MEDICAL DEVICE INSIGHTS

January 2018, Issue #3

As we welcome the new year 2018, 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

The top regulatory news affecting the healthcare sector worldwide

After 2 years of hiatus, excise tax on medical devices to return this 2018
Read More

AiMeD: "increase basic customs duty on medical devices to promote domestic manufacturing"
Read More

Next-gen medical devices to receive fast track approval in South Korea
Read More

TGA's Priority Review Designation Gives Opportunity for Faster Review Process

The option is available for conformity assessment applications and inclusion in the ARTG. Would it be worth the additional fees? Read More

HSA Implements Strategies for Faster Review of Therapeutic Product Applications

The Verification Route for MIV-1 application was fully implemented last December 2017 and the TAT of 50 days will be introduced for NDA, GDA and MAV this April 2018. This opens more options with stakeholders' regulatory strategies/priorities. Read More

US FDA

We take a look a year back in 2017 into some of FDA's milestones in the past year, modernising FDA's Regulatory Programs:

- launched a pilot program exploring a new way of regulating digital health device

- provided more clarity for the manufacturers of low-to-moderate-risk medical devices on specific requirements, and lessen unnecessary submissions to the FDA

- draft guidance for manufacturers of 3D printed medical devices

- new searchable database to better inform and educate patients and health care professionals of the adverse events reported with drug and biologic products

- using real world data to better inform on regulatory decision-making. Read More

Looking Ahead, plans for 2018, the FDA plans to:

- propose an alternate approach to the traditional 510(k) clearance process
- to issue a new draft guidance on the Least Burdensome Provisions
- looking forward into the establishment of a new pre-market and post-market evaluation system (NEST) Read More

Updated Version of the EU Manual on Borderline Classification Released
The updated manual (Version 1.18 dated Dec 2017) is now available for public use in the EU website. The manual serves as a guidance tool to different stakeholders.
Read More

CFDA's Stricter Regulations for Online Sale of Medical Devices Up this Year
The "Measures" will come into force on March 2018. Albeit a bit late into the e-commerce revolution, CFDA makes a bold declaration of authority over the presence of a regulated trade in a platform highly susceptible for abuse. Read More

Do you have any particular questions or do you want to get industry expert insights about any of our regulatory topics? Perhaps you may want to reach out to us.

Special Feature

The start of the year was highlighted with the Talent Mobility Workshop organised by Mahidol University, Bangkok,Thailand. Talent Mobility Programme is an initiative of Thailand 4.0 ("Opportunity Thailand") which is a multi-sectoral development plan by the Thai government.

This is the 2nd year running, and the Workshop aims to bridge the gap between the researchers and the industry by enabling knowledge, experience sharing, and talent nurturing through the various organisations –hence enabling the "mobility of the talent".

Read More in Our Blog Page

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.

INDONESIA: Ease of restrictions on some imported goods hope to clear bottlenecks in import

Although healthcare goods remain to be in the red line checking zone, the easing up of restrictions on other goods will help to indirectly fasten processing time because of increased availability of resources. Read More

GERMANY: Germany raises the bar for the global campaign against emerging diseases

Germany organised the first meeting of all G20 ministers last year and was also instrumental in setting up the Coalition for Epidemic Preparedness. Read More

SINGAPORE: Singapore to see a revamped healthcare law

The draft Bill will replace the Private Hospitals and Medical Clinic Act. The purpose of changes is essentially to safeguard patient safety and welfare, strengthen regulatory clarity, improve governance of healthcare providers and ensure continuity of care and accountability. Read More

AUSTRALIA: Licensing demands huge hurdle in cannabis market dominance

Local cannabis manufacturers are looking forward to expand their market reach, however, only after they have overcome the stringent licensing requirements. Read More

CHINA: Distrust in the country's medical system urges patients to turn to US doctors

Advisors believe the issue is not with the doctors but in the system. When patients go to a doctor, they also look for support, affordability, and comfort. Read More

PHILIPPINES: PH Investment landscape beefs up with joint effort of 28 government agencies

The Philippine FDA is one with 27 other government agencies (collectively IPUNET) in this goal. Philippines will benefit well with this kind of initiative to be able to compete with its neighbouring markets. Read More

THAILAND: Health warning out as substandard orthodontic products spread online

Despite health risks, consumers are attracted to the low price of service and goods versus their counterparts. Apart from the corrective measures, more public awareness and vigilance campaigns should be implemented. Read More

Industry Insights

A Step Closer to RenalGuard System®'s Promise for Better Congestive Heart Failure Management

After positive first-in-man feasibility study, practitioners have more hope on a better protection of kidney health for patients both at risk from the disease itself and the limitations of the available therapeutic options. Read More

Japanese Trading House Invest into Management Unit of Indonesian Conglomerate

At roughly 25% stake, the trading company will leverage on its past experience from its home country to address a rising trend of lifestyle diseases across Asia. This adds in to the rising number of mergers/partnerships in the industry. Read More

Fit like a glove: Top Glove inks deal with Aspion
Read More

Australia's ideal environment for biotech clinical trials
Read More

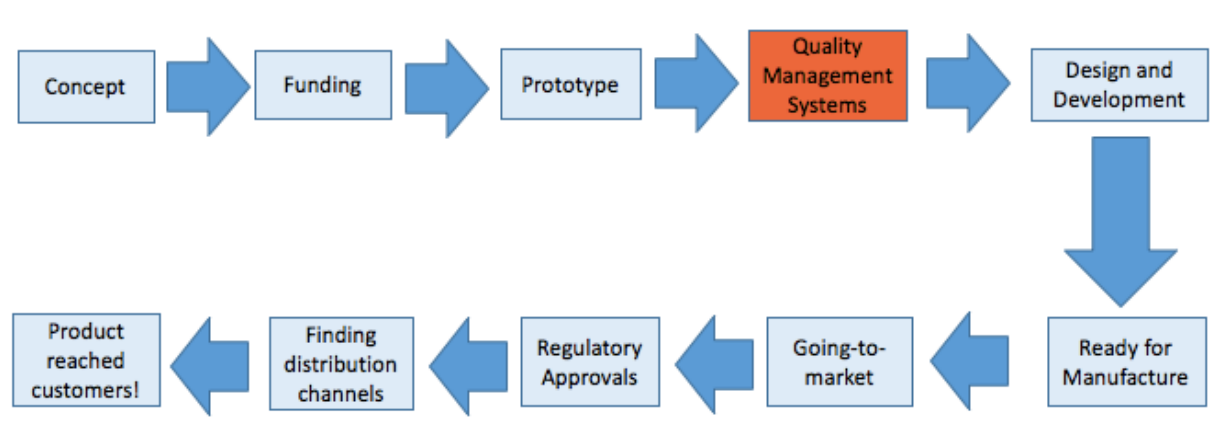
Roche's specially designed card simplifies blood collection
Read More

Laennec digital pathology imaging system approved by the HSA
Read More

JOURNEY TO PRODUCT COMMERCIALISATION

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

*For this issue, we will get useful tips on the **Quality Management System**.*



Templates - to use or not to use?

Everyone perhaps will feel that using templates to establish your quality management system is a quick a fuss free way. It does help to some extent to ensure things are not missed out. However, using templates can mean that the orgnisation is 'pigeon holed' to a way of working that may or may not be suitable for the organisation - because every organisation is unique.

What can be templated?
Document headingsformating that helps to ensure the required content is there e.g. authority/responsibility matrix, indicating links to related procedures/records etc.

What canot be templated?
The actual content - because this is unique for every organisation and its available resources

Layout, presentation and platform (online, paper, phone etc) - because different organisations have different ways to ensure effective consumption and accessibilty of the quality system.

The total number of documents - same reason as above.

But, templates meant for execution of activities such as validation protocols/reports, risk analyses etc. are encouraged.

Hope it helps, Cheers!

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

COMPANY SPOTLIGHT

MEDISAVE

Medisave provides innovative solutions and products for operating theatres, hybrid operating rooms, ICU/NICU units, surgical preparation rooms and other hospital areas and also focuses on products and services for core processes in surgery, in Indonesia.

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Sign up now and explore your possibilities

ACCESS-2-HEALTHCARE PHOTO COMPETITION

A brand new **NIKON D3400 with 18-55MM AND 55-200MM Kit** is up for grabs! Check out our Flickr page for more details.

Access-2-Healthcare helps medical technology companies gain market entry in various countries.

Learn more about us through our Slideshare

Would You Like to Join Us?

Market Access Specialist
(Hanoi, Vietnam)

Project Manager
(Singapore)

Radiation Equipment Expert / Radiation Control Officer
(Jakarta, Indonesia)

Apply Here. Due date: Feb 2018

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..Missed out on our previous issue? Click to view the DEC 2017 issue.

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