MedTech GATEWAY

May 2019, Issue #11

Happening right now @ CMEF Shanghai! Despite the feeling of a conservative market from the uncertainties of trade wars, the worldwide MedTech industry continue to grow at a positive rate, offering a wide range of products, innovations and technologies.

Access-2-healthcare strives to get in touch with the latest information to practice in Medical Device Market, and with you!

Highlights

Regulatory Round-Up *FDA guidance on device performance bench tests, Canada guidance for medical devices manufactured by 3D printing, CMS new Add-on payment pathway for breakthrough MDs and more*

In-Country Focus *PerkinElmer open largest lab instrument in Singapore, Japanese regulators extend participation in MDSAP and more*

Special Feature *New Healthcare Innovation Centre in Singapore*

Industry Insights *New device to treat children's ADHD, Cardiac pacemaker powered by heartbeat and more*

Journey to Product Commercialisation *"Funding"*

REGULATORY ROUND-UP

The top regulatory news affecting the healthcare sector worldwide

FDA's Guidance on Device Performance Bench Tests

FDA issued guidance with its recommendations for information about non-clinical bench performance testing for medical devices that manufacturers should include in premarket submissions. The guidance outlines what to include in test report summaries, test protocols and complete test reports.

Learn more

THAILAND: New Medical Device Act

Medical Device Act (No. 2), BE 2562, has been in effect since 30 April 2019, which aims to supervise and promote the medical device industry to be in line with international standards by prescribing control of medical devices according to the level of risk. Learn more

CHINA: Guidelines for the technical review of the registration of active medical devices

In order to strengthen the supervision and guidance of the registration of medical device products and further improve the quality of registration examination, the State Drug Administration China has released the Guiding Principles for the Technical Review of the Registration of Active Medical Devices

Learn more

CANADA: Supporting Evidence for Implantable Medical Devices Manufactured by 3D Printing

Health Canada today published new guidance describing the information and evidence that companies should provide when applying for a medical device licence for a 3D printed implantable medical device. This guidance represents the first phase of health policy for 3D printing of implantable medical devices in Canada. Learn more

EPHA Submission on EU-US Regulatory Cooperation Activities

Following the agreement on July 2018 between European Commission President Jean-Claude Juncker and US President Donald Trump to launch a new phase in the trade relationship between the United States and the European Union, EPHA has made a submission highlighting public health concerns around medicines and medical devices, digital health and antimicrobial resistance. Learn more

New MDCG guidance on timelines and legacy devices in Eudamed

The Medical Devices Coordination Group (MDCG) has issued two guidance documents. The first is on the timelines for entering certain data into the Eudamed database by manufacturers, the other is about so called "legacy devices" and their Unique Device Identification (UDI) data in relation to Eudamed. Check out and Learn more

Do you have any particular questions or do you want to get industry expert insights about any of our regulatory top? Perhaps you may want to ***reach out to us.***

IN-COUNTRY FOCUS

We dedicate this part of our newsletter to give you a peek in the in-country happenings or news in parts of the world where we have local presence.

USA

FDA Allows Breast Implant Linked to Cancer to Remain on the US Market

According to a statement issued by Amy Abernethy, FDA principal deputy commissioner, and Jeffrey Shuren, director of the agency's Center for Devices and RadiologicalHealth, the agency said it would not ban textured breast implants now but will increase efforts to collect and disseminate information about risks involving the device. Learn more

3M to Buy Medical Device Manufacturer Acelity

3M is acquiring the privately held medical device maker Acelity Inc in a deal valued at $6.7 billion. Acelity, under its KCI brand, makes advanced wound dressings and specialized systems that use a vacuum to seal off acute or chronic wounds, promoting faster healing. Learn more

SINGAPORE

Perkin Elmer Opens the Largest Lab Instruments Manufacturing Facility in Singapore

PerkinElmer, a leading American medtech company, opened its newest life science lab instruments and diagnostics manufacturing facility at the JTC MedTech Hub in Jurong. The Singapore facility is the company's largest instrument manufacturing facility globally. Learn more

Ekso Bionics®' EksoGT Exoskeleton Adopted in Singapore for Groundbreaking Clinical Study

The National University Health System (NUHS) in Singapore has adopted three EksoGT exoskeletons for a groundbreaking clinical study. Learn more

JAPAN

Japanese Regulators Extend Participation in Medical Device Single Audit Program (MDSAP)

The Japanese Ministry of Health, Labour and Welfare (MHLW) is extending the country's participation in the MDSAP through early 2020. The MHLW's decision to maintain participation in MDSAP helps ensure continuity of the program, which allows medical device manufacturers to meet quality requirements across Japan, the US, Canada, Brazil and Australia using a single certification. Learn more

INDUSTRY INSIGHTS

Medical Technology Industry and innovation news worldwide

New Device Could Treat Children's ADHD Without Medication

The FDA recently approved the first medical device to treat ADHD in children. The device is worn on the forehead at night and delivers a mild electrical nerve stimulation designed to improve focus in kids with attention deficit hyperactivity disorder.

Learn more

China will impose an import official tax on a large number of US pharmaceutical products

On May 13, the Ministry of Finance, China issued a notice saying that since June 1, 2019, the tariff rate will be increased for some imported goods originating in the United States. It contains recombinant human insulin and its salts, blood pressure testing equipment and apparatus, ibuprofen, B-type ultrasonic diagnostic apparatus, color ultrasonic diagnostic apparatus and other large quantities of medicines and medical equipment products.

Learn more

CPI Supports ItoM Medical to Develop Smart Vest for Asthma Treatment

CPI is working alongside ItoM Medical BV and Blumorpho to support the development of a wearable medical device focused upon improving treatment for children with uncontrolled asthma. The device, a next generation smart vest prototype, will benefit from CPI's expertise in the printable electronics sector.

Learn more

Healthtech Company partners with Academic Health Science Networks for Medica 2019

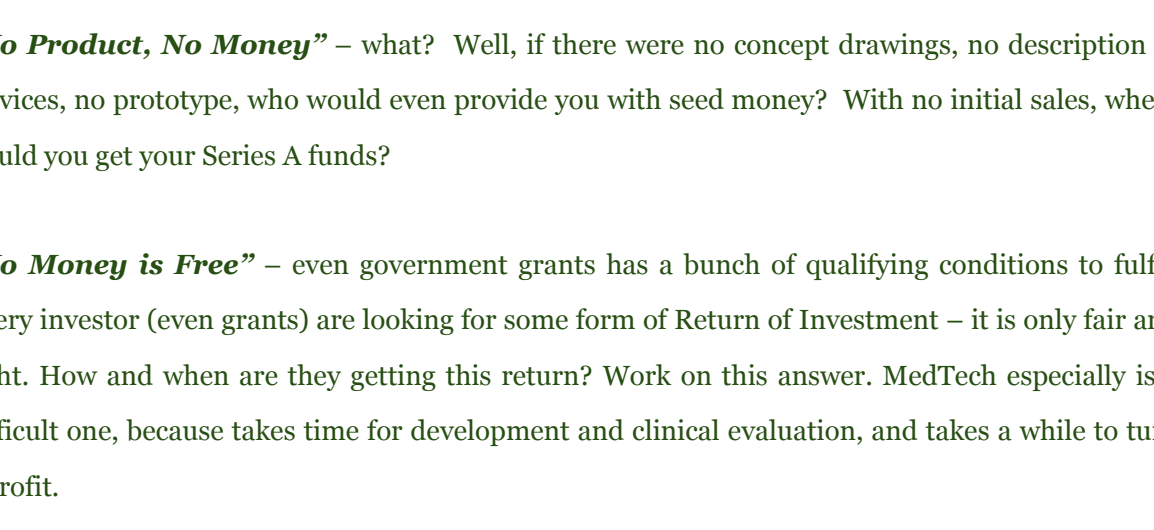
The Academic Health Science Networks (AHSNs) will take a group of British health innovators to MEDICA 2019 – the largest healthcare exhibition in the world – in partnership with the Association of British HealthTech Industries (ABHI).

Learn more

Scientists in China Develop Cardiac Pacemaker Powered by Your Own Heartbeat

A research team has developed an implantable medical device that can harvest energy from heartbeats rather than batteries, according to a recent report published in the journal Nature Communications. According to the study, the device and the body form an interconnected symbiotic system. Both the energy source and stimulus target of the symbiotic device is the body. Learn more

JOURNEY TO PRODUCT COMMERCIALISATION



" No Money, No Talk" should be changed to ***"No Money, No Product"***. **FUNDING** is required in all stages of commercialisation and the way to source, pitch and raise funds, vary from stage to stage. What are some common fundamentals?

"No Product, No Money" – what? Well, if there were no concept drawings, no description of services, no prototype, who would even provide you with seed money? With no initial sales, where would you get your Series A funds?

"No Money is Free" – even government grants has a bunch of qualifying conditions to fulfil. Every investor (even grants) are looking for some form of Return of Investment – it is only fair and right. How and when are they getting this return? Work on this answer. MedTech especially is a difficult one, because takes time for development and clinical evaluation, and takes a while to turn a profit.

"If you don't ask for it, you won't get it" – be clear to ask for the actual funds required, for what purpose, for what outcomes. Even if you have the best idea in the world, keeping quiet about it or not being specific about your needs, gets you absolutely nowhere.

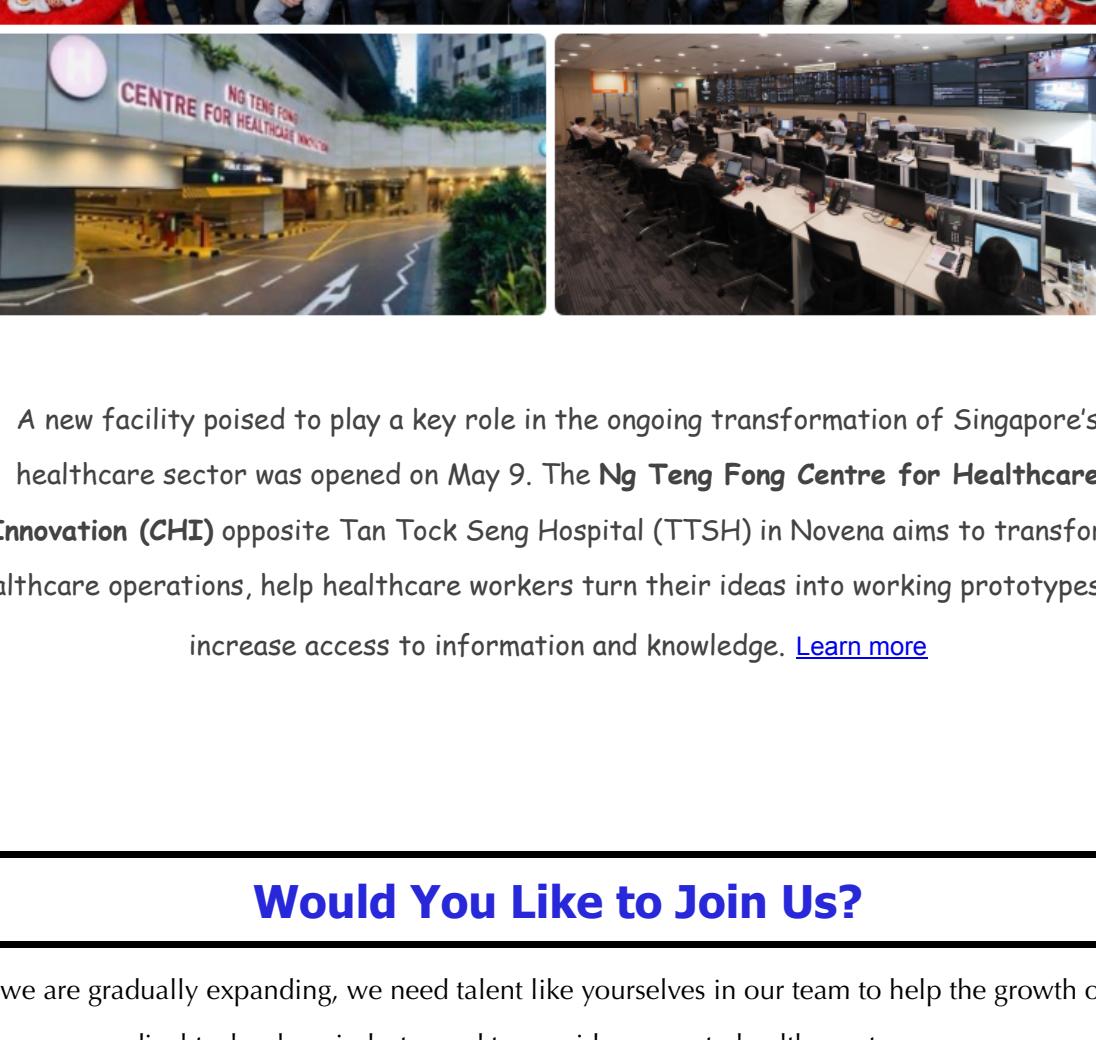
"Money don't drop from the sky" – no one 'owes' you anything, they don't 'owe' you to invest in your product or idea. You have to work for it- reach out, be prepared, show that you have already personally and heavily committed to your cause, and think of that return in investment for your investors, would go a very long way in keeping your MedTech commercialisation journey adequately funded.

Missed our product commercialisation advice from the last issues?
Click to view: ***Concept I Prototype I QMS***

Special Feature

JUST SOMETHING SPECIAL FOR THIS MONTH

Healthcare innovation centre opens in Novena, Singapore



A new facility poised to play a key role in the ongoing transformation of Singapore's healthcare sector was opened on May 9. The **Ng Teng Fong Centre for Healthcare Innovation (CHI)** opposite Tan Tock Seng Hospital (TTSH) in Novena aims to transform healthcare operations, help healthcare workers turn their ideas into working prototypes and increase access to information and knowledge. Learn more

Would You Like to Join Us?

As we are gradually expanding, we need talent like yourselves in our team to help the growth of the medical technology industry and to provide access to healthcare to everyone.
Contact to join us now!

Local regulatory Expert
(Australia)
Learn more

Administrative Assistant
(Part Time)
(HCMC, Vietnam)
Learn more

QA Manager
(Singapore)
Learn more

Supply Chain / Logistics Executive
(Phillipines)
Learn more

Software QA Engineer -
Medtech (Contract)
(Thailand)
Learn more

Supply Chain / Logistics Executive
(Indonesia)
Learn more

Access-2-Healthcare helps medical technology companies gain market entry in various countries.

Learn more about us through our SlideShare

MISSED OUR LAST ISSUE?

In our last issues, we have gone through the top regulatory news of worldwide healthcare industry: new EU regulation (MDR, IVDR), updates from IMDRF and US FDA to name a few...
Click to view the *APRIL 2019* newsletter.

Facebook Twitter LinkedIn Photo Competition e-mail us