MedTech GATEWAY

November 2019, issue #17

Please let us know if any medical devices are designed as beautiful as this Museum or the automobile contents in it!
@Ferrari Museum, Modena, Italy

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 *INDIA To Require Registration Of All Current Non-Notified Devices MDR Notified Body; EUDAMED delay for 2 years and more*

In-Country Focus *Indonesia to Host OIC Country Technical Meeting; Singapore SWITCH conference 2019 and more*

Industry Insights *Developing a Safer, More Accurate Way to Detect Prostate Cancer; New healthtech research institute to launch in Manchester and more*

Journey to Product Commercialisation
Regulatory Approvals more

Special Features
24th AHWP Annual Meeting more

TGA Australia:

Submissions received: Proposed new medical device classification for substances introduced into the body via a body orifice or applied to the skin

A total of twelve (12) submissions were received in the related consultant. This feedback will inform the work to develop the proposed regulatory amendments.

Learn more

India Plans to Bring All Medical Devices Under CDSCO Oversight in December

The Indian government is planning to give the Central Drugs Standard Control Organization (CDSCO) oversight of the import, manufacture and sale of all medical devices in December.

Learn more

US FDA

Statement on concerns with medical device availability due to certain sterilization facility closures

With the recent and potential closure of large ethylene oxide sterilization facilities, the FDA is concerned about the future availability of medical devices and impending medical device shortages.

Learn more

Learn more about Ethylene Oxide Sterilization for Medical Devices

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 We'll track the designated and withdrawn Notified Bodies as a permanent feature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)
6. DARE!! Services B.V.(Netherlands)
7. BSI Group B.V. (Netherlands)

Recent Withdrawals

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

Swissmedic Details Plans to Align Combination Product Rules With EU

The Swiss Agency for Therapeutic Products (Swissmedic) has set out plans to align its approach to drug-device combination products with that of the EU, ensuring regulatory harmonization after the EU brings in new rules covering medical devices.

Learn more

EMA Updates Q&A on MDR, IVDR

The Question and Answer (Q&A) document provides practical considerations concerning the implementation of the medical devices and the in vitro diagnostic medical devices regulations.

Learn more

European database on medical devices (EUDAMED) will be delayed for 2 years

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.

PHILIPPINES

2019 Joint Annual Convention of The CT-MRI Society of The Philippines and Ultrasound Society of The Philippines

Learn more

SINGAPORE

SWITCH conference 2019

Singapore Week of Innovation and TeCHnology is the foremost global platform for deep tech ecosystems in the areas of manufacturing, urban solutions, health and biomedical sciences and digital services - where innovators, investors and collaborators connect. Apart from exhibitions and conferences, there were also SLINGSHOT 2019 and TechInnovation.

Learn more

INDONESIA

Indonesia to Host OIC Country Technical Meeting

The event took place at the Ministry of Health office, Jakarta which was attended by representatives from 14 OIC member countries. This workshop is a manifestation of Indonesia's commitment as an OIC Center of Excellence on Vaccines and Biotechnology Products.

Learn more

CHINA

China and EU regulators meet to harmonize manufacturing standards

Representatives fromChina’s NMPA and EMA convene to share expertise on GMP for APIs, GCP standards, and on the environmental impact of manufacturing.

Learn more

Developing a Safer, More Accurate Way to Detect Prostate Cancer

A biomedical engineer at Worcester Polytechnic Institute(WPI) is creating a new medical robot that uses minimally invasive technologies to safely and accurately detect and monitor prostate cancer, the second-leading cause of cancer-related deaths among American men.
Learn more

New healthtech research institute to launch in Manchester

A new multi-million pound research institute that will maximise Manchester's academic strengths in digital health and advanced materials to discover innovative health and care solutions is being launched by a consortium, led by The University of Manchester.
Learn more

Medtronic launches first AI endoscopy system to detect colorectal polyps

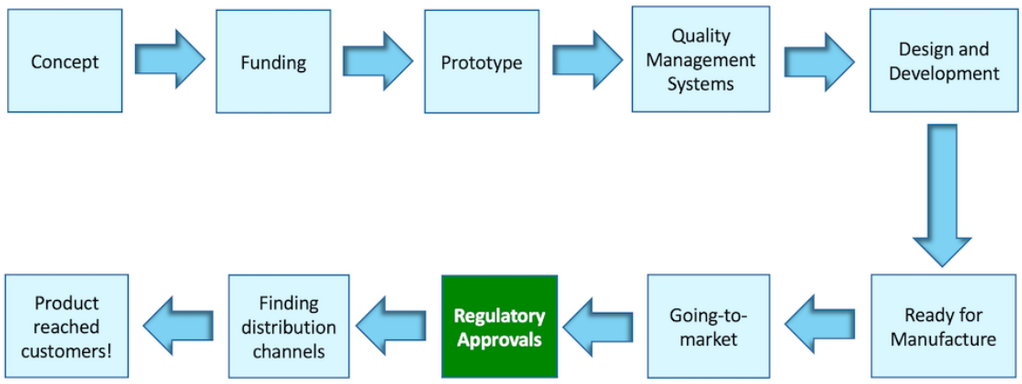
Medtronic has launched the GI Genius intelligent endoscopy module, a system that uses artificial intelligence (AI) to detect colorectal polyps. It provides physicians with a solution in the fight against colorectal cancer. Learn more

LPIXEL Announces Approval and Launch of Japan's first Deep Learning-Powered SaMD for Brain MRI, EIRL aneurysm

"EIRL aneurysm," is an image analysis software that uses deep learning to identify suspected aneurysms from brainMRI. EIRL aneurysm will be the first deep learning-powered software as a medical device (SaMD) for brain MRI to receive approval from thePharmaceuticals and Medical Devices Agency (PMDA) in Japan. Learn more

JOURNEY TO PRODUCT

COMMERCIALISATION



Regulatory affairs can be very tricky!

It is not just some set of rules that you can just follow, but many different shades of grey.

Is it deliberately so to confuse the industry? Absolutely not – in fact, it is sometimes vague or broad sounding specially to cater for the enormous variety of medical technology out there. And leave room to allow for discussion to ensure faster market entry.

Some regulated countries may have a lot of requirements (e.g. China), takes a lot time (e.g.China), but you may be surprised that it is very structured, clear, forward thinking, yet leaving that bit of room to allow for all the variations. This is the best form of regulation – balancing the structure to ensure safety and efficacy, yet providing the flexibility.

Appreciate your regulator! When we help medical technology companies gain approvals, we appreciate them too!

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

Special Features

24th Asian Harmonization Working Party (AHWP) Annual Meeting

The 24th Asian Harmonization Working Party (AHWP) annual meeting for Medical Devices & Supplies kicked off on November 11 at the Grand Millennium Hotel Muscat under the patronage of H.E. Sayyid Sultan bin Yarub Al-Busaidi, Advisor of Ministry of Health for Health Affairs.The Meeting is organized by the Ministry of Health (MOH), represented by the Directorate General of Pharmaceutical Affairs & Drug Control (DGPADC). 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!

Software QA Engineer -
Medtech (Contract)
(Thailand)

Learn more

Quality Systems Manager
(Singapore)

Learn more

Local regulatory Expert
(Australia)

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. Learn more about us through our SlideShare

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

MISSED OUR LAST ISSUE?

In our last issues, we have gone through the top regulatory news of worldwide healthcare industry: EMA Releases EudraVigilance List of Important Medical Event Terms; First TÜV SÜD MDR Certificate issued; ISO/TC 210: Quality management and corresponding general aspects for medical devices to name a few.

Click to view the OCTOBER 2019 newsletter
Or vist our website for more issues and feedback!

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