MedTech GATEWAY

#Access2MDInsights
June 2018, Issue #8

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 *A brief look into the current state of ASEAN AMDD integration among member states, regulatory changes in China, US and Singapore*

In-Country Focus *Australia's centralized health record system, Japan's initiated global standard for promising technology, Thailand's step further to a reformed narcotics law*

Product Commercialisation Advice *Due Diligence - How should you do it?*

Special Feature *This issue we visit one of the leading events that showcase Asia's most innovative developments - Innovest 2018*

Industry Insights *Healthcare in mobile technology, latest news on large conglomerates, innovator accelarator programs, promising bioelectronic medicine*

Access-2-CoWork *Strange as it sounds, we now have a co-working space in the Philippines!*

REGULATORY ROUND-UP

The top regulatory news affecting the medical technology sector worldwide

EUROPEAN UNION

ENVI issues a draft proposal document in response to their views on the regulation for HTA Cooperation which is "unsustainable and much highly susceptible for errors." Learn More

AUSTRALIA

TGA tightens some MD applications for inclusion to ARTG in response to the reported reliability concerns of eight European Notified Bodies. Learn More

US FDA

US FDA Reclassifies some Class III medical devices and exempts select medical devices from pre-market notifications

Medical Image Analyzers have been proposed to be re-classified from Class III to Class II to lessen regulatory burden such as CAD devices for mammography breast cancer, ultrasound breast lesions, radiograph lung nodules, and radiograph dental caries detection. Coincidentally, 1000+ Class II medical devices are now exempt from 510(k) review. On both circumstances, it is imperative that included devices must meet regulatory controls, including the applicable general and special controls. Sponsors are urged to assess their necessary action with respect to their devices' currrent standing amidst the changes. Learn more about the proposed reclassification here and the final exempt list here.

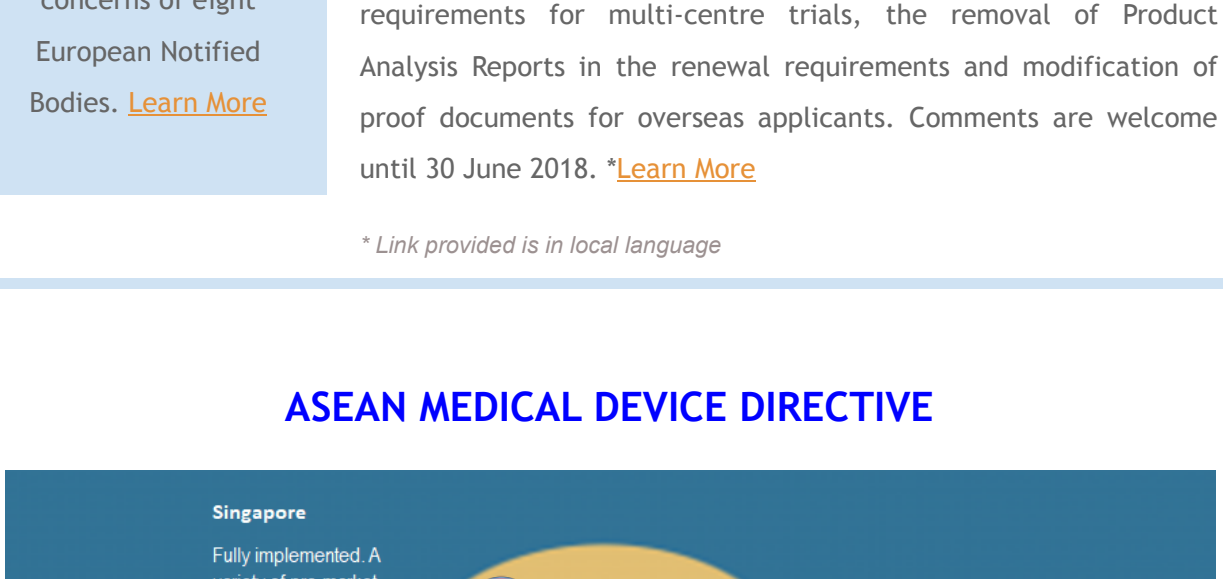
CHINA

CDA releases list of proposed amendments to medical device and IVD approvals

The amendment calls for the simplification of ethics approval requirements for multi-centre trials, the removal of Product Analysis Reports in the renewal requirements and modification of proof documents for overseas applicants. Comments are welcome until 30 June 2018. *Learn More

** Link provided is in local language*

ASEAN MEDICAL DEVICE DIRECTIVE


Medical Device Directive
Singapore
Fully implemented. A variety of pre-market changes to improve and hasten market entry to boost the local economy
Indonesia
One of the most organised regulatory frameworks in ASEAN. Is the Halal certification for devices going to be mandatory?
Malaysia
Fully implemented, and in enforcement phase. All devices are required to be registered or applications forwarded by 30 June 2018. New labelling requirements are in the works and targeted for implementation by 3Q 2018.
Thailand
Partially implemented. The Thai FDA also welcomes a new director for the Medical Device Control Division. Many initiatives within for capacity building and streamlining of regulatory pathways
Cambodia
Implementing phase wise. Enforcement and technical knowledge transfer are current challenges.
Vietnam
Implementation now in Jan 2019 -that is just months away. Industry and the DMEHW are working closely together to ensure Vietnam can meet the next deadline of Jan 2019.
Philippines
Transitioning now. Transactions with FDA have also recently transitioned into paperless processing with the establishment of the FDA e-portal.
Laos
Implementing phase wise and included in regulations for some years. Enforcement and technical knowledge transfer are current challenges.
Brunei
Not yet implemented. There is a draft AO in the works targeted for implementation this 2018. For now, comply with RCED.
Myanmar
Still trying hard to kickstart. Import licensing applies.

In 2015, the ASEAN Medical Device Directive (AMDD) agreement was signed in by all the 10 ASEAN countries - Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand and Vietnam. The agreement is to be fully implemented by 2020. Now, with less than 2 years, what is the current state of ASEAN integration into the member states' local regulations? READ MORE

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

Centralized digital health record system soon to launch

The country sees the need for a system that will make sharing of health records between various practitioners seamless. The National Health Interoperability Roadmap is developed to make this possible. Learn More

GERMANY

IQWiG releases updated general methods in english version

"General Methods 5.0" is now available in english version. The updated version includes new chapters on HTA reports addressing topics proposed by the public and on the assessment of new examination and treatment methods largely based on high-risk medical devices. Learn More

INDONESIA

Universitas Indonesia partners with Keio University to strengthen Cybersecurity

The Faculty of Engineering of the Universitas Indonesia (FTUI) signed a MoA with Keio University in Japan on 29 March 2018. The agreement was signed to to strengthen cooperation on cybersecurity activities. Learn More

CHINA

China's collaborative efforts to improve quality continue on a positive direction

Collaboration between government, industry and society has improved medical quality and accessibility in the country. China's management on medical quality has gradually standardised and professionalized over the years and will continue to improve. Learn More

THAILAND

Three bills pass first reading, a step closer to drug law reform

Three narcotics policy bills are approved for first reading by NLA. If finalised, it will address the nation's issue on overcrowded prisons apart from healthcare benefits. Learn More

PHILIPPINES

Private firms partner for better healthcare in Region VII

SHINE OS+ electronic medical record system of Smart Communications and AJWCC with its existing reporting tool have partnered in order to enhance the region's health programs. Learn More

SINGAPORE

MOH and SMC to further regulate Telemedicine practice soon

With Singapore's ageing population, telemedicine has proven to be beneficial for both simple acute and chronic disease management by improving accessibility to care. MOH and SMC will be regulating the telemedicine under the upcoming Healthcare Services Act (HCSA) in 2020. Learn More

MALAYSIA

Health personality suggests ombudsman to review MOH medical supplies purchases

Galen Centre for Health and Social Policy proposes to establish an independent body to review the Health Ministry's medical supply and services procurement practices following allegations of trade monopoly by select individuals. Learn More

JAPAN

New Japan oriented international safety standard for Next Gen medical technology

Medical plasma technology to sail through smoother global regulations thanks to Japan's initiated safety standard. Learn More Learn More

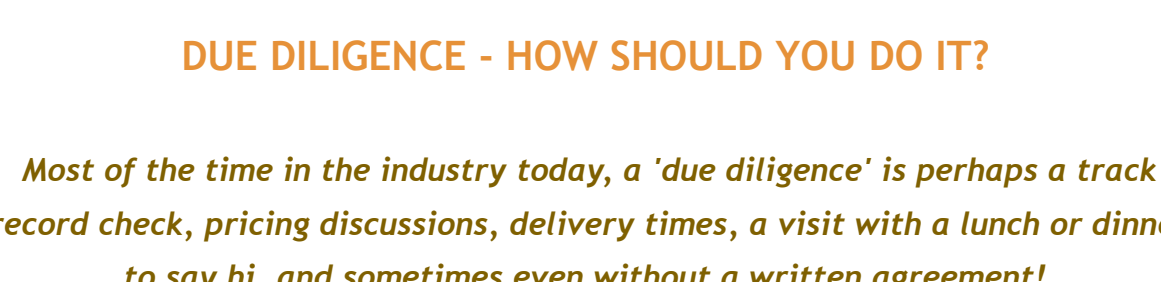
Have an in-market question or need a local market study? Click on the respective country link and check with our team members

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

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.

*For this issue, we will get useful tips on **Due Diligence**.*



DUE DILIGENCE - HOW SHOULD YOU DO IT?

Most of the time in the industry today, a 'due diligence' is perhaps a track record check, pricing discussions, delivery times, a visit with a lunch or dinner to say hi, and sometimes even without a written agreement!

Finance	IT	General Management	Regulatory	Quality
Purchasing	Operations	Marketing	Legal	Distributors
Sales Team	Supply Chain	Manufacturing	Supplier control	

You can see many functions listed. That's generally all the functions in an organisation. ***But what does it have anything to do with business due diligence?***

The answer: You have to have sufficient expertise to check all these functions to the right level to have a comprehensive idea.

Why must business due diligence need to be that comprehensive?

Most due diligence efforts involve legal, finance, procurement, quality, or commercial teams. Operating in an integrating fashion is rare. The times in which we typically require such top-to-bottom approach is during acquisition exercises but acquisition activities are very penetrating and if you're just having an intention to partner, it may make the prospective partner very uncomfortable asking to an appropriate level very important.

Most organisations don't have this comprehensive expertise, so the first step to start is to recognise this is the single most important reason why market entry often fails, and that is because of the failure with the first business partner.

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

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

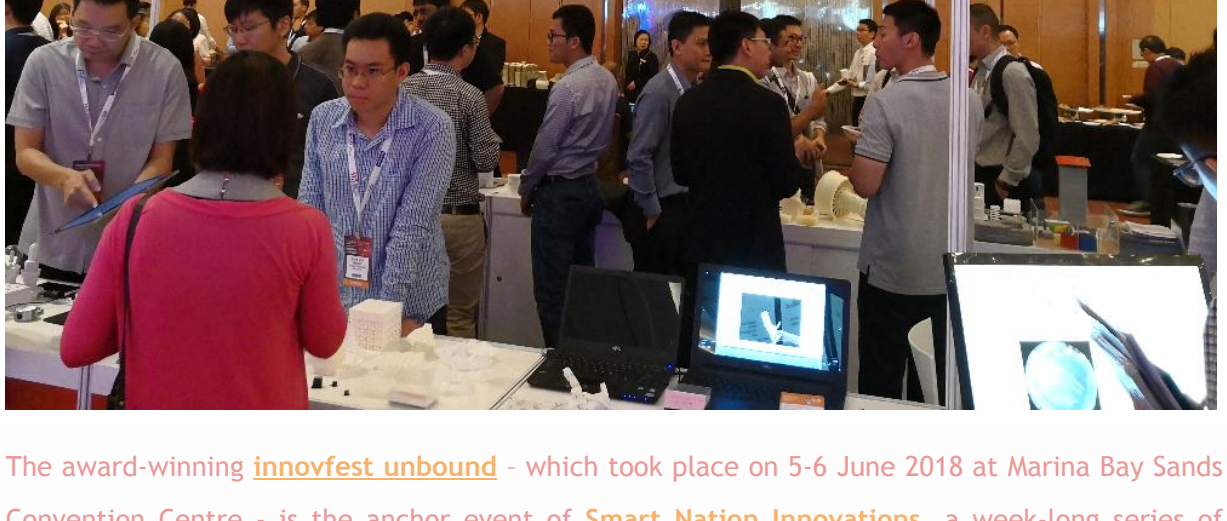
I WOULD LIKE TO KNOW MORE

SPECIAL FEATURE

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

Innovest 2018





The award-winning innovfest unbound - which took place on 5-6 June 2018 at Marina Bay Sands Convention Centre - is the anchor event of Smart Nation Innovations, a week-long series of events that showcase Asia's most innovative developments. In 2018, over 12,000 entrepreneurs, brands, corporates, investors and tech start-ups from 100+ countries met and shared new ideas, build partnerships and celebrate digital disruption. In partnership with Infocomm Media Development Authority (IMDA), innovfest unbound is organised by NUS Enterprise and unbound and is Southeast Asia's most exciting innovation festival. **Learn More**

INDUSTRY INSIGHTS

Medical Technology Industry and innovation news worldwide

- **50 Startups worldwide selected for 2018 showcase and accelerator** Learn More
- **J&J to sell their sterilization unit to Fortive for $2.7B** Learn More
- **Bioelectronic drug for Chron's disease shows promise in clinical trials** Learn More
- **Pfizer Adds 600M USD to its Venture Group** Lean More
- **Diabetics can now do continuous glucose monitoring via mobile phone** Learn More
- **API allows patients to keep confidential health records in mobile phones** Learn More

COMPANY SPOTLIGHT

Orasis Medical Technologies is a distributor of surgical products and surgical instruments in Canada. Their product line include bioceramic orbital implant FCI, sizers and sphere introducer, needle holder, suture forceps, pierse corneal colibri forceps, and iris forceps.

You now can explore a potential partnership with Orasis Medical Technologies via the **Partners' Portal** by Access-2-Healthcare - a NO-cost, low-risk method for sourcing channels and new partners. Sign up now and explore your possibilities

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)

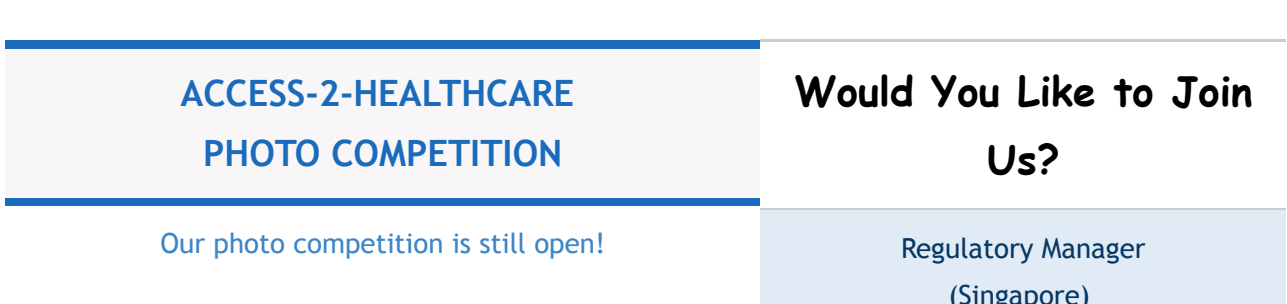
Your **NIKON D3400 with 18-55MM AND 55-200MM Kit** awaits! Check out our Flickr page for more details. And very soon we'll be adding our Instagram page!

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 MAY 2018 newsletter.

Facebook Twitter LinkedIn Photo Competition e-mail us