Happy New Year! Same dreams in this new year with fresh starts.

Stay safe with the current Covid-19 situation.

While cases are going up, industry happenings are going up as well.

Access-2-Healthcare is providing new business models and fresh news as usual in our MedTech Gateway.

AUSTRALIA

Consultation: Australian Regulations definition of Central Circulatory System (CCS)

TGA consulted on changes to the classification rules in Proposed changes to the classification of medical devices used in direct contact with the heart, central circulatory system and central nervous system. The reforms will continue to improve the safety, performance and quality of medical devices inAustralia and improve health outcomes for patients who require medical devices.

Learn More

SINGAPORE

New Initiatives for Registration of Therapeutic Products

TPB is introducing a streamlined approach for stability data requirements for registration and variation applications, which replaces the current requirement for site-specific data where multiple drug product and drug substance manufacturing sites are sought in the application.

Learn More

UNITED KINGDOM

United Kingdom Implements New Post-Brexit Medical Device Information System

This guidance is divided into sections on the different rules that apply in Great Britain, Northern Ireland and the EU. Great Britain is England, Wales and Scotland.

Learn More

UNITED STATES

FDA Finalizes Speedier Medical Device Pathway Alternative To Breakthrough Status

FDA published final guidance on its new Safer Technologies Program for MedicalDevices (STeP) program, targeted at products with significant safety benefits in non-life-threatening or reasonably reversible conditions less serious than those eligible for the agency's Breakthrough Devices Program.

Learn More

Designated NBs

1. **3EC International (Slovakia) –2265 (**MDR scope**)**
2. **BSI (Netherlands)** – 2797 (MDR scope & IVDR scope)
3. **SGS FIMKO OY (Finland)** – 0598 (MDR scope)
4. **CE Certiso (Hungary)** –2409 (MDR scope)
5. **DARE!!! Services (Netherlands)** – 1912 (MDR scope)
6. **DEKRA Certification (Germany)** –0124 (MDR scope & IVDR scope)
7. **DEKRA Certification (Netherlands)** – 0344 (MDR scope)
8. **DNV GL Presafe (Norway)** –2460 (MDR scope)
9. **DQS Medizinprodukte** – 0297 – (MDR scope)
10. **GMED (France)** – 0459 (MDR scope)
11. **IMQ (Italy)** – 0051 (MDR scope)
12. **Intertek IMNB (Sweden)** – 2862 (MDR scope)
13. **MDC Medical Device Certification (Germany)** – 0483 (MDR scope)
14. **MEDCERT (Germany)** – 0482 (MDR scope)
15. **NSAI (Ireland)** – 0050 – (MDR scope)
16. **TÜV Rheinland LGA (Germany)** – 0197 (MDR scope & IVDR scope)
17. **TÜV SÜD (Germany)** – 0123 (MDR scope & IVDR scope)
18. **UDEM Adriatic d.o.o. (Croatia)** – 2696 (MDR Scope)

Recent Withdrawals

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

PHILIPPINES

FDA Protect And Promote The Right To Health Of All Filipinos Through The Regulation Of Health Products

FDA was given the responsibility to regulate health products, including vapor products and heated tobacco products (HTPs).

Learn More

CHINA

NMPA Signs MoU On Regulatory Cooperation Of Medicines, Medical Devices, Cosmetics With Italian Ministry Of Health, Italian Medicines Agency

Under the framework of the MoU, regulators of the two countries will strengthen exchanges in laws and regulatory information, enhance mutual understanding and push forward on both mutual benefit.

Learn More

UNITED KINGDOM

GMDN Agency welcomes UK-wide Medical Device Information System

From 1st January 2021 all medical devices placed on the market must be registered by their manufacturers with the MHRA as part of a UK-wide Medical Device Information System (MDIS).

Learn More

UNITED STATES

ACP Releases Framework to Reduce Healthcare Disparities

ACP released a framework of high-level principles and recommendations on such issues, which includes recommendations that U.S. policymakers commit to understanding and addressing disparities in health and health care.

Learn More

Industry Insights

UNITED KINGDOM

Vatic Launched On-The-Spot COVID-19 SalivaTest

Vatic, a newly established UK-born healthtech company, is launching an on-the-spot-result saliva test to identify current COVID-19 infections, who is infectious and who can pass on the virus.

Learn More

ISRAEL

Pi-Cardia Successfully Treats First Patients with ShortCut™ Device

ShortCut is a dedicated device designed to split the leaflets of a pre-existing valve to enable safe Transcatheter Aortic Valve Replacement (TAVR) in patients at risk for coronary obstruction or compromised coronary access.

Learn More

CHINA

Inventory of 100 Innovative Medical Devices

FDA recently reviewed and approved the application for registration of the innovative product "iliac artery bifurcation stent system" produced by Lifetech (Shenzhen) Co., Ltd. for the treatment of abdominal iliac aneurysms or common iliac artery tumor. This is the 100th innovative medical device approved for marketing since the National Drug Administration set up a fast-track approval channel for innovative medical devices.

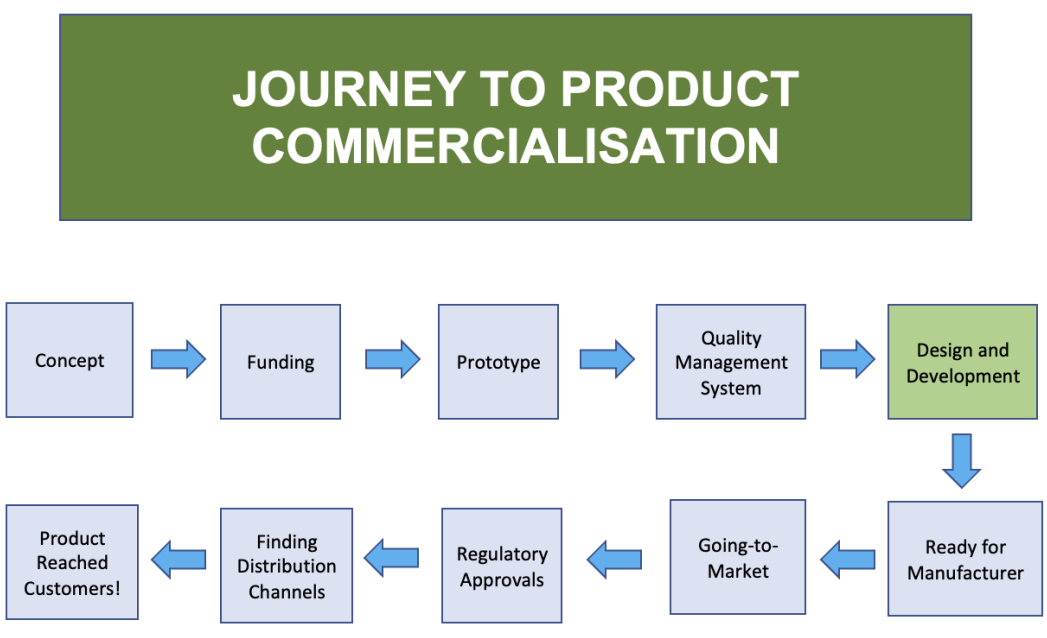
Learn More

JAPAN

NEC Releases New AI Diagnosis-Support Medical Device Software For Colonoscopies

NEC announced the development of its WISE VISION Endoscopy, an AI diagnosis-support medical device software for colonoscopies, which was just released in Japan and is expected to soon be available in Europe. Colorectal cancer is the most common cancer in Japan and the second most common in Europe, it originates from precancerous lesions and it is possible to suppress the progression to cancer by detecting and removing lesions at the polyp stage during endoscopy procedures.

Learn More



Having Risk Management Ingrained

There was this company that had constant fights between QC and production and the design team with regards to test and inspection. Why the fights?

A typical conversation:

“We need inspection”
“What are the inspection criteria?”
“This is similar to the other product, so just inspect the same. Besides, we don’t have the apparatus for another type of test”
“can we just do visual inspection? It’s also faster”
“.....”

There are so many things going wrong in this conversation, where do we start?

Risk management. Why?

Because it is via risk management that you decide if a step of the clinical workflow, product, or process

1. From the clinical workflow, you can determine which steps create foreseeable misuse. Or which points in which the product specifications must be spot on
2. From the product, the form factor, features, and requirements determine the failure modes
3. From the production processes, there are areas of equipment or operator errors, environmental variations

In implementing risk controls, there are 3 main methods
- Design out
- Inspect
- Warn (Information for safety)

How would the above example do better with risk management?
- Drawings will determine dimensional or functional specifications; therefore the responsibility is with the supplier controlling the quality of the part
- Do we have the appropriate inspection at incoming, or pass this inspection to production, or have a final test? What will the sample sizes be according to the risk level of the product or process?
- What are some things in which we can never mitigate and just leave it for theInstructions for Use or a warning sign?

Therefore, having a good foundation in design control or process control isn’t enough, integrating appropriate processes for risk management is key to downstream product quality, clarity in roles and responsibilities, and production efficiency. And you can sleep easier too!

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.

ICHMT 2021: 15. International Conference on Healthcare and Medical Textiles

- Date: February 04-05, 2021
- Venue: Bangkok, Thailand

ICAIHMLS 2021: 15. International Conference onApplied Informatics for Health, Medical and Life Sciences

- Date: February 15-16, 2021
- Venue: London, United Kingdom

ICCMME 2021: 15. International Conference on Computational Microbiology and Medical Ecology

- Date: February 22-23, 2021
- Venue: Paris, France

Insight Blog

Keen to know more on what is going on in the medical industry? Check out on our blog posts including Funding Schemes and Medical Taiwan Exhibition, where our colleagues has attended first-hand.

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

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

Local Regulatory Expert (Part Time) Australia

Regulatory Affairs Manager (Full time) Indonesia

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