



## MEDICAL DEVICE INSIGHTS

November 2017, Issue 1

By Access-2-Healthcare

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

#### CHINA FDA

Don't Miss the Boat!

Nifty Tips  
on Calculating  
Product License  
Renewal Timelines  
for the CFDA.

[Read Here](#)

### In This Issue

- MDSAP, MHRA on Brexit, China's imminent change in MD classification and many more

- This issue's Product Commercialization Advice: How to create a strong Unique Value Proposition

- In focus: Medigroup, an Australian company specialising in advanced surgical devices and prosthesis

- Looking into the latest innovations in the Medical Device industry

## REGULATORY ROUNDUP NEWS

Our Regulatory Roundup for this month's issue.

Here we give you an overview of the top regulatory news affecting the healthcare sector worldwide.

#### CFDA's MD classification catalogue revision imminent but the public urged to voice out

China FDA's changes in Device Classification poised to take effect early 2018 could mean additional challenges for Medical Device companies. CFDA has given a chance for Med Tech companies to share their views. [Read More](#)

#### Brexit talks ongoing and its impact on the Medical Device Industry is still a blur

With MHRA fate still uncertain, heavy implications for MA applications and CE Marking System threaten affected organisations. The Med Tech sector is asking for "sensitive approach" to minimise impact to the industry. [Read More](#)

#### Global harmonization efforts against regulatory variations have extended to audit processes with the MDSAP. But is the Industry ready for it?

The recent report of the MDSAP trial period on 5 participating countries proves its great promise of creating new opportunities especially for medical device manufacturers. The question remains if the implications on costs will be well accepted by these industry players particularly of small to medium organisations. [Read More](#)

#### Clinical Trial patients take center stage with FDA's first Patient Engagement Group Meeting

This initiative from US FDA to bring more of the patients' perspectives into the Medical Device trial decision-making process is indeed a bold move to deepen the role of patients in clinical trials and hear their actual voices beyond investigator charts, study parameters, Patient Diaries and Questionnaires. [Read More](#)

#### "Rampant unethical practices" force India's regulatorsto tighten stem cell guidelines

[Read More](#)

#### A diverse line-up of technology companies take part in FDA's pilot digital health program

[Read More](#)

#### Canada to see an upsurge in its outdated fees for pharmaceutical and medical device companies

[Read More](#)

#### FDA Releases 5 Medical Device Guidance Documents

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#### Regulatory challenges and liability risks surround 3-D printed medical devices in the EU

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## Industry Insights

#### MUSE System receives first Purchase Order from Izaasa Hospital in Spain

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#### Public Health to getenhanced with IBM's AI and Analytics

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#### India and Japan join force for diagnostic sector enhancement

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#### Senior Whole Health is now acquired by Magellan Health.

[Read More](#)

#### Bayer's Accelerator Program gives innovation a boost with its selection of 4 start-upcompanies into their program

The Grants4Apps (G4A)Accelerator is a collaborative match made in heaven as start-ups are given opportunities to work on their business models and ideas with the financial and technical support of big industry players like Bayer. [Read More](#)

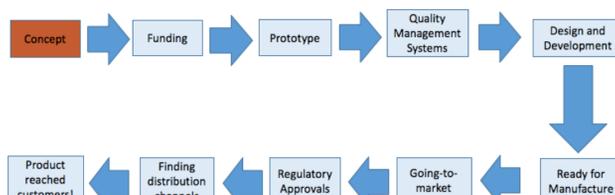
#### Take a selfie and spot cancer with the 3D printed smartphone add-on feature

This development in technology takes diagnostic testing to a new level by allowing detection of cancer with a single shot. But is it economically sound enough to replace standard blood testing? [Read More](#)

## JOURNEY TO PRODUCT COMMERCIALISATION

This section of our Newsletter is dedicated to provide readers with thorough guidance from our in-house experts. 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 product concept stage.



### "Need for Tech", or "Tech for Need"?

How do you develop a strong Unique Value Proposition for your innovation?

It may seem obvious that one would prefer 'Need for Tech'. But more often, we are faced with tech and not exactly sure what to do with it. The pressure for needs-based research mounts, looking more closely into the commercialisation potential of the invention.

#### It's not the Tech that satisfies the Need - it is the Solution

A solution consists of the process, players, and technology.

- Where and how does your solution (not your tech) resolve the need?
- Is this the right tech for the solution?
- Does the tech and/or solution cause any negative impact to the need?

When you can answer these questions, you would have a much better conversation with your funding agencies and investors.

### COMPANY SPOTLIGHT

Medigroup is an Australian medical and surgical device company that specializes in complex wounds, vascular, plastics and cardio-thoracics.

You can explore a potential partnership with Medigroup 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

### ACCESS-2-HEALTHCARE PHOTO COMPETITION

#### Are you passionate about healthcare and technology?

[Share this and GET A CHANCE TOWIN A DIGITAL CAMERA!](#)

Just 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**.

Your submissions will be evaluated based on:

- **quality of the image/video**
- **content** – best depiction of 'access to healthcare'
- **local relevance** – relevance of image/video to the current healthcare needs of your country

Submit your image/video [here](#) and have an additional chance to have your work showcased on Access-2-Healthcare's website.

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

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