



Two consecutive Oktoberfests have been cancelled, never happened since WWII. Then again, the Olympics have never been postponed before, so there's a first for everything. Perhaps seeing this newsletter from [Access-2-Healthcare](#) is a first.

As vaccination rates go up globally, life goes on, albeit in a different way. CMEF Shenzhen, and Medica, are planned to be full-fledged, in-person events. It will feel great to connect face-to-face again.

Regulatory Round Up

PHILIPPINES



Magdalena, Laguna

Philippines: Guidelines on the licensing of retailers of medical devices in the Philippines

Philippines FDA published a circular on October 7, 2021, on guidelines on the licensing of retailers of medical devices in the Philippines. The circular aims to specify the establishments classified as retailers of MDs and provide specific requirements for responsibilities and post-licensing inspection.

[Learn More](#)

INDIA



Tirthan Valley

India: Submission of post-approval changes application through SUGAM Portal

On September 27, 2021, CDSCO published a notice on submission of post-approval changes application. To streamline the procedure, all submissions are to be done through the online portal. CDSCO will no longer accept hard copy or e-mail applications after October 8, 2021.

[Learn More](#)

CHINA



Guilin

China: Establishment of national technical division for clinical evaluation of medical devices

On September 27, 2021, NMPA announced its plan on setting up a technical division focusing on clinical evaluation of medical devices. This division will also oversee other various activities, such as clinical trial quality management, clinical data exchange and clinical data processing, to name a few.

[Learn More](#)

UNITED STATES



United States: List of Artificial Intelligence and Machine Learning (AI/ML) Medical Devices

The US FDA has published a list of approved and marketed AI/ML-enabled medical devices to provide transparency to stakeholders and the public. It also serves as a resource about these devices and FDA’s work in this area.

[Learn More](#)

AUSTRALIA



Australia: Reclassification of spinal implantable medical devices

Australia TGA published a guidance on transitional arrangements and obligations of sponsors and manufacturers dealing with spinal implantable medical devices. The purpose is to assist in understanding how to comply with new regulatory requirements.

[Learn More](#)

EU's Notified Body Tracker

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 Rheinland Italia SRL (Italy) – 1936 ([MDR scope](#))
17. TÜV SÜD (Germany) – 0123 ([MDR scope](#))
18. TÜV SÜD (Germany) – 0123 ([MDR scope](#) & [IVDR scope](#))
19. UDEM Adriatic d.o.o. (Croatia) – 2696 ([MDR Scope](#))
20. Eurofins Expert Services Oy (Finland) – 0537 ([MDR scope](#)),
21. Eurofins Product Testing Italy S.r.l (Italy) – 0477 ([MDR scope](#)),
22. ISTITUTO SUPERIORE DI SANITA' (Italy) – 0373_([MDR scope](#)),
23. 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

UK: Fund to help end cycle of homelessness and hospital readmissions

People experiencing homelessness in England to be supported through pilot projects, backed by £16 million, to provide temporary accommodation, care and support. The objective is to end the cycle of people leaving hospital to return to the streets and then being quickly readmitted to hospital.

[Learn More](#)

UNITED STATES

US: CDC to Invest \$2.1 Billion to Protect Patients and Healthcare Workers from COVID-19 and Future Infectious Diseases

Today, the Biden-Harris Administration announced a \$2.1 billion investment to improve infection prevention and control activities across the U.S. public health and healthcare sectors. The Biden-Harris Administration, working through the Centers for Disease Control and Prevention (CDC), is investing American Rescue Plan funding to strengthen and equip state, local, and territorial public health departments and other partner organizations with the resources needed to better fight infections in U.S. healthcare facilities, including COVID-19 and other known and emerging infectious diseases.

[Learn More](#)

CHINA

China: Chinese authorities issue directive to beef up hospital security

Chinese authorities have issued a directive to strengthen security and ensure order in hospitals across the country. The directive, aimed at protecting the safety of medical workers and creating a favorable environment for both staff and patients, asks medical institutions to install a more standardized security control system. Hospitals should hire a certain number of security guards -- no less than 3 percent of the total number of the medical staff on duty or 0.3 percent of the daily outpatient volume, according to the directive.

[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](#)

AUSTRALIA

Australia: Australian Health Protection Principal Committee (AHPPC) statement on visitation in residential aged care facilities

Access to residential aged care facilities (RACF) by visitors is essential to reduce the impacts of social isolation on elderly people. Visitors provide aged care residents with a range of benefits including providing emotional support and supporting physical activity. Older people in residential care should be allowed to take advantage of reduced restrictions and participate in activities outside the RACF such as outdoor exercise and visitation with friends and family. AHPPC agreed all jurisdictions will revise their public health orders to remove restrictions on visitation to RACF, including for prospective residents and their families or representative, and to promote safe visitation. This includes allowing daily face-to-face visits as well as trips outside the RACF.

[Learn More](#)

Industry Insights

JAPAN

Japan: VFMCRP announces approval for TAVNEOS® (avacopan) for the treatment of ANCA-associated vasculitis in Japan

Vifor Fresenius Medical Care Renal Pharma (VFMCRP) today announced that Japan’s Ministry of Health and Labor Welfare (MHLW) has granted its partner, Kissei Pharmaceutical Co., Ltd., marketing authorization approval for TAVNEOS® for the treatment of patients with granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA), the two main types of ANCA-associated vasculitis, a rare and severe autoimmune renal disease with high unmet medical need.

[Learn More](#)

UNITED STATES

US: Genentech’s Anti-Amyloid Beta Antibody Gantenerumab Granted FDA Breakthrough Therapy Designation in Alzheimer’s Disease

Genentech, a member of the Roche Group (SIX: RO, ROG; OTCQX: RHHBY), today announced that gantenerumab, an anti-amyloid beta antibody developed for subcutaneous administration, has been granted Breakthrough Therapy Designation by the U.S. Food and Drug Administration (FDA) for the treatment of people living with Alzheimer’s disease (AD). This designation is based on data showing that gantenerumab significantly reduced brain amyloid plaque, a pathological hallmark of AD, in the ongoing SCarlet RoAD and Marguerite RoAD open-label extension trials, as well as other studies. Learnings from these studies have been incorporated into the optimized design of two ongoing parallel, global, placebo-controlled and randomized Phase III trials, GRADUATE 1 and 2. The pivotal trials are evaluating gantenerumab in more than 2,000 participants for more than two years and are expected to be completed in the second half of 2022.

[Learn More](#)

FINLAND

Finland: GlucoModicum and Phillips-Medisize sign a design and development program for the rapid scale-up of its needle-free continuous glucose monitor

GlucoModicum, a company transforming glucose monitoring with precise, needle-free magnetohydrodynamic (MHD) technology, announced today that it has signed a design and development collaboration with Phillips-Medisize, a Molex company, a global leader in front-end design, development and manufacturing for highly regulated industries such as pharma, diagnostics, and medtech.

[Learn More](#)

ITALY

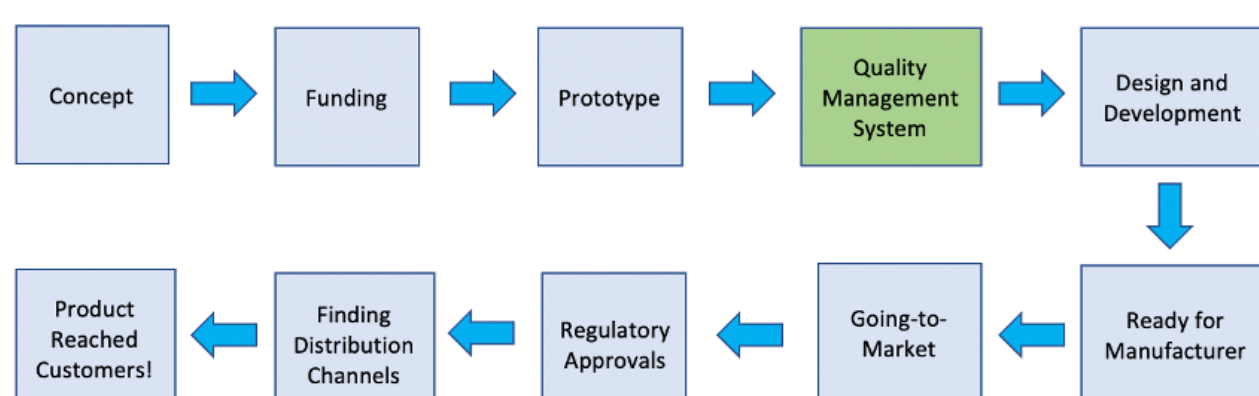
Italy: CrestOptics introduces DeepSIM super resolution confocal microscope module

CrestOptics S.p.A., a manufacturer of high-end microscopy solutions and advanced systems for fluorescence microscopy and diagnostic applications, today announced the launch of **DeepSIM**, a super resolution module designed to enhance the imaging capabilities of confocal microscope systems. The DeepSIM module can be used

with [Crest's X-light V3 spinning disk](#), or alternative confocal systems, to offer high-resolution images for life science researchers.

[Learn More](#)

JOURNEY TO PRODUCT COMMERCIALISATION



Quality Management System

One of our projects, we went about deploying a quality management system to the company. And it was the usual stuff – project plan, kick off, training, action list, provide framework and templates to start off, determining the scope of the QMS...

Along the way, something appears amiss to the team

“How come the SOPs do not tally with the clauses? We appear to have too few SOPs?!”

“All that is important is that the documents document what your processes are, what you are doing, within a framework defined by the standard”

“Scratch head”

A quality management system needs to be established AND maintained. It is like a human being - once born, we have to take care of it. No, indeed, it is not just about templates. For that matter, after certification, this is where the journey really starts.

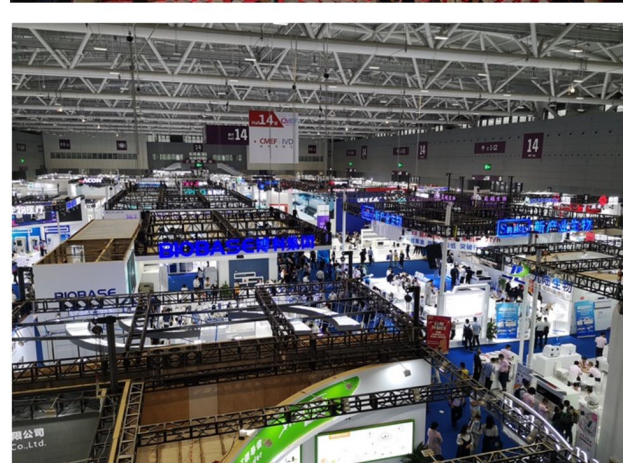
Then the Quality Manual was brought up, where it details the inter-relationship between the various SOPs, and the clauses of the standard/regulations. This also shows that the quality management system has a scope that covers the scope of the organisation adequately.

Whew!

Documented process ownership is what that is needed for the organisation. Therefore, each process owner can utilize what had been set up through the quality management system for the benefit of the company.

Special Features

On-site presentation of the 85th China International Medical Devices (Fall) Expo (CMEF 2021)



The 85th China International Medical Devices (Fall) Expo (CMEF 2021) is held on October 13-16, 2021 at the Shenzhen International Convention and Exhibition Center (Bao'an District), and the conference will continue to uphold the vision of "Analytic Science for the Future", with academic presentations, forums and instrument exhibitions on the theme of "Life, Life, Ecology - Facing a Green Future".

This time round, our team member Larry is here to provide us with the exhibition situation and the latest happenings in the exhibition. Get to know more from the [blogpost](#).

Events

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

[Medlab Asia and Asia Health - The virtual edition](#)

[returns](#)

October, 20-22, 2021 | N.A

[Technology for society - are we getting it right?](#)

November, 10-11, 2021 | 22:00 - 00:00 +08

[Introduction to UWL Learning Technologies \(for new staff\)](#)

November, 4, 2021 | 11:00 - 14:00 GMT

[Surgical Technology Virtual Information Session](#)

November, 18, 2021 | 8:00 PM - 9:30 PM EST

[Medical Assisting & ECG/IV Therapy Virtual](#)

[Information Session](#)

November, 17, 2021 | 3:00 PM - 4:30 PM EST

[Central Processing Tech Information Session: Online](#)

November, 16, 2021 | 10:30 AM - 11:30 AM EST



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