MEDICAL DEVICE INSIGHTS

December 2017, Issue #2

As we're heading towards the Holidays, Christmas, and the turn of the New Year, 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

QUICK TIPS

Transition deadline towards ISO13485:2016 is getting closer with just less than 2 years. Some burning questions still linger:

"Are we in the right track with our transition activities?"

"Should we go for MDSAP or ISO13485?"

"Can we use the same risk management process for products for our Quality System, or is it something else? How do we comply?"

Drop your quick questions here and we will answer you.

In This Issue

- **Regulatory Round Up**: IMDRF's harmonised AE code-a year later, EU Notified Bodies designation listing out, 3D Printing getting more attention, cardiac stents and pelvic mesh devices caught in heated discussions across borders

- **Special Feature**: Happenings around the recently concluded 22nd AHWP Annual Meeting in New Delhi, India

- **Industry Insights**: A breakthrough in Patient Compliance monitoring, Cybersecurity emerging as an apparent major player in MD safety, MD Packaging companies' solutions for sustainability

- **Product Commercialisation Advice** for this issue: Prototyping

- **Companies in Focus**: Two companies that aim to impart effective and sustainable quality learning practices to industry partners: LTIC (Singapore) and CGI KK (Japan)

REGULATORY ROUND-UP

The top regulatory news
affecting the healthcare sector worldwide

Post Market Surveillance Updates

Early this 2017, the International Medical Device Regulators Forum (IMDRF) published the guideline on a harmonised terminology for reporting Adverse Events (AE). The 14-page document aims to improve detection by adverse event management systems allowing faster response by both the medical device industry and regulatory agencies. Read More

In the latter part of 2017, FDA and EC have initiated efforts to adopt the new guideline into their system.

US FDA

Although the FDA's eMDR system is not fully configured to accept the IMDRF codes, stakeholders who would like to request a new adverse event code to be added into their system should follow the IMDRF code request process as the FDA no longer accepts adding new AE codes. Read More

EUROPEAN COMMISSION

The new AE codes are expected to be implemented into the European vigilance reporting starting from Q2 of 2018. Additionally, the revised Manufacturer Incident Reporting Form which captures the IMDRF nomenclature codes will also be available at the Commission website . Read More

3D Printing: A "new wave of technology" taking healthcare by storm, but the FDA is keen to keep its path controlled

3D printing has come a long way to become highly significant to the evolution of Medical Devices. With more healthcare applications being discovered for this additive technology, the US FDA is in full force to implement a comprehensive regulatory pathway for this innovation. Read More

List of EU Notified Bodies designation codes released, manufacturers wait on as applications are sent for designation against MDR and IVDR regulations

The list specifies the scope of designation of notified bodies. The challenge now is for the notified bodies to submit their applications ASAP and pass their audit against the new regulations. Earliest applicants are expected to receive results by July 2019. Read More

Indian regulators pressed for a bold decision on cardiac stent prices as multinational companies threat withdrawal of existing stents from the market

Implemented on February 2017, the cardiac stent prices cap was expected to run for only a year. Now its time is drawing to a close and the NPPA is faced with immense pressure from all sides to come up with a decision that will allow a win-win situation for manufacturers, hospitals and patients. Read More

Continued use of pelvic mesh devices under heated scrutiny in the land down under as public outcry calls for its ban

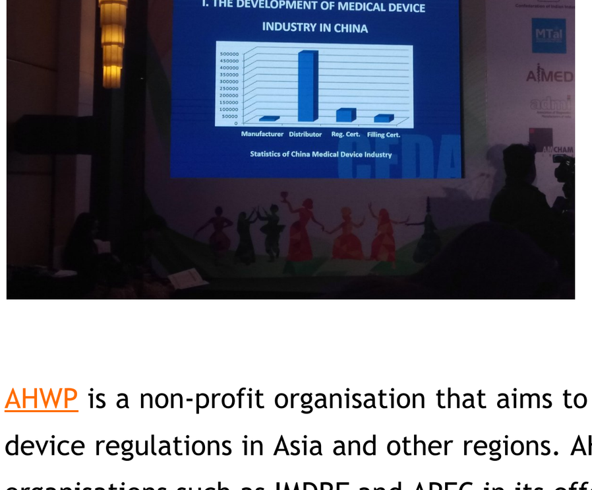
TGA is faced with a predicament as social health groups call for total ban of pelvic mesh devices despite assurance from the regulator of its risk benefit profile. The regulator and several health groups are now in the talks for an immediate and sound resolution. Read More

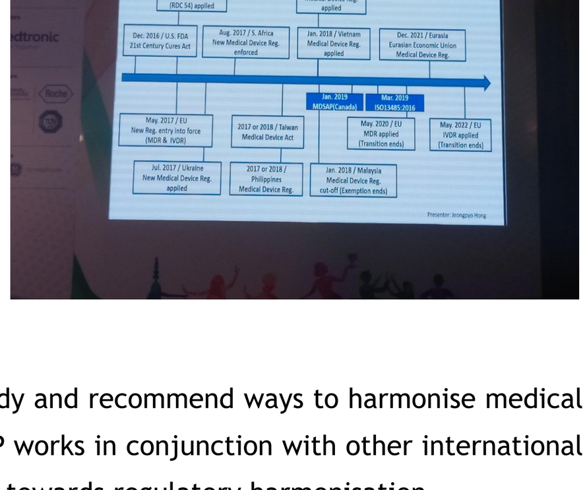
Special Feature

The 22nd Asian Harmonisation Working Party (AHWP) Annual Meeting was held in New Delhi, India, 4-8 Dec 2017.

The conference gathered key international players and industry leaders from its 31 member countries with the goal to shape the development roadmap of the medical device industry. This year's focus was on ways to harmonize the medical device regulations in Asia and in other regions as well as on major regulatory and policy updates in the medical device sector.

A few discussion highlights in the conference include innovations in medical technology, UDI, medical software, e-IFU and the rising popularity of 3D printing. We have noted two of the most impactful materials presented in the meeting – an upcoming roadmap of some of the regulatory changes around the world, and a very interesting figure of the medical device distributors in China.





AHWP is a non-profit organisation that aims to study and recommend ways to harmonise medical device regulations in Asia and other regions. AHWP works in conjunction with other international organisations such as IMDRF and APEC in its efforts towards regulatory harmonisation.

Industry Insights

FDA approval of the world's first pill with an Embedded Sensor

The New England Journal of Medicine estimates 33 to 69 percent of medication-related hospital admissions in the US are due to poor medication adherence. Will the introduction of this new technology allow to address this prevalent issue in patient drug therapy? Read More

Cybersecurity as a necessity: an undeniable fact for the technology-dependent industry

Following the voluntary recall of some few thousand pacemakers due to their vulnerability to hackers, the industry is stirred to acknowledge the major role of cybersecurity in Medical Device safety. Read More

Italian medical device group Esaote to be acquired by Chinese investors

The acquisition includes a private equity fund which was co-founded by Alibaba head Jack Ma and was said to help speed up the company's growth as well as increase its access to the Chinese market. Read More

MD Packaging Market finds lucrative solutions in cost-effective packaging materials Read More

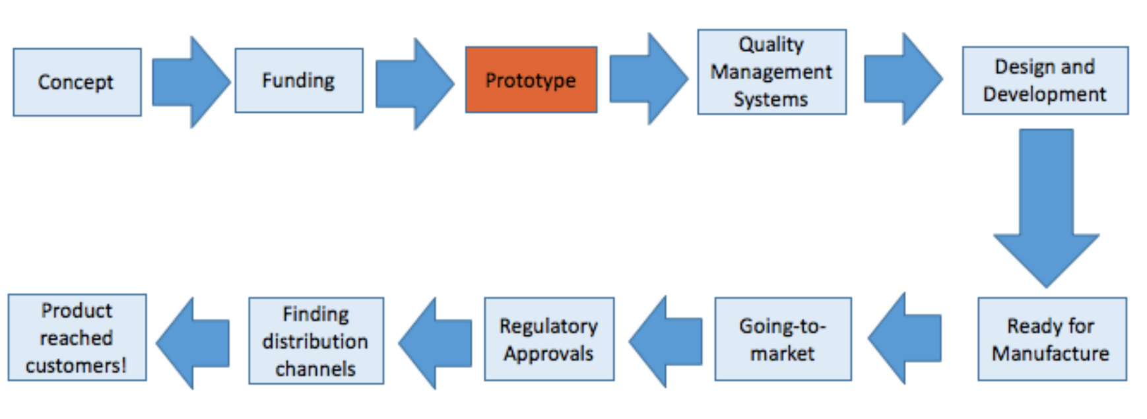
A breakthrough in opioid addiction battle, new device could help alleviate Opioid Withdrawals Read More

Sanofi and J&J shine with latest study showing both companies' soaring clinical trial transparency scores 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 ***Prototype Stage****.*

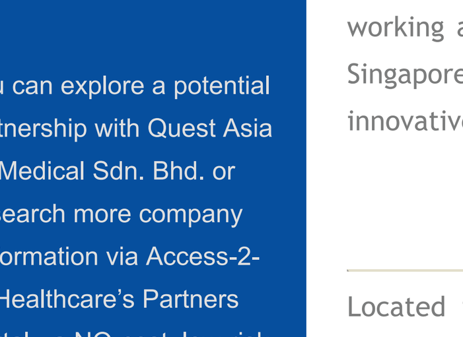


Almost every designer will say "let's get it to work first, then worry about looking nice". And indeed, 'getting it to work' may mean 2 sensors, and a hand-soldered board. Or just a wireframe and a few mods of an open-source algorithm. We need the tech to work first. However, sometimes it's more than just about "wanting to look nicer".

Usability *and* ***manufacturability*** *should already be considered way ahead once the raw technology has been proven to work, because ultimately the product needs to be manufactured and is at the hands of the end user. Failure to consider them early enough could mean backtracking, redesign, and more critically, spending more time and resource which hampers your race to market launch.*

COMPANY SPOTLIGHT

Quest Asia Medical Sdn. Bhd. was formed in Malaysia in 2013. This company specialises on rapid test kits which provide fast on-the-spot diagnosis on different medical conditions like dengue, HIV and influenza.



You can explore a potential partnership with Quest Asia Medical Sdn. Bhd. or search more company information via Access-2-Healthcare's Partners Portal - a NO-cost, low-risk method for sourcing channels and new partners. Sign up now and explore your possibilities

LEARNING SMARTLY

The theme is LEARNING, as we feature 2 companies - a resource centre that is in partnership with the Singapore Institute of Technology and a Japanese firm whose main focus is on laboratory quality compliance.

LEAN Transformation Innovation Centre

CGI 株式会社CGI

LEAN TRANSFORMATIVE INFORMATION CENTRE (LTIC)

LTIC offers avenues for sustainable and effective employee development practices through specialised programmes, masterclasses and conferences that promote LEAN thinking and practices. The company aims to share lean knowledge with local and regional participants from the industry and community by working alongside local companies and in collaboration with the Singapore Institute of Technology, one of Singapore's most innovative learning institutions. Learn more about LTIC here.

CGI KK (Japan)

Located in Tokyo, CGI KK's goal is to bring the essential QMS elements into clinical laboratories by providing staff education, competency assessment, and by supporting world-class accreditation and certification programs. CGI ensures this is achieved by utilizing the right tools for high-quality information transfer such as unique proprietary software systems, information development, and other in-house products resulting from years of experience, expertise, and innovation. Learn more about CGI here.

ACCESS-2-HEALTHCARE PHOTO COMPETITION

Our photo competition is on!

Send us a short video or photo which best depicts "Access to Healthcare" in your country. Do take note, two important elements must be present - healthcare and medical technology.

Judging criteria: quality of the image/video, content – best depiction of 'access to healthcare' and local relevance – relevance of image/video to the current healthcare needs of your country

Submit your image/video here and win a brand new digital camera! You will also have an additional chance to have your work showcased in Access-2-Healthcare's website.

3 winners will be chosen. Prizes will be sent via airmail.

About Us

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

Click on below links for more information about Access-2-Healthcare

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Would You Like to Join Us?

Project Manager
(Singapore)

Supply Chain/ Logistics Executive
(Jakarta, Indonesia)

Market Access Specialist
(Hanoi, Vietnam)

General Manager
(Philippines)

General Manager
(Malaysia)

Apply Here.
Due date: Jan 2018