One year, millions of great technological stories. From alterations of rules and regulations affecting medical devices and the betterment of technology to innovations and new programs supporting the healthcare industry.

As COVID-19 is continuously wreaking havoc to various countries, a support package has been implemented providing early gifts this Christmas season for the healthcare sector and the release of DOH in the Philippines, which is one of the countries that is very particular about Christmas, by the long-awaited benefits for the frontliners.

Thus, Access-2-Healthcare gives you the power to unfold different stories

Regulatory Round Up

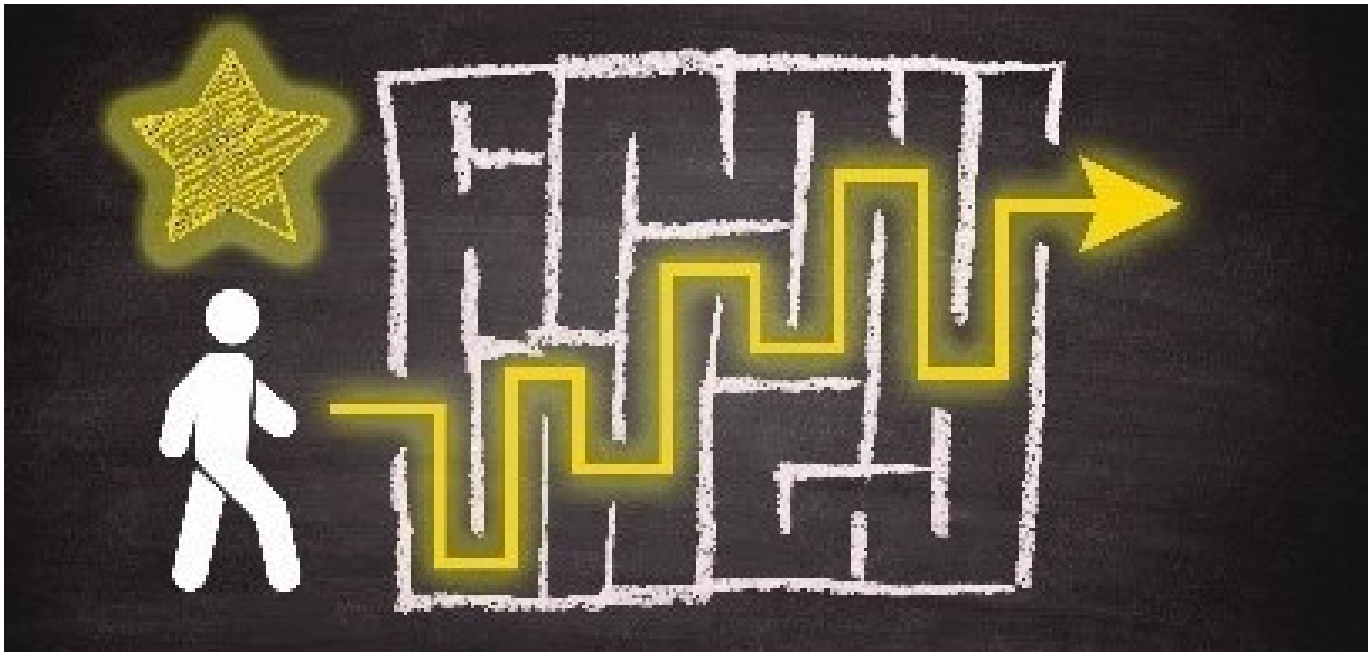
SINGAPORE

Pocket Pain: Increased Regulatory Fee for Health Products

Three percent increase, effective on July 1, 2022, will be levied on health products as a portion of the required regulation fee, including medical devices, to offset the cost of registration, licensing, notification, and permit issuance. One dollar minimum increase will be imposed, with a ceiling of $200 per charge item.

Learn More

UNITED STATES



United States: eSTAR for De Novo Pathway

The FDA has expanded the use of eSTAR submission to include De Novo devices. On or after January 3, 2020, De Novo's final rule's implementation, voluntary eSTAR De Novo requests may be filed to the FDA. Following draft advice is expected to be for De Novo requests on the content of the eSTAR for a particular submission type.

Learn More

VIETNAM

Changes to Decree 98/2021 ND-CP Impact Multiple Areas of the Medical Device Industry

The Vietnamese Ministry of Health issued Decree 98/2021 ND-CP last November 8, 2021. The new decree will take effect on January 1, 2022, and will supersede Decrees 36/2016, 169/2018, and 03/2020/ND-CP previously issued. Among the changes made are the necessity for a Market Authorization (MA) Licence, the elimination of the third-party classification procedure, the authorization of numerous distributors/importers under a single MA licence, and mandatory submission onto the pricing portal for price transparency

Learn More

JAPAN

Japan: JQMS Aligning with MDSAP

Medical Device Single Audit Program (MDSAP) reports may now be used to demonstrate compliance with Quality Management Systems (QMS) for medical device and IVD producers and distributors in Japan. The notice specifies the required paperwork and supplies, as well as any associated expenses.

Learn More

CANADA

Addressing Shortages of Medical Devices: Reporting Guidelines are Out

It was announced on November 30, 2021, that Health Canada will be implementing new reporting guidelines for medical device shortages as early as March 1, 2022. Reporting medical device shortages will be mandated for manufacturers of medical equipment from Class I through IV as well as importers of Class I medical devices.

Learn More

Designated NBs

1. **3EC International (Slovakia) – 2265** (MDR scope)
2. **BSI (Netherlands) – 2797** (MDR scope & IVDR scope)
3. **CE Certiso (Hungary) – 2409** (MDR scope)
4. **CERTIQUALITY S.r.l. – 0546** (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 & IVDR scope[MA1])
8. **DNV Product Assurance AS (Norway) – 2460** (MDR scope)
9. **DQS Medizinprodukte (Germany) – 0297** (MDR scope)
10. **Eurofins Expert Services Oy (Finland) – 0537** (MDR scope)
11. **Eurofins Product Testing Italy S.r.l. (Italy) – 0477** (MDR scope)
12. **GMED SAS (France) – 0459** (MDR scope & IVDR scope[MA2])
13. **IMQ (Italy) – 0051** (MDR scope)
14. **Istituto Superiore Di Sanita' (Italy) – 0373** (MDR scope)
15. **Intertek Medical Notified Body AB (Sweden) – 2862** (MDR scope)
16. **KIWA CERMET ITALIA S.P.A – 0476 (**MDR scope)
17. **MDC Medical Device Certification (Germany) – 0483** (MDR scope)
18. **MEDCERT (Germany) – 0482** (MDR scope)
19. **NSAI (Ireland) – 0050** (MDR scope)
20. **SGS Belgium NV (Belgium) – 1639** (MDR scope)[MA3]
21. **SGS FIMKO OY (Finland) – 0598** (MDR scope)
22. **TÜV Rheinland Italia SRL (Italy) – 1936** (MDR scope)
23. **TÜV Rheinland LGA (Germany) – 0197** (MDR scope & IVDR scope)
24. **TÜV SÜD (Germany) – 0123** (MDR scope & IVDR scope)
25. **UDEM Adriatic d.o.o. (Croatia) – 2696 (**MDR scope)

Recent Withdrawals

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

1.

In-Country Focus

AUSTRALIA

New Year, New Code: New Therapeutic Goods Advertising Code on January 1, 2022

The Therapeutic Goods Advertising Code (TGACode) establishes minimal standards for legally advertising therapeutic goods to Australian consumers. It assures that marketing and advertising for therapeutic products are performed in a manner that promotes product quality, is socially responsible, and does not mislead or deceive the customer. The TGA is happy to publish the Therapeutic Goods Advertising Code 2021(link is external) (the 2021 Code) after an 18-month consultation period with stakeholders which will take effect on the 1st of January 2022.

Until 30 June 2022, advertisers have the opportunity to transfer from the existing Code to the new one, the 2021 Code. This six-month period allows marketers to use either the existing Code or the new Code in place of the present one.

An overriding goal of making it simpler to understand and apply the advertising laws was the driving force for the creation of the 2021 Code under the Therapeutic Goods Act 1989. Moreover, updated guidance materials will be made available on the TGA's website in January 2022 to help marketers comply with the 2021 Code of Advertising Practice. In the first half of 2022, we'll be holding webinars on the Code modifications as well.

Learn More

CHINA

Boost Your Well-being: China rolls out measures to address Population Aging

Chinese authorities have issued a new set of guidelines aimed at improving the quality of life for the elderly, as well as their feeling of security and satisfaction. According to a joint communist party-state council document, a wide variety of steps will be taken to ensure that China's seniors are cared for in a coordinated way while addressing the problem of population aging. Elderly care services will be improved both at home and in the community in China, according to the guideline

.

Learn More

UNITED STATES

GAIHN and Global AR Lab & Response Network Paved $22 Million Award from CDC to 30 Organizations Combating Diseases

Nearly 30 organizations around the world have received $22 million from the Centers for Disease Control and Prevention (CDC) to combat antimicrobial resistance and other healthcare threats through two new networks: the Global Action in Healthcare Network (GAIHN) and the Global AR Laboratory and Response Network (Global AR Lab & Response Network).

More than 50 countries around the world will benefit from the creation of these two new networks and short-term research projects, which will build programs that focus on preventing infections in health care through proven infection control; build laboratory capacity to detect antimicrobial-resistant organisms in healthcare; develop new and innovative ways to more rapidly detect and respond to threats like AR and COVID-19.

Learn More

UNITED KINGDOM

Support package for care sector protection this winter

A package of additional measures aimed at protecting the social care industry from COVID-19 will be implemented, including a £300 million investment in employee recruitment and retention. The social care industry is receiving additional help as part of a package of new measures aimed at preventing the spread of the Omicron strain.

Vaccines remain the greatest line of defense, and the NHS will step up efforts to contact residents of care homes who have not yet had their boosters. Specialist vaccination teams are being expanded and deployed to ensure that the booster is provided to all care home residents and employees, as well as individuals who are housebound and their caretakers — with those most at risk receiving the injection first.

Learn More

PHILIPPINES

Medical Device

DOH: PHP 15.7B BENEFITS FOR HEALTHCARE WORKERS RELEASED

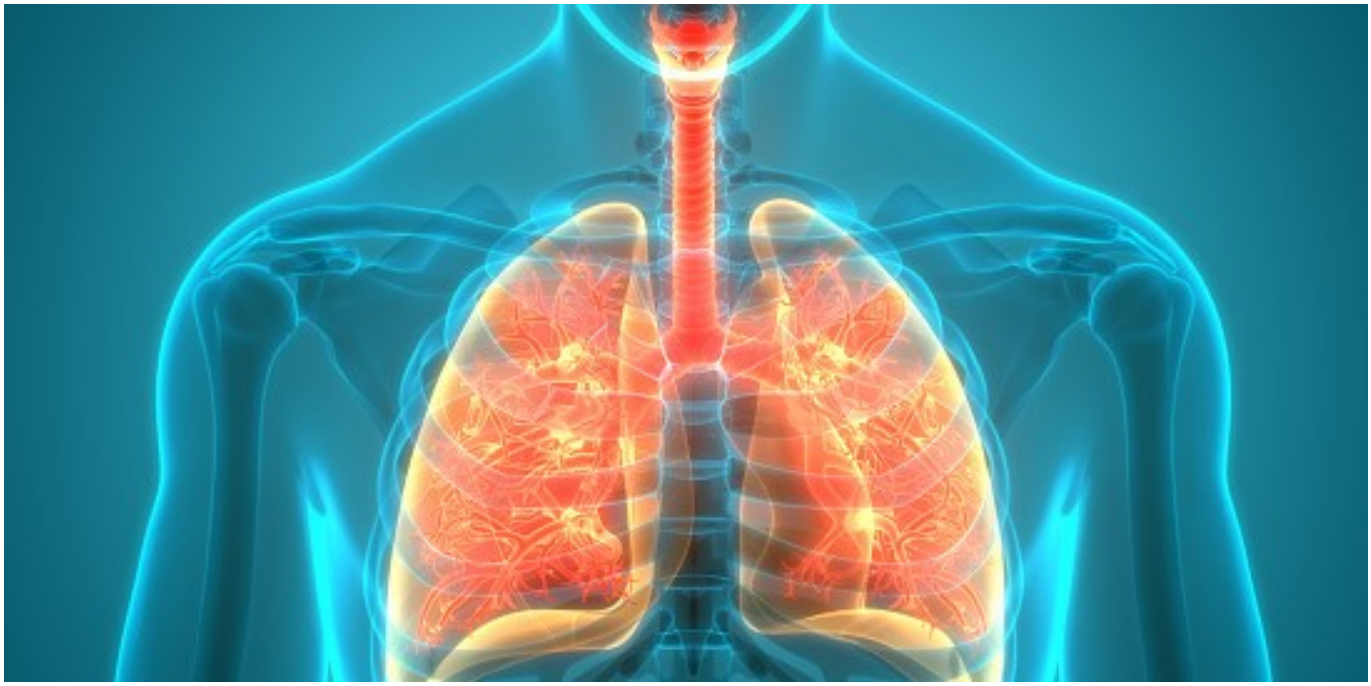
The Department of Health (DOH) revealed that benefits of Php 15,719,085,923 have been awarded to healthcare employees as of November 26, 2021. This is based on the most recent reconciled statistics in the Statement of Allotment, Obligation, and Balances (SAOB) and is included in the total amount distributed of Php 16,229,088,025.2 as updated on November 23, 2021, with the difference for reconciliation.

According to the DOH, Php 7,915,760,434 in Special Risk Allowance (SRA) has been granted to 486,585 healthcare employees for the period December 20, 2020 to June 30, 2021. While Php 6,555,957,185 was paid as SRA and active hazard duty pay (AHDP) to 315,652 and 390,662 healthcare employees, respectively, last year. Additionally, 103,413 healthcare employees got MAT benefits totaling Php 1,231,098,680.

Learn More

Industry Insights

UNITED KINGDOM



WHO Improved Childhood TB Diagnoses Through 42 Technology Partnership

An innovative stool sample processing kit developed by 42 Technology (42T), FIND, the global alliance for diagnostics, and Rutgers University (Rutgers) has been instrumental in the World Health Organization's (WHO) recent policy update to enhance tuberculosis (TB) detection in children [ref 1].

Around 10 million individuals were affected by tuberculosis (TB) in the year 2020, with 1.1 million of them being children. However, even though tuberculosis may be cured and avoided, the disease can be difficult to detect and manage in children.

Learn More

AUSTRALIA

Driving to World-class Medical Research with the New biotech incubator in Melbourne

CSL, WEHI, and the University of Melbourne announced that they have won financing to establish a start-up incubator to assist and develop early-stage Australian biotech enterprises. The incubator, which will be housed in CSL's new global corporate headquarters in the world-class Melbourne Biomedical Precinct, will facilitate start-up enterprises in translating excellent medical research into commercial results.

The estlabushment of this innovation was mad epossible with the financial and in-kind contributions from CSL, the University of Melbourne, and WEHI, as well as a contribution from Breakthrough Victoria, an independent investment management firm that manages the Victorian Government's historic $2 billion Breakthrough Victoria Fund. The said incubator is set to debut in 2023 and will be able to house up to 40 early-stage enterprises from around Australia.

Learn More

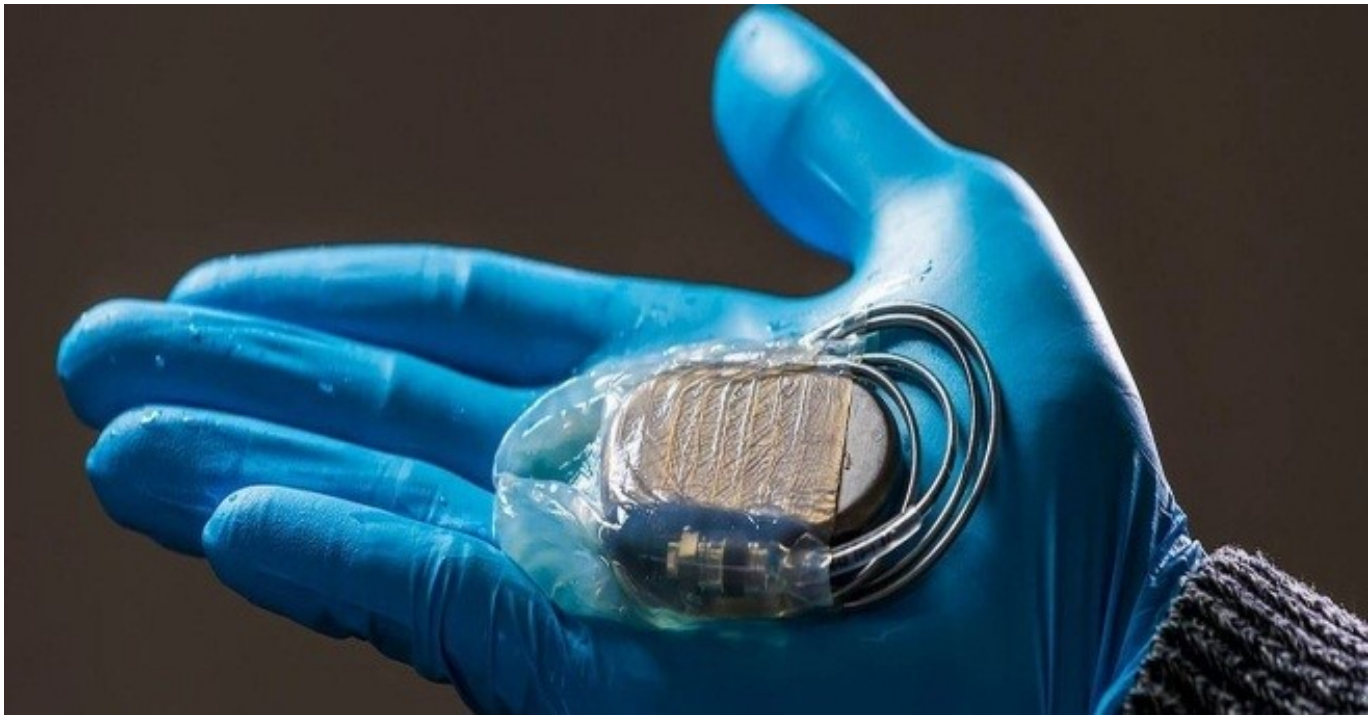
SOUTH KOREA

Achievement Unlocked: Lunit INSIGHT MMG, Wins FDA Clearance

Brandon Suh, CEO of Lunit said that “I am delighted to deliver the great news and to introduce Lunit INSIGHT MMG to healthcare professionals and institutions across the US. With our AI solution, we hope to increase the efficiency and accuracy of mammography screening as well as chest x-ray triaging. We can assist radiologists diagnose diseases at an earlier stage, helping patients be treated at the right time.”Lunit, a major medical AI provider, announced that their AI solution for breast cancer diagnosis, 'Lunit INSIGHT MMG,' has received FDA 510(k) clearance. The company's AI solution for both chest x-ray and mammography, together with its chest x-ray triaging solution 'Lunit INSIGHT CXR Triage,' is now commercially accessible throughout the United States.

Learn More

SWITZERLAND



Hylomorph Secures 5.2 Million CHF Series-B Funding

Hylomorph, a fast developing clinical-stage medtech business with a track record of national and worldwide acclaim, has announced the successful conclusion of a 5.2 million CHF Series B funding. Simultaneously, the firm received 0.9 million CHF in fresh non-dilutive capital. These "booster injections" seek to safely bring the company's product portfolio, starting with the blockbuster Hylomate®, to FDA and CE mark approval. By co-leading the funding round alongside Geneva Smart Invest (GSI) and the Start Angels Network (SAN), and featuring Verve Ventures and Zürcher Kantonalbank, the existing investors made a clear signal of their sustained support (ZKB). EFI Lake Geneva Ventures, a Geneva-based fund focused on Swiss innovation, joined the Series B investor syndicate.

Learn More

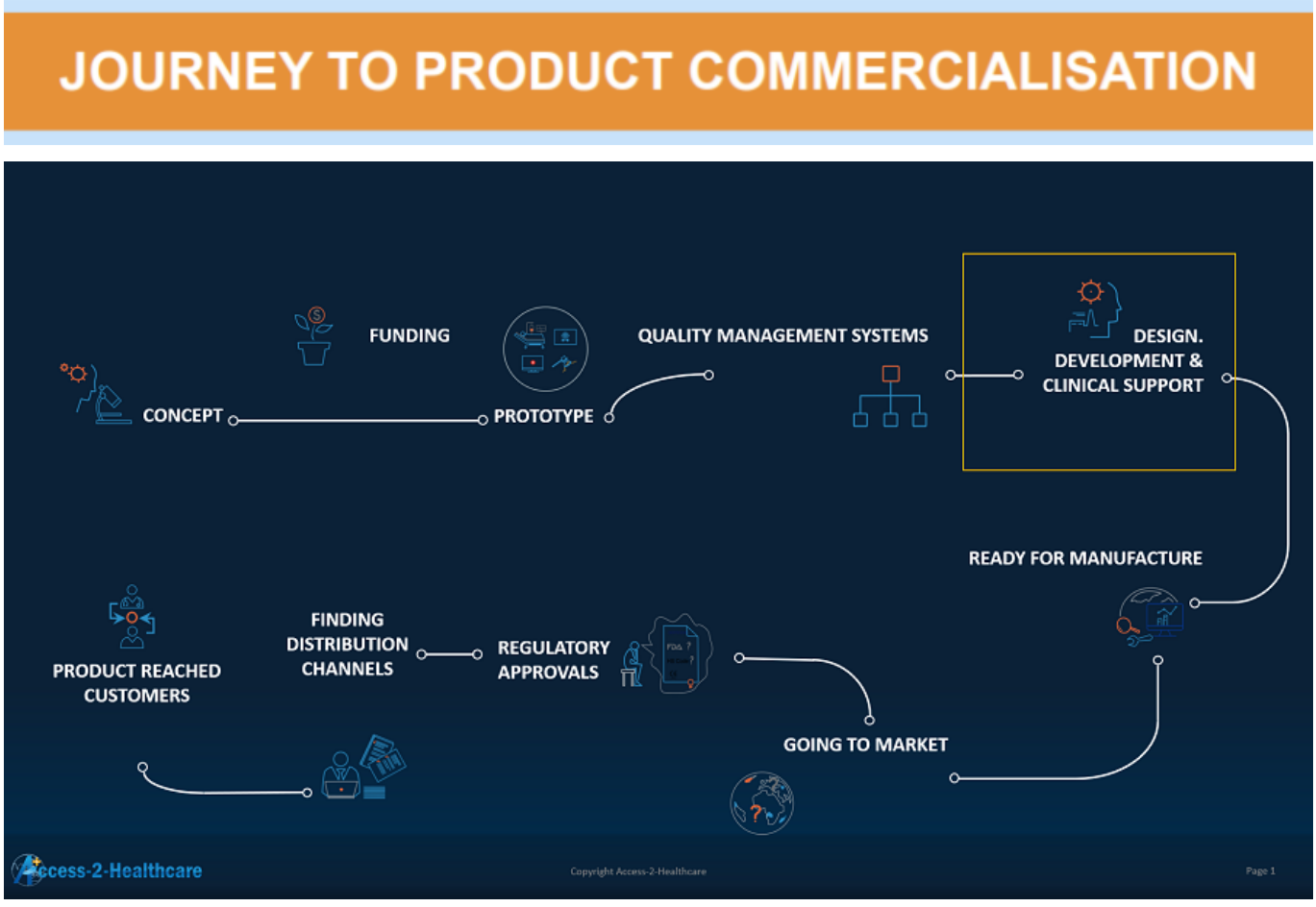
UNITED KINGDOM

Clinical Grade Expansion: Lifelight raised over $8 million from its inception for Global Monitoring

Lifelight is pleased to report that they have collected more than $8 million to date to pursue its mission of transforming every device on the world into a self-monitoring healthcare platform. From the start, NHS England has backed Lifelight's mission with grants and equity investment, including a $1.5 million award from SBRI Healthcare, a distinguished NIHR & NHSX AI in Health Award, and various grants and loans from Innovate UK.

Notably, over $3.5 million has been raised in the previous 14 months alone to combat the pandemic. Accelerated by Coronavirus, Lifelight is poised to play a major role by enabling physicians to monitor a patient's vital signs remotely, allowing precise vitals measures to continue in real time with no touch — a necessary capability during a pandemic. Equipping professionals to accurately evaluate a patient's physical state in order to get a better result.

Learn More



A STEP BACK BEFORE PRODUCT DESIGN

“Once we have product requirements, we can design the product”

No, not really.

Why?

Product requirements follow the this ‘formula’ for its input / references

- User needs/ voice of customer
- National or international Standards

- Predicate risk analysis from same or similar products
- Material or engineering requirements
- Production considerations/requirements
- Regulatory requirements, including traceability (e.g. UDI)

As a result, certain elements of the product requirements must be addressed in detail (e.g. which symbol for labelling, materials used are this material, these are some foreseeable faults and misuses , etc).

Because a product is made up of many different parts, it is not possible to list all of the criteria for every single one of those parts. When it comes to functional needs, designers often look to the design aspects that resulted in that particular design "solution" (we just design it this way). When the product is a system, each component may be considered a medical device in and of itself. As a result, the time and cost involved in creating a new product are two important considerations. Failure to achieve quality standards, product requirements, safety and dependability, and a host of other factors may have a significant impact on an organization's long-term success and even its existence.

In certain circumstances, the input for design validation may be taken from product needs, particularly in terms of usability. The design output may be validated to some extent when it is fed into the process. Unless otherwise stated, the majority of design validation is performed on the design input items themselves.

Product Requirements documents are beneficial when paired with intended use statements, and it helps to describe the device in the technical file.

Specifications for a product are objective, quantifiable, and hence, verifiable in nature. It's distinct from a product specification in that it's always accompanied with numbers. Dimensions, tolerances, materials, or a specialized software function are all examples of variables. Thus, better and safer products are created when the needs of the intended product are taken into account throughout the design process.

SPECIAL FEATURE

FULL OF ENDORSENTS: 25TH MEETING AHWP/GHWP DECEMBER 1, 2021

On December 1, 2021, the 25th Meeting of the Asian Harmonization Working Party (AHWP)/Global Harmonization Working Party (GHWP) was held through Zoom conference, led by Mr. Ali M. Al-Dalaan, Chair of AHWP/GHWP who endorsed several information, including the "Regulatory Mechanism for Medical Devices Including In Vitro Diagnostic Medical Devices and Software as Medical Devices During A Public Health Emergency." The next physical annual meeting will be held in China by the end of 2022, subject to further evaluation concerning the COVID-19 pandemic situation and associated travel restrictions.

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

Market Access for MedTech
1st June to 6th June 2021 | 13:00 - 15:00 BST

inXso 2021 MedTech Series

How to Use Real World Data from LTHT for Research-virtual session

16th June 2021 | Wed, 14:00 - 16:00 BST

Soft, smart, multifunctional, agile and aware surgical robots: Day 1

Wed, June 9, 2021 | 9:00 PM – 11:00 PM +08

AI-assisted Surgery – Perspectives and Challenges

Thu, June 3, 2021 |10:00 PM – 10:45 PM +08

Bangladesh Medical & Healthcare Virtual Expo

Mon, 21 Jun 2021, 11:30 – Thu, 24 Jun 2021, 20:00 +08

2021 CAPCaT Big Company/ Little Company Showcase

Thu, Jun 17, 2021, 9:00 PM – Fri, Jun18, 2021, 12:00 AM +08

16th June 2021 | Wed, 9:00 AM - 10:00 AM EEST

Society, Robots and Us: Hiring for Inclusive Robotics

22nd June 2021 | Tue, 6:00 PM PDT

MSc Medical Education: University of Warwick - Info Webinar

Tue, Jun 1 2021 | 19:00 – 20:00 +08

Medical Assisting & ECG/IV Therapy Virtual Information Session

8th June 2021 | 9:00AM - 10:30 AM EDT

21st June 2021 | 4:00PM - 5:30 PM EDT

Discover What's Next: Information Technology

Tue, 22 June 2021 |3:00 PM – 4:00 PM +08

Fusion - Type 1 Diabetes Technology and Devices for Adults

Sat, 26 June 2021 |17:00 – 20:30 +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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