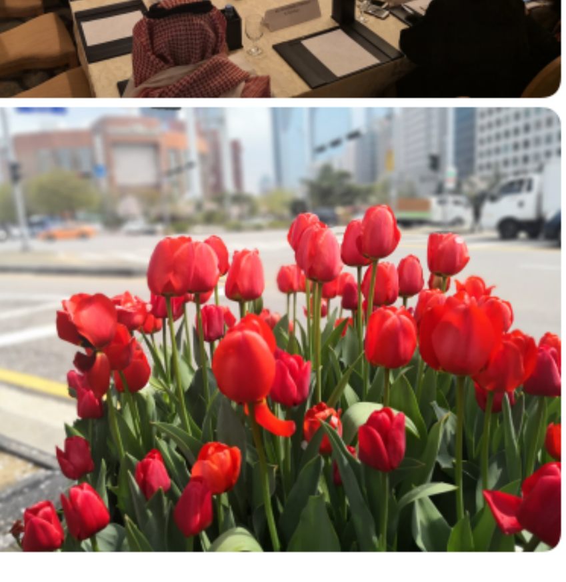
MedTech GATEWAY

April 2019, Issue #10

MedTech Insights returns!

We have taken a 10 month break and used that time to gather feedback on how our newsletter should be improved.The surprising thing was that the common feedback was - keep going!



In This Issue

REGULATORY ROUND-UP

The top regulatory news affecting the healthcare sector worldwide

US FDA

We have had a bolus of news from the US FDA as they're getting very active in engaging with the indsutry, pushing out new guidance and programs. Here are some of them.

Promotes Evolving Regulation of Medical Device Materials

In a statement released on March 15, 2019, US FDA announced new efforts to evaluate the long-term safety and efficacy of materials used in the manufacture of implantable medical devices.
Learn more

Considers Less Restrictive Protocols for Some AI-Based Medical Devices

The agency wants to create a framework that would safely allow the AI in medical devices to make reactive choices without prior approval from the agency. Check this out and also Learn more

IMDRF Works to Speed Entry of Devices Across Multiple Countries

The International Medical Device Regulators Forum (IMDRF) proposed updates on Wednesday to clinical evaluation documents in support of rapid market entry across multiple jurisdictions.
Learn more

Australia Unveils Device Action Plan

Australia's Therapeutic Goods Administration (TGA) released a three-part medical device action plan, part of which will make adverse event reports more timely, as well as enhance public awareness on and the agency and device regulatory system. Learn more

MDA published the First Edition of Medical Device Guidance Document

This Guidance Document was prepared by the Medical Device Authority (MDA) to help the industry and healthcare professionals in their quest to comply with the Medical Device Act (Act 737) and the regulations under it, and/or to facilitate their business endeavour. Learn more

The Basic GMDN membership is made available as a free service

The GMDN, the de facto global standard for identifying the world's millions of medical devices, has been made freely available to all users for the first time on April 1, 2019.
Learn more

Phillipines delays launch of new Medical Device Regulation

Administrative Order 2018-0002 is supposed to take effect on April 11, 2019; however the implementation date has been delayed. Extra time is needed for the CDRRHR to finalized guidelines.

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.

AUSTRALIA

Australia stops short of breast implant ban

Australian regulators opted not to ban any breast implant devices after calling a meeting of its expert working group on breast implant associated anaplastic large cell lymphoma (BIA-ALCL). Instead, the TGA will ask all implant manufacturers for additional information prior to making decisions. Learn more

US

CTA Brings Together Tech Giants, Trade Associations to Improve Efficiencies in AI and Health Care

Big names in technology, including Google, IBM,AT&T, and Fitbit, are teaming up with the Consumer Technology Association (CTA) to develop standards and recommend best practices around the use of artificial intelligence in healthcare. Learn more

THAILAND

Medical Product Cooperation Council of Thailand (MPCT)

Joining hands with both public and private network, the signing ceremony for the memorandum of cooperation was in the establishment of the Medical Product Cooperation Council of Thailand (MPCT). This aims to promote Thai medical products to the world standard, from the source to destination as well as enhance the efficacy of the process. Learn more

BRAZIL

Chembio's diagnostic test win approval in Brazil

Chembio's DPP Zika/ Dengue/ Chikungunya multiplex test allows stimultaneous and discrete detection of antibody for both active (IgM) and prior exposure (IgG) to the Zika, Dengue and Chikungunya viruses, which is important for both treatment and surveillance.
Learn more

SINGAPORE

George Clinical establishes new presence in Singapore

George Clinical, a global scientifically backed clinical research organization, (CRO) has expanded its footprint in Asia with the addition of a new presence in Singapore. The new office and entity in Singapore, which was established in July, were requisites for George Clinical to act as a local clinical trial sponsor for the firm's international client base.
Learn more

INDUSTRY INSIGHTS

Medical Technology Industry and Innovation News Worldwide

AXA Announces Shortlist for Health Tech & You Awards

The AXA Health Tech & You Innovation and ExcellenceAwards have been recognising entrepreneurs in early stage start-ups or later stage businesses. These categories have been shaped through the advice of the AXA Health Tech & You Expert Group, comprising of figures technology, health, charity, consumer advocacy, medical, design and media. Learn more

FDA Approves Innoblative's Radiofrequency Ablation Device

This radiofrequency ablation (RFA) applicator is designed to remove dysfunctional soft tissue using heat generated from a medium-frequency alternating current.Various long-term clinical studies have shown that RFA of soft tissue could mitigate complications and reoperation rates.When combined with a radiofrequency electrosurgical generator, SIRA RFA is expected to help coagulate and ablate large surface areas in open abdominal surgical procedures.
Learn more

Med-Tech Innovation Expo 2019

Taking place at the NEC Birmingham, UK, the Med-TechInnovation Expo 2019 runs from 15th to 16th of May. With 200 exhibitors, the Med-Tech Innovation Expo gives attendees an invaluable chance to meet designers, engineers, manufacturers, and innovators from the medical and healthcare industries. Learn more

Startup Develops 'quadwave microcurrent' Pain Killing Device

The device comes with several sticky pads that attach to the affected area, which deliver bioelectrical pulses through the skin. They mimic the body's natural electrical microcurrent system, which helps cells to regenerate and repair and reduces inflammation. It treats pain by sending pulses through the skin to the nerve endings in the affected area, blocking pain signals from travelling to the brain. Learn more

JOURNEY TO PRODUCT COMMERCIALISATION

This section of our Newsletter is dedicated to provide readers with expert guidance on product commercialisation. We will discuss a useful advice a month, on a different step of the product development process.

In this issue, we get started with the very first step- the Concept of your product!

What are the different between Tech Push and Need Pull?

Technology Push is when research and development in new technology, drives the development of new products. Technology Push usually does not involve market research. It tends to start with a company developing an innovative technology, applying it to a product, and then marketing.

Market Pull is when the market demands for a solution, searches for this solution, then creates or adapts technology to develop this solution to fulfill the need. It involves market study, deep interviews, and data analytics from available market insights. It tends to start with one or more individual identifying the need, the solution, then gathering resources to develop the solution.

Both are equally challenging in the MedTech environment. The specificity of our market segment – with very specific reimbursement and regulatory requirements, combined with a very conservative mindset to adopt change – makes it extremely challenging to 'push' the tech. This same conservative mindset also prevents 'pulling' great solutions to be implemented.

Success comes when you can crack the market need, not be overly enamoured by sexy tech, and provide the best fit of the solution (even if the tech is very basic!) at the right areas.

Healthcare only succeeds if you care about the greater good – because when you do, the money comes along the wa

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

Special Feature

EUROPEAN COMMISSION

The Medical Devices Regulation and In-Vitro Diagnostic Medical Devices Regulation will come into force on May 26, 2020 and May 26, 2022 respectively. During this time of transition, the European Medical Device Coordination Group (MDCG) has announced many updates in Eudamed, which is a major part of Europe's new medical device and IVD regulations, as well as released other important information.
Let's check them out!

Italian medical device nomenclature to be adapted for Eudamed database

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The European Commission announced the selected medical device nomenclature to support the IVDR and MDR implementation will be the Italian CND nomenclature, to be mapped to the GMDN nomenclature. The CND nomenclature will be made available in the future Eudamed.
Learn more

EU Device Coordination Group Offers Eudamed Guidance

The EU's Medical Device Coordination Group (MDCG) released two new documents explaining how legacy devices can be registered in Eudamed without a unique device identifier (UDI) and how device companies will have until November 2021 to register device data elements in Eudamed.
Learn more

MDCG Article 54(2)b interpretation of Regulation (EU) 2017/745

The European Commission published the MDCG 2019-3 Interpretation of Article 54(2)b from the Medical Devices Coordination Group (MDCG) that urges clarification of the corresponding article in the new MDR.
Learn more

New guidance documents from the Medical Devices Coordination Group on UDI-DI

The MDCG endorsed additional/updated guidance documents which support the Unique Device Identification implementation under the upcoming IVD and MDRegulations regarding Unique Device Identification UDI-DI.
Learn more

Would You Like to Join Us?

As we are gradually expanding, we need talent like yourselves to join us in our journey to help the growth of the medical technology industry to provide access to healthcare to everyone. Just do it - just contact us!

Local Technical Expert (Australia)	RA, Logistics (Indonesia)	Administration in HCMC (Vietnam)
Sales/ Business Development Lead (Germany)	Outreach Manager Logistics (Phillipines)	Software V&V Engineer RA outreach (Indonesia)
Sales/ Business Development Lead (US)	Customer-facing Manager QA Manager (Singapore)	

Apply Here!

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 past issues, we have tackled about the top regulatory news that affect the healthcare industry worldwide: MDSAP, ISO13485: 2016, IMDRF AE Codes and EU MDR/IVDR to name a few..
Click to view the JUL 2018 newsletter.

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