MedTech GATEWAY

June 2019, issue #12

It is OK to be boring! Yes, scanning around the globe in the medical technology scene for the past month has positively left us.. bored. Conservatism is still on the rise - people with money but not willing to invest. Much activity happens at the operational levels in hope of improvement - just not sure to what extent.

Access-2-healthcare 's **MEDTECH GATEWAY** allows you to be closer in touch with the latest in the Medical Technology Markets, Regulations, Policies in Medical Device Market.

Enjoy!

Highlights

Regulatory Round-Up *Updates on GS1's UDI guideline, IMDRF's guidance on personalized devices, China Technical Guide for electronic submission of medical device registration and more*

In-Country Focus *New Mexico Tariffs and affects to US medtech manufacturers, Australia AICC(WA) Health & Medical Innovation Delegation to Israel and more*

Industry Insights *PMCA Early Tool to diagnose Parkinson's disease, Neuromodulation device to treat migraines from an Israel start-up and more*

Journey to Product Commercialisation *"Prototyping"*

CHINA: Technical Guide for Online Registration Applications & 2018 Medical Device Registration Work Report

With the aim to improve the registration system, NMPA published technical guidelines on the electronic submission of medical device registration applications

Learn more

as well as its 2018 report on medical device registrations

Learn more

CANADA: Health Canada Sets Steep Price Increases for Medical Devices

Manufacturers of Class II, III and IV devices will have to pay 75% of its costs for pre-market evaluations, 67% of right-to-sell application costs and 100% for establishment licenses. The new fees, set to go into effect beginning on April 1, 2020, will be set at 50% to 100% of costs, with most will be phased in over four to seven years.

Learn more

VIETNAM: Further implementation Guidelines of Decree 36 and 169 for Medical Devices

Department of Medical Devices and Construction held a meeting for the industry which aims to reinforce the implementation of Decree 36 and

THAILAND: Gathering Comments on the Draft Ministerial Regulations

After the new version of Medical Device Act B.E. 2562 (2019) in April, the FDA revision of 4 ministerial regulations and they are in the public hearing step.

Learn more

Decree 169 in the management of medical devices. Learn more

And a whole bunch of stuff in the EU!

About Notified Bodies

GERMANY: TÜV SÜD Becomes Second NB to be Designated Under EU MDR.
Learn more

In the meantime...

UK: Lloyd's exits notified body services
Learn more

MDCG 2019-6 Questions and answers: Requirements Relating to Notified Bodies
Learn more

COCIR Offers Recommendations on Notified Bodies, Grace Period
Learn more

About Unique Device Identification

GS1 Updates UDI Guideline

.... on applying its system of standards to FDA's unique device identification requirements.
Learn more

Commission Implementing Decision (EU) issuing entities for the operation of unique equipment identifiers (UDIs)

The Commission Implementing Decision (EU) 2019/939 of 6 June 2019 was released, regarding the designation of issuing entities for the operation of UDI system in the field of medical devices.
Learn more

IMDRF posts guidance on personalized medical devices

.... which harmonizes the application of the existing regulatory pathways based on personalized device type. Learn more

The EMA Posts Draft Guidance on Drug-Device Combinations

The European Medicines Agency (EMA) recently released a draft guideline on the quality requirements for drug-device combinations to inform developers of drug products with integral, co-packaged or otherwise enabling devices of their obligations under the regulations set to come into force in Europe next year. Learn more

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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.**

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

Roche and GE Healthcare introduce NAVIFY Tumor Board

Roche announced the release of NAVIFY Tumor Board 2.0, the first collaboration product from their partnership with GE Healthcare, this new version is initially available in the United States and Canada with additional markets to follow in the near future. Learn more

New Mexico Tariffs To Hit Medical Device Makers Hard

The US president's new announcement that he will impose a 5% tariff on imports from Mexico beginning in early June—and would multiply the tariff month by month if illegal border crossings are not halted. The possible tariffs could impact a whole host of U.S. industries, especially medical device companies which depend on

Mexican manufacturers as a part of their supply chain. Learn more

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GERMANY

Smith & Nephew Announces Completion of Brainlab Orthopaedic Joint Reconstruction Business Acquisition

Smith & Nephew plc, the global medical technology business, announced it has completed the acquisition of the Munich-based Brainlab orthopaedic joint reconstruction business. Learn more

JAPAN

Japan Allows Focused Ultrasound to Treat Essential Tremor Patients

INSIGHTEC®, a global medical technology innovator of incisionless surgery, announced that it has received national reimbursement from the Japanese Ministry of Health, Labour and Welfare (MHLW) for treating essential tremor.

Learn more

MALAYSIA

EMvision Medical Devices Limited Signs Non-Binding Memorandum of Understanding with Keysight Technologies Malaysia Sdn. Bhd

EMvision Medical Devices Limited has signed non-bindingMemorandum of Understanding ("MOU"), with Keysight TechnologiesMalaysia Sdn Bhd, to collaborate on a new generation of personalized, highly integrated, and

high-performance vector network analysis solution for the healthcare sector.

Learn more

AUSTRALIA

AICC(WA) Health & Medical Innovation Delegation to Israel

The Australian Israel Chamber of Commerce (AICC WA) regularly hosts trade delegations to Israel for WA business leaders and professionals. Highlights of the AICC(WA) Israel delegation include a showcase of medical device start-ups, diagnostic robotics, and clinical research.

Learn more

Coulter Partners Opens in Sydney and Singapore, Makes Three Key Appointments

Life sciences-focused executive search firm Coulter Partners has opened new offices in Sydney and Singapore in addition to making three key appointments. Steven Johnson joins the firm as executive director in Sydney, while Martin Grindrod takes over as director in Singapore.

Learn more

TAIWAN

Rakuten Medical Opens Two New Offices In The Netherlands And Taiwan

Rakuten Medical, a clinical-stage biotechnology company developing precision-targeted cancer therapies based on its proprietary photoimmunotherapy (PIT) platform, has established new office locations in both Amsterdam, Netherlands and Taipei, Taiwan.

Learn more

PMCA Early Detection Tool to Diagnose Parkinson's disease Received FDA Breakthrough Designation

The U.S Food and Drug Administration (FDA) has granted a BreakthroughDevice designation to Amprion's proprietary technology, Protein Misfolding Cyclic Amplification (PMCA) — a device that holds the potential to diagnose Parkinson's disease at a much earlier stage than current diagnostic methods. Learn more

SFC Fluidics Partners with PercuSense and Diabeloop to Improve Diabetes Care

SFC Fluidics, Inc. (SFC) has partnered with two companies, Diabeloop SA and PercuSense, Inc., as part of the Industry Development and Discovery Partnership that was awarded to SFC Fluidics in 2018 by JDRF, for

Medical and Healthcare Fair Finishes Three-Day Run

The 10th HKTDC Hong Kong International Medical and Healthcare Fair, organised by the Hong KongTrade Development Council (HKTDC) and co-organised by the Hong Kong Medical andHealthcare Device Industries Association (HKMHDIA), finished its three-day run from 14th to 16th May. The fair welcomed more than 12,000 buyers from 61 countries and regions, an increase of 8% compared with last year. Learn more

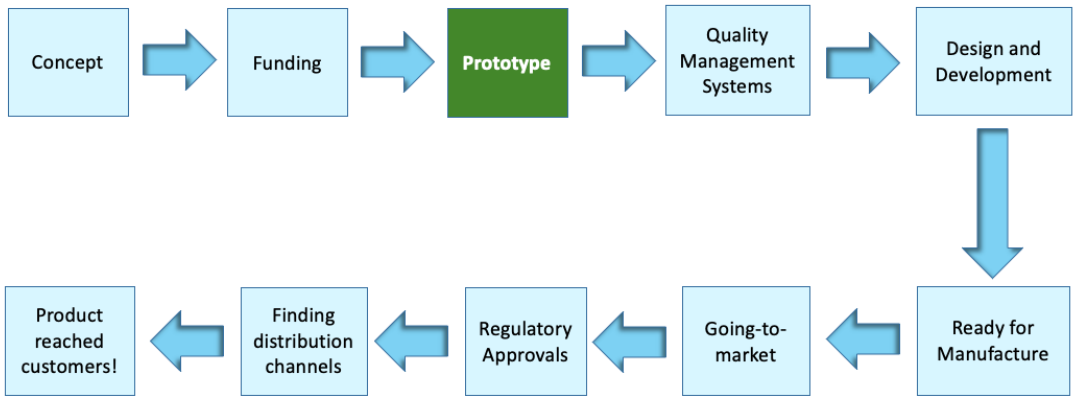
Israeli Startup Gets FDA Nod for Neuromodulation Device to Treat Migraines

Nerivio Migra is a breakthrough electronic device for acute treatment of migraines. It consists

the development of a single integrated pod artificial pancreas (AP) system for people with type 1 diabetes (T1D). Learn more

of a bioelectric patch which is placed on the upper arm and an associated smartphone app which controls the electrical impulses and records data. Learn more

JOURNEY TO PRODUCT COMMERCIALISATION



Prototyping

To Go For Looks or to Make It Work?

After getting the concept and value proposition sorted out, the next step is to decide on the form factor, to house the technology that you've placed. We do ***prototypes*** for a few reasons. One of it is to advance the design effort to prove with evidence the various proofs of concept (that it can be used, it can work, it can be manufactured..), another is to provide something for future users/customers to have a 'feel' of things. That leads to the prototype being your single most important marketing tool, to future investors and stakeholders.

With available resources, usually after the first-generation prototype, we have to decide if we wish to refine or change the form factor, or place more effort to ensuring the outcome more accurate or effective. ***If there is a resource crunch, in the medical device industry, which way should you go?***

The single most important factor in medtech (amongst many others, of course), is that the device is usable by its users. They would like to know how your concept and value proposition fit into their clinical workflow, and if it is a positive or a negative to them. They would like to know if there are additional risks either to the user, patient, or environment that can be identified, and to provide feedback to the engineers to modify the prototype.

Usually the clinical workflow has a direct impact on the effectiveness, cost saving, productivity - all of which are of great interest to the healthcare industry, and therefore the investors and funding agencies. Thus if the prototype is sufficiently 'finished' from the form factor perspective, just about able to show what the clinical workflow is about, it's preferable to place the effort in doing so, than to raise a devices' accuracy from 85% to 92% - that can be done in the next stage when you have gotten the user buy-in and funding, as the last incrementals of design outcome are usually the most difficult to realise.

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

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)	**Administrative Assistant** (Part Time) (HCMC, Vietnam)	**Quality Systems Manager** (Singapore)
Learn more	Learn more	Learn more
Supply Chain /	**Software QA Engineer**	**Supply Chain /**

Logistics Executive (Phillipines)

Learn more

- Medtech (Contract) (Thailand)

Learn more

Logistics Executive (Indonesia)

Learn more

Access-2-Healthcare

helps medical technology companies with their product development, market launch and to 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: Canada guidance for medical devices manufactured by 3D printing, CMS new Add-on payment pathway for breakthrough MDs and New Healthcare Innovation Centre in Singapore to name a few.

Click to view the MAY 2019 newsletter

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