



MedTech GATEWAY

#Access2MDInsights
March 2018, Issue #5

Access2Healthcare 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 RoundUp *CFDA's major overhaul, Stakeholders prep for UK transition, TGA's resource for SMEs and many more*

Special Feature *A look into our newsletter in numbers and our newsletter survey*

In-Country Focus *Penang's rise in health sector, Siloam hospitals' online expansion and biosensor technology*

Industry Insights *NGO-Private partnership symbol of hope, very promising devices to watch out for from drug delivering contact lenses to bionic kidneys*

Product Commercialisation Advice *How to prevent R&D from throwing DFM and Design Transfer over the wall*

REGULATORY ROUNDUP

The top regulatory news affecting the healthcare sector worldwide

<p>AUSTRALIA: TGA offers one stop resource of support network for SME's Learn More</p> <p>INDIA: CDSCO to tighten rules for Medical Device Lab testing facilities Learn More</p> <p>BRAZIL: The product Registration re-validation procedures are ironed out with structured timelines Learn More</p> <p>KENYA: List of lower limb prostheses specifications made available for public Learn More</p> <p>SINGAPORE: CorpPass for full implementation by Q3 2018. Stakeholders urged to register Learn More</p>	<p>CHINA: CFDA undergoing major regulatory changes The changes involve both internal restructuring and reorganisation as well as external changes involving new relationships with institutions and ministries. Learn More</p> <p>JAPAN: Quality standards keep up with the times Industries to stay ahead of quality, efficiency and performance with 25 new standards and revised 76 existing standards. Learn More</p> <p>EUROPEAN UNION: Affected Industries brace for UK's transition to third country Economic operators prepare for the imminent changes prior to UK withdrawal from the EU set to be final by 2019. Learn More</p>
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Do you have any questions or inquiries?

ASK OUR REGULATORY TEAM

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

<p>TGA Updates Prostheses Guidelines Private Health Insurance (Prostheses) Rules 2018 (No. 1) has been made available to the public Learn More</p>	<p>Global partnership for health Solomon Islands and Australia ink MOU towards the goal of better medicine testing Learn more</p>
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CHINA

<p>CFDA opens new draft for comments Public was urged to comment on CFDA's draft guidelines of medical equipment for controlling rare diseases Learn More</p>	<p>Technology and Health in China High technology solutions give better access to quality healthcare in the rural areas of China Learn More</p>
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INDONESIA

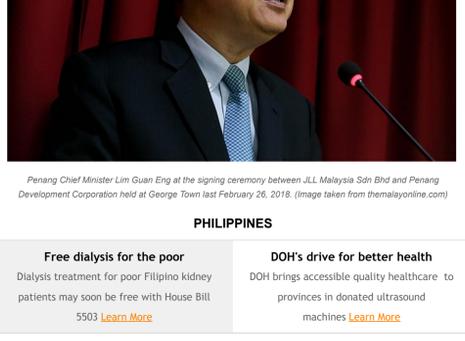
<p>MOH updates for MD registration MOH paves way for faster MD registration through Permenkes No. 62 Learn More</p>	<p>Health giant and online presence Siloam Hospital Group expands online with BookDoc partnership Learn More</p>
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GERMANY

<p>Pre-slot requirements removal BfArM removes prior slot request requirements for new DCP applications for faster transactions Learn More</p>	<p>Letters issued for damage control Medcomp has issued product recall letters to customers for defective catheter kits Learn More</p>
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MALAYSIA

<p>Reference Updates for stakeholders The new edition of DRGD revised last January 2018 has been released for public reference Learn More</p>	<p>Penang's rise in health sector MD manufacturer Japan Lifeline Co Ltd is bringing its first ever overseas factory to Penang Learn More</p>
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Penang Chief Minister Lim Guan Eng at the signing ceremony between JLL Malaysia Sdn Bhd and Penang Development Corporation held at George Town last February 26, 2018. (Image taken from themalayonline.com)

PHILIPPINES

<p>Free dialysis for the poor Dialysis treatment for poor Filipino kidney patients may soon be free with House Bill 5503 Learn More</p>	<p>DOH's drive for better health DOH brings accessible quality healthcare to provinces in donated ultrasound machines Learn More</p>
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SINGAPORE

<p>Cybersecurity tightens with new Act Stakeholders to comply with increased measures to ensure safety in industries utilising technology Learn More</p>	<p>SG with Israel for revolutionary tech BGN Technologies partners with Biosensorix to revolutionise diagnostics thru biosensor technology Learn More</p>
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THAILAND

<p>Continued partnership signed Bhutan and Thailand sign renewal of MOU to continue cooperation in Health Learn More</p>	<p>CGH's assertive expansion efforts CGH plans to spend billions in lieu of expansion efforts in the next three years Learn More</p>
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Have an in-market question for our local teams? Click on the country link to ask your questions.

[Australia](#) | [EU](#) | [Indonesia](#) | [Malaysia](#) | [Philippines](#) | [Singapore](#) | [Thailand](#)

INDUSTRY INSIGHTS

Medical Technology Industry and innovation news worldwide



"Strengthening primary care and the broader referral system is an essential building block towards the attainment of universal health coverage in Africa," - Farid Fozoua, President and CEO, GE Healthcare Africa

<p>A promising NGO-Private Collaboration builds hope in Ethiopia More healthcare jobs to boost in demand as Amref and GE partner for a better primary and referral care in Africa Learn More</p>	<p>BIONIC KIDNEY: A long way to go into reality but bionic device aims to revolutionise kidney care Learn More</p>
<p>Japan pioneers novel initiative The aim of the program is to recycle single-use devices (SUDs) to cut rapidly escalating medical costs and to reduce waste Learn More</p>	<p>CLOUD HEALTHCARE API: Google steps into the healthcare cloud Learn More</p>
<p>Blood Pressure on the fingertips Still in prototype stage but this Smart App could be the answer to a better BP management thru more accessible monitoring Learn More</p>	<p>Fit2Kit™: Patient-driven tech eases health practices with handy features Learn More</p>
<p>A WINNER IN THERAOPTIX'S CONTACT LENSES: SUSTAINX delivers of drug through your regular contact lenses Learn More</p>	

Is there an industry related question that you would like to ask?

ASK OUR EXPERTS

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 Ready For Manufacture.



"Design for Manufacturing" and "Design Transfer" are often seen as 'do it later' or the infamous line - 'throw it over the wall'.

Ever wondered why it happened? This often happens in startups for a fairly predictable reason - are they for the long haul or looking to exit?

With this uncertainty there's perhaps reluctance to focus on manufacturing, and the preference is always to outsource. In larger companies and SMEs the issue is more because of the usual 'silo-ed' behaviour in various departments.

Therefore, right in the beginning of the project of a new product or a design change: - form a multi-disciplinary team as your project team

- involve production right from the start
- process design is just as important as product design,
- consult purchasing to prevent selecting too many suppliers
- resist from trying to 'test everything in production

design the problem out even if it takes more engineering effort.

Missed our product commercialisation advice for the last issues? [CLICK HERE](#).
Concept | Prototype | QMS | Design and Development

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

I WOULD LIKE TO KNOW MORE

SPECIAL FEATURE

The numbers have spoken! Here are some fun facts about #Access2MDInsights.

AS OF NOVEMBER 2017, WE'VE SENT OUR NEWSLETTER TO OUR NETWORK

'good content, allows me to be aware of the MD industry' - medtech SME

'# - RA manager in China

'provides a gateway to a part of the world that I wouldn't have gotten' - Industry veteran in Finland

'I forwarded it to a friend that may have interest, and may be interested to work with you' - SG investor

ACCESS2MDINSIGHTS IN NUMBERS

- 1 IN 4 OPENS THE NEWSLETTER
- 1 IN 9 CLICKS SOMETHING SOMEWHERE
- 1 IN 10 RETURN TO READ PREVIOUS ISSUES THAT THEY HAVE MISSED
- 3 IN 4 READS MORE THAN 1 ISSUE
- 50% of readers read only the top half of the newsletter
- 4 IN 5 READERS READS NEWS ABOUT YOUR OWN COUNTRY
- 1 IN 4 READERS EXPLORES NEWS THAT ARE FAR FROM WHERE YOU STAY

We would like to hear from you!

We have prepared a short survey for the newsletter. This survey can help us improve our future releases with regards to content, relevance and design - to enhance the reading experience for you.

Every opinion matters so don't forget to click the link below to answer the survey.

TAKE ME TO THE SURVEY

swisslog
Member of the KUKA Group

COMPANY SPOTLIGHT
Leading change through intelligent automation solutions

Swisslog designs, develops and delivers best-in-class automation solutions for forward-thinking hospitals, warehouses and distribution centers. Their competency is in realizing integrated technology, backed by decades of industry experience.

You now can explore a potential partnership with [Swisslog](#) or search more company information - through a NO-cost, low-risk method for sourcing channels and new partners - Partners' Portal. [Sign up](#) now and explore your possibilities

Would you like to join us?

Market Access Specialist (Hanoi, Vietnam)

Project Manager (Singapore)

Software QA Engineer - Medtech (Germany)

Apply [Here](#) and [Here](#).
Due date: 31 Mar 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.. Click to view the [FEB 2018](#) newsletter.

