Is it rain, or shine? With Easter over, Sakura season getting through, and in the midst of spring (or autumn in the Southern Hemisphere), the weather has turned topsy-turvy. Rain, or shine, Access-2-Healthcare still goes on, supporting various MedTech companies navigate through this maze of challenges in the healthcare industry. Here's the 28 issue of our MedTech Gateway - Enjoy! This month we have a bumper group of Regulatory changes! It's getting a bit of a challenge to keep up and we're doing our best. Feel free to reach out to us if you have further questions.

Regulatory Round Up

AUSTRALIA

Australia: Updates to Clinical evidence guidelines: Medical devices

Australia’s TGA issued a final guidance on clinical evidence requirements in response to updated regulations. Clinical evidence requirements apply to all medical devices and in vitro diagnostics listed on ARTG.

Learn More

CHINA

China: NMPA publishes revised medical device regulations

China’s NMPA (National Medical Products Administration) has published revised Regulations on the Supervision and Administration of Medical Devices which introduces changes to existing Order No. 650. These new regulations will be implemented on June 1, 2021.

Learn More

TAIWAN

Taiwan: New Taiwanese medical device regulations set for May 2021

Taiwan Food and Drug Administration (TFDA) will enforce new medical device regulations with effect from May 2021. TFDA aims to improve the management system of medical technology and manufacturers, protect rights and interests of clinical trial subjects, and strengthen post-market activities to ensure quality and safety of medical devices.

Learn More

VIETNAM

Vietnam: New draft decree to replace Decree 36/2016/ ND-CP

Vietnam DMEC has issued a new draft decree on medical equipment. For medical equipment (Class B,C & D) not on the list of import license (Circular 30) is allowed to continue to be imported until the end of December 31, 2022 according to demand.

Learn More

NEW ZEALAND

New Zealand: New Zealand pushes ahead with GMP changes

The New Zealand Medicines and Medical Devices Safety Authority (Medsafe) is going ahead with its planned changes to good manufacturing practices (GMPs) after receiving largely positive feedback to a consultation. Medsafe will publish the updated edition of the NZ Code of GMP on their website on Apr 19, 2021. The updated NZ Code of GMP will come into effect on May 3, 2021.

Learn More

Designated NBs

1. BSI (Netherlands) – 2797 (MDR scope & IVDR scope)
2. BSI (UK) – 0086 (MDR scope & IVDR scope)
3. CE Certiso (Hungary) –2409 (MDR scope)
4. DARE!!! Services (Netherlands) – 1912 (MDR scope)
5. DEKRA Certification (Germany) –0124 (MDR scope & IVDR scope)
6. DEKRA Certification (Netherlands) – 0344 (MDR scope)
7. DNV GL Presafe (Norway) –2460 (MDR scope)
8. DQS Medizinprodukte – 0297 – (MDR scope)
9. GMED (France) – 0459 (MDR scope)
10. IMQ (Italy) – 0051 (MDR scope)
11. Intertek IMNB (Sweden) – 2862 (MDR scope)
12. MDC Medical Device Certification (Germany) – 0483 (MDR scope)
13. MEDCERT (Germany) – 0482 (MDR scope)
14. NSAI (Ireland) – 0050 – (MDR scope)
15. TÜV Rheinland LGA (Germany) – 0197 (MDR scope)
16. TÜV SÜD (Germany) – 0123 (MDR scope)
17. TÜV SÜD (Germany) – 0123 (MDR scope & IVDR scope)
18. UDEM Adriatic d.o.o. (Croatia) – 2696 (MDR Scope)
19. Eurofins Expert Services Oy (Finland) – 0537 (MDR scope)
20. ISTITUTO SUPERIORE DI SANITA' (Italy) – 0373 (MDR scope)
21. SGS FIMKO OY (Finland) – 0598 (MDR scope)

Recent Withdrawals

1. DQS Polska – 2282
2. ECM Germany – 0481
3. LRQA – 0088
4. QS Zurich – 1254
5. DNV GL – 0434

In-Country Focus

UNITED STATES

US: BD MAX™ Molecular Multi-Drug Resistant Tuberculosis Test To Be Included In WHO Updated Consolidated Guidelines On Tuberculosis

BD (Becton, Dickinson and Company) (NYSE: BDX), a leading global medical technology company, today announced that its BD MAX™ Molecular Multi-Drug Resistant Tuberculosis (MDR-TB) Assay was included in the moderate complexity automated NAAT class of molecular diagnostic technologies that were recognized for high diagnostic accuracy for tuberculosis testing by the World Health Organization (WHO) in advance of an update to its guidelines for TB diagnostic tests.

Learn More

UNITED STATES

US: Accelerating Medical Device Innovation with Regulatory Science Tools

The FDA’s Center for Devices and Radiological Health (CDRH) is helping to ensure that device developers have the right test methods to evaluate new innovations. The Catalog of Regulatory Science Tools collates a variety of regulatory science tools that CDRH’s Officeof Science and Engineering Labs (OSEL) has developed, with new tools added asthey become available. These methods expand the scope of innovative science-based approaches to improve development and assessment of emerging medical technologies. The catalog includes more than 100 tools, including laboratory methods, tissue-mimicking phantoms, and computational modelling and simulations.

Learn More

SINGAPORE

Singapore: MOH Appoints Multilateral Healthcare Insurance Committee

The Ministry of Health (MOH) has appointed 12-member Multilateral Healthcare Insurance Committee (MHIC) to provide a platform for healthcare providers, payors, consumer representatives and the Government to collaboratively address issues related to health insurance. The MHIC's appointment will come into effect on 27 April 2021.

Learn More

EUROPEAN UNION

EU: EU assessment of high-risk medical devices faces in-depth review

The project launch comes as new EU medical device regulations come into force on 26 May 2021, increasing the requirements for clinical evidence on high-risk medical devices. However, there are no specific EU recommendations on the design and conduct of trials for high-risk devices. In addition, medical device developers have expressed concerns that the new rules may inhibit innovation and delay market access.

Learn More

Industry Insights

UNITED KINGDOM

UK: Oxford Endovascular Ltd raises $10m to develop its origami engineered medical device to prevent brain haemorrhage

Oxford Endovascular, a pioneering British MedTech company and spin-out from Oxford University, is developing a treatment for brain aneurysms, that will overcome challenges with existing medical devices. The raise will enable the company to complete development work and gain first in-human data through an early feasibility clinical study.

Learn More

TAIWAN

Taiwan: OOOPDS – a surgical planning software received TFDA Class II Medical Device Certification

Taiwan Main Orthopaedic Biotechnology announced that their OOOPDS 3D medical image reconstruction and surgical planning medical software has received TFDA Class II certification. OOOPDS is the most comprehensive 3D surgical planning software in Taiwan.

Learn More

UNITED STATES

US: New technology for the treatment of pediatric epilepsy

Specialists at Mayo Clinic Children's Center in Rochester, Minnesota, can provide innovative treatments for children with epilepsy. Working closely with Mayo Clinic research teams, these specialists are able to offer cutting-edge options to eliminate or reduce seizures in children."Experts from various specialties come together to make decisions about medications and treatments. The research and clinical teams function seamlessly together," says Kai J. Miller, M.D., Ph.D., a neurosurgeon at Mayo Clinic Children's Center. "We're actively developing new technology so patients can receive the most novel therapies to treat seizures and preserve brain function." Mayo Clinic Children's Center has a pediatric team dedicated to the care of children with epilepsy.

Learn More

SINGAPORE

Singapore: Pharma giant Sanofi investing in $638m vaccine production centre in Singapore

Pharmaceutical giant Sanofi Pasteur is investing €400 million (S$638 million) over five years to build a vaccine production centre in Singapore, giving a boost to the Republic's growing biomedical manufacturing cluster. Announcing its investment on Monday (April 12), the French multinational corporation said the project is expected to create up to 200 local jobs and enable the firm to quickly respond to future pandemic risks.

Learn More

UNITED STATES

US: Microsoft Makes Big Bet on Health-Care AI Technology with Nuance

Microsoft Corp. is making a massive bet on health-care artificial intelligence. The software giant is set to buy Nuance Communications Inc., tapping the company tied to the Siri voice technology to overhaul solutions that free doctors from notetaking and better predict a patient's needs. Microsoft may announce the deal as soon as Monday if talks are successful, according to people familiar with the matter.

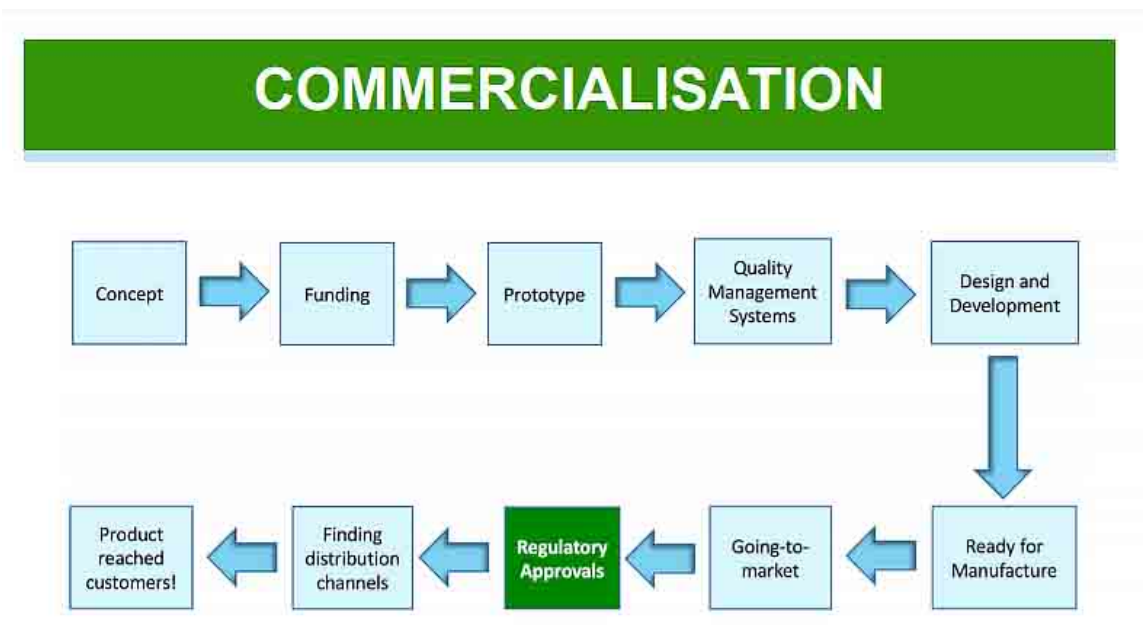
Learn More

GERMANY

Germany: Gold Sensor Lives Under Skin for Months Measuring Drugs and Biomarkers

Researchers at the Johannes Gutenberg University Mainz in Germany have developed an implantable biosensor that can measure concentrations of various biomarkers and drugs in the body. Unlike many implantable devices, the sensor can reside in place under the skin for many months without being rejected by the body or losing its functionality. The system uses receptor-studded gold nano particles that change color when an analyte of interest binds to them.

Learn More



Navigating the changing regulatory landscape - Showing Empathy Always Pays

Global regulations change all the time

Sure, this statement comes along very easily, and often top of the ranting charts of any sales, marketing, engineering, or regulatory professional. Have you wondered if the regulatory authority themselves are ready for it?

Regulations may change, people do not change – that quickly.
Regardless of the number of years of transition, it is still incredibly challenging to squeeze a career-full of biomedical and technology knowledge into the minds of the regulatory reviewers. It does not help if some of the regulatory changes were drafted years ago and by the time it is approved and implemented, technology has moved on and now it is back to discussing those 'grey' areas all over again, albeit different ones from perhaps 5-10 years ago.

While many may complain about the lack of speed, efficiency, or knowledge of the regulatory authorities that have just implemented new regulations, why not take a different approach, and perhaps it may result in a different, more positive outcome?

Offer your knowledge, to enable your regulators.
For manufacturers, you know your own product the most. True that there is this perpetual concern over intellectual property protection, however the more the regulators know your product, the more they feel confident that you have taken the appropriate steps to ensure safety and efficacy.

Be prepared with all the questions regulators may ask, by preparing the answers.
Imagine if you are an electronics engineer and then you get a sterilized product and learning biocompatibility for the first time. How challenging would that be? Pre-empt questions from the regulatory authority, prepare to defend your position with sound objective evidence.

Clarify, clarify, clarify!
Clarify, if they have understood your initial submission's contents
Clarify if you understood the regulator's questions.
Clarify if they have understood your response.

Give regulators the time – and space.
Knowledge takes a long time to sink in. Regardless of the number of meetings, amount of information, Digestion needs time. Give your regulators the space to internalise the knowledge you have provided, and for them to make the judgement call.

Stick to objective evidence.
"I feel". is not something we would like to hear from regulators. Try as far as possible to stick to the objective evidence.

Appreciate the intricacy of Language.
This appears obvious, and oftentimes English turns out to be the universal language platform. It is also the most easily misunderstood. If something does not sound right to you, refer to the point on "Clarify".

Regulators are humans too, they have fears, reservations, and they need support. At the same time, manufacturers, distributors are no less human, with similar fears, reservations, and need support as well. If we team up well, we can excel, leading to faster market entry and access to Healthcare.

Events

Starting with newsletter this month, we will be launching a new section - Events, which put together with suggested monthly events in the medical industry around the world.

Intelligent Health AI 2021

- 11th May 2021 | 09:00 – 18:00 London, (GMT+1)

Technology Enhanced Learning

- 18th May 2021 | 20:30 – 22:00 (GMT+08)

Medical device innovation in the NHS

- 11th May 2021 | 21:00 – 22:15 (GMT+08)

Healthcare Innovation Readiness Programme for SMEs

- 25th May 2021 | 20:00 – 23:00 (GMT+08)

Access-2-Healthcare

We help medical technology companies with their product development, market launch and to gain market entry in various countries. Learn more about us

Would You Like To Join Us?

Supply Chain / Logistics Executive (Part / Full Time) Indonesia

Supply Chain / Logistics Executive (Part / Full Time) Philippines

Local Regulatory Expert (Part Time) Australia

Regulatory Affairs Manager (Full time) Indonesia

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