Understanding And Navigating The Regulatory Landscape For Clinical Evaluation Reports**

Will your Clinical Evaluation Reports (CERs) be "at-risk"? With additional regulatory requirements for substantive literature and clinical trial data, some device manufacturers--including those with Class II or III devices on the market--have lost their CE Mark, incurring significant financial losses and increased regulatory requirements. This webinar will discuss practical approaches to producing rev. 4 compliant CERs, and some of the procedural updates that should be considered as the MDR replaces the MDD in 2020. Register at: <https://tinyurl.com/y67lwydy>

## ASSOCIATION SPOTLIGHT Capital City Innovation

Capital City Innovation (CCI) is the 501(c)(3) not-for-profit that is providing vision, strategic direction, advocacy, and synergy among organizations and individuals who are creating, growing, and sustaining Austin's Innovation District. It was founded by Central Health, Seton Health, and The University of Texas at Austin and began operations in 2017.

The CCI Innovation District is a one-of-a-kind downtown neighborhood - the current and future home to innovators who are working out new ways to create healthier communities. The Innovation District is anchored by the new Dell Medical School at the University of Texas and its associated Dell Seton Medical Center, by Central Health's Brackenridge campus redevelopment, by the Waller Creek chain of parks, and by the Texas State Capitol Complex.

OUR VISION: An inclusive community where Austinites collaborate to create new models of health and economic growth for all.

OUR MISSION: To support and encourage innovation among academic institutions, health organizations, companies, startups and entrepreneurs, developers, government, and creative individuals by combining creative place-making and programs that promote partnerships.

Find out more about Capital City Innovation at <https://www.capitalcityinnovation.org/>

CCI Partner And Community Events Calendar:

<https://www.capitalcityinnovation.org/events?view=calendar&month=04-2019>

## WOMEN IN SCIENCE & WOMEN'S HEALTH

### **That Image Of A Black Hole You Saw Everywhere? Thank This Grad Student For Making It Possible**

Dr. Katie Bouman developed an algorithm that was crucial in producing an image of a black hole when she was a graduate student in computer science and artificial intelligence at MIT. Dr. Bouman, who will take a job this fall as an assistant professor at California Institute of Technology, and her collaborators developed different algorithms with different assumptions built in, tested them and integrated the results to produce the groundbreaking image.

<https://www.cnn.com/2019/04/10/us/katie-bouman-mit-black-hole-algorithm-sci-trnd/index.html>

### **Oral Contraceptives May Cut Ovarian Cancer Risk**

An analysis of data from 20 studies presented at a meeting of the American Association for Cancer Research found use of oral contraceptives was associated with lower risk of dying from aggressive ovarian cancer. The observed risk reduction increased the longer the contraceptives were used.

<https://tinyurl.com/y5ad4oaf>

### **Boardroom Ready Helps Biotechs Find Qualified Female Board Members**

Research shows that companies with diverse boards are more likely to succeed, and as chair of Executive Women In Bio's Boardroom Ready program, Carolyn Brougham helps biotech companies identify new talent and helps prepare qualified women for board seats. Mary Thistle, Bill & Melinda Gates Medical Research Institute chief of staff, was in the first Boardroom Ready graduating class and now serves on three corporate boards. Read more about how programs like Boardroom Ready help identify new female talent and overcome the barrier of having no previous board experience:

<https://www.lifescienceleader.com/doc/connecting-women-who-are-boardroom-ready-0001>

## UPCOMING EVENTS

**Capital City Innovation Has Compiled Partner And Community Events:**  
<https://www.capitalcityinnovation.org/events?view=calendar&month=04-2019>

MAY 3, Temple, TX

### **Annual MedTech Symposium & Pitch Competition**

Temple Health and Bioscience District's Annual MedTech Conference & Pitch Competition "Growing to Success: Startup and Beyond" at the Hilton Garden Inn. This year's programming will focus on the next stages of developing and commercializing your business. THBD will select ten entrepreneurs and startup applicants to pitch and compete for the chance to win up to \$10,000 in funding. In addition to programming, our conference offers multiple opportunities to network with key industry contacts.

Register at <https://tinyurl.com/y2logx4e>

MAY 4, San Marcos, TX

### **Texas State New Ventures Program Pitch Competition**

Texas State is launching New Ventures with an inaugural pitch competition. Meet innovators, startups, market experts, and more from all over the country. See finalists present their disruptive solutions in dynamic industries including CPG, Medtech, Agtech, Renewables, and Community Platforms. Finalists will be competing for over \$100,000 in cash and prizes. Register at: <https://tinyurl.com/yy6jfmwz>

MAY 6, (FREE)

### **Webinar: MassChallenge Houston**

Want to learn more about MassChallenge Texas but aren't able to attend an in person event? That's OK! We have a webinar series just for you. Attend this Meet MassChallenge Texas webinar to learn about the #MCTX19 Houston startup program; Monday, May 6, 1.00 to 2.00 PM CT.

Register for this free webinar through Eventbrite <https://tinyurl.com/y3ug4p3w>

MAY 7, Austin, TX (FREE)

### **Health Equity Forum: Leadership Perspectives on Equity & Optimal Health for All**

At Dell Med's second Health Equity Forum, Mike Geeslin, Stephanie Mayfield Gibson, M.D., and Jewel Mullen, M.D., will discuss leadership challenges in ensuring health equity.

How do leaders committed to community well-being talk about and accomplish their work while addressing the needs, demands and skepticism of multiple constituencies? How do we ensure that everyone stays in the conversation, even when we know that laws and policies never align with everyone's values? How do you do this in your own work?

Register at: <https://dellmed.utexas.edu/events/leadership-perspectives-on-equity-optimal-health-for-all>

MAY 14, Austin, TX

### **CEO Mothers: The Superwomen of Startups | Mixer + Panel**

Starting a business isn't easy. Being a mother is even harder. And if you are doing BOTH roles, you are Superwoman. Because May is the month to celebrate all of the mothers in our lives, MassChallenge Texas and The Riveter Austin are teaming up to honor female founders that are also mothers.

All are welcome at this inclusive event at The Riveter Austin to hear from a group of female-founder-mother startup panelists what its really like to start a business and simultaneously tackle motherhood.

Food & Beverages will be served! Register at: <https://tinyurl.com/y3p75yeq>

MAY 16-17, Austin, TX

**The Healthcare Transformation Summit**

The Healthcare Transformation Summit, sponsored by Austin Healthcare Council and Modern Healthcare, is a one-and-a-half-day event that brings together the industry's top hospital and health system executives and suppliers. We invite you to attend to learn about the value-based future of healthcare, understand advancements in supply chain, and identify valuable partnerships.

To attend, please register with code **AUSTIN19**

Full agenda and conference details at <https://www.transformation-summit.modernhealthcare.com/>

MAY 30, Austin, TX

**Monthly Learning Series – Texas Health CoLab**

**In Vitro Diagnostics: Development and Regulatory Pathways**

In vitro diagnostic (IVD) devices usually comprise pathology tests and related instrumentation used to conduct testing on human bodily fluids or tissue samples to assist in clinical diagnosis. Regulatory and legal requirements applied to IVDs are set within the changing landscape, under guidelines similar to medical devices in the US. In contrast, in the EU, IVDs are defined and regulated separately from other medical devices under a separate directive. In this presentation we will review a robust IVD development and regulatory process that has led to several successful regulatory pre-market authorizations. Join us for happy hour at Scholz Garten afterwards!

Register at: <https://txhealthcolabmay2019-invitrodiagnostics.eventbrite.com>

JUNE 10, Austin, TX

**BioAustin BioBash Spring 2019**

The premier networking event for the Austin's growing Biotech, Healthtech, Medtech and Life Science community will be held on June 10<sup>th</sup>. Come see why Austin has been ranked the third fastest growing Life Science cluster in the US. Monday, June 10, 6.00 to 8.00 PM CT at the Mean Eyed Cat, Austin TX.

Register at: <http://bit.ly/BioBashSpring2019>

JUNE 17-18, Las Vegas, NV

**Medical Device R&D Summit**

The Medical Device R&D Summit is the premium forum bringing together medical device R&D executives with leading solution providers. The Summit is a great place for focused discussion on cutting-edge technology, strategy and implementation of solutions to forward-thinking medical device companies interested in staying ahead of the market.

The one-on-one business meetings provide access to senior R&D executives within the largest medical device corporations across the United States. A thorough selection process ensures a qualified audience, which grants unparalleled business and networking opportunities in a luxurious and stimulating environment.

For the full program contact: [minac@marcusevanscy.com](mailto:minac@marcusevanscy.com)

<https://events.marcusevans-events.com/meddevice-19/>

JULY 18, Austin, TX (FREE)

**Texas Medical Device Alliance (TMDA) Quarterly Meeting**

SAVE THE DATE!

## CAREER CORNER

### Abbott

- Clinical Research Scientist
  - Program Manager, Heart Failure
  - Multiple Positions
- <https://www.jobs.abbott/us/en/search-results?keywords=austin>

### Aeglea Biotherapeutics

- Process Engineer/Sr. Process Engineer
  - Sr. Clinical Project Manager
  - Multiple positions
- <http://www.aegleabio.com/biotechnology-careers/#career-opportunities>

### ALKU - Texas

- Pharmaceutical QA Specialist
  - Epic ASAP Analyst
  - Epic Grand central Prelude Analyst
- Contact Logan Blake, Regulatory & Scientific Recruiter at [lblake@alku.com](mailto:lblake@alku.com)

### Arsenal Products

- Director of Engineering
  - Mechanical Engineer Machine Design
  - Multiple positions
- <https://arsenal-products.careerplug.com/account>

### Endocare, Inc.

#### Director, R&D and Engineering (Austin, TX)

Provides technical leadership and management oversight for R&D activities related to the development of cryo ablation and microwave ablation devices. Requirements: Degree in Electrical, Mechanical or related discipline (Masters & Ph.D. are preferred); A minimum of 15 years of related experience within the medical device industry; Experience managing teams where hardware, software, and disposables were part of product development; Knowledge in RF energy and cryotherapy systems.  
Contact: Audrey Coleman ([audrey.coleman@endocare.com](mailto:audrey.coleman@endocare.com)), HR Director

### Medical Device Search Group

#### Sr. Director/Director, Regulatory Affairs (Orange County, California)

Are you interested in working for an organization that is making a difference in people's lives every day? I am working with a medical device company that develops innovative neuroendovascular technologies for the treatment of vascular disease. The company is high-growth, customer-focused and has an entrepreneurial spirit. This company engages in the development of catheter-based, minimally invasive, neuro-endovascular technologies for therapeutic advantages for cerebral aneurysms and other neurovascular diseases. The company's products include WEB Aneurysm Embolization System used for the treatment of intracranial neck bifurcation aneurysms; and delivery and detachment systems, access

### Asuragen

- Senior Scientist: Research, Bioinformatics
  - Production Scientist
  - Multiple Positions
- <https://asuragen.com/careers/>

### Luminex (TX)

- Associate Scientist
  - Tech Support Specialist – Flow Cytometry
  - Multiple Positions
- <https://www.luminexcorp.com/about-luminex/careers/open-positions/>

### Molecular Templates (Austin, TX)

- Manager, Cell Biology
  - Regulatory Affairs Specialist
  - Multiple positions
- <http://mtem.com/careers/>

### Syneos Health

- Clinical Project Leader
  - Senior CRA
  - Multiple positions
- <https://www.syneoshealth.com/careers>

products, intraluminal devices, occlusion balloons, and flow diverters, as well as polymer, platinum, and hydrogel coil products. It markets its products through a network of specialty distributors primarily in North America, South America, Europe, Africa, the Middle East, and the Asia Pacific.

Contact: Andrew Brown, Medical Device Search Group, Inc., (786)372-4343,  
[abrown@medicaldevicesearchgroup.com](mailto:abrown@medicaldevicesearchgroup.com), [www.medicaldevicesearchgroup.com](http://www.medicaldevicesearchgroup.com)

### **FDA Quality and Regulatory Consultants (FDAQRC)**

FDA Quality and Regulatory Consultants LLC offers specialized Quality and Regulatory Consulting for Pharmaceutical, Medical Device and Biotech companies. Due to our Food and Drug Administration experiences, we provide customized, value-added solutions, processes and enhanced quality standards to optimize business. <https://fdaqrc.com/careers/>

### **Paratus Diagnostics**

Paratus Diagnostics is always looking for exceptional talent to join our growing team. Conveniently located in San Marcos, we are right in the middle of the rapidly growing Austin to San Antonio technology corridor. With about 5,000 square feet of laboratory and office space, we research, develop, manufacture, and test the Paratus *PreparedNow*® System right in the heart of Texas.

Full listing of Paratus open positions <http://paratusdiagnostics.com/careers>

#### • **Multiple Positions**

Interested candidates should apply directly to Paratus CEO Dr. John C. Carrano at [jcarrano@paratusdiagnostics.com](mailto:jcarrano@paratusdiagnostics.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. Send inquiries and resume to [sarah.fletcher@skillsalliance.com](mailto:sarah.fletcher@skillsalliance.com)

## **Looking For Opportunities**

### **Well-Qualified Interns From Austin Community College Biotechnology Program Looking For Positions!**

Contact Dr. Linnea Fletcher, Department Chair ([linneaf@austincc.edu](mailto:linneaf@austincc.edu) or call 512 -223-5912), or Steven Spurlock ([sspullock@austincc.edu](mailto:sspullock@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/>

### **Jack Zamen: Biomedical Engineer Intern**

I am a freshman engineering student at Texas A&M University. Next year I will be majoring in biomedical engineering. I am looking for an internship this summer at a medical device company in Austin. I am disciplined, a hard worker, take direction well and a team player. I can provide my resume for review. Please contact me at: Jack Zamen, [jzamen18@gmail.com](mailto:jzamen18@gmail.com) | 512-800-5852.

**Stephanie Cohen: Bioengineer**

I am looking for an entry-level engineering role. I have a bachelor's degree in Engineering Physics (specialized in Bioengineering) and Physics. My experience with medical devices includes systems engineering, quality assurance, and inspection/repair. I have optics and optical design experience. I also have experience with quality assurance and testing of software, both manual and automated, some programming experience with Python, C++, and javascript/Groovy. I'm bilingual in English and Spanish. I am seeking employment in Austin and the surrounding area, and I'm also willing to relocate and open to remote work as well. Contact me at [stephanie.cohen1@gmail.com](mailto:stephanie.cohen1@gmail.com).

LinkedIn: [www.linkedin.com/stephanie-cohen](http://www.linkedin.com/stephanie-cohen)

## TEXAS LIFE SCIENCE ORGANIZATIONS

**ATX Women in MedTech**

[womeninmedtech@gmail.com](mailto: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](http://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>

## 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](mailto:operations@texmda.org) to learn more.

#### Capital City Innovation/BioAustin/TMDA/AHT/TX Health Catalyst/Capital Factory/ Health Tech Austin

We are mapping the Austin's landscape in healthcare/life sciences/biotech/medtech. Anyone interested in volunteering to collect/compile this information as a team? If you are, please contact Scott Collins at [scott@bioaustin.com](mailto:scott@bioaustin.com).

#### ATX Women in MedTech

Looking for volunteers to support community outreach, event management, PR, sponsorship and more. Email [womeninmedtech@gmail.com](mailto: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](mailto:scott@bioaustin.com)

## THANKS TO OUR TMDA SPONSORS!



With warm regards,

Dana Abramovitz, Diya Banerjee, Elisa Maldonado-Holmertz, Victoria O'Dell, and Tamiko Oguri  
on behalf of BioAustin, Texas Medical Device Alliance (TMDA), and Austin HealthTech (AHT)