MedTech GATEWAY

#Access2MDInsights

May 2018, Issue #7

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 medical technology sector worldwide

EU

The EUDAMED Continues to Develop

The nomenclature system will establish links to the device's regulatory pathway milestones as well as include a validation system Learn more

BRAZIL

ANVISA releases DICD, Specific Clinical Trial Dossier and Clinical Trial Notification manual Learn More

AUSTRALIA

TGA to make amendments on biologicals regulatory framework

Learn More

Quality Practitioners Around the World Heartily Welcome the Gifts of Spring

This past month or so have brought about many good news for medical device companies, and especially the Quality practitioners.

In light of the comments received, Health Canada has continued to work in collaboration with the MDSAP Consortium to identify additional opportunities for audit duration reductions to support its transition to the new MDSAP program by January 1st, 2019 Learn More

The European Cooperation on Accreditation and the Inter-American Accreditation Cooperation, have just signed the IAF Multilateral Recognition Arrangement (MLA) for ISO 13485 with the International Accreditation Forum, to support enforcement of the requirements for international Accreditation, and allow any medical device manufacturer worldwide to get an IAF-MLA marked ISO 13485 certificate, so long as the manufacturer is using a CAB that is operating under one of the Accreditation Bodies participating in the IAF initiative for ISO 13485.

The FDA also intends to harmonize and modernize the Quality System regulation for medical devices. The revisions will supplant the existing requirements with the ISO 13485:2016. The revisions are intended to reduce compliance and recordkeeping burdens on device manufacturers by harmonizing domestic and international requirements.

We are right in the thick of the development of all these positive initiatives, which help the medical device industry strive towards the vision of *"one quality certificate, accepted everywhere"*

The AHWP Technical Committee Leaders Meeting in Beijing, China

8-9 May 2018

The meeting facilitated the development of guidance documents with AHWP leaders, advisors and WG members, conduct capacity building programs, tackle key regulatory framework changes and ongoing harmonisation implementation.

The leaders touched on current challenges in implementation of various standards as well as current trends in the industry which are rising in popularity such as AI and 3D printing. Among the key topics discussed - Guidance Documents on cybersecurity, 3D printing, promotion/advertisements and approval of reagents, Nomenclature for revision control, Code of Practice for good engineering maintenance management of medical device, survey on ISO13485 alignment with per country QMS requirements. Another point of discussion was interestingly on the acronym of 'AHWP", where "A" stands for "Asian". With a third of the member countries outside of the Asia continent, perhaps a name change? What do you think?

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

TGA seeks public opinion for the implementation of a claimer

The claimer for efficacy assessed non-prescription medicines will help consumers on more informed health decisions Learn More

GERMANY

Health minister sees to address issues on healthcare inequalities

The plan is faced with the challenge on how to get essential stakeholders on board Learn More

INDONESIA

MOH implements transparency in governance and bureaucracy reform

The program is a joint task of several MOH units to improve the ministry's performance Learn More

CHINA

Draft Chinese Depositary Receipt rules are out to public for comments

Will the CDRs be helpful for the country in their goal to keep big techs home?
Learn More

THAILAND

Healthcare activists say "No" to the country's healthcare reform efforts

The National Health Policy Board puts the Public Health Ministry in hot water as people sector cry foul over under-representation claims Learn More

PHILIPPINES

DOH reactivates Regional comittee on TB in Region 6

With case detection rate for the drug-resistant TB below target, DOH aims to bolster the government's efforts to eliminate TB in the country Learn More

SINGAPORE

MOH awards health and biomedical initiatives of industry practitioners

MOH NMRC awards $60 million to three new research projects under the (OF-LCG) programme and launched the New Clinician Innovator Award Learn More

MEDICAL TECHNOLOGY ADVANCEMENT

GE Healthcare and A*STAR co-develop innovative medical technologies Learn More

MALAYSIA

Malaysia launches CPG on the Management of Diabetes in Pregnancy

This much-awaited CPG will help clinicians manage diabetes cases in pregnancy according to latest current evidence within available resources Learn More

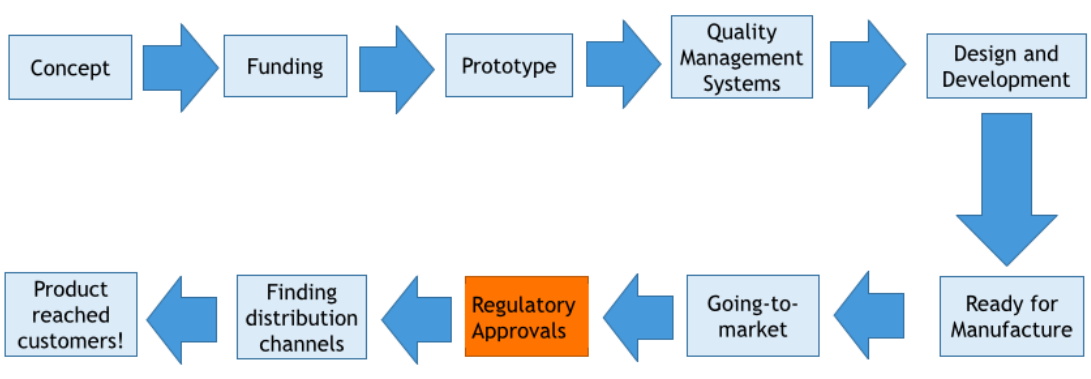
Have an in-market question or need a local market study? Click on the respective country link and check with our team members

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 **Regulatory approvals.***



Should you or should you not get a license holding?

What is License Holding?

It is an authorised representative of the product from the foreign manufacturer deals with the regulatory authority of the country on behalf of the foreign manufacturer.

The distributor concentrates on import, storage, distribution, sales and marketing of the product for the manufacturer.

What are the various scenarios and when is license holding considered the best strategy?

1. If there is uncertainty in the market and uncertainty in the credibility of distributor.
2. Your choice of distributors and their ability to control sub-distribution for larger countries.
3. Who are the users of product and their extent of spread in the country.
4. If business opportunities available are high or uncertain.

The business partner and local government are key issues.

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

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

I WOULD LIKE TO KNOW MORE

SPECIAL FEATURE

Rarely we would be so unbashedly feature ourselves. But this time, in the spirit of cooperation with our new strategic partners, we should :)

Access-2-Healthcare signs MoUs with Leave a Nest and DevHub@Rangsit University to enable advanced prototyping capabilities and usability compliance for medical device startups

In Osaka with the Superfactory lead, the Prefecture Governor-General(!) and Leave a Nest

Yes, that is indeed Dr Arthit Ourairat, Owner of Rangsit University, Jeff Hamilton is holding the signed MoU

One of the key activities of medical device startups' journey towards product launch, is the need to have advanced stage prototyping representing the increasing maturity of product development, leading to further proof of concept in the form of usability verification, animal trials, or first-in-human trials.

Access-2-Healthcare recognises the scacity of such critical resources and networks in this region, and have signed Memorandum of Understanding with two groups:

- DevHub as supported by Rangsit University in Bangkok, Thailand. DevHub will develop a usability testing hub within Rangsit University and initially will be focused in areas of medical technology robotics, monitoring, IoT, and catheterisation - within 6-9 months. We are also available for usability consulting (IEC 62366, Human Factors Engineering). The next phase is to create a medtech makerspace gathering the best minds in Thailand to enable advanced prototyping.

- Leave a Nest, an organisation linking researchers to the industry, and provides opportunities for well-established Japanese manufacturing companies to refresh themselves and embrace modern medical technology. We have the support of 3 different manufacturing groups in 3 prefectures of Japan for advance prototyping right now, and incorporating industrial design and usability elements in the prototypes.

MEDTECH EVENTS

Sharing some thoughts on the places went, and meetings attended with everyone

The Annual CXO LEAN Summit in Singapore has a Strong Healthcare Flavor

This year's theme was "Placing Patients at the Heart of Healthcare Transformation"

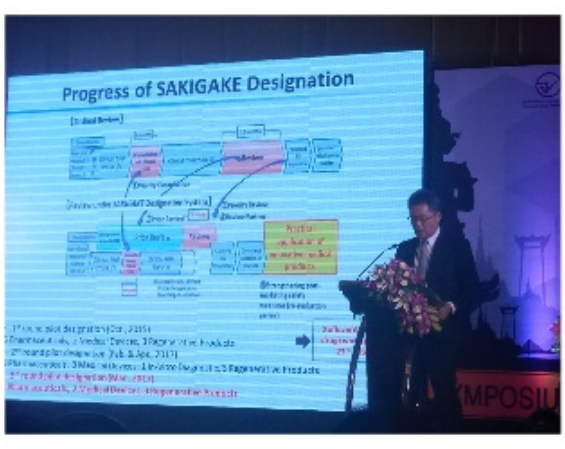
More than 300 participants from various healthcare organisations attended the summit. Among the event highlights was the learnings on the 5 key elements of the Lean Transformation Framework: Strategy deployment, Process improvement, Leader behavior and management systems, Manpower development, and Organisational mindset and culture. The Singapore Institute of Technology have been our good supporters and have always kindly invited our participation.

The 5th Thailand-Japan Regulatory Symposium in Bangkok, Thailand

This symposium was cohosted by the Thai FDA, and the PMDA. The Symposium aims to strengthen Thailand and Japan's relationship and cooperative framework for regulation of medical products and promote thorough understanding of regulatory systems of the two host countries. We were invited by the Thai FDA to participate.

In general it was a mutual understanding and promotion of the current pharmaceutical and medical device industry of the respective countries, as well as the new regulatory pathways that was spurred on by new technologies (real world evidence, additive manufacturing for custom devices, software).

One of the most unforgettable experience was the fact that almost NO one spoke English - all Thai was translated to Japanese via simultaenous interpretation, and vice versa. BUT, when it comes to the presentation, the slides are all in English! Such is the importance of harmonisation..to (literally) speak the same language.



COMPANY SPOTLIGHT

PT Global Dispomedika is an importer and trading company in Indonesia. It was established on the basis of idealism from their holding company, and run using the concept of modern management and always tries to distribute high quality products, at reasonable prices and quick timelines.

You now can explore a potential partnership with PT Global Dispomedika 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

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?

Market Access Specialist
(Hanoi, Vietnam)

Project Manager
(Singapore)

Software QA Engineer - Medtech
(Germany)

Apply Here.
Due date: 30 May 2018

WE LOVE YOUR FEEDBACK.
Like us or Hate us, let us know!

TAKE ME TO THE SURVEY

REALLY, 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 APRIL 2018 newsletter.

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