



MedTech GATEWAY

#Access2MDInsights
February 2018, Issue #4

新年快乐，心想事成，恭喜发财，万事如意！

Our Chinese readers must be gearing up for food, and more food, visiting and some cashflow from giving and taking 红包, while others may be smarting from the post-St. Valentine's Day activities. [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 *CFDA on more internationally aligned policies, TGA's probable path to decentralized conformity assessment procedures, Malaysia's expanding HALAL industry and many more*

In-Country Focus *A promise of potential partnerships for PH, Thailand's remarkable act on kidney care, China's advancing healthcare platform and more*

Special Feature *Mini MD: Empowering non-clinical professionals with basic clinical education for better healthcare collaboration*

Industry Insights *Medical Technology saving the environment, small innovations that promote quality of life for cancer patients, diabetes patients; partnerships and more*

Journey to Product Commercialisation *Design and Development Phase: Design Input: Garbage In, Garbage Out!*

REGULATORY ROUND-UP

The top regulatory news affecting the healthcare sector worldwide

<p>US FDA</p> <p>Impacted stakeholders have the chance to know in detail about the FDA's expectations for the content of custom device annual reports on a webinar that is scheduled 27th Feb 2018. Learn more</p>	<p>AUSTRALIA: Bill for faster approvals pushed</p> <p>The bill aims to remove regulatory burdens for faster market entry approval. Will quality be consistent with decentralized conformity assessments? Learn more</p>
<p>China FDA</p> <p>China further pushes efforts for a more foreign friendly MD regulatory environment as it opens its doors to clinical trial data from foreign trials. Learn more</p>	<p>GERMANY: Coalition parties disagree on healthcare</p> <p>The coalition treaty finally sealed but resolution on the two-tier healthcare system, which has been under heavy discussion, still unclear Learn more</p>
<p>EUROPEAN UNION</p> <p>In the works for years, EU finally laid out HTA plans in a proposal to "boost the co-operation" amongst EU member states for assessing the health technology. Learn more</p>	<p>INDONESIA: A potential partnership with Colombia</p> <p>More prospects of country's healthcare improvements seen through knowledge exchange as MOU planned to be agreed with Colombia. Learn more</p>
	<p>MALAYSIA: HALAL industry widens its reach</p> <p>2018 brings positive news to Malaysia, some medical devices may be able to be Halal certified. Learn more</p>
	<p>PHILIPPINES: Vaccine issue still causing unrest</p> <p>As after effects of the Dengvaxia mess continue to plague the country, the Health Secretary steadfast with stance on separation of FDA from DOH. Learn more</p>
	<p>THAILAND: Industry standards continue to grow</p> <p>Stakeholders to keep your eyes on the new additions to the existing TISI compulsory standards and more drafts due for approval this 2018. Learn more</p>

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](#)

IN-COUNTRY FOCUS

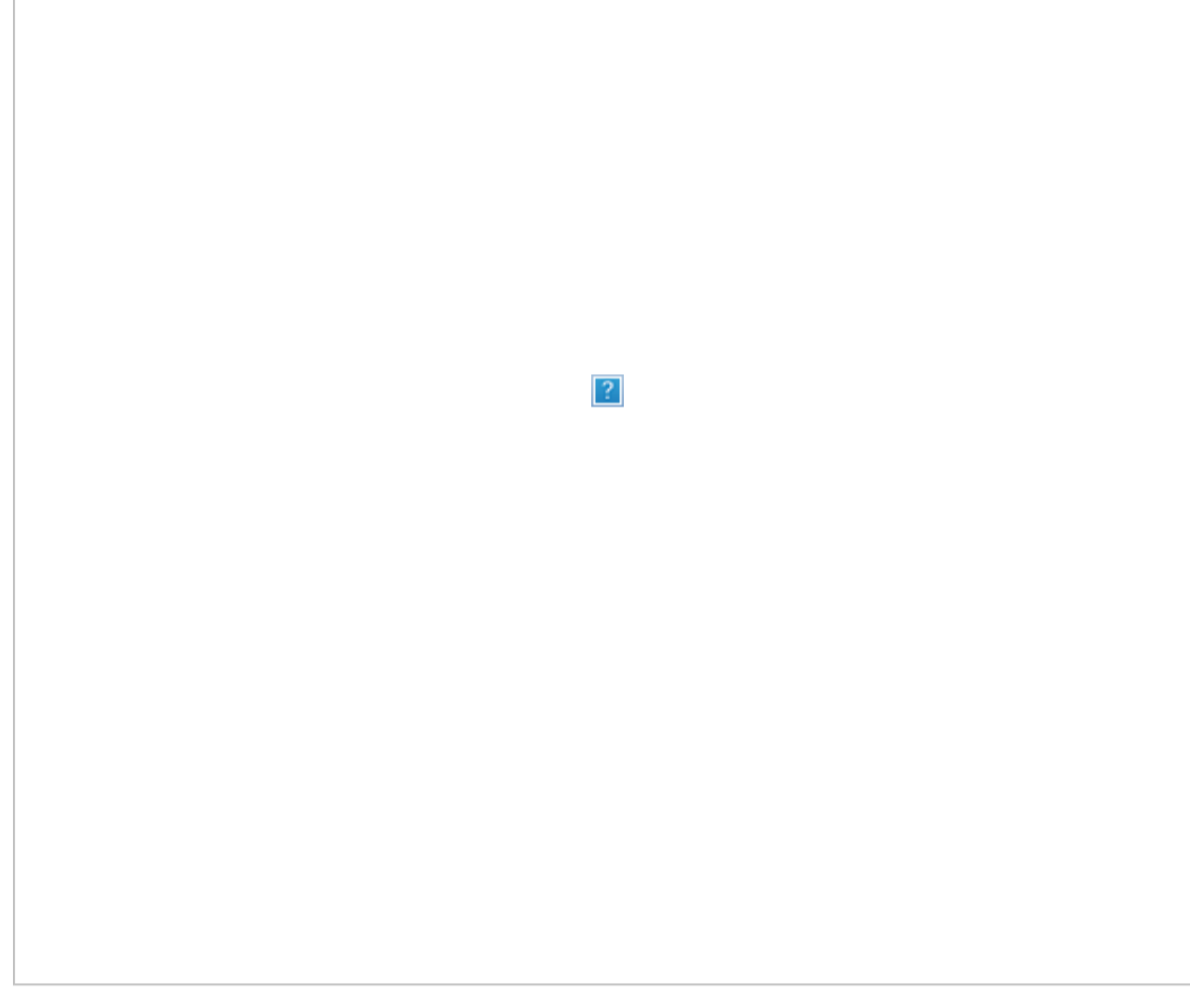
We dedicate this part of our newsletter to give you a peek in the in-country happenings or news in parts of the world where we have local presence.

AUSTRALIA: A peek at China's robust business environment in land down under
Before his talk at the Newcastle seminar of 14Feb, Bo Ji provides insights about doing business in China and on how to succeed in this "wonderland" market. [Learn more](#)

CHINA: "When fast is better" - Tech giants break old systems with fast solutions
Large tech companies in China are literally reshaping access to healthcare through various time relevant technology solutions. [Learn more](#)

INDONESIA: Health crisis an eye opener to bigger social issues
The measles health crisis is declared over. What lies to be seen is the government's move on the root of the problem that plagues the poor towns like Papua. [Learn more](#)

MALAYSIA: Medical Tourism promise forges a foreseeable partnership
With Penang's full potential for medical tourism in Malaysia still to be seen, combined efforts from government and private sectors is essential to boost the market. [Learn more](#)



PHILIPPINES: PH's healthcare spending showing good prospects to EU investors
"The big one" is coming to PH healthcare sector by 3rd quarter of 2018 as the EU weighs in on heavy dependence on MD imports to open potential business partnerships. [Learn more](#)

GERMANY: Unconventional therapy is a double-edged sword
Schools are seeing the benefits of the sand vest on ADHD but its use sparks concern on issues of social stigma. Is this therapy causing more harm than good? [Learn more](#)

THAILAND: The country's benevolence transcends borders
Thailand's free CAPD is more than just a free therapy to kidney patients but a hope to people with no access to care. WHO urges other countries to follow. [Learn more](#)

INDUSTRY INSIGHTS

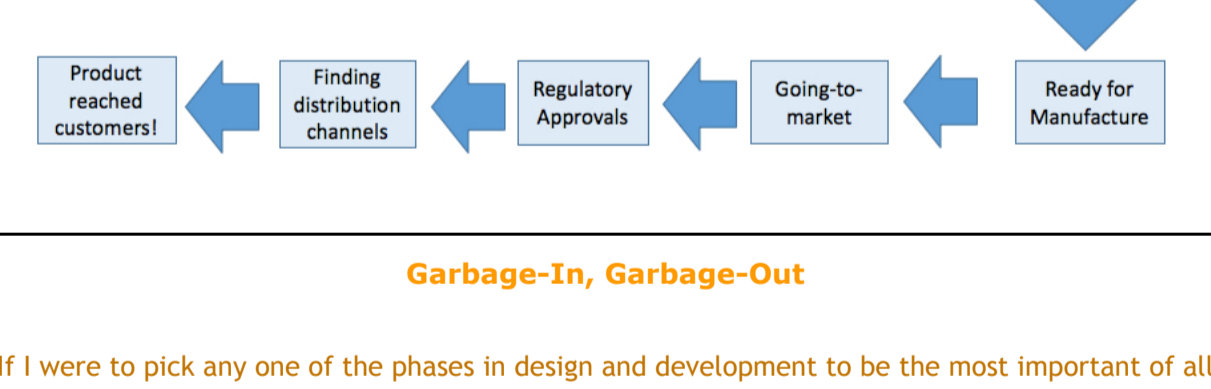
Medical Technology Industry and innovation news worldwide

<p>Small in size but big on promise</p> <p>Proudly made in Malaysia, the first stethoscope with AI features is seen as the country's gateway to becoming a Medical Device hub. Learn more</p>	<p>Partnership of an Indian MD innovator and a German global leader in MD Learn more</p>
<p>Innovation "Breathes Life" into cancer treatment quality</p> <p>The innovation shows promise of improved quality of cancer therapy. Radiation therapy will not be as risky as toxic effects can be avoided just by ensuring proper breathing. Learn more</p>	<p>Quality of Life pushed for Diabetes patients with 2 innovations Learn more</p>
	<p>When technology doesn't only save lives but also the environment Learn more</p>
	<p>Scottish MD company sees the chance of growth as funds come in to its aide Learn more</p>

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 Design and Development.



Garbage-In, Garbage-Out

If I were to pick any one of the phases in design and development to be the most important of all - it has to be **design input**. All of your:

- marketing history, market studies
- key market insights, opinions
- user stories, user scenarios
- complaints, product recall history
- technological advances and many more

...form your design input, and drives key deliverables, such as your intended use, which drives your device classification, clinical activities, standards compliance, and so on and so forth.

So make design input something all functions take part in, for a better, safer product.

Hope it helps, Cheers!

Missed our product commercialisation advice from the last issues?
Click to view: [Concept](#) | [Prototype](#) | [OMS](#)

Special Feature

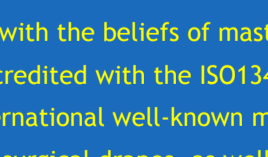


How do professionals in healthcare - with otherwise varying fields of expertise - keep up with clinical physicians in the key decision making process?

The Mini-MD Program

answers this question with education

The Mini-MD Executive Program is a 2-day program designed for a broad spectrum of professionals. The goal is to empower professionals with the basic knowledge of medical sciences so that they can spark innovation, foster collaboration, and be able to consider issues beyond the limits of their individual areas of expertise. [Learn more here](#) Mention "Access-2-Healthcare" and receive a 20% discount!



<p>ACCESS-2-HEALTHCARE PHOTO COMPETITION</p> <p>A brand new NIKON D3400 with 18-55MM AND 55-200MM Kit is up for grabs! Check out our Fllickr page for more details.</p> <p>Access-2-Healthcare helps medical technology companies gain market entry in various countries.</p> <p>Learn more about us through our Slideshare</p> <p>We have also revamped our website</p>	<p>Would You Like to Join Us?</p> <p>Market Access Specialist (Hanoi, Vietnam)</p> <p>Project Manager (Singapore)</p> <p>Software QA Engineer - Medtech (Germany)</p> <p>Apply Here and Here. Due date: Mar 2018</p>
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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.
Click to view the [JAN 2018](#) newsletter.

