MedTech GATEWAY

#Access2MDInsights

July 2018, Issue #9

Access-2-healthcare aims to keep everyone up-to-date to the latest medical technology industry and regulatory news/updates to provide pertinent information useful to practices within the Medical Device industry

In This Issue

Regulatory Round-Up *US FDA recognizes a new ANSI standard, price hike in the EU, SHFDA's successful "Pilot Work Plan"*

In-Country Focus *Indonesia's policy on mercury-containing MD's, Malaysia's new policy under Act 737, Philippine FDA's new proposed fees*

Product Commercialisation Advice *Product Reaching Customers - How do you actually know that your product reached the customers?*

Special Feature *Let us visit the Medical Devices ASEAN (MDA) 2018 event held in Bangkok, Thailand*

Industry Insights *GSK buyout of Novartis Consumer Healthcare, MIT's innovation on diagnostics, China's first smart procurement and medical supply company*

Access-2-CoWork *Business trip to the Philippines? Come co-work with us!*

REGULATORY ROUND-UP

The top regulatory news affecting the medical technology sector worldwide

EUROPEAN UNION

Pharmacovigilance fees surge by 1.7%. Drugmakers should watch out for increase in fees for its conduct of pharmacovigilance activities by 3Q 2018. Learn More

INDIA

IPC to initiate a national workshop on materiovigilance with the purpose of guiding stakeholders on MD reporting guidelines across the country Learn More

US FDA

UL 2900-1 published as an ANSI standard

In light of the complexities and challenges associated with cyber risk on the network-connectable devices and accessories, this new standard will help manufacturers demonstrate the safety of their devices comprehensively, particularly during premarket submissions and notifications. Learn More

FDA issues draft labelling guidance for devices containing lubricious coatings

The guidance aims to assist stakeholders on information to be included in device labelling and to enhance consistency of coating-related information as well as promote safe use of these products. Learn More

CHINA

Shanghai FDA expands medical device registration pilot amidst positive feedback

Following the smooth progress and positive reactions since implementation last December 2017, SHFDA's "Pilot Work Plan" has expanded its coverage to the whole city from the initially limited pilot at the free trade zone. Stakeholders are confident that the pilot will bring more positive outcomes. *Learn More

SWITZERLAND

Swissmedic announces planned overhaul in the processing FSC and MC for medical devices

This systems change to electronic processing via the Swissmedic Portal is expected to address increasing review timelines. The system is to be rolled out September this year, however, new fees are also anticipated by 1Q 2019. Learn More

** Link provided is in local language*

We're in the forefront of actually contributing in regulatory development worldwide. Do you have any questions on upcoming regulations or regulatory approval needs?

ASK OUR REGULATORY TEAM

IN-COUNTRY FOCUS

We dedicate this part of our newsletter to give you a peek in the in-country happenings, Medical Technology and Innovation news in parts of the world where we have local presence

AUSTRALIA

NHMRC introduces next three draft modules of its 'Guidelines for Guidelines' series

The guidelines offer practical advice on how to meet NHMRC's Standards for Guidelines Learn More

GERMANY

Germany healthcare to be pumped by participation of various sectors

A forum was recently concluded which involved major decision makers from various industries to collaborate for the country's healthcare boost. *Learn More

INDONESIA

Government reiterates policy on mercury-containing MD's

All MD's containing mercury will only be allowed circulation in the country until 31 December 2018 irregardless of license validity post the stipulated date. *Learn More

CHINA

China issues third draft rule for MD trials

The draft rule covers site inspections of clinical trials for devices that are in the process of product registration to evaluate compliance with GCP and ensure data integrity. *Learn More

THAILAND

TISI signs MOU with UL for better safety standards in Thailand

The MOU allows the exchange of standards information between UL NFP and TISI as well as cooperation and collaboration between the organizations on safety related standards issues. *Learn More

PHILIPPINES

PFDA proposes new schedule of fees for MD registration

The fees will be in line with the upcoming new MD risk classification. Stakeholders to watch out for the finalised fees within the year. Learn More

SINGAPORE

MOH seeks public opinion on proposed changes to the IDA

MOH is inviting feedback on proposed amendments to the Infectious Diseases Act (IDA) that ensures that Singapore's ability to prevent and control infectious diseases remains relevant and up to date. Lean More

MALAYSIA

MDA adds new policy under the Medical Device Act (Act 737)

Export only MD's are now exempted from registration provided that these will not be marketed in Malaysia and must comply with other relevant policies. Learn More

JAPAN

PMDA issues "Pharmaceutical and Medical Devices Safety Information" document

The publication intends to facilitate safer use of pharmaceuticals and medical devices by the healthcare providers. Learn More

Have an in-market question or need a local market study? Click on the respective country link and check with our team members

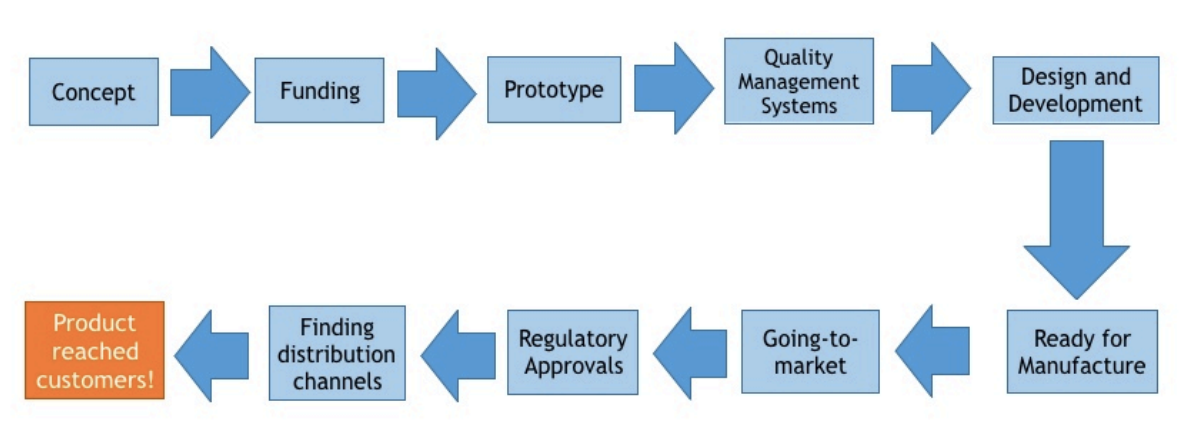
Australia | EU | Indonesia | Malaysia | Philippines | Singapore | Thailand

** Link provided is in local language*

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.

Your Product has reached customers!



Product Reaching Customers

How do you actually know that your product reached the customers?

Distribution records - how do you create distribution records? By agreeing with the distributor/dealer/direct office to maintain these records, isn't that obvious?

No, and that is the issue.

Many companies leave this important aspect out in the eagerness to launch the product in the marketplace, or actually have the traceability system in place, but didn't actually implement it in the field.

What is the impact of not doing it?

Products cannot be effectively tracked, uncertainty of where the source of a product complaint (or product compliment) may come from, unable to determine an accurate range of affected products during product recall... potentially recalling a large range of products (just to be on the safe side).

Always agree with the distribution channel on the correct and required granularity of traceability for your product, including accessories, spares, consumables, software versions. ***And document this in the written agreement.***

Missed our product commercialisation advice from the last issues? **CLICK HERE.**

Concept I Prototype I Quality Systems I Design and Development I Ready for manufacture I Go-to-Market I Regulatory Approvals I Finding Distribution Channels I Product reached Customers

If you have more questions on the topics share, just reach out to us.

I WOULD LIKE TO KNOW MORE

SPECIAL FEATURE

In this issue we share to you the leading events that showcase Asia's most innovative developments

Medical Devices ASEAN (MDA) 2018

11th -13th of July 2018 Bangkok, Thailand

Medical Devices ASEAN (MDA) 2018 has inaugurated its first event on the 11th -13th of July 2018 @IMPACT Exhibition & Convention Center, Bangkok, Thailand.

More than 4,000 medical professionals all around the region with major delegation from the leading hospitals and healthcare facilities making up about 150 companies and organisations were present. The Minister of Health, the Secretary General of Thai FDA amongst the distinguished guests who have graced the event. **Learn More**

INDUSTRY INSIGHTS

Medical Technology Industry and innovation news worldwide

GSK announces $13B buyout of Novartis' 36.5% stake in its Consumer Healthcare Joint Venture Learn More

Accuron MedTech Partners with SPRING Singapore to Co-invest in SG's Innovative Start-Ups Learn More

MIT researchers develop an algorithm which exponentiates analysis of medical images and 3D scans Learn More

Sanofi and Advent finalize acquisition of Zentiva Lean More

TLA HealthTech Working Group and the Health Foundry event showcased innovative startups and initiatives working in the MS and pharmaceutical sector Learn More

idsMED and WeDoctor Form China's first smart medical supply chain and procurement company Learn More

ACCESS-2-HEALTHCARE PHOTO COMPETITION

Our photo competition is still open!

Remember, to qualify, 2 elements must be present - healthcare and medical technology
(take a peek at some of our entries below)

Your **NIKON D3400 with 18-55MM AND 55-200MM Kit** awaits! Check out our Flickr page for more details. And very soon we'll be adding our Instagram page!

Would You Like to Join Us?

Regulatory Manager (Singapore)

Software QA Engineer - Medtech (Germany)

Apply Here.
Due date:
30 August 2018

WE WELCOME YOUR FEEDBACK

Like us or Hate us, let us know!

TAKE ME TO THE SURVEY

WHO ARE WE?

Access-2-Healthcare helps medical technology companies gain market entry in various countries. We also help medical device startups launch their producfts and help solve a TON of problems when you've already launched your products overseas. Learn more about us through our Slideshare and our our website

MISSED OUR LAST ISSUE?
Click to view the JUNE 2018 newsletter.

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