MedTech GATEWAY

October 2019, issue #16

... unless medical technology startups are adequately resourced & products sufficiently mature to move forward!

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 *5th MDR Notified Body; FDA guidances with Digital Health Content and more*

In-Country Focus *U.S. exempts more Chinese medtech products from tariffs; Asia Pacific Medtech Forum 2019 in Singapore and more*

Industry Insights *Launch of world's first heart attack alerting technology in Australia; FDA approves Biofourmis' Biovitals Analytics Engine and more*

Journey to Product Commercialisation
Going-to-market more

Special Features

ISO/TC 210 meetings more

IMDRF 's draft principles and practices for pre-and post market medical device cybersecurity

Like FDA, IMDRF supports a total product life cycle approach to the cybersecurity of medical devices, and described a security risk management process designed to identify, evaluate and control risks at each step from initial conception to end of support.

Learn more

EMA Releases EudraVigilance List of Important Medical Event Terms

This is a list of important medical event (IME) terms for users of its EudraVigilance safety database, intended to support classification of suspected adverse reactions and analyses of aggregated safety data.

Learn more

AUSTRALIA:

Considers Relaxing Rules on Self-Test IVDs to Improve Screening

TGA is collecting feedback on the regulation of self-test in vitro diagnostic (IVD) devices. Australia has allowed the sale of self-testIVDs for HIV since 2014 and is now assessing whether to relax the rules on other types of diagnostic.

Learn more

US FDA

FDA Guidances with Digital Health Content

Learn more

FDA continuous efforts in 510(k) medical device program

Learn more

Statement on continued efforts to evaluate materials in medical devices

CDRH Learn, FDA's Center for Devices and Radiological Health (CDRH) web page for multimedia industry education

Learn more

Learn more

... updates related to UK's Brexit

Exceptions and modifications to the EU guidance on good pharmacovigilance practices that will apply in a no-deal Brexit from UK's MHRA

Lean more

ABPI details Brexit plans at PIPA conference

The Association of the British Pharmaceutical Industry (ABPI) announced its latest Brexit contingency plans at the PIPA Conference 2019, stating that it still firmly believes that leaving European Union with deal in place is best way to minimise potential disruption.

Learn more

EU's Notified Bodies Tracker

The transition deadline for the European Medical Devices Regulation (MDR 2017/745) will be here soon while the list of NBs still keep changing. We'll track the designated and withdrawn Notified Bodies as a permanent feature

Designated NBs

1. BSI (UK)
2. TÜV SÜD (Germany)
3. DEKRA (Germany)
4. IMQ (Italy)
5. TÜV Rheinland (Germany)

Recent Withdrawals

1. QS Zürich (Switzerland)
2. UL International Ltd. (UK)
3. LRQA (UK)

First TÜV SÜD MDR Certificate issued

TÜV SÜD Product Service has issued their first Medical Device Regulation (MDR) certificate since receiving notification in May 2019, which is a certificate for a Class III (high risk) device from BIOTRONIK.

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**!

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.

US

Five accelerators selected to speed development of innovative medical products for biodefense and other security needs

The new additions to the network provide geographic coverage into areas of the country previously under-represented in the network, aiming to support innovative products and solutions developed around the U.S.

Learn more

U.S. exempts more Chinese medtech products from tariffs

The U.S. has exempted another 18 medical devices or device components from the 25% tariffs imposed on Chinese goods by the Trump administration. The new list includes ultrasound, X-ray, MRI and infusion equipment.

Learn more

SINGAPORE

Asia Pacific Medtech Forum 2019

On the eve of the fifth annual Asia Pacific MedTech Forum, regional medical technology association brings together twelve companies, across global MedTechs and local HealthTech startups, to present the APACMed Connected Care Innovation Showcase.

Learn more

INDIA

Central Drugs Standard Control Organisation (CDSCO)'s details of the laboratories cleared to test medical devices and in vitro diagnostics (IVDs).

CDSCO posted a list of four organizations that can test certain medical devices and sent a separate notice about evaluating IVDs to 25 healthcare centers. Both texts relate to the medical device rules that India implemented at the start of last year.

Learn more

CHINA

Joins IMDRF's Post-Market Device Safety Data Exchange Scheme

China has joined IMDRF national competent authority report (NCAR) exchange program which supports the global distribution of post-market safety information in an attempt to stop medical devices from causing serious harm to patients.
Learn more

Medical Review Center has launched the English series of medical device registration review
Learn more

INDUSTRY SIGHTS
Medical Technology Industry and innovation news worldwide

Launch of world's first heart attack alerting technology in Australia

The AngelMed Guardian sets out to be first of FDA approved, fixed cardiovascular supervising gadgets that alarms patient of forthcoming heart attacks.The Guardian is proposed for use in patients who have recently endured an ACS occasion and who stay at high hazard for repetitive occasions.
Learn more

FDA approves Biofourmis' Biovitals Analytics Engine

Singapore-based health IT start-up Biofourmis has received510(k) clearance from the US Food and Drug Administration (FDA) for the use of Biovitals Analytics Engine for ambulatory physiological monitoring.
Learn more

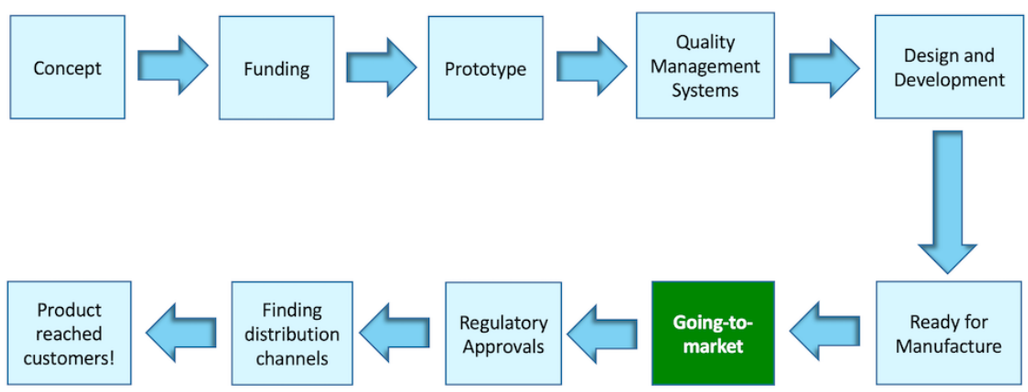
Australian research develops first polymer heart valve

In a world first, a US patient has successfully received a polymer heart valve jointly developed by CSIRO, Australia's national science agency, and medical device company Foldax® Inc.. Learn more

5th Edition of Medical Device Innovation Camp

Over the five days of MEDIC, from September 28 to October 2, 2019 in the Powai campus, India, participants formed interdisciplinary teams and work on real-life projects guided by mentors. They will learn how to define an unmet need, develop an innovative solution, deliver a validated product, and deploy it in the market. Learn more

JOURNEY TO PRODUCT COMMERCIALISATION



Going to Market – Fly there!

For many medical technology small-to-medium sized enterprises, the initial forays of understanding of the market often involves some form of ***market research*** carried out by market research companies. The research details tend to be generic to the sector, based on pre-existing information that were gathered previously. Sometimes for the money invested, it can be a little underwhelming.

Instead of paying that few thousands (hopefully not more!), for this high-level study, since you know what you wish to ask, and whom you would like to engage with. Why not arrange for those meetings, take the money, and fly to the country to find out for yourself? Then the ***market knowledge*** would be specific to your product and your product only- and not overly generic.

The crux is to have these very specific, market-centric questions to have answers, so that the entire business model for the market,

approach, positioning, pricing, delivery, and post sales support, can be determined. Sometimes these answers need further digging, and you may not have sufficient time or expertise to find these answers. This is when you can consider finding help from companies that have in-country presence to help you.

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

Special Features

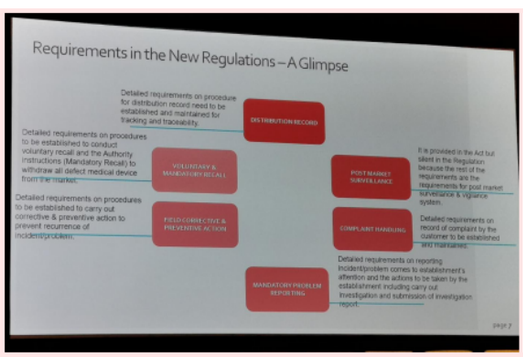
ISO/TC 210: Quality management and corresponding general aspects for medical devices

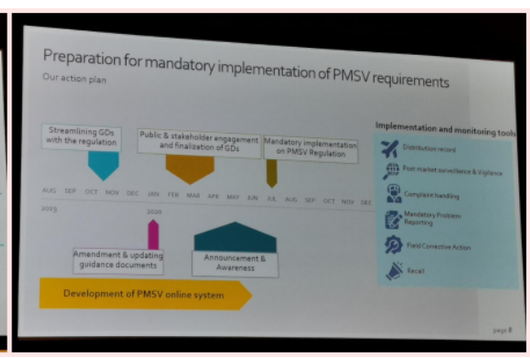
From 7 to 11 October 2019, the ISO/TC 210 meetings were held in the United Kingdom. The meetings addressed the standardization of requirements and guidance in the field of quality management and corresponding general aspects for medical devices as well as standards for small bore connectors. Learn more

Malaysia Medical Device Expo 2019

Malaysia Medical Device Expo is an initiative by Medical Device Authority (MDA), a government agency under the Ministry of Health Malaysia, to bring light to latest innovative technologies and advances of global medical devices.
The event took place from 15-17 October as a conference-cum-exhibition which provide a forum for discussion on updates in medical device regulatory control as well as communications and sharing of relevant information such as new inventions and innovations, research and development in medical technology and industry. Learn more

Medical device Authority Malaysia's sneak peek of the new update to their regulations come 1st July 2020





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!

Software QA Engineer -
Medtech (Contract)
(Thailand)

Quality Systems Manager
(Singapore)

Learn more

Local regulatory Expert
(Australia)

Learn more

Learn more

Supply Chain / 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.

Access-2-Healthcare has been recently awarded as
Best SME Medical Technology Consulting Solutions Provider - Asia Pacific, by Global Health & Pharma
Learn more

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: MHRA guidance and publications about a possible no-deal Brexit; US FDA 510(k) Program; First neuromodulation device for heart failure and Medical Fair in Thailand to name a few.
*Click to view the **SEPTEMBER 2019** newsletter*

Facebook Twitter LinkedIn Photo Competition e-mail us

/