Bigger groups gathering, less use of masks, special travel lanes for the fully vaccinated, a physical Medica – all of us are trying to live with what had been looming over us over the past 2 years. With autumn and the temperatures turning colder, there are some signs again, could this be another storm brewing. Regardless, we will weather the next storm together with you.

Regulatory Round Up

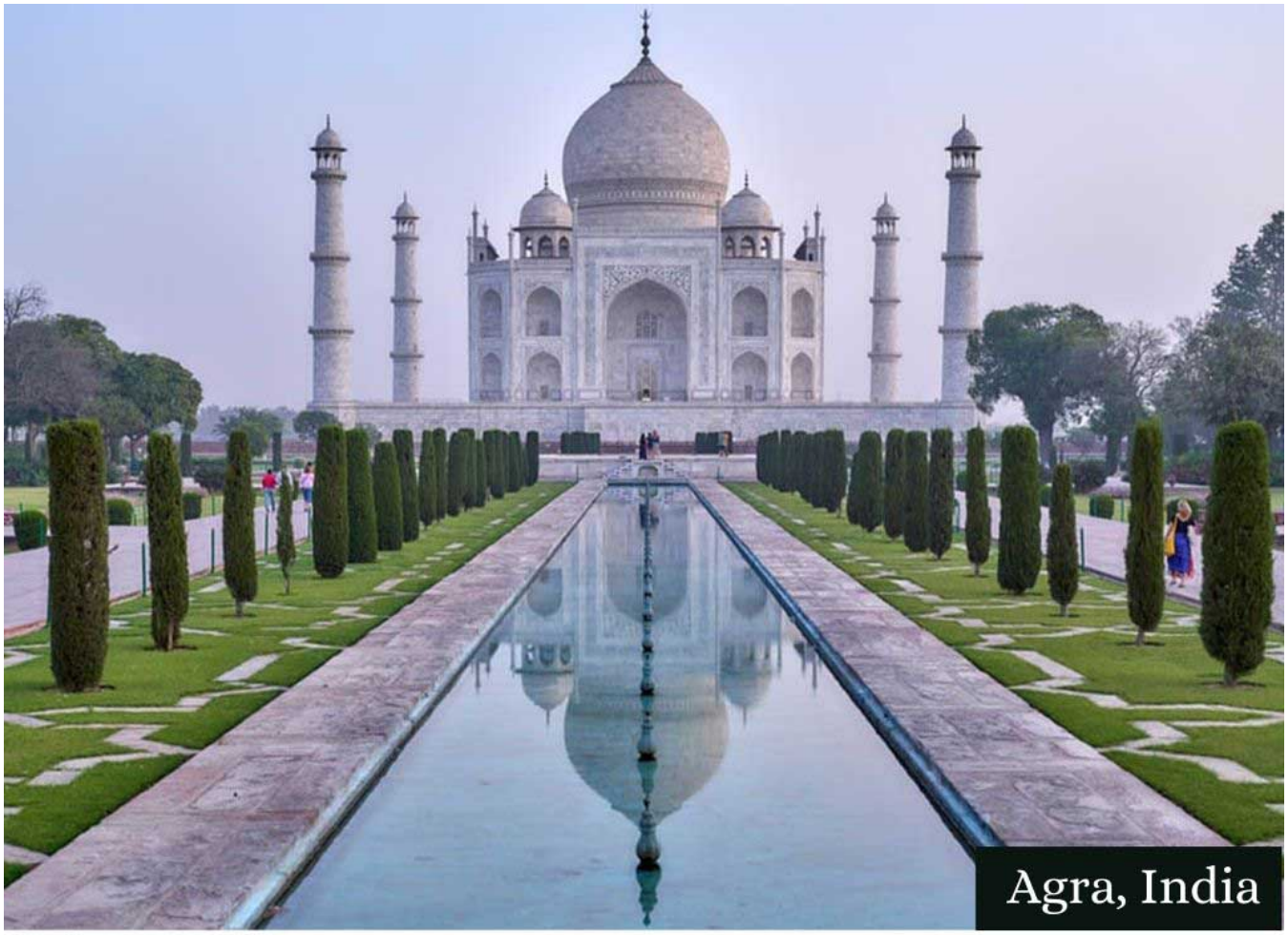
MALAYSIA

Malaysia: Registration of drug-device combination products

Malaysia Medical Device Authority (MDA) released an updated guidance on registering combination products on October 6, 2021. It added a new section on the management of post-marketing incidents involving combination products and covers the reporting process.

Learn More

INDIA



India: Changes to ISO 13485 requirements

As part of the proposed new rule in MDR 2017, device manufacturers or importers must submit ISO 13485 certificates as part of their registrations. Applicants have until November 30, 2021 to declare their intention to obtain ISO 13485 certification no later than May 31, 2022. Failure to do so by the stipulated date will result in cancellation of provisional registration without any notice.

Learn More

EUROPE

Europe: Q&A on repackaging and relabelling activities under Article 16 of Regulation 2017/745 and 2017/746

The EU Medical Device Coordination Group (MDCG) published a Q&A document (MDCG 2021-26) about obligations by Article 16 under Regulation 2017/745 and 2017/746 on repackaging and relabelling activities, including supplying of information and translation of information supplied by manufacturer, and changes to the outer packaging of a device already placed on the market.

Learn More

UNITED STATES

United States: Draft guidance on Content of Premarket Submissions for Device Software Functions

On November 4, 2021, FDA published a draft guidance on Content of Premarket Submissions for Device Software Functions which describes software in devices that falls under the purview of FDA when assessing the safety and effectiveness of devices in premarket submissions. Industry stakeholders are welcome to provide comments on the draft guidance by February 2, 2022.

Learn More

AUSTRALIA

Australia: Extended deadline for custom-made medical devices registration

Australia TGA extended the deadline to register custom-made medical devices transitioning to inclusion in the Australian Register of Therapeutic Goods (ARTG) by 12 months to August 25, 2022. An exemption is made to allow the supply of up to 5 of a kind patient-matched device to be supplied in a financial year without requiring an ARTG inclusion.

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. CERTIQUALITY S.r.l. – 0546 (MDR 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)
17. TÜV Rheinland Italia SRL (Italy) – 1936 (MDR scope)
18. TÜV SÜD (Germany) – 0123 (MDR scope)
19. TÜV SÜD (Germany) – 0123 (MDR scope & IVDR scope)

20. UDEM Adriatic d.o.o. (Croatia) – 2696 (MDR Scope)
21. Eurofins Expert Services Oy (Finland) – 0537 (MDR scope)
22. Eurofins Product Testing Italy S.r.l (Italy) – 0477 (MDR scope)
23. ISTITUTO SUPERIORE DI SANITA' (Italy) – 0373 (MDR scope)
24. SGS FIMKO OY (Finland) – 0598 (MDR scope)

Withdrawals

1. BSI Assurance UK Ltd – 0086
2. DQS Polska – 2282
3. ECM Germany – 0481
4. GMED SAS (France) – 0459
5. Presafe (Denmark) – 0543
6. SGS United Kingdom Limited (UK) – 0120

In-Country Focus

UNITED KINGDOM

US: CDC To Invest $26 Million in Advanced Outbreak Forecasting and Analytics

The Centers for Disease Control and Prevention (CDC) today announced $26 Million in funding to develop next-generation infectious disease forecasting and analytics. The agency will provide $21 million to support research and development of advanced infectious disease models and analytical tools. The awards will support three years of work at five leading academic institutions: University at Albany, State University of New York; Johns Hopkins University; Stanford University; the University of Utah and Harvard T.H. Chan School of Public Health. The CDC also announced $5 million to support collaborations with the National Science Foundation and the Department of Energy to further advance federal infectious disease modeling capabilities. These funds will support rapid-response research projects and provide access to high performance computing resources.

Learn More

SINGAPORE

Singapore: NEW CLINICAL CLAIMS RESOLUTION PROCESS ESTABLISHED TO RESOLVE IP CLAIM DISPUTES

From 9 November 2021, a Clinical Claims Resolution Process (CCRP) will be established to resolve claim disputes of a clinical nature between private Integrated Shield Plan (IP) policyholders, IP insurers, medical practitioners and medical institutions. IP insurers are also expanding their panels to include a wider pool of specialist doctors by end 2021.

2. The Ministry of Health (MOH) had announced in April 2021 that the Multilateral Healthcare Insurance Committee (MHIC)[1] had been set up to collaboratively address issues related to health insurance. Amongst other issues, the MHIC was studying the establishment of a claims complaints process to provide a streamlined and integrated avenue to address disputes, and working to expand the size of IP insurer panels. The MHIC has made progress on both these fronts, and MOH has accepted the MHIC’s recommendations on these areas.

Learn More

CHINA

China: China to promote TCM accessibility for children

China's health authority has issued a document on plans to promote children's health over the next five years. The document includes measures to provide better traditional Chinese medicine (TCM) services for kids at community clinics and home. The document, issued and published by the National Health Commission, said medical and health institutions have been encouraged to use TCM techniques in basic medical treatment, disease prevention and healthcare services for children.

Learn More

SINGAPORE

Singapore: PROTECTING THE VULNERABLE, SECURING OUR FUTURE

Singapore entered the Stabilisation Phase on 27 September 2021 to slow down the rate of transmission and protect our healthcare system. We have used this time to do several things. We have built up COVID-19 Treatment Facilities to complement our hospital and community care facilities. We have also bolstered manpower, employed technology, and streamlined processes for the Home Recovery Programme (HRP), which allows the majority of individuals with mild or no symptoms to recover safely in their own homes.

Learn More

UNITED KINGDOM

UK: More support for women experiencing the menopause

Government action to cut the cost of repeatable HRT prescriptions and a new Menopause Taskforce means women experiencing the menopause will be better supported. Women will benefit from cheaper and easier access to HRT to relieve

symptoms of the menopause following commitments made in Parliament at the second reading of Carolyn Harris MP's private members' bill.

Working with NHS England, the government will look to implement longer prescribing cycles, in line with National Institute for Health and Care Excellence (NICE) guidelines, so women receive fewer prescriptions, reducing the need to pay frequent prescription charges. The government has asked NHS England to review current practice and the barriers to implementing NICE guidelines.

Learn More

UNITED KINGDOM

UK: QuantuMDx secures £15 million equity investment from Vita Spring and enters into Cooperation Agreement discussions with Sansure Biotech

QuantuMDx Group Limited ("QuantuMDx"), today announces it has secured a £15 million equity investment from Vita Spring IVD Fund, L.P. ("Vita Spring"), a Hong Kong-based venture capital firm focused on early and growth stage medical companies with disruptive technologies and global market potential. Proceeds from the financing will be used to further the development and evolve the Q-POC™ platform to increase its functionality. The Company also plans to expand the menu of tests for Q-POC™ adding a multiplex respiratory panel, sexually transmitted infections (STIs), and HPV, amongst others, to the current SARS-CoV-2 assay.

Learn More

SWITZERLAND

Switzerland: Achiko initiates development of dengue diagnostic test

Achiko AG (SWX: ACHI, ISIN CH0522213468) ("Achiko", the "Company") a global healthtech company currently developing technologies that seek to deliver rapid, affordable diagnostic testing for Covid-19 and a range of other pathogenic diseases announced today the development of a DNA aptamer-based dengue fever diagnostic test.The Company previously received emergency use approval in Indonesia for its proprietary, low-cost rapid Covid-19 diagnostic test AptameX™ integrated into a digital platform, Teman Sehat™ ("Health Buddy"), and has recently secured initial purchase orders. AptameX is based on aptamer technology, a synthetic (artificial) DNA that tightly binds to the spike protein (S1) on the virus' surface, which is then targeted by the test. It is cost-effective and widely applicable to a vast range of healthcare and medical diagnostics. Achiko intends to offer an array of diagnostic tests based on single-stranded DNA aptamers and enable test kits to be produced with improved accuracy and offered at a low cost.

Learn More

UNITED STATES

US: SLINGSHOT 2021 - GRAND WINNER

CONGRATULATIONS QuantumCyte and its AI-integrated tissue dissection solution for modern pathology, that provides deep insights into patients' diseases, who would have been missed, otherwise.

Learn More

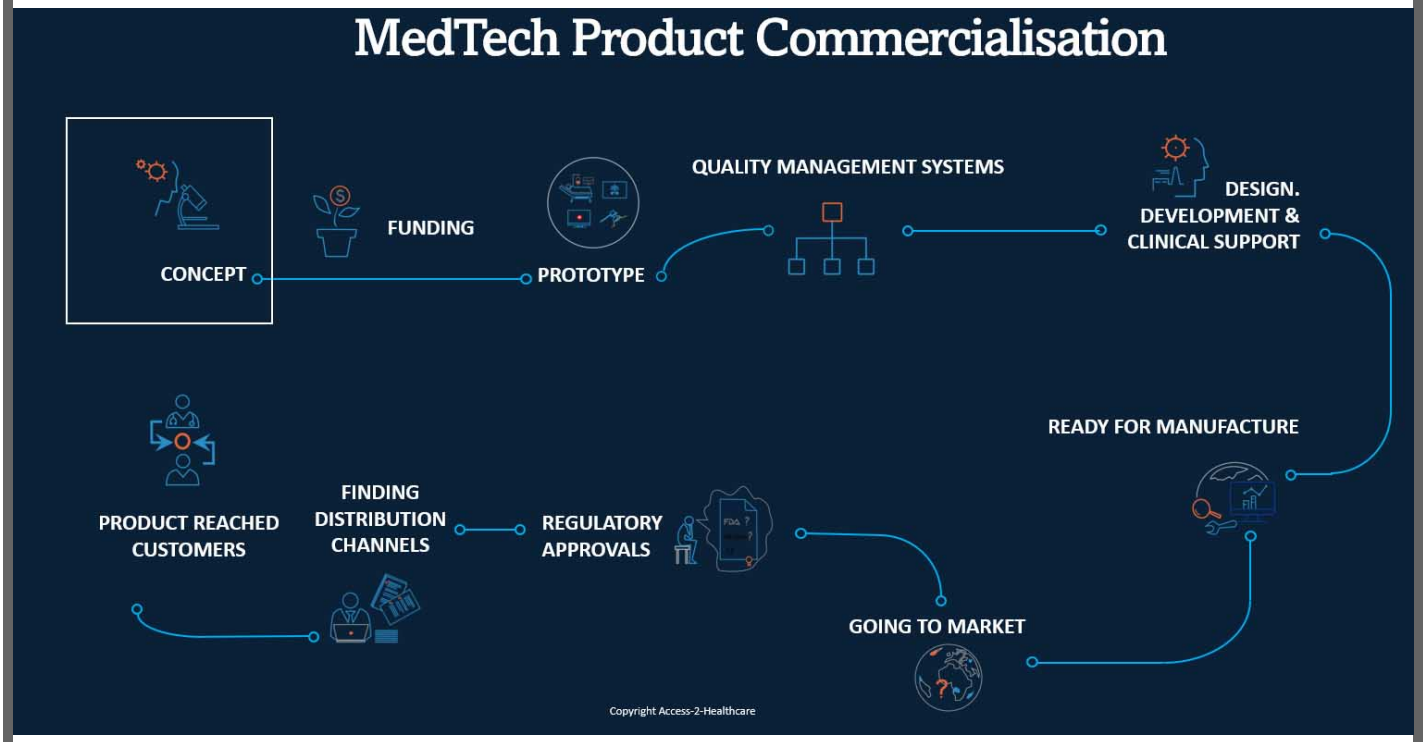
SINGAPORE

Singapore: Smith+Nephew establishes its first Medical Education Centre for the Asia Pacific region in Singapore

Smith+Nephew (LSE:SN, NYSE:SNN), the global medical technology business, today announces its first dedicated Medical Education Centre to support customers

across the Asia Pacific region. Strategically located in Singapore, the centre will support the safe and effective use of Smith+Nephew's products as well as the professional development of healthcare professionals across the region. It is expected to be operational by mid-2022.

Learn More



Going along with the Project

Design and Development Guidance

There are always these same old, same old, questions

1. When does R&D stop, and design controls start?
2. When do we start our verification activities?
3. All the pre-verification/validation, surely, they must count, right?
4. What is the difference between the Project Plan and the Design and Development Plan?

Well, these are not very difficult questions (1. After Proof of Concept, and Design Inputs are gathered. 2. When the design is 'frozen'. 3. No, they do not. 4. One takes care of the overall launch of the product, the other ensures the design control process is followed)

The more pertinent question should be - whether the design and development plan need to sync with the project plan? The answer is a resounding, yes!

The project plan, in the broad sense, other than the design and development of the product, would document and manage the supply chain planning, production planning including procurement, human resource, marketing of the product and finding sales channels.

Oftentimes, the 'safest' way is to wait for the product design to be 'frozen,' the production line ready (either in-house or outsourced), and the materials are confirmed.

In fact, which may be a tad too late.

What will often be missed out is the parallel nature of the design and development plan, where it provides the framework for design activities

During prototype stage, the design inputs are already being gathered – that needs to be documented. True that the prototypes are sent out for various testing (safety testing, usability). they would form the basis of the verification activities later.

Why design documentation may have come in too late could be the concern of too many design changes (change control), and the 'flexibility' of design iterations is lost. Well, if the intended use, indications, and features do not change, iterations would be fine. How would you know if there were no design inputs to check again?

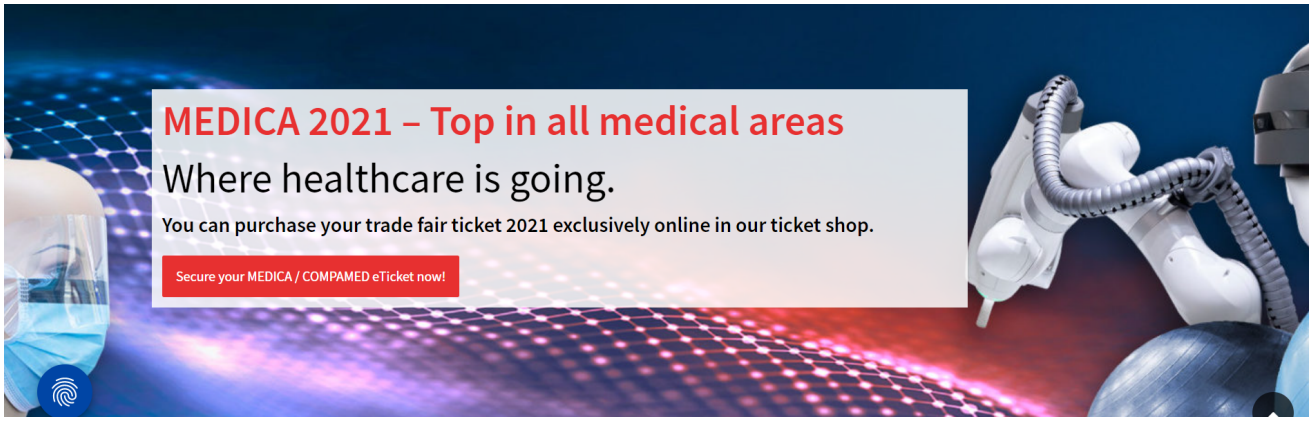
If it is a software, product, this connection is even tighter, because of the risk of the product being fully produced even before the first line of design input is being written!

Truly, the nature of medical device development asks for a lot of plans

- Design and development
- Usability
- Risk management
- Clinical investigation

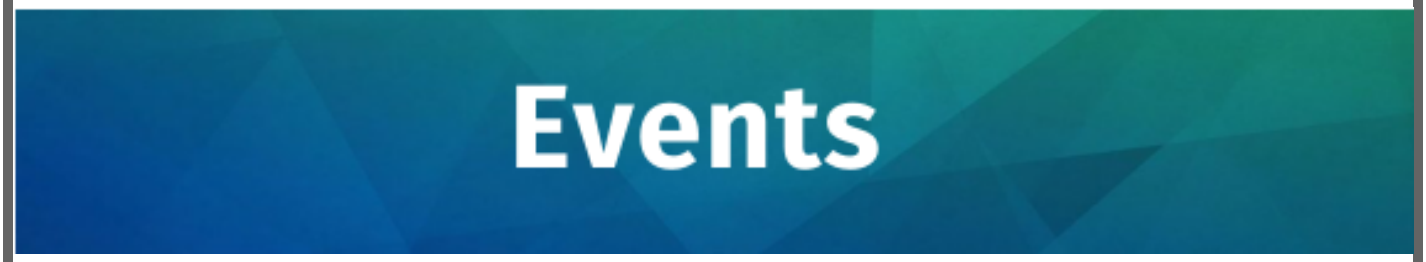
All of which are inter-related and needs to be in sync with the Project Plan.

The Leading International Trade Fair for the Medical Sector - Medica 2021



The Medica is the world's largest medical trade fair for medical technology, electromedical equipment, laboratory equipment, diagnostics and pharmaceuticals. The fair takes place once a year in Dusseldorf and is open to trade visitors only. Rising life expectancy, medical progress and the growing awareness of the people for their health are helping to increase the demand for modern treatment methods.

On the whole the organisers welcomed on the 4 days of the fair, from 18. November to 21. November 2019, about 5598 exhibitors from 68 countries and 121369 visitors from 176 countries on the Medica in Düsseldorf.
The Medica will take place on 4 days from Monday, 15. November to Thursday, 18. November 2021 in Düsseldorf.



We put together a collection of medical industry events around the world for the following month, just in case you may be interested. We take no commission for posting them - it is just our way to share information

Surgical Technology Information Session

December, 14, 2021 | 4:00 PM - 5:00 PM EST

Industrial Technologies Project

December, 10-11, 2021 | 18:00 - 00:00 +08

CCC-Cloud Technology Associate 2 Days Training in Mexicali

December, 1, 2021 | 9:00 AM - 5:00 PM PST

Fusion - Type 1 Diabetes Tech and Devices for Children and Young People

Prepared Childbirth - Medical Intervention

December, 8, 2021 | 7:00 AM – 8:00 AM +08

December 4, 2021| 18:00 – 21:35 +08

33rd Annual Holiday Knee & Hip Course: 2-Day Allied Health Track

December, 3-5, 2021 | 9PM - 1AM +08

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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helpme@access2hc.com

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