On this Thanksgiving, we want to share our genuine appreciation for you. We wouldn't be where we are today without you!

Access-2-Healthcare has no exception – we are providing new business models and fresh news as usual in our MedTech Gateway.

CHINA

Setting the Standards for Clinical Evaluation

The NMPA agreed to establish a national medical device clinical evaluation standardization technical task force to further the standardisation of clinical activities and evaluation. Note the MS Word document on the bottom left corner.

Learn More

UNITED STATES

Process to Request a Review of FDA's Decision Not to Issue Certain Export Certificatesfor Devices

This guidance describes the information that CDRH and CBER, in collaboration with the ORA, will provide to a person whose request for a CFG for a device is denied, and the process for seeking review of such a denial.

Learn More

SOUTH KOREA

An Introduction of Korean Regulations on Digital Therapeutics to the International Community

The Ministry of Food and Drug Safety (MFDS, Minister Kim Ganglip) published 4 types of Review Guidelines in English to actively promote Korean regulations onDigital Therapeutics (DTx), AI medical devices, etc., which are considered as the main technology in non-face-to-face era, to the international community.

Learn More

TAIWAN

No More Travel -Taiwan FDA Suspends On-site Inspections for Foreign Medical Device Manufacturers

TFDA announced the temporary suspension of on-site inspections of overseas medical device manufacturers for the duration of the COVID-19 pandemic. New medical device manufacturer inspection applications and review of urgent cases, TFDA will continue to accept new inspection applications, but on-site inspections and fee payments will both be postponed until after the pandemic has abated.

Learn More

SINGAPORE

Public Consultation on the Proposed Regulation forCell, Tissue and Gene Therapy Products under the Health Products Act

The Health Sciences Authority (HSA) invites public feedback on the proposed regulation for cell, tissue and gene therapy products (CTGTP), a new category of health products.

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. **3EC International (Slovakia)** –2265 (MDR scope)

Recent Withdrawals

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

SINGAPORE

Implementing Structured, Comprehensive Strategies To Reduce Mental Healthcare Costs In Public And Private Sectors

Mental health includes our emotional, psychological, and social well-being. It affects how we think, feel, and act. To cope with the potential increase in demand for mental health services in the community, MOH together with the AIC, continues to work with community partners such as the SSA to develop mental health services under the Community Mental Health Masterplan.

Learn More

UNITED STATES

FDA Finalizes Guidance on Microneedling Devices

FDA has finalized guidance explaining when it considers microneedling devices to be medical devices subject to premarket notification (510(k)) requirements. The final guidance has been revised to reflect the classification of microneedling devices for aesthetic use as Class II devices.

Learn More

EUROPE

Medtech Europe Statement Concerning Protective Equipment: Warning Against Counterfeit Products, Fraudulent Web Activity And Falsified Or Misleading Certificates

The use of protective equipment such as personal protective equipment (PPE) or consumable medical devices including masks, respirators, gloves and gowns remains critical in protecting against the transmission of COVID-19.

Learn More

UNITED STATES

MellingMedical and Nova Eye Medical Improving Veteran Access to Glaucoma Care with New Agreement

MellingMedical has signed a distribution agreement that will improve VHA access to sophisticated surgical equipment designed to treat glaucoma.

Learn More

AUSTRALIA

Synchron Develops Small Brain Device – Stentrode To Help Paralysed Patients

The demonstrating use of the Stentrode was successful, which enable patients with severe paralysis to resume daily tasks such as online banking, shopping and texting, which previously had not been available to them.

Learn More

UNITED STATES

Blink Science to launch Biosensor Device for Covid-19 Detection

Blink Science™ has patented electronic technology that provides immediate health status results and will revolutionize healthcare and POC diagnostic testing. Called blinkTEST, the new device is designed to offer health reports that can be analysed immediately to diagnose acute and chronic conditions

Learn More

UNITED STATES

FDA Permits Marketing of New Device Designed to Reduce Sleep Disturbance Related to Nightmares in Certain Adults

FDA has put its stamp of approval on a new digital therapeutic that helps reduce sleep disruption in patients with PTSD or nightmare disorder.

Learn More

TAIWAN

Ministry of Science Technology (MOST) Developed Novel Screening Device for Stroke Risk Assessment

MOST has successfully developed the world-first rapid screening device for the risk assessment of stroke using motion analysis, image decomposition and reconstruction, feature extraction, and AI algorithm.

Learn More

Scope Creep Is Creepy

Typically, in any MedTech prototyping, the requirements are captured by the clinician, or the principal investigator, and shared with the engineering team, to conceptualise and prototype. As the project is being defined, the scope of engineering work is being agreed upon.

Scope creep: Adding additional features or functions of a new product, requirements, or work that is not authorized (i.e., beyond the agreed-upon scope).

Why is there scope creep? What is the impact to MedTech development?

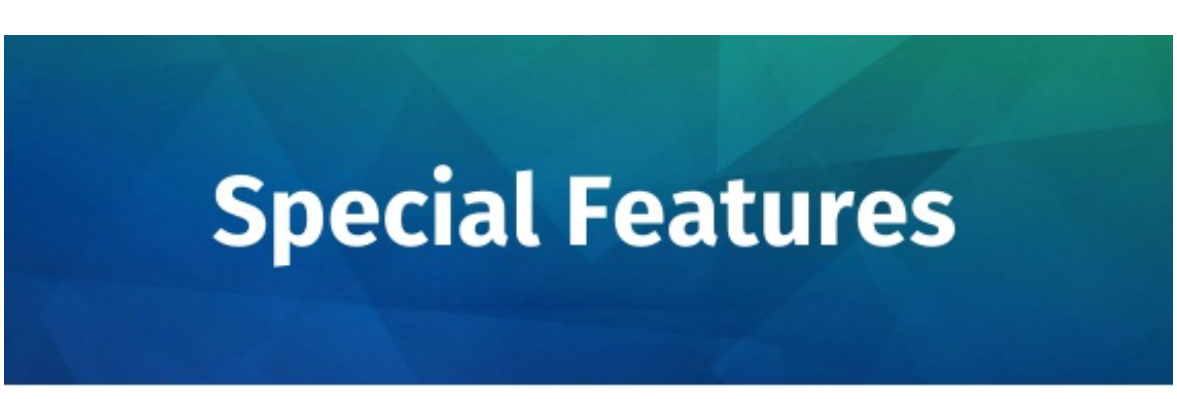
It usually sneaks up because the agreed-upon scope is
- Not sufficiently defined in detail
- Not discussed with all stakeholders involved and with their consensus (not 100% agreement)
- Not discussed and agreed promptly to get on with the work

In the MedTech prototyping, the scope is usually a combination of
- Clinician requirements
- Patient requirements
- Other stakeholder requirements
- Safety/regulatory requirements, and
- Functional requirements

Prototyping is also meant to be iterative, and defining what constitutes a ‘design iteration’ is critical to preventing scope creep.

As more redundant features are being added, or features being added on top of one another, assessing the risk of the device (risk analysis, FMEAs) become increasingly laborious.

Ultimately, it is the clinicians and the users/patients that determines if the device that is being developed really improves their lives or patient outcomes. That should never be far away from a MedTech engineer’s line of sight.



Normally during this time of the year people will either be heading to RSNA or to MEDICA, amongst other events during the events month. Even Standards Plenaries such as those in ISO and IEC tend to be held during this time. But alas, now everything is online.

Virtual Medica put together an interesting forum and conference program for everyone with live and also pre-produced highlight contributions on the latest trends and developments in the global medical technology industry.

Exciting discussion rounds and top-class lectures by renowned speakers provided information from 16 to 19 November 2020 on topics relating to medical technology, health IT, laboratory medicine, sports medicine, disaster medicine, health economics and politics.

Learn More

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.

- MEDICAL FAIR ASIA 2020 Digital Edition

- ~~MEDICAL FAIR ASIA 2020 Digital Edition~~
- Date: 9th - 18th December 2020

- **IndianPharma Expo**
- Date: 17th -19th December 2020
- Location: Pragati Maidan, New Delhi, India

- **Iran Health**
- Date: 25th - 28th December 2020
- Location: Tehran International Exhibition Center, Tehran, Iran

- **China (Shenzhen) International Medical Devices Exhibition**
- Date: 28th - 30th December 2020
- Location: Shenzhen Convention & Exhibition Center, Shenzhen, China

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

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

Facebook LinkedIn

Our mailing address is:

helpme@access2hc.com