FIME
By Informa Markets

Daily Dose

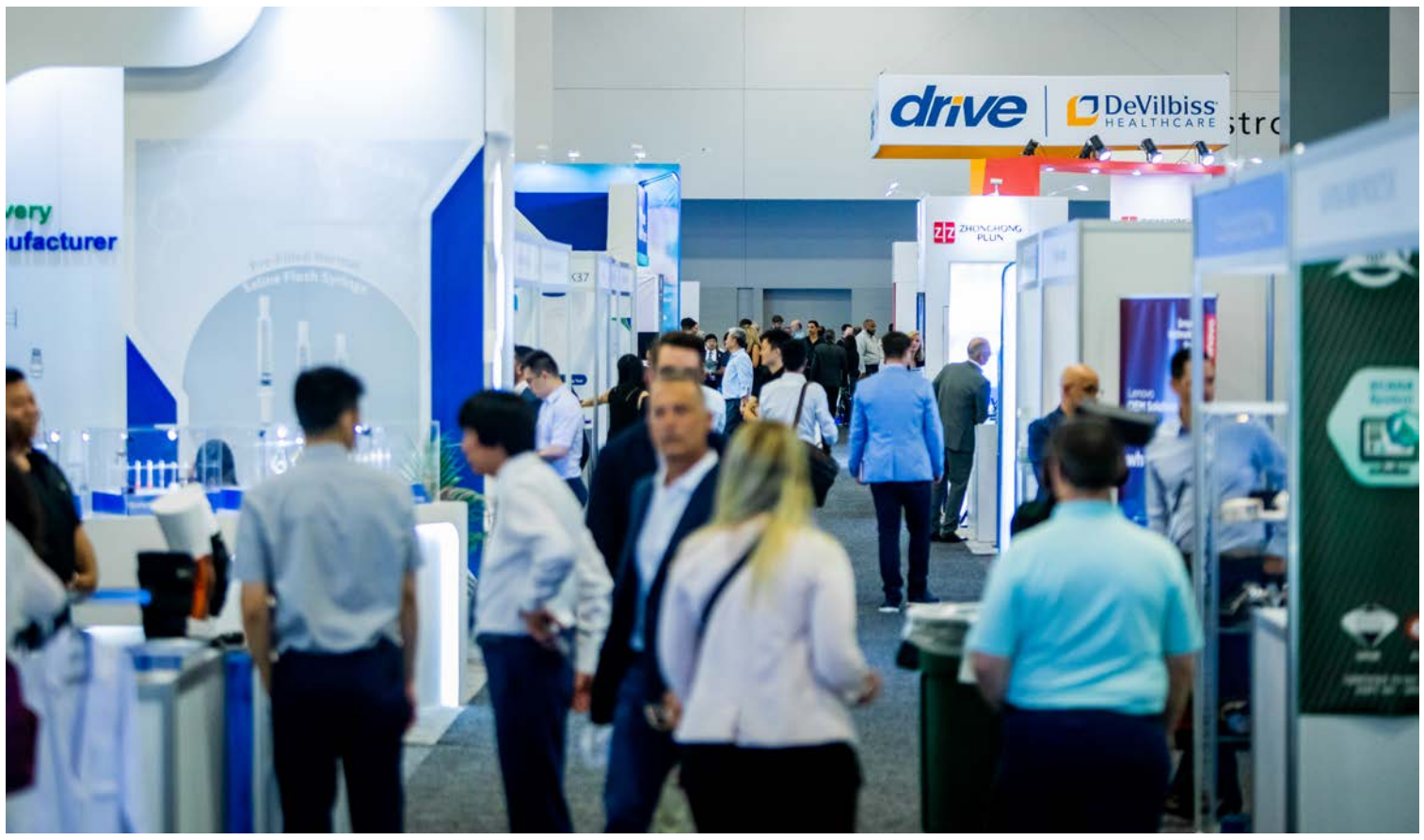
Days 1-3, Wed-Fri, 19-21 June 2024

The official daily newspaper of FIME 2024

Discover America's medtech excellence

Explore future-ready investments in healthcare innovation and product leadership.

By Farhana Chowdhury



Driven by a combination of robust R&D infrastructure, a strong regulatory framework, and significant investment from both private and public sectors, the US stands at the crossroads of healthcare innovation with a booming medical device sector that is poised for growth.

According to a report by Business Fortune Insights, the country's medical devices market is anticipated to grow to $291 billion by 2030. This marks a CAGR of 6.1 per cent, up from $192.78 billion in 2023 during the forecast period. A key driver of the industry's growth is the continuous demand for improved healthcare solutions due to an ageing population and the prevalence of chronic diseases.

Companies in this field are heavily investing in developing cutting-edge technologies such as wearable health monitors, minimally invasive surgical devices, and AI-driven diagnostic tools. This phenomenon is also playing a role in creating high-quality opportunities, which supports nearly two million jobs, directly and indirectly.

The Food and Drug Administration (FDA) also plays an essential part in ensuring the safety and efficacy of these devices through rigorous approval processes. The US' emphasis on innovation, paired with a strong regulatory environment, ensures that the medical device industry will continue to thrive and advance healthcare outcomes domestically and globally.

To honor its continuous achievements and showcase the region's prowess to the rest of the world, Florida International Medical Expo (FIME) returns for another edition between June 19 and 21, welcoming leaders from across the globe to exchange ideas to pave the way for sustainable businesses, share knowledge and solutions to some of the pressing topics that concern the healthcare industry.

This year is packed with a host of exciting conferences under the Business and Innovation Health Hub umbrella, with engaging sessions led by the healthcare's cream of the crop. With a carefully curated selection of topics, professionals take away strategies to drive collaborations with start-ups and medtech organizations, understand global business practices and tap into markets in other parts of the world, learn about the main regulatory issues in Latin America and insights into the ever-evolving world of healthcare and industry potential, to name a few. These will provide an intimate look at enhancing entrepreneurship, improving the supply chain and enabling digital transformation in a dynamic healthcare landscape

Small ventures carry huge potential and FIME understands the importance of having a healthy environment for concepts to develop and flourish. The Innov8 Start-Up Competition is one such opportunity that gives 20 of the most promising ventures a platform to present their ideas and innovations to a panel of esteemed judges for a chance to nurture and continue their revolutionary initiatives.

Product launches are also in store to give visitors a first look at the latest innovations and explore various partnership opportunities. While each organisation brings unique solutions to the forefront, Vision AI is among the most awaited. The web-based platform is expected to revolutionize the detection of retinal diseases, creating an environment for efficient referrals and enabling the timely management of eye conditions triggered by diabetes. Vision AI will also showcase retinal imaging technology to detect Alzheimer's and heart diseases. Adding to the list of breakthroughs in medical imaging, StriXion™ by JPI Healthcare Solutions will present their multi-modal system that covers various needs in X-ray, fluoroscopy, and tomosynthesis.

The three-day show is packed with much to discover and explore. With an area of 150,000 square feet and 1,300 exhibitors from 55 countries, visitors can indulge in a variety of categories inclusive of orthopedic devices, laboratory, pharma and nutrition, physiotherapy and rehabilitation, imaging, healthcare and general services, medical equipment, infrastructure, as well as IT systems, solutions and digital health.

Floor Plan

FIME at a glance

Health Biz and Innovation Talks

Dive deep into the latest technologies, trends and strategies shaping the future of healthcare business.

Day 1 (June 19)

11:00 Next gen of telemedicine will revolutionize the current remote digital health universe
Experience the transformative potential of next-generation telemedicine, poised to revolutionize the current landscape of remote digital health.

11:20 Driving hospital innovation: Collaborating with startups & med-tech companies
In this session, explore how hospitals cultivate innovation by forging partnerships with startups and medical device firms, fostering advancements in healthcare delivery.

Day 3 (June 21)

11:00 Investing in tomorrow's health: VC Insights into healthcare startup funding
Gain valuable insights into the investment strategies, trends, and opportunities in healthcare startup funding from experienced venture capitalists at the forefront of healthcare innovation.

11:45 Beyond borders: Steps to establishing a strong presence for international med tech in the US
Discover how international med tech companies can expand into the US market by partnering with academic medicine and hospital systems.

Panel

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Business and Trade Series

Gain essential insights into navigating global healthcare business complexities, including LATAM, US, and other markets.

Day 1 (June 19)

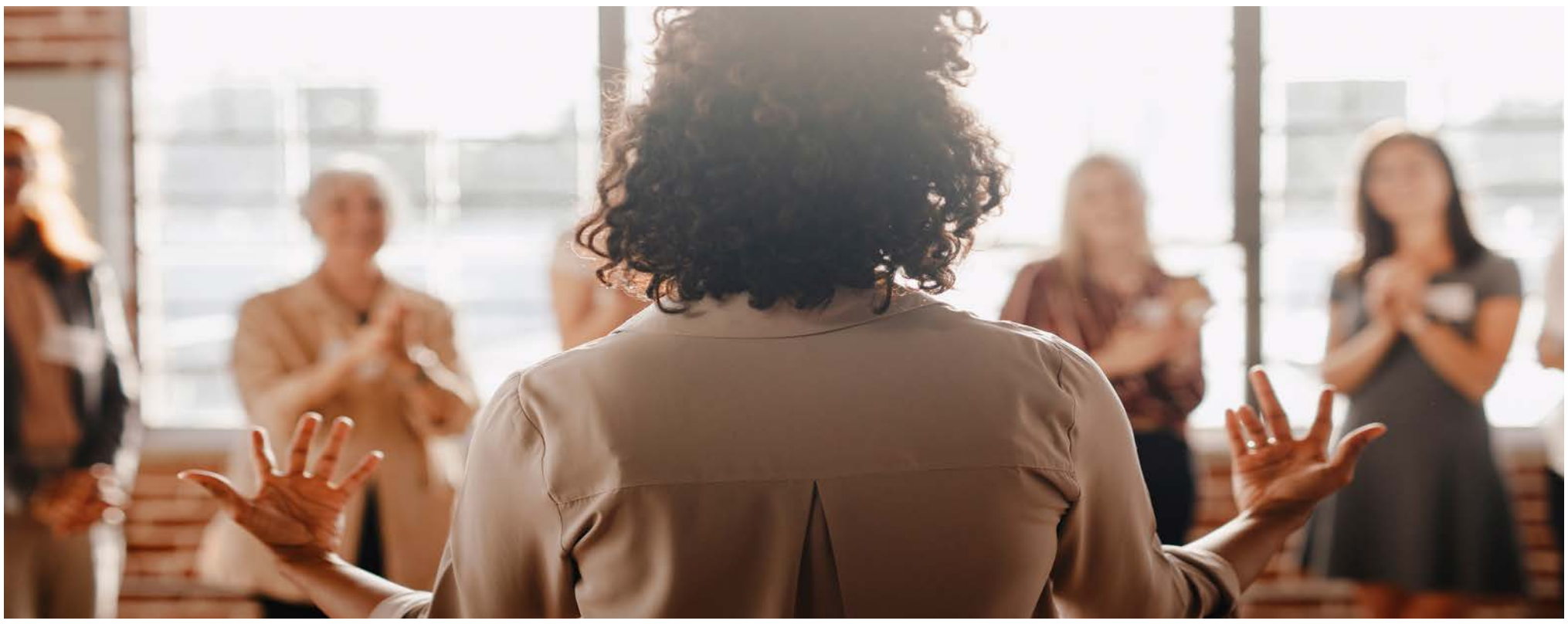
14:00 How to Navigate the US Health System Sales Cycle
15:30 We Put the No in Innovation

Day 2 (June 20)

11:00 Main regulatory issues for LATAM - How to surf LATAM's regulatory issues
11:50 Building the Optimal Sales Organization to sell into the US Market
14:15 Doing Business with the World

Pioneers of healthcare at FIME 2024

From revolutionizing various sectors to making a difference in human lives, meet notable organizations that continue to raise the global standard of healthcare.



By Farhana Chowdhury

The Miami Project to Cure Paralysis

Exhibitor stand #Z97

The Miami Project employs a multidisciplinary approach, integrating neurology, neurosurgery, rehabilitation, and more, with the goal to translate lab discoveries into clinical treatments. Notable advancements include their work with Schwann cells to promote nerve regeneration.

Since its establishment in 1985 to find a cure for paralysis and improve the lives of those with spinal cord injuries, the center has grown to become one of the world's largest and most comprehensive facilities dedicated to spinal cord injury research.

It is further committed to community outreach, providing resources and support for individuals with spinal cord injuries and their families, and advocating for increased awareness and funding. Financial support comes from private donations, grants, and fundraising initiatives, enabling The Miami Project to maintain its cutting-edge research and support programs aimed at ultimately curing paralysis.

ForHearts Worldwide

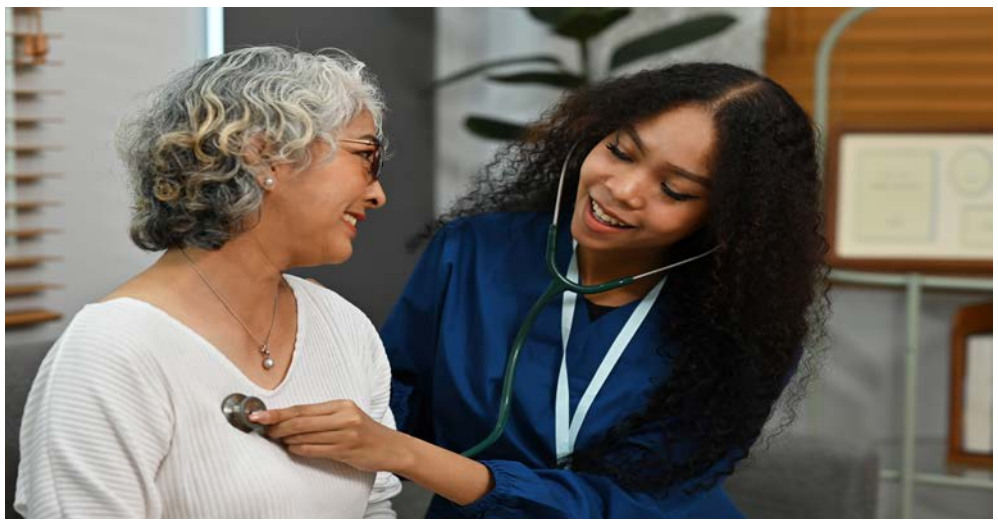
Exhibitor stand #Z93

Despite breakthroughs in cardiac care, several patients across the globe suffer from a lack of access to quality pacemakers, which are known to aid in several treatable medical cases. This became the foundation on which ForHearts Worldwide was built.

The non-profit organization, brainchild of Guatemalan physician Dr. Federico Alfaro and American cardiology professor Dr. Henry D. McIntosh, provides brand-new cardiovascular implantable devices alongside a lifetime of follow-up care to those that meet the economic and medical criteria.

To date, ForHearts Worldwide has saved nearly 18,000 lives in 20 countries, where transplant patients ranged from newborn babies to seniors. The number of survivors continues to grow as the organization incorporates them into specialised clinics led by respective in-country doctors.

ForHearts Worldwide is now on the lookout for partners for its new program, The Pacemaker Club, as it expands its mission to assist those in the US. At FIME, they will be on-site to provide additional educational and training opportunities. *Contact Ldelise@forhearts.org to learn more*.



Mercy Ships

Exhibitor stand #Z95

Established in 1978 by Don Stephens, Mercy Ships is a humanitarian organisation that operates vessels with volunteer professionals to provide life-changing surgeries to those in need. This is dispatched every year to various destinations, notably to African nations, where treatments are offered free of charge. Additionally, they provide training to local healthcare workers.

Its primary mission is to increase access to healthcare, build medical capacity, and improve health infrastructure. Over the years, Mercy Ships transformed millions of lives through its medical services and training programs.

Powered by partnerships, the organization embodies compassion and global solidarity, with many Americans contributing as volunteers, donors, and supporters.

The Life Science Women's Network

The Life Science Women's Network plays an active role in supporting women and helping them advance in the life sciences sector, with resources, networking opportunities, and a platform for professional development. The organization welcomes women in all career stages — from students and early-career professionals to seasoned experts and leaders — and fosters an inclusive environment for them to thrive.

In addition to mentorship programs, educational workshops and webinars, experience and knowledge-sharing events and community outreach, the organisation provides career resources, job boards and coaching. The network further recognizes outstanding achievements and contributions by women in life sciences through various awards and accolades, creating inspirational role models and driving gender equality forward.

ShieldLine USA

Exhibitor stand #A12

Quality and risk control are essential keywords in the healthcare industry in order to ensure patient safety, effective treatment, and overall healthcare efficiency. With this intricately weaved into its business virtue, ShieldLine USA offers top-of-the-line production and distribution of disposable medical products.

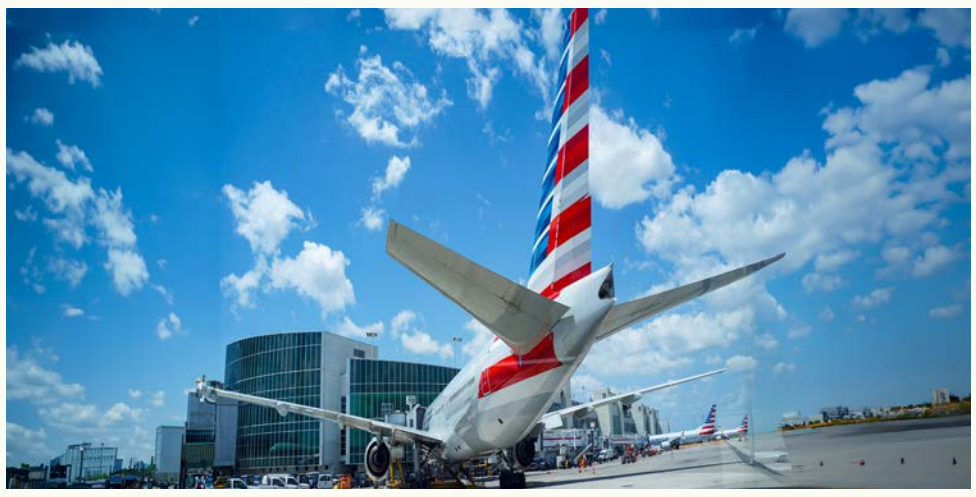
The organization has a carefully curated portfolio of wound care, gloves, surgical supplies, safety products and everyday healthcare essentials, to name a few, that possess the highest standards in patient care while maintaining a cost-effective tag for healthcare facilities, rehabilitation centres and nursing homes.

Miami International Airport — a certified pharma hub

Exhibitor stand #I93

Catering to the global healthcare supply chain involves meeting a set of stringent requirements to ensure the safe, efficient, and reliable transportation of healthcare products, including pharmaceuticals, medical devices, and biological content. This is no easy feat but in 2015 Miami International Airport (MIA) ticked all the boxes to become the first airport in the Western Hemisphere to be certified under the International Air Transport Association's Center of Excellence for Independent Validators in Pharmaceutical Logistics (IATA CEIV Pharma) program.

MIA's status as a pharma hub is supported by its extensive infrastructure, including temperature-controlled facilities and advanced handling equipment. The airport's strategic geographic location also makes it an important gateway for pharmaceutical shipments between North and South America, as well as to Europe and Asia. MIA's collaboration with logistics providers and adherence to international best practices enhance its capability to efficiently manage the complex requirements of pharmaceutical logistics, thus supporting the global healthcare supply chain.



Demystifying medical devices import

Preparation and understanding are key to medical device importers seeking the most efficient processing of their import entries.

By Ruth Dixon

The Food and Drug Administration (FDA), Office of Import Operation's mission is to protect consumers and enhance public health by ensuring timely access to safe, effective, and quality FDA-regulated products of foreign origin. An integral part of this mission is ensuring that medical devices offered for important into the US meet regulatory requirements and requirements found in the Federal Food, Drug, and Cosmetic Act (FD&C Act). The FDA conducts regulatory review of imported medical devices with the support of US Customs and Border Protection authorities and resilient collaboration with other partner government agencies and import community.

For medical device importers seeking the most efficient processing of their import entries, preparation and understanding are key. To process the volume of imports into the US, FDA systems interface with CBP system to allow for the FDA electronic admissibility reviews of FDA-regulated entries. FDA-regulated products imported into the US must comply with FDA's laws and regulations. The importer is responsible for making sure these products comply with all US requirements. Therefore, being proactive in understanding the nuances of regulations, required affirmations of compliance, useful documentation, and expectations to import is critical for preventing potential delays (or worse, refusal of goods). Products which do not comply with US requirements at the time of importation are subject to refusal of admission.

To help comply with CBP requirements, most importers hire a Customs Broker to act on their behalf to facilitate the importation process. By preparing the required information and accurate documentation to provide to a broker, a medical device importer can increase the likelihood of a smooth and timely importation process. This includes details such as product descriptions, product codes, intended use in the US, pertinent addresses of manufacturers, shippers, and importers, and the required affirmations of compliance (i.e., registration, listing, premarket notification/approval numbers, etc.).

The FDA Supplemental Guide outlines all data elements required to be provided in the transmission of an entry. Lastly, importers should be familiar with FDA's Import Alerts. Products and firms subject to Detention without Physical Examination (DWPE) will be detained and refused entry unless the importer can demonstrate that known violation(s) are not present in their product and/or that the root cause of the violation has been addressed to ensure a safe and effective product.

For an overview of medical devices and the requirements that FDA verifies and enforces at the time they are imported or offered for import into the US, visit the official Importing Medical Devices FDA website. Being proactive in understanding if your product is a medical device and identifying what are the applicable affirmations of compliance, requirements and regulations associated to the medical device and firm(s) is essential in facilitating the importation of the medical device.

An effective way to follow-up on an entry with FDA is to use the FDA's Import Trade Auxiliary Communication System (ITACS) as it allows the import trade community to upload entry documentation and any additional information requested by the FDA entry reviewer. You may check on the status of an entry via (ITACS) by using the US Customs and Border Protection (CBP) entry number. Additionally, ITACS allows trade to provide the location of goods for lines selected for examination and to view the expected lab completion date for those lines which have been sampled. Furthermore, when there are medical emergency situations associated to an entry, we encourage immediate communication to FDA as sometimes entry information transmitted do not capture the urgency.

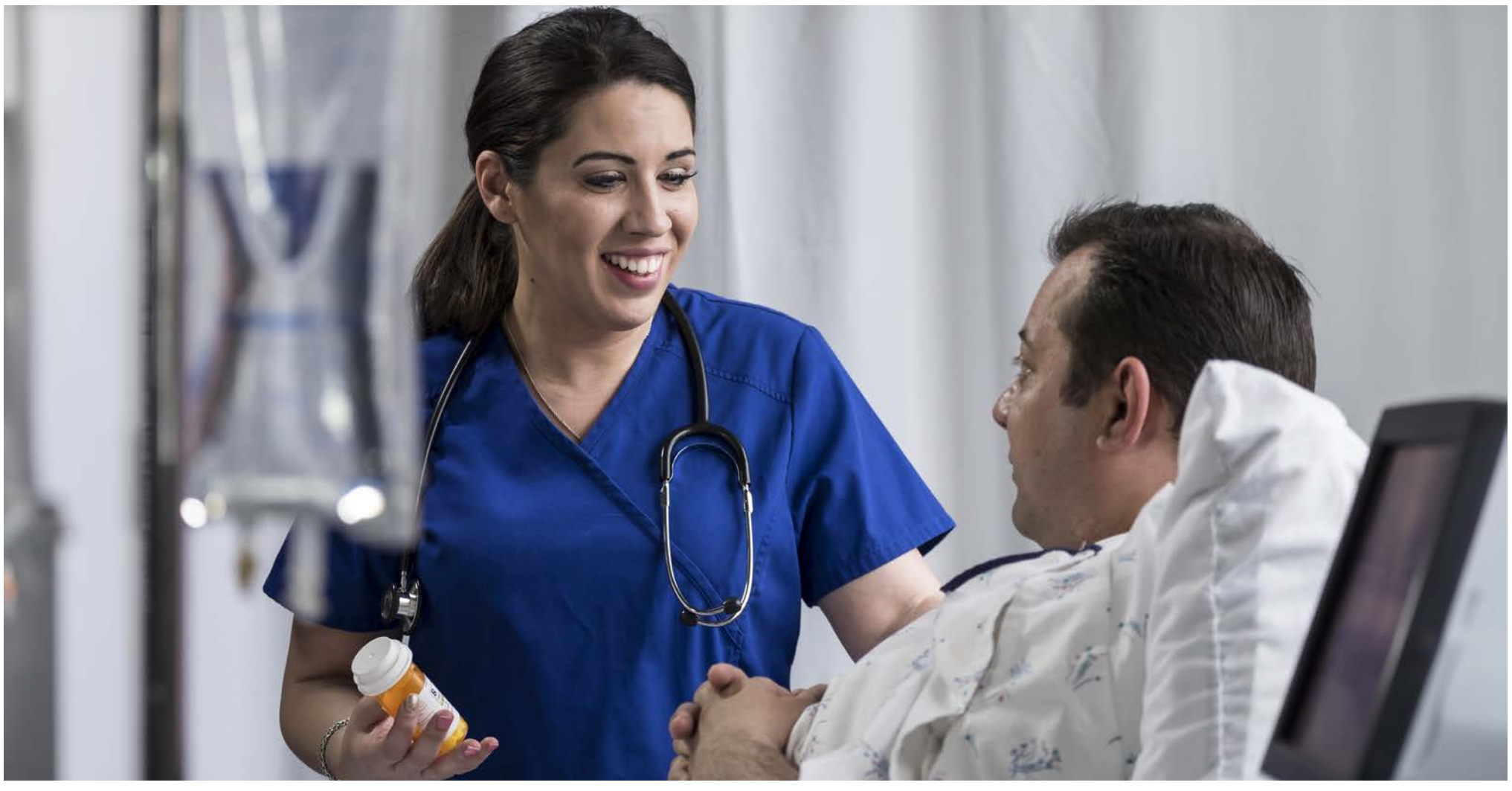
In conclusion, navigating the import process for medical devices requires an understanding of the product you wish to import, verifying the product and related firms meet regulatory requirements, and preparing the proper information for importation. By following these guidelines and leveraging available resources, importers can increase their chances of successful importation.

An effective way to follow-up on an entry with FDA is to use the FDA's Import Trade Auxiliary Communication System (ITACS) as it allows the import trade community to upload entry documentation and any additional information requested by the FDA entry reviewer.

Ruth Dixon is the Program Division Director, Division of Southeast Imports, Office of Regulatory Affairs, US Food and Drug Administration.

How to enter and seize opportunities in the US medical market

The key to success lies in building an optimal sales organization with the aid of dedicated reps to sell into the US' dynamic market.

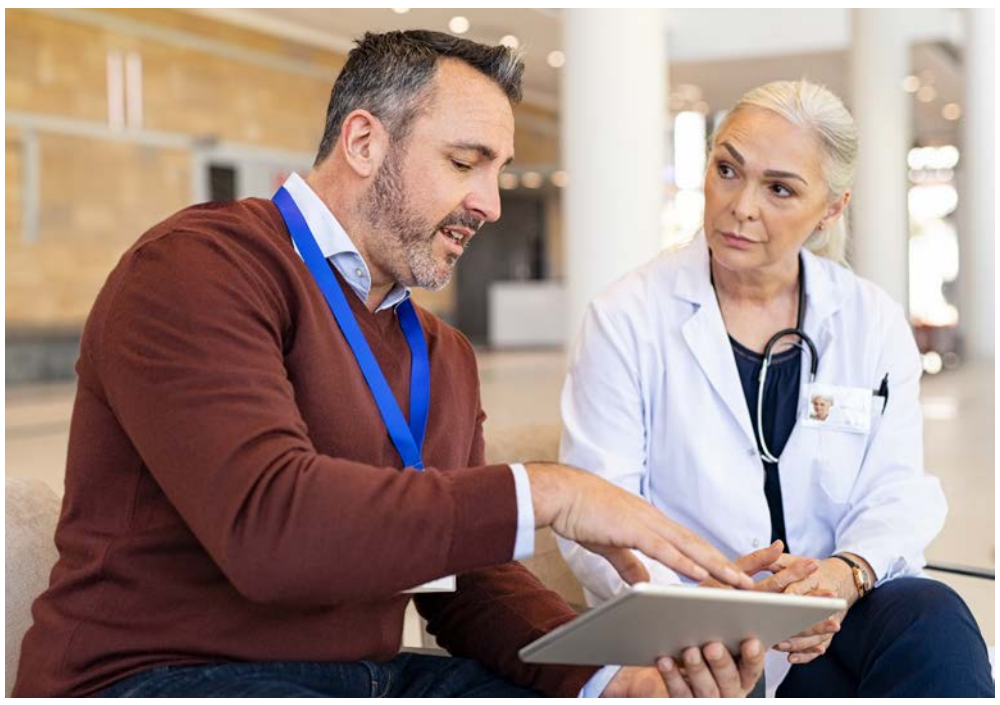


By Zach Selch

The United States medical market stands as a significant opportunity for international companies, given its immense size and profitability. With healthcare expenditures reaching $3.8 trillion in 2019, representing nearly half of global healthcare spending, the US market is indeed alluring. However, despite this substantial investment, the US healthcare system faces challenges in delivering quality care, with health outcomes often lagging behind those of other industrialized nations. This dynamic underscores both the promise and the complexity of entering the US market. This disparity drives the average margin for healthcare sales to over twice that of Germany – to over 70 per cent.

Entering the US medical market poses significant challenges, particularly in establishing the right sales organization. Estimates suggest that small foreign manufacturers should anticipate expenditures ranging from $2 million to $5 million over the first 36 months, highlighting the financial risks involved. Moreover, data indicates that over 80 per cent of international companies attempting to enter the US market fail to achieve profitability, emphasizing the importance of a well-thought-out strategy.

Often people consider the US regulatory landscape as the primary obstacle. While challenging, the regulatory process is predictable and not wildly different from other processes. There are thousands of very competent consultants who can achieve regulatory approval for you in a predictable timeframe and cost.

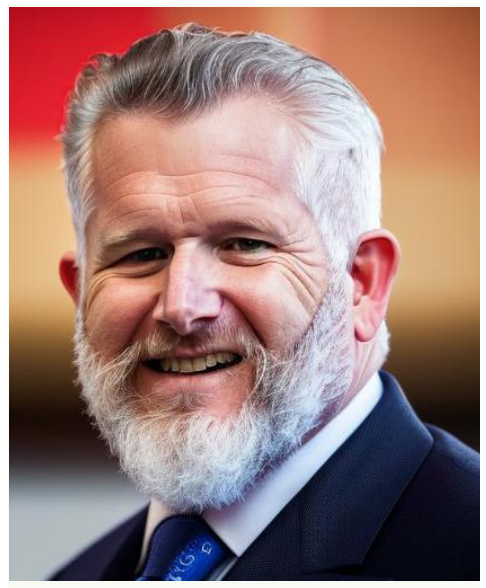


The primary hurdle, and one that is almost universally unexpected for international companies, lies in understanding the nuances of the US sales landscape. Unlike in many international markets where distributors actively sell and create demand, US distributors typically focus on order fulfillment, expecting others to generate demand. This fundamental difference can leave foreign companies perplexed, as they grapple with the need to build demand while navigating the intricacies of the market.

However, amidst these challenges lies a potential solution: the two-tiered approach to sales organization. By leveraging independent representatives for demand creation and distributors for logistics, companies can navigate the complexities of the US market more effectively.

Independent sales representatives, often referred to as reps, play a crucial role in the success of companies entering the US market. These professionals operate as contractors rather than employees, leveraging their extensive networks and industry expertise to promote and sell products on behalf of manufacturers. With established relationships across various market segments, independent reps possess invaluable insights into customer needs and preferences, enabling them to effectively communicate the value proposition of products to potential buyers. Their autonomy allows them to focus on specific territories or market segments, tailoring their sales approach to suit local preferences and market dynamics. By partnering with independent reps, companies gain access to a cost-effective and scalable sales force without the overhead costs associated with hiring and managing a direct sales team. Additionally, independent reps often bring years of experience and industry knowledge to the table, further enhancing their effectiveness in driving sales and market penetration.

In conclusion, while the US medical market presents its share of obstacles, it also offers significant potential for growth and profitability. The key to success lies in building a sales organization that can sell to the various government entities, the GPOs (that represent over 15 per cent of total buying power) as well as all the other potential customers that you face in this giant and profitable market. With careful planning and the right partners, international companies can seize the opportunities available in this dynamic market.



Zach Selch is an international sales growth leader, the Principal at Global Sales Mentor, and a trusted partner in navigating the complexities of the US medical market and achieving success in this lucrative arena.
He will be speaking at the main stage on June 20 at 11.50am.

Collaborate with startups and medtech companies to drive hospital innovation

Forging partnerships with firms like Digireha can help hospitals foster transformative advancements in healthcare delivery.

By Moeko Takagi

When designed for humans, AI and technology have the power to change lives. Digireha Inc., a digital healthtech company headquartered in Tokyo, Japan, is proving this by challenging innovation in rehabilitation through the use of gamification-based applications, sensors, and databases.

It all started when Yuki Oka, Founder and CEO of Digireha, came across a young girl Mako, who was diagnosed with Fukuyama-type congenital muscular dystrophy and suffering from unmotivating rehabilitation. Upon hearing her story, Oka developed the Digireha app to make rehabilitation more enjoyable.

In the early days, the tool focused on improving rehabilitation for children with special needs. Since then, it expanded its reach to serve the 2.4 billion patients around the world who need rehabilitation. The system has already been introduced in 80 hospitals and facilities in Japan alone. Furthermore, academic research is being conducted in cooperation with hospitals followed by the publication of academic papers.

From a startup company's perspective, partnerships between hospitals and medical device companies and startups can foster innovation and promote transformative progress in healthcare. There are three reasons for this:

First, through partnerships, we can bring innovation to the healthcare industry more quickly than ever before. Today's technology landscape continues to evolve at a dizzying pace, and digital transformation professionals will work together to open new possibilities.

The Digireha system, for example, quantifies a variety of pre- and post-rehabilitation information on a patient's rehabilitation and compares the patient's progress. These figures can be viewed on a dashboard in an easy-to-understand manner not only by medical professionals but also by patients' families and caregivers. This fosters an environment of better care for patients not only in the hospital but also in the community.

As part of its future vision, the application — based on patient big data — will have a real-time response function based on patient motivation and skills. Thereby we expect patient success stories and high self-esteem. We will motivate people who find it reluctant to come to the hospital and aim to create a positive environment to do their best through the power of digital technology.

Secondly, a new market can be expanded based on credibility, the network of the hospital and the startup's idea and ability to execute. Through the value of Digireha's services and its educational benefits, it can not only become indispensable to the market and its stakeholders but also create solid social value to facilitate the resolution of new issues.

The elderly, the sick, and children with special needs often feel socially isolated, which is why we must foster a sense of social solidarity and provide new social systems through digital technology. If people can manage their own digital health data and share it with those who need it, they can establish sustainable and extended support throughout their lives.

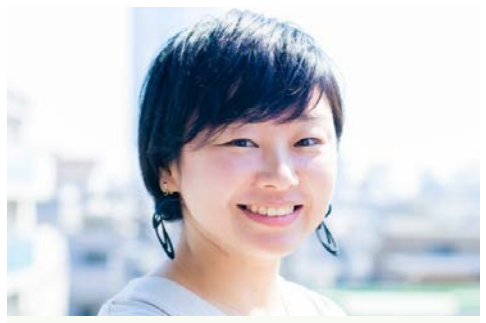
This is especially beneficial for parents of those with special needs, who are often concerned about who will take care of their children in the future when they are long gone. Such anxieties could be alleviated by the accumulation of data over the years, which could also increase the number of people who have a deep understanding of their children. Such an event can be considered not only for disabled children but also for elderly caregivers, and data can serve as a voice for them to deepen communication.

Finally, the most important objective is to increase people's well-being through the power of digital transformation. Digireha will expand overseas, starting with Delhi, India this year, and the United States in 2025. Based on the knowledge accumulated at hospitals and daycare facilities in Japan, Digireha's products will be delivered to the world.

Digireha currently conducts academic research through joint trial programs with research institutions and hospitals in the US, which makes it a reputable organisation to partner with and fosters a level of safety and security when localizing this product for people in the country.

We understand the challenges of the global healthtech market in the US and India, and growing from there, we aim to build on health to improve the well-being of many people and create a world where no one is left behind, especially the elderly, the sick, and children with special needs.

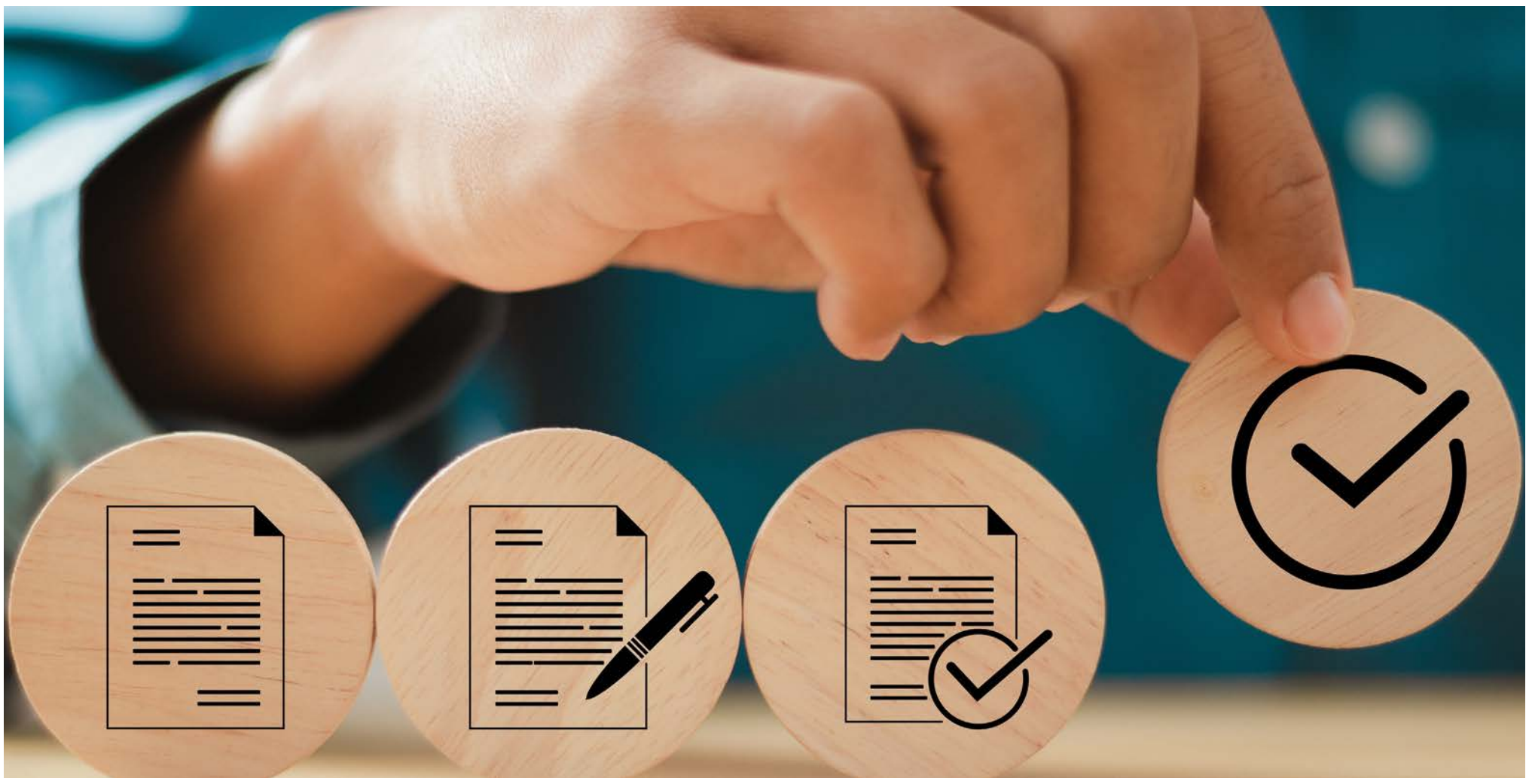
Technology can make our lives unhappy or happier, depending on how it is used. We at Digireha aim to be a health platform that supports all people around the world, fostering health and self-determination for all, including those with special needs, through technology. We believe that by partnering with hospitals and healthcare organizations, we can share our vision and create a better world.



Moeko Takagi is the Global Partnerships Division Manager at Digireha, Japan, and part of the panel, 'Driving Hospital Innovation: Collaborating with Startups & Med-Tech Companies' on June 19 at 11.20am.

Four common mistakes startups make when submitting to the US FDA

Expert tips to avoid errors that could be costly, and delay product launches in the medical device market.



By Tracy Eberly

While medical device startups may have innovative ideas and technologies, they face significant hurdles in obtaining regulatory approval compared to well-established corporations. Some of these challenges are due to the complex and stringent nature of the regulatory environment, resource constraints, and regulatory inexperience. Throughout my 30-year career in the device space, I've worked with hundreds of startups and have compiled a few costly mistakes companies should avoid making.

Not involving a regulatory affairs professional in the early development stages

Developing a medical device without regulatory affairs input often leads to delayed launch and increased costs. The complexity of the US FDA and EU regulations and standards can be confusing for startup companies. Regulatory affairs professionals can guide you on the eventual classification of your device, which defines the level of documentation required to obtain approval.

Identifying and mitigating risks early in the development process is also essential for ensuring the safety and efficacy of the medical device. Regulatory affairs professionals can help assess regulatory risks associated with the device's design, intended use, manufacturing processes, and clinical data requirements. We advise clients to check in with regulatory professionals early and often when designing a new medical device.

Underestimating the cost of bringing a medical device to market

The costs associated with bringing a medical device to market are substantial. Depending on the device's risk classification, companies can expect to spend hundreds of thousands, if not millions, of dollars as they take their device from concept to clearance. Understanding the costs associated with regulatory compliance, product development, manufacturing, clinical trials, and marketing allows manufacturers to create realistic budgets and secure adequate funding.

Companies risk underestimating their financial needs without a clear understanding of these expenses, leading to funding shortages and delays in product development or market entry. Cost estimation provides insight into potential financial risks associated with the development and commercialization process.

Manufacturers can identify areas where costs may exceed projections and develop contingency plans to mitigate financial risks. Additionally, understanding the cost implications of regulatory requirements helps companies assess the feasibility of bringing their device to market within budgetary constraints.

Overly broad or unsubstantiated claims

The US FDA and EU regulatory bodies require medical devices to undergo rigorous testing and evaluation to ensure their safety and effectiveness. The Indication for Use for the device must be focused and accurate. Making your Indication for Use overly broad risks rejection from your approval authority. We often advise clients to apply for a narrow indication on their first submission and then expand that indication on subsequent submissions.

Making exaggerated or unsupported claims about a medical device's capabilities raises concerns. Marketing material must balance a fine line between "fluff" and unsubstantiated claims. Off-label usage does occur, but device manufacturers are prohibited from marketing a device for any use other than the approved Indication for Use. Engaging in misleading marketing practices undermines the ethical responsibility healthcare providers uphold and can harm patients by promoting ineffective or unsafe treatments.

Making multiple unsubstantiated claims about a medical device can have severe consequences for startup companies, including regulatory sanctions, legal liabilities, damage to reputation, market rejection, loss of investor confidence, and ethical concerns. Startups must prioritize transparency, integrity, and evidence-based communication when promoting their products in the healthcare industry.

Weak document control and quality management system

The US FDA and the EU regulatory body require medical device manufacturers to establish and maintain robust quality management systems (QMS) to ensure the safety and effectiveness of their products. A weak QMS can lead to non-compliance with regulatory requirements, potentially resulting in delays in product approval or market withdrawal. Document control and QMS are essential for maintaining the integrity of critical documents, such as design specifications, manufacturing procedures, and quality records. Without effective document control, companies risk using outdated or incorrect documents, which can compromise the safety and efficacy of the medical device.

A weak QMS may also lead to inconsistencies in product quality and performance. Document control and QMS are crucial in identifying, assessing, and mitigating risks associated with developing, manufacturing, and distributing medical devices. Inadequate document control makes it difficult to track changes and updates, increasing the likelihood of errors or deviations that could pose risks to patient safety. A weak QMS may also result in inadequate risk management practices, leaving the startup vulnerable to potential hazards and liabilities.

Traceability is essential in the medical device industry to ensure accountability and facilitate recalls or corrective actions when necessary. A robust document control system enables the startup to track the history and status of documents throughout their lifecycle, including revisions, approvals, and distribution.

Without proper document control, tracing the origin and handling of critical documents becomes challenging, impeding the ability to effectively address quality issues or regulatory inquiries.

Tracy Eberly is the Founder and CEO of Fang Consulting. His session, 'We Put the No in Innovation' will take place on June 19 at 3.30pm.

US hospital leaders believe in the power of AI and analytics, Zebra Study

The findings also underscore the need for hospitals to ensure real-time availability of medical assets for optimal patient care.

Zebra Technologies Corporation, a leading digital solution provider enabling businesses to intelligently connect data, assets, and people, recently announced findings of its latest hospital vision study titled, Critical Supplies, Critical Outcomes: The Quest for Excellence in Materials Management. The study confirmed most (84 per cent) US and UK non-clinical hospital leaders believe integrating automated and digitised inventory tracking systems of anything used or administered at patients' bedsides is a priority for their organisations.

Hospital asset inventories must be managed precisely to ensure clinicians have the essential supplies, equipment, and medications readily available to provide the best patient care. Yet materials management is an ongoing challenge for hospitals which can impede positive outcomes. A McKinsey report indicates nurses expressed the desire to reduce time spent searching for medical assets by half during shifts to increase their ability to focus on patient care.

Seven in 10 (74 per cent) hospital leaders surveyed acknowledge procedures or surgeries canceled due to out-of-stock, low-stock, or lost supplies is a significant problem for their organisations. Additionally, over three-fourths (77 per cent) of them agree clinical staff spend too much time searching for medical equipment, materials, or supplies when needed, and 75 per cent say it's a challenge to recover all recalled or expired items.

There is also a lack of faith in clinicians' reporting systems to track adverse events resulting from inventory issues. Seven in 10 (76 per cent) hospital leaders agree their organisations need to improve systems for clinicians to report problems relating to out-of-stock, low-stock, or lost inventory, equipment, or supplies to improve patient safety. Technology and digital solutions can help reduce inventory and reporting issues by providing enhanced tracking, visibility, and forecasting capabilities.

"Hospital staff must be able to identify, track, and capture the location and status of critical resources in real-time," said Rikki Jennings, Vertical Industry Principal Lead, Zebra Technologies. "That's why we see rapid investment in location and automation solutions. Non-clinical hospital leaders working in new ways with technology behind the scenes can help improve the workflows of front-line clinicians and enhance the patient experience."

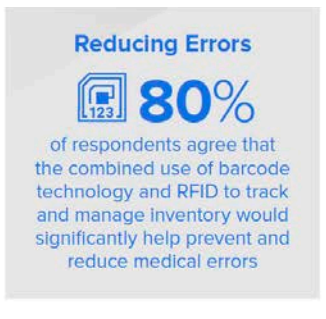
Digitisation of inventory management helps boost efficiency and patient care

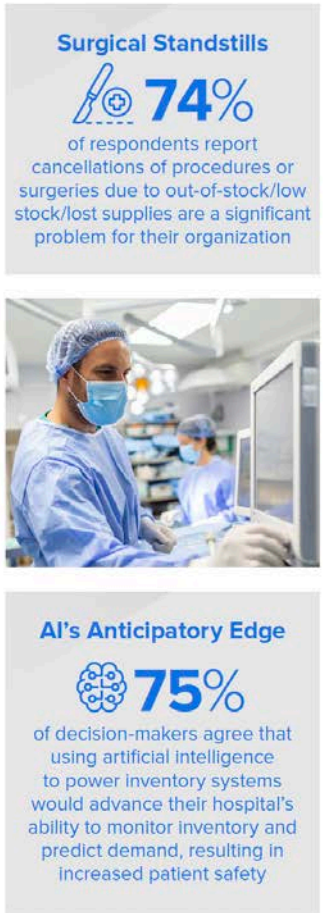
Hospital leaders have a significant impact on clinical staff and the delivery of patient care.

Zebra's study revealed a link between hospital leaders' materials management and clinicians' efficiency, productivity, and ability to provide the best patient care.

They must ensure medical supplies, equipment, and medication are visible and accessible. Most (84 per cent) hospital leaders acknowledge their role and responsibility in tracking and managing hospital inventory directly impacts patient safety.

A substantial nine in 10 hospital leaders agree it's vital to track inventory in real-time across categories including pharmaceuticals, consumable/medical supplies, sterile instruments, and implants. Over half of those surveyed believe real-time location systems (RTLS) and radio frequency identification (RFID) will improve inventory management. Nearly seven in 10 hospital leaders indicate they plan to deploy RFID (68 per cent) and RTLS (69 per cent) solutions within the next five years.





The Zebra study also confirmed that outdated or disparate inventory systems get in the way of accurately managing inventory. Four in 10 hospital leaders agree the most challenging workflows are manual cycle counting in clinical storerooms/wards, lack of real-time recording of supply use in surgical spaces, and order fulfillment or replenishment of items in central storerooms.

Hospitals leveraging technology and digitization can strengthen hospital workflows, benefiting physicians, nurses, support staff, and patients alike. Eight in 10 hospital leaders believe real-time location tracking is essential to optimal patient care. They also agree the combined use of RFID and barcode scanners to track and manage inventory would significantly help prevent and reduce medical errors.

Artificial Intelligence (AI) adds more inventory visibility and accuracy

Hospital leaders believe in the power of AI and analytics. In fact, eight in 10 say AI would improve inventory accuracy and visibility in their organisations. About seven in 10 agree predictive analytics (73 per cent) and prescriptive analytics (65 per cent) would also improve inventory management. AI analytics solutions can help forecast inventory needs using historical data to help make more informed and accurate decisions. Hospital leaders are expanding their implementation of AI solutions: three in 10 say they currently deploy AI, and six in 10 say they expect to deploy it over the next five years.

Nearly eight in 10 (78 per cent) hospital leaders also say it's a priority to use data and analytics to improve materials management. They agree using AI would advance their ability to monitor and predict demand, resulting in increased patient safety. While only 14 per cent say they are currently using advanced analytics and demand forecasting to predict inventory needs, 82 per cent expect to deploy it within the next one to five years.

Survey background and methodology

Zebra commissioned Azure Knowledge Corporation to conduct an online survey among 280 non-clinical decision-makers in large hospitals (1,000+ beds) in the United States and the United Kingdom. These respondents are responsible for overseeing one or more of the following inventory categories: medical devices, durable medical equipment, implants, consumables, medical supplies pharmaceuticals, or sterile instruments.

References available on request.

Hospital leaders recognise the criticality of managing inventory in real time and are turning to RFID, RTLS, and AI analytics to improve tracking, visibility, and accuracy.

The role of integration in achieving true digital health transformation

A strategic approach to integration involves investing in interoperable systems, fostering a culture of innovation, and ensuring compliance with data protection regulations.

By James Davis

In today's healthcare landscape, the integration of various technological systems is crucial for achieving true digital health transformation. Today, it is essential to understand how integration serves as the cornerstone of modern healthcare innovation, ultimately enhancing patient outcomes and operational efficiency.

Integration in healthcare involves the seamless combination of various information systems and technologies to create a unified platform for data exchange and workflow management.

True digital health transformation requires more than just technological advancements; it necessitates a cultural shift and strong leadership to foster collaboration across different healthcare sectors when approaching this challenge from an integrated care perspective. Success in interoperability depends on three critical aspects: technology, relationships, and an enabling environment. W.N. Leutz's five laws for integrating medical and social services provide a valuable framework for understanding the complexities of integration and highlight the importance of aligning policies, resources, and stakeholder engagement to drive successful integration initiatives (Leutz, 1999).

Integrated systems provide healthcare providers with immediate access to comprehensive patient records. This access is critical for making informed decisions and reducing medical errors. For instance, when a doctor can review a patient's history, current medications, and lab results in real time, the care provided is more accurate and timely.

Moreover, integration improves patient engagement. Patients can access their health information through portals, schedule appointments, and communicate with their providers more efficiently, fostering a more patient-centric approach, more on both of these scenarios later.

Operational efficiency

From an operational perspective, integration reduces redundancy and optimises resource use. Administrative tasks such as billing and scheduling, often bogged down by inefficiencies, can be streamlined. Automating these processes and ensuring system interoperability reduces costs and enhances service delivery.

Integration also supports advanced analytics and data-driven decision-making. Aggregating data from multiple sources allows healthcare organisations to gain insights into population health trends, identify areas for improvement, and implement targeted interventions. This capability is especially crucial in public health settings, where resource allocation and policy decisions must be based on accurate and comprehensive data. Whilst these benefits seem clear, the incentives for it to happen vary from one geography to the next and are a key driver as to why some countries have well-utilised HIEs and others have none.

Cultural and organisational integration

True digital health transformation requires more than just technological advancements; it necessitates a cultural shift and strong leadership to foster collaboration across different healthcare sectors when approaching this challenge from an integrated care perspective. Success in interoperability depends on three critical aspects: technology, relationships, and an enabling environment.

Integration in healthcare goes beyond mere technological challenges and encompasses people, processes, and cultural shifts within healthcare settings. C. Auschra's literature review on the barriers to integration highlights that organisational culture and inter-organisational relationships are significant obstacles that need addressing to achieve successful integration (Auschra, 2018).

1. Technology: Systems must communicate and share data effectively. This includes adopting standards for data capture and sharing, addressing technological fragmentation, and simplifying multiple approaches to data sharing.

2. Relationships: Building trust and fostering good working relationships between staff across various organisations is essential. This involves recognising the benefits of interoperability and creating digital 'champions' who lead and promote digital transformation initiatives within their organisations, with a tight grasp on the governance of data.

3. Enabling environment: Aligning funding, capacity, skills, education, and governance supports interoperability efforts. This includes ensuring that staff have the necessary skills and training to use digital tools effectively, that there is sufficient funding for digital transformation projects, and that national policies support interoperability initiatives.

Why integration in healthcare is not quite so easy

While the benefits of integration are clear, achieving it is not without challenges. These include technical barriers, organisational resistance, and data privacy concerns. A strategic approach to integration involves investing in interoperable systems, fostering a culture of innovation, and ensuring compliance with data protection regulations. Collaboration with technology providers, as showcased at FIME, plays a crucial role in overcoming these hurdles. Let's take a brief look at four key hurdles to overcome:

Technical barriers: One primary barrier is the fragmentation of healthcare systems. Many organisations use different EHR systems with varying data standards and protocols, complicating data sharing. Adopting common data standards and ensuring system interoperability can address this issue. Additionally, integrating legacy systems with modern technologies can be complex and costly, but necessary for achieving true interoperability.

Organisational resistance: Resistance to change is another significant challenge. Healthcare providers may be reluctant to adopt new technologies or change workflows, particularly if they are accustomed to existing systems. Engaging staff in the transformation process, providing training and support, and demonstrating the benefits of integration can help overcome this resistance.

Data privacy and security: Data privacy and security are critical concerns. Implementing robust data protection measures, such as encryption, access controls, and regular security audits, is essential for safeguarding patient data. Healthcare organisations must also comply with regulations like the GDPR in the EU and HIPAA in the US, which set stringent requirements for handling patient data.

The role of national policies: National policies play a crucial role in driving interoperability initiatives. For example, the NHS Long Term Plan in the UK aims to improve interoperability by focusing on access to records for patients and clinicians. Similarly, the US Office of the National Coordinator for Health Information Technology (ONC) has established standards and frameworks to facilitate data sharing across healthcare systems.

Transformative Impact: A Holistic View

Improved patient outcomes

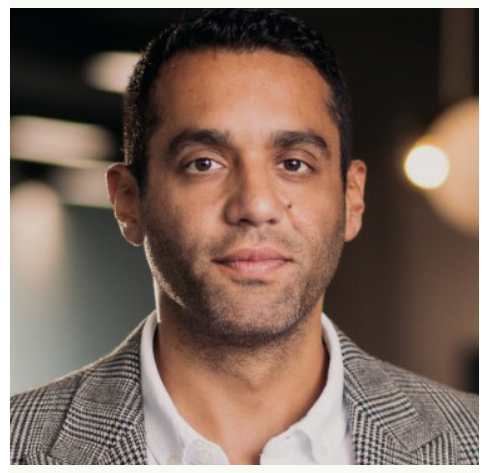
- Reduction in medical errors: Integrated systems reduce the risk of errors by providing complete patient information at the point of care.
- Enhanced chronic disease management: Continuous monitoring and data integration enable better management of chronic diseases, leading to improved patient outcomes and quality of life.
- Increased patient satisfaction: Empowering patients with access to their health information and engaging them in their care journey increases satisfaction and adherence to treatment plans.

Enhanced operational efficiency

- Optimised resource utilisation: Streamlined workflows and reduced administrative tasks free up resources for direct patient care.
- Cost savings: Reducing redundant tests, avoiding medical errors, and improving care coordination lead to significant cost savings for healthcare providers.
- Scalable solutions: Integrated systems provide a scalable solution that can adapt to the evolving needs of healthcare organisations.

Technical barriers, such as the fragmentation of healthcare systems and the complexity of integrating legacy systems, are well-documented obstacles. Organisational resistance and data privacy and security are additional challenges that require robust data protection measures and compliance with regulations like GDPR and HIPAA. I truly believe that by embracing integration, we pave the way for a more efficient, patient-centric, and data-driven future in healthcare, ultimately leading to better patient care and sustainable health systems globally.

References available on request.



James Davis is the CEO of Inicio Health, UK, and part of the panel, 'Driving Hospital Innovation: Collaborating with Startups & Med-Tech Companies', which takes place on June 19 at 11.20am.

Insights into regional medical devices regulatory affairs to reach LATAM

Selecting a skilled and suitable regulatory partner is critical for tapping into the Latin American market. Sidelining regulatory issues may lead to serious risks for companies.

By Mónica Mabel Guaita and Magdalena Ferrari del Sel

The Latin American region comprises 20 countries (depending on classification/ sources), many of which are categorized as emerging countries with a population that is estimated to have reached 657 million people as of 2024 (CEPAL).

The Latin American market, with several local manufacturers, has outstanding world-renowned professionals who are highly trained in using the latest technology, research and development. Therefore, the region shows a strong trend as an import market for high-tech medical equipment and medical devices.

These are some of the reasons why the Latin American market represents a region of strategic interest for building alliances with qualified partners who have experience in such markets. Disregarding the regulatory issues may imply significant risks for companies that wish to enter the Latin American market. Choosing a skilled and suitable regulatory partner plays an important role in this enterprise and selecting the right one is critical.

Regulatory clearance is a prerequisite for manufacturers to get access to new markets. Latin America poses a challenge for medical device registration as each country has its regulatory legislation or its particular way of applying the same legislation, as it happens among different Mercosur countries.

Although there are different regional trade agreements in force — Free Trade Agreements, Trade blocks, Common Markets, etc. like Mercosur, ALCA, and Pacific Alliance (Alianza del Pacífico) — these agreements do not comprise all countries in Latin America nor have a direct correspondence with a single product regulatory clearance as it happens in the European Union and its medical devices regulations applicable throughout the community and the CE marking.

It may also happen that some countries in this region issue legislations, but these are not applied, or are partially applied taking into account the available resources at the moment of application and/or political and economic changes that impact the system.

Besides, sometimes regulations and requirements to access the Latin American markets change and new requirements are gradually incorporated or are based on practical experience acquired by local RA on the go. This situation, combined with the fact that when the government changes there might be turns in high-level public positions, may result in changes in management and implementation of regulations.

Another aspect that should be considered is the different legislation frameworks regarding medical product license ownership. In general, manufacturers are usually concerned about keeping control of their product licenses and it is exactly at this point where good regulatory advice is fundamental to avoid future problems related to product importation and marketing issues.

MMGC SRL offers manufacturers the possibility to address this issue by thinking together about their regional regulatory strategy and supporting them to make the right considerations to choose among the different holding options possible based on each local legislation.

In MMGC SRL, we usually see that clients launching in the region have an in-house regulatory staff strongly oriented to, and highly specialized in, European medical devices regulations (MDR), FDA regulations or others. However, when entering the Latin America region, they are not familiar with the local healthcare regulations.

In such cases, we recommend they seek support by outsourcing their Regulatory Affairs Management in the region, particularly at the beginning. In this way MMGC usually works by centralizing the regional regulatory issues in close cooperation with their in-company staff to define the best regulatory strategy for each country and, as we share the same regulatory language, the communication among the people involved is fluent.

Currently, several Latin American regulatory agencies are gradually migrating from long and heavy paper-based procedures to online submissions for medical device registrations and license renewals. Nevertheless, as mentioned above, the implementation of these updates is usually gradual and highly based on practical experience acquired on the go by the regulatory authority.

To manage medical device registrations efficiently, it is critical to have expertise and knowledge of these local characteristics.

On the other hand, there are some common guidelines that allow to group countries and manage regulatory issues of Latin American countries in a centralized way.

Centralized Regional Management of Regulatory Affairs offers advantages and avoids extra costs and delays in registrations. In addition, manufacturers have the option to start with one Latin American country of interest and to expand the market to other countries afterwards, therefore optimizing the use of documentation.

MMGC SRL is a Consultancy Company that specializes in Medical Device Regulatory Affairs, a company composed of a multidisciplinary team of professionals that combines training and more than 25 years of expertise from public and private sectors. We have extensive experience working with international medical device companies to gain regulatory access to markets in Latin America. The tailored-service approach we offer enables us to provide solutions to large, medium and small-sized companies, as well as to serve local and international businesses and local direct distributors.

Monica Mabel Guaita

Monica Mabel Guaita is the CEO and Founding Partner of MMGC SRL (a regulatory affairs consulting firm), and **Magdalena Ferrari del Sel** is a Regulatory Affairs International Senior Consultant. Monica will speak on June 20 at 11.15am as part of the "Main Regulatory Issues for LATAM — How to Surf LATAM's Regulatory Issues" session.

Next generation wearables set to transform patient care

Advanced wearables may provide the ideal solution to address the rising burden of chronic diseases.

By Neeraj Nitin Jadhav

In the past few years, wearables have carved out a significant space for themselves as they have evolved from promoting wellness to strengthening lives and outcomes. The COVID pandemic has played a pivotal role in accelerating the demand for wearable devices as more people have recognised the importance of assessing and monitoring their health remotely using these devices. An estimated 1.1 billion users worldwide used wearables in 2022, which is expected to increase further and help in offering global healthcare cost savings of US$200 billion in the near future.

As wearables grow in popularity, the devices are witnessing drastic changes to their form and making them an intricate part of our daily lives. Rather than looking like a watch, or fitness band, the next generation wearables are taking the form of clothing, headsets, or unobtrusive skin patches. Furthermore, aside from diverse form factors, these devices are incorporating different components such as various sensing technologies including electrochemical sensors and colorimetric sensors, artificial intelligence (AI)/machine learning (ML) algorithms, ultrasound transducers, electrodes, and drug delivery mechanisms.

This integration of sophisticated components has allowed next generation wearables to offer continuous and long-term health monitoring as well as on-demand therapy as compared to just tracking steps taken or calories burned provided by the earlier generation wearables. With individuals becoming more tech-savvy coupled with heightened health awareness levels, there is an increased demand for devices that can monitor the user's health, provide insights, and also improve health outcomes.

The next generation wearables are making deeper inroads in our lives and in the process drastically changing the healthcare landscape. By personalised, moment-to-moment health analysis, individuals can detect clinical deterioration in early stages and subsequently take proactive steps to prevent them from occurring. Clinicians can remotely monitor their patients' health data, resulting in fewer in-person visits while allowing them to optimise their workloads. Furthermore, remote monitoring of patients' vitals also minimises hospital readmissions, thus reducing healthcare costs for the providers. The high burden of chronic diseases responsible for causing 74 per cent of all annual deaths globally is creating an urgent need for a more decentralised healthcare system and the next generation wearables seem to be the ideal solution to address this need owing to their ever-increasing applications in patient monitoring, diagnostics, and therapeutics.

Next generation wearables as tools for monitoring and therapy

Improved disease monitoring

Next generation wearables such as skin patches or clothing embedded with multiple sensors are being used to monitor parameters such as heart rate, body temperature, as well as levels of different body analytes. The data generated by these sensors is then analysed by AI/ML algorithms to provide insights into an individual's health status. Through the use of gentle nudges and personalised notifications, these devices are enabling positive behavioural changes in users by motivating them to maintain healthy lifestyles, facilitating nutritional modifications, and encouraging them to get adequate sleep.

This continuous engagement is transforming the value of health among individuals from a periodic concern to a day-to-day commitment, emphasising the importance of proactive measures over reactive interventions.

For example, RDS SAS, has developed a multi-sensor wearable patch to continuously monitor levels of vitals such as heart rate, skin temperature, and respiration rate in patients and provide notifications about the early signs of clinical deterioration to the individuals and enable clinical actions to be taken for improving their health.

With individuals becoming more tech-savvy coupled with heightened health awareness levels, there is an increased demand for devices that can monitor the user's health, provide insights, and also improve health outcomes.

Body conformable skin patches are also being evaluated for continuous monitoring of wound healing status in the patients. For instance, researchers at the National University of Singapore have developed a paper-thin skin patch that can continuously track different wound biomarkers with 97 per cent accuracy to determine if the wounds are healing properly and detect wound infections. The skin patch can significantly improve the quality of wound care and prevent incremental treatment costs for the patients.

Wearable ultrasound monitors, in the form of patches, are being developed that can image organs within the body, such as the heart, kidneys, or bladder, without the need for an ultrasound operator. The ability of the wearable ultrasound patches to remain adhered to the skin while enabling continuous imaging has facilitated their use in areas including assessment of cardiac health, monitoring foetal growth, diagnosing musculoskeletal injuries, and early detection of anomalies, including cancer. Pulsify Medical has developed an ultrasound skin patch for continuously and accurately measuring and monitoring an individual's cardiac performance, including cardiac output, on a long-term basis.

Therapeutics through Next Gen Wearables

Neuromodulation therapy

Through use of neuromodulation, next generation wearables in the form of headsets, sleeves, socks, and ankle-worn garments are playing a pivotal role in the effective management of chronic conditions such as mental disorders, chronic pain, urological and neurological conditions. The devices use neuromodulation technologies such as transcranial direct current stimulation and peripheral neurostimulation for selectively stimulating specific brain regions as well as nerve pathways to enhance cognitive function, modulate psychiatric symptoms, control bladder functions, and reduce pain. These devices also incorporate sensors for detecting noxious nerve signals and accordingly deliver adaptive personalised stimulation using AI algorithms that are customised to the patients' needs.

Drug delivery

Wearable drug patches that facilitate subcutaneous drug delivery through use of dissolvable microneedles or ultrasonic waves are emerging as a pain-free method for drug administration. Delivering drugs through the skin is an appealing route for drug administration as it enables good drug bioavailability which is essentially useful for wound healing, pain relief, and treatment of skin cancers. Furthermore, subcutaneous drug delivery offers less systemic toxicity and is more local, comfortable, and controllable. For example, researchers at the Massachusetts Institute of Technology are developing a wearable patch that uses ultrasonic waves for targeted, painless drug delivery through the skin for treating a variety of skin conditions.

Current roadblocks and the path ahead

Concerns related to unauthorised access to patients' health data can significantly impact the adoption of next generation wearables. Insecure wireless connectivity as well as cloud storage of patients' vital information can make them vulnerable to cyberattacks. Use of multi-layer security framework in the next generation wearables that uses automated tools to quickly detect any potential attempts to gain unauthorised access to patients' data or device controls can help in preventing sophisticated attacks. Furthermore, deployment of wearable biometric security that allows only authorised users to access patients' data or device functions using their unique physiological characteristics can also help in reducing cybersecurity risks.

Issues related to limited battery life are preventing the use of these devices for longer durations. To overcome this challenge, deployment of different energy harvesting mechanisms such as triboelectric energy, or biofuel that can harness energy from different sources including patients' motion, or body fluids can be considered to power these devices. Researchers at the University of North Texas have developed a wearable sensor that generates electrical energy when bodily fluids repeatedly come into contact with a charged electrode that is, in turn, used to power the device.

The shift towards battery-free, self-powered, next generation wearables will truly be a game changer as they will address some of the pertinent issues faced by users such as the battery dying at inconvenient times or the hassle of regularly charging them.

Key growth opportunities for next generation wearables

Since the next generation wearables space is highly competitive, and constantly evolving, it is essential that the developers adopt a sustainable monetisation model that drives recurring revenues. Wearable companies can focus on shifting from the current hardware sale model to recurring revenue models like subscriptions related to wearables' premium features such as advanced analytics, and personalised coaching, which can deliver more consistent and reliable revenue streams for them.

Digital biomarkers generated from the next generation wearables can be used by healthcare providers to predict patient readmissions and accordingly deliver appropriate therapies for given patients at the appropriate time.

Through the use of predictive analytics, past and current patient health data obtained from these devices can be used to gain a comprehensive understanding of disease patterns, population health trends, and treatment outcomes.

This vital information can be used by the government to draft proactive public health measures and evidence-based healthcare policies in order to effectively tackle future epidemics. Furthermore, the digital biomarkers generated from the next generation wearables can be used by healthcare providers to predict patient readmissions and accordingly deliver appropriate therapies for given patients at the appropriate time. Payers can employ digital biomarkers to further stratify patients and build personalised treatment plans, including prior authorisation schedules.

Device manufacturers should also partner with health insurance companies to offer discounts on health insurance premiums or other incentives to patients using these devices. This approach offers a win-win deal for the patients as they save on health insurance premiums while also maintaining good health.

Conclusion: Ushering personalised, holistic healthcare through next generation wearables

At present, next generation wearables are empowering patients with knowledge, tools, to improve their health. They are also aiding healthcare professionals in the early detection of diseases, enabling them to provide timely, personalised treatments to patients. In the future, they will cease to be mere devices and will act as catalysts of global healthcare renaissance, heralding an era of proactive and effective health management.

Neeraj Nitin Jadhav is the Industry Analyst, TechVision at Frost & Sullivan.

Unraveling the complexity: Navigating the US healthcare system's sales cycle

Collaborative ventures aimed at streamlining procurement processes, optimizing resource utilization, and driving innovation have yielded tangible dividends. Read on to discover more.

By Kenneth C. Wong

In the realm of healthcare economics, the United States stands as a pivotal case study, juxtaposed between soaring expenditure and fluctuating outcomes. As we delve into the labyrinth of statistics, policies, and partnerships, a nuanced understanding of the American healthcare landscape emerges.

The US allocates a staggering chunk of its GDP to healthcare spending, far outstripping its global counterparts. Roughly 17.7 per cent of the nation's GDP is funneled into healthcare, as per the latest data. This figure, while emblematic of the country's commitment to healthcare, places it at the zenith of global healthcare expenditure. Comparatively, countries like Switzerland and Germany trail behind, dedicating around 12 per cent and 11 per cent of their GDP, respectively, to healthcare.

Yet, juxtaposed against this colossal spending, the question arises: Are Americans reaping commensurate benefits in terms of health outcomes? Regrettably, the answer is a resounding NO. Despite its lavish investment, the US lags behind its peers in several key health metrics. Life expectancy, infant mortality rates, and preventable mortality rates all paint a sobering picture of subpar health outcomes.

A deeper dive into the American healthcare infrastructure reveals a labyrinth of hospitals and healthcare systems. The US boasts over 6,200 hospitals, ranging from small community clinics to sprawling medical centers. These institutions wield significant purchasing power, collectively spending billions annually on supplies directly tied to patient care. Major manufacturers and suppliers such as Johnson & Johnson, Medtronic, Medline, Cardinal Health, and GE Healthcare dominate this intricate supply chain, supplying everything from MRI machines to sutures to disposable syringes.

However, amidst this bustling marketplace, a paradigm shift is underway. Innovations geared towards monitoring hospital spending and clinical outcomes are gaining traction. Advanced analytics platforms and AI-powered solutions offer tantalizing prospects for optimizing resource allocation and enhancing patient care. By scrutinizing expenditure patterns and clinical data, healthcare providers can pinpoint inefficiencies and drive tangible improvements in patient outcomes.

But how does the US government ensure accountability and quality amidst this complex web of transactions? Enter core measures — a set of standardized metrics designed to evaluate clinical performance across various domains. These measures, endorsed by organizations like the Centers for Medicare & Medicaid Services (CMS), serve as yardsticks for assessing the quality of care delivered by hospitals. From mortality rates to readmission rates, these metrics offer invaluable insights into the efficacy of healthcare delivery.

Yet, for suppliers and manufacturers navigating the intricate landscape of US hospitals, challenges abound. Stringent regulations, fierce competition, trade wars, and reimbursement uncertainties pose formidable barriers to entry. The selling process itself is often protracted and multifaceted, involving intricate negotiations and rigorous product evaluations. Success hinges not only on the quality and efficacy of the product but also on forging robust partnerships with healthcare providers.

Amidst these challenges, however, glimmers of hope emerge in the form of exemplary partnerships between hospitals and vendors. Collaborative ventures aimed at streamlining procurement processes, optimizing resource utilization, and driving innovation have yielded tangible dividends. From implementing just-in-time inventory systems to co-developing cutting-edge medical technologies, these symbiotic relationships underscore the transformative potential of strategic collaboration.

The evaluation and adoption of medical supplies and services for hospitals involve a diverse array of stakeholders, each playing a crucial role in the decision-making process. Here are the key stakeholders typically involved:
Hospital Administrators and Executives: Hospital administrators and executives hold ultimate responsibility for the procurement decisions within the hospital. They oversee the strategic direction of the institution, including budget allocation and resource management. Their input and approval are essential for the adoption of new medical supplies and services.
Clinical Staff and Physicians: Clinical staff, including physicians, nurses, and other healthcare professionals, play a vital role in evaluating the efficacy and usability of medical supplies and services. Their firsthand experience with patient care informs their feedback on the suitability of different products and their impact on clinical outcomes.
Supply Chain, Materials Management, and Procurement Teams: Supply chain, materials management and procurement teams are responsible for sourcing, purchasing, and managing inventory of medical supplies and services within the hospital. They collaborate closely with clinical staff to assess needs, evaluate vendors, negotiate contracts, and ensure timely delivery of supplies.
Quality Improvement and Patient Safety Teams: Quality improvement and patient safety teams focus on ensuring that medical supplies and services meet established quality standards and contribute to positive patient outcomes. They may conduct evaluations, audits, and assessments to monitor the performance and safety of products and services.
Finance and Budgeting Departments: Finance and budgeting departments play a critical role in evaluating the cost-effectiveness of medical supplies and services. They analyze budgetary constraints, conduct financial assessments, and provide input on the affordability and long-term sustainability of procurement decisions.
Regulatory and Compliance Officers: Regulatory and compliance officers ensure that medical supplies and services comply with applicable laws, regulations, and industry standards. They assess the regulatory landscape, review vendor qualifications, and verify product certifications to mitigate legal and compliance risks.
Vendor Representatives and Suppliers: Vendor representatives and suppliers offer products and services to hospitals and actively engage with stakeholders throughout the evaluation and adoption process. They provide product demonstrations, offer technical support, address concerns, and negotiate contracts to secure sales.
Patient Advocates and Advisory Groups: Patient advocates and advisory groups represent the interests of patients and advocate for products and services that prioritize patient safety, comfort, and satisfaction. They may participate in product evaluations, offer feedback from a patient perspective, and advocate for patient-centered care.
Technology and Innovation Teams: Technology and innovation teams explore emerging trends, research new technologies, and assess innovative solutions that have the potential to improve patient care and operational efficiency within the hospital. They may pilot test new products and services and facilitate knowledge transfer to clinical staff.
External Consultants and Subject Matter Experts: Hospitals may engage external consultants and subject matter experts to provide specialized expertise, conduct assessments, and offer recommendations on the selection and adoption of medical supplies and services. These consultants bring industry insights, best practices, and impartial perspectives to the decision-making process.

By involving these diverse stakeholders and fostering collaboration, hospitals can make informed decisions about the evaluation and adoption of medical supplies and services that best meet the needs of patients, clinicians, and the organization as a whole.

In conclusion, the American healthcare landscape is a tapestry of paradoxes — a juxtaposition of lavish spending and lackluster outcomes, of innovation and inertia, of challenges and opportunities. As we navigate this complex terrain, one thing remains abundantly clear: the imperative of forging synergistic partnerships, driving innovation, and fostering a culture of cost-conscious clinical accountability to usher in a new era of healthcare excellence.

If you would like to learn more, please join me and an expert panel on June 19 at 2pm as we discuss how to navigate the US health system sales cycle.

Kenneth C. Wong is the Consultant, Adjunct Professor, Board Member of Fellow of the American College of Healthcare Executives (FACHE).

Delivering care to an aging population

Healthcare providers stand to benefit from the advancement of telehealth.

By Jackleen Samuel

As the Baby Boomer generation ages, the United States is on the precipice of a seismic demographic shift. By the year 2040, the number of people living in the US over the age of 65 is expected to more than double to 80 million, while the number of people over the age of 85 — the group often in need of the most care — will nearly quadruple from 2,000 to 2,040. This is not just affecting healthcare at home, but also abroad, as the world's population faces a similar trend. Virtually every country in the world is experiencing this significant social transformation, as we see exponential growth in the number and proportion of senior and elderly populations.

In many ways, this is a credit to modern medicine. We are now able to provide better care for larger segments of the population than ever before and, as a result, we are living longer and healthier. However, as we see this steady increase in these populations, our healthcare system will have to rise to the challenge of maintaining and even surpassing that same level of care, which presents a problem given the current state of our overburdened and understaffed healthcare system. If we are to meet the needs of our aging population, we will have to transform the way in which healthcare is performed and delivered on a nationwide scale.

Hospitals and medical facilities all over the country are stretched thin. Between staff shortages, razor-thin budgets, and the rising demands on the time and resources of our healthcare professionals, we are faced with a serious issue regarding the effective delivery of healthcare services and treatment. We are delaying appointments, waiting longer to be seen and when we finally do get in front of a doctor, we are usually unsure of how much it'll cost and how much time the doctor even has for us. This is not the fault of the physicians, many of whom are now forced to push a never-ending line of patients through their offices to treat as many as they can. Healthcare is losing its personal touch. It is becoming more about numbers and less about building personal relationships.

Healthcare has a delivery problem. Care is becoming less convenient, less accessible, and less effective. Patients are going longer between appointments or forgoing treatment altogether due to the hassle and difficulty associated with navigating a fractured and slow-moving system. This is dangerous for patients of all ages, but particularly our senior and elderly populations who are more likely to suffer from chronic illnesses.

Regular visits and check-ups are our primary means of taking proactive measures against larger and more complicated health problems that can arise. These conditions that would have been either alleviated or otherwise prevented with more accessible and convenient healthcare, now become needless drains on our healthcare resources and, most importantly, the continued health and well-being of the patient.

Digital health technologies have emerged in the years since COVID-19 to become integral tools in our efforts to revolutionize the level of care available to the public. Virtual and mobile healthcare services provide the potential to effectively transform not only the way in which doctors and patients interact but also how individuals engage directly with their own personal health. The highest levels of treatment and care are available in the comfort of patients' homes, while medications and prescriptions are delivered directly to their doors. This is a particularly important paradigm shift in healthcare delivery for senior and elderly populations that have difficulty reaching important appointments and picking up vital prescriptions. This means that seniors will no longer have to wait weeks or months to be seen by doctors and will never again have an interruption in their medication schedules that can lead to serious illness and degradation of their health.

Both patients and healthcare providers stand to benefit from the further development and advancement of telehealth technologies. By allowing hospitals and medical centers to expand the scope of the services they provide outside of hospital and medical facility walls and into the communities they serve, our aging population will have direct access to comprehensive and preventative care.

Treatment will be more convenient, more comfortable, and, through these efforts, patients will be healthier. This will help to prevent many of the conditions that would have otherwise led seniors to suffer through lengthy hospitalizations and even rehospitalizations for the continued effects of chronic illnesses that then put undue and avoidable stress on our hospitals. This will allow these facilities to effectively allocate their time and resources to patients who require a hospital setting for care.

As seniors represent a higher and higher proportion of our country's population, an already overburdened healthcare system will have to become more agile and more flexible. By employing these virtual and mobile strategies, our doctors and nurses will be able to see more patients and do so more regularly, keeping patients healthier and happier well into their golden years.

Through the adoption of digital health technologies, it is possible to revolutionize the way in which healthcare is delivered and meet the demands of shifting demographics in not only the United States but all around the world. As our population grows older and wiser, our healthcare system and payor sources must similarly become smarter and more efficient.

Jackleen Samuel is the Founder and CEO of Resilient Healthcare.

Fueling innovation: Inside FAU's Research Park and its Global Ventures Program

The Park offers a platform to nurture pioneering initiatives in medical technology.

By Abigail Sears

Located in Boca Raton, Florida, 45 minutes north of Miami, the Research Park at Florida Atlantic and its Global Ventures program are places where entrepreneurial med tech companies and academia collide.

Spanning 70 acres, the Research Park is widely regarded as South Florida's premier hub for new pioneering research initiatives and technologies. The Research Park is proudly partnered with Palm Beach and Broward Counties, along with the City of Boca Raton, to drive regional innovation and growth.

Instrumentum, an offsite surgical instrument sterilization company, is one of the latest to join the Park. With a focus on delivering high-quality instruments to laboratories, academic institutions, and industry professionals, Instrumentum serves as a trusted partner in advancing scientific discovery and technological innovation.

Daniel Johnson, CEO of Instrumentum recently reflected on his experience of joining the Park and how it has propelled his business.

"From the first meeting with Andrew Duffell and the Research Park's leadership, we have experienced the tangible and consequential assistance that this association with FAU affords," said Johnson.

"Warm hospitality, community introductions, development guidance, FAU integration, referrals to subject matter experts, access to staffing channels, and networking opportunities with other innovative companies are just some of the compelling advantages of being located in the Research Park at Florida Atlantic."

Global Ventures, located in the park, is an incubator for tech companies who have already established a presence within their industry and ready for their next level of growth. It was also one of the first international soft landings programs in the country, welcoming foreign tech firms expanding to the US.

Global Ventures has many benefits for its tenants including, shared conference and break rooms, game areas, central mail facilities, flexible terms on office and lab space, and access to FAU resources and benefits.

Currently hosting 28 companies from over 10 countries, Global Ventures serves a number of tech verticals, with a key focus on medical innovation. One of these companies is Triangulate Labs, a total body photography company working to end skin cancer mortality through their Skinmap platform.

"Triangulate Labs is a company with expertise in computer vision and AI. We created it to help solve skin cancer after my sister was diagnosed with terminal cancer", said Bill Hall CEO and CO-Founder of Triangulate Labs. "Triangulate makes Skinmap, a patented Total Body Photography (TBP) system designed to give dermatologists better information so that they can catch skin cancers earlier and more easily."

Skinmap is a rapid and efficient system that helps dermatologists track changes in patients' skin, a crucial indicator for cancer prognosis. It allows for quick digitization of skin in less than 60 seconds, aiding in early detection and providing patients with peace of mind, all while generating new revenue for dermatologists.

To help grow this innovative and necessary medical detection product, Hall decided the Research Park at Florida Atlantic was the place to do it.

"The Research Park has enhanced our company's visibility and reach," said Hall. "Regular seminars provide information on useful topics ranging from crowdfunding to immigration. The Park's networking opportunities have proven incredibly valuable to us and have led to opportunities and business connections. Hearing other companies' experiences with vendors, government proposals, funding opportunities, and area trade shows has helped us make the right call a number of times."

Aside from the testimonials and firsthand accounts of success from companies like Instrumentum and Triangulate Labs, the numbers paint an equally compelling picture of the Research Park's impact.

In 2023, the Park supported 971 jobs and saw an average of 15 per cent growth in revenues over 2022. Four of these companies ranked on INC 5000 list of the fastest-growing companies in the country.

From job creation to economic growth, the data reinforces the idea that this hub of innovation is making waves in the South Florida community and beyond.

With an impressive track record of job creation, revenue growth and more, the Research Park and Global Ventures is more than ready to propel additional companies to success in the years to come.

"We are incredibly proud of the innovative med tech companies within our Global Ventures program and at the Research Park," said Ryan Lilly, Global Ventures Program Manager. "Their groundbreaking work is not only advancing medical technology but also significantly improving patient outcomes. These companies exemplify the spirit of innovation and excellence that we strive to cultivate here."

Global Ventures

- Triangulate Labs
- DNA Labs
- HelixVM
- Ultimaxx Health
- Accenius
- Hawkeye MedTech

Research Park companies

- Thema Brain Health
- Instrumentum
- Flospine
- Aventusoft
- Pur Form
- Diowave
- Genesis Care
- Glades Medical
- MPLT
- PBISM
- University MRI

To learn more about **Research Park and Global Ventures**, **visit stand I92A**, website: *www.researchparkfau.com*, or contact **Andrew Duffell**, President: *aduffell@research-park.org*; or **Ryan Lilly**, Global Ventures Program Manager: *rlilly@research-park.org*

Five medtech startups to watch out for

New and former startups specialising in medical technology are paving the way for US' economic growth and improved healthcare delivery.

By Jennifer Orisakwe

The medical technology industry is always changing to deliver cutting-edge technical solutions that address the demands of patients, healthcare professionals, and the larger medical community. But how does one typically determine whether startups in the field are gaining traction quickly?

A successful medtech startup possesses a number of essential characteristics, including innovative products, scalable solutions, gaining swift market adoption, substantial funding, positive customer feedback, and achieving key regulatory approval round out the key traits of a thriving medtech startup.

Geographic expansion and building a strong team are important indicators of success without negating recognition through awards, a strong intellectual property portfolio, and proven clinical efficacy which further contributes to a startup's growth and credibility. It is noteworthy that the United States is anticipated to generate the highest income when compared globally, with $215.80 billion in sales in 2024. Below are a few among many US-based medtech start-ups on the rise, listed in no particular order:

Clivi

Clivi is transforming diabetes care in Latin America with its digital clinic platform. Founded by an experienced team, Clivi recently secured a $10 million seed round. The company's AI-driven approach to diabetes management has achieved significant results, including a reduction in A1C levels by 2.4 per cent, potentially extending life expectancy by over four years. Clivi aims to serve one million people within the next five years and become the leading diabetes clinic in Mexico within a year.

Carbon

Specialising in virtual care and telehealth services since its founding in 2015, Carbon raised $622.5 million in Series D funding, which is a clear indicator of trust from investors. Patients can schedule same-day appointments for urgent care and primary care on its platform, which also makes prescription medication delivery easier. Furthermore, Carbon Health's "Carbon Health Vaccinate" program helped administer approximately 1.49 million immunizations during the COVID-19 pandemic, which unarguably played a vital role.

Parachute Health

The New York-based business known for its innovative strategy for streamlining the digital ordering process for supplies and durable medical equipment (DME), was founded in 2014 and has raised $15.3 million. Its ePrescribing software offers real-time order progress notifications, expedites delivery, and minimizes paperwork. Serving more than 200,000 clinicians, Parachute Health's platform is extensively utilized and was included in the New York Digital Health 100 in 2023.

Nutrisense

Nutrisense is recognized for its innovative solution in tracking blood sugar levels through a continuous glucose monitor (CGM) and mobile app. Founded in 2018 in Chicago and backed by $31.4 million in Series A funding, Nutrisense offers a program that includes a wearable sensor, expert guidance, and health coaching. The company achieved $40.5 million in revenue in 2023 and has 15,000 customers, highlighting its growing influence in personalized health monitoring.

Resolve Medical

This medtech startup stands out for its innovative use of AI to enhance diagnostic accuracy in radiology. Established in 2015, the company offers a cloud-based solution that assists radiologists in analyzing medical images and identifying potential abnormalities. This technology improves the efficiency of the diagnostic process, potentially leading to early detection and treatment of diseases, which is very necessary for enhancing healthcare quality.

How to surf LATAM's regulatory issues - perspectives from Brazil

Brazil has gained international visibility in the health control of medical devices with the development of governance practices and a regulatory model.

By Laura Baroni

Brazil represents the largest medical device (MD) market in South America and thus, it is a much sought-after destination for several manufacturers around the world, with commercial interest in launching their products.

According to the Brazilian Alliance of Innovative Health Industry (ABIIS), edition 45 of the Economic Bulletin, in the accumulated period from January to December 2023, the US was the main country of origin of Brazilian imports of MDs, of which Brazil purchased $879 million — or 17.2 per cent of the 5,101 billion in MD imports. Countries like Germany (15.8 per cent) and China (11.4 per cent) were also important product suppliers for Brazil.

The Bulletin also states that the US was the main supplier of MDs for Brazil in 11 market segments. In another five segments, China is the main supplier. In the IVD reagents segment, Germany appears as a relevant player.

The Brazilian National Health Surveillance Agency (ANVISA) regulates all health-related products. It is mandatory to have a local legal representative for product liability, and the local legislation classifies the MDs depending on the nature of the application or operation and the intrinsic risk they pose to the health of the patient, operator or third parties involved. The definition of the need for safety and efficacy documents is entirely related to the classification of the product, depending on its nature and risk class.

MDs are classified into four risk classes (RDC 751/2022 DMs; RDC 830/2023 IVDs) that differ in classification rules considering whether the product is active in terms of action or energy conversion; whether it is invasive or non-invasive in terms of applicability; and in relation to the length of stay with the patient, whether it is transient, short or long-term. For higher-risk MD (classes III/IV), the presentation of clinical studies to prove efficacy and safety is mandatory.

On the other hand, products that fall into risk classes I/II undergo a simplified notification process, and the presentation of clinical studies, in this case, is only required when the product is considered innovative in design, raw material or indication for use. In the current days, there are still challenges for foreign manufacturers to enter the Brazilian market, and this includes local-specific certifications such as INMETRO (National Institute of Metrology, Quality and Technology); integration of Brazil's local requirements into the R&D stages and Clinical Evaluation for innovative and risk class III/IV products.

Another challenge is to face the long line for license approval. For implantable and orthopedics products, for example, the timeline for approval can take around 12 months. For other products (equipment and IVD) the scenario is more favorable, with shorter timelines (around three to six months).

Globalization and the fast advancement of new technologies have presented a major challenge to all regulators around the world. According to ANVISA, the volume of submissions along with the complexity of documentation (complex and diverse studies) for analysis, as well as an increase in external demands, and the shortage of human resources has been a constant challenge faced by the General Management of Technology and Health Products (GGTPS), prolonging the estimated time to complete the submissions' analyses.

In the last two decades, Brazil gained international visibility in the health control of MD, developing governance practices and promoting arrangements in the regulatory model to align with the global convergence scenario. To support this mindset, ANVISA's Strategic Plan developed for the period from 2024 to 2027 has priorities related to the Agency's essential responsibilities and to face the challenges and needs of a future that is already present in Brazil's health regulation.

As defined within the Strategic Objectives, obtaining recognition as an international reference health authority is one of the agencies' priorities. The Strategic Plan also mentions that, in an era of global healthcare public partnerships, regulatory agencies have sought the alignment with global dynamics of interdependence and regulatory trust practices (reliance) for products and health services, facilitating the approval of medicines, vaccines and MDs.

Several actions are already implemented and in force, facilitating the approval processes for the registration of MDs imported into Brazil. Regarding Good Manufacturing Practices Certification, ANVISA has already implemented two initiatives:

1. Brazil is part of the Medical Device Single Audit Program (MDSAP) that allows manufacturers of MDs to hire an Auditing Body, authorized within the scope of MDSAP, and carry out a single audit that will cover the relevant requirements of Participating Regulatory Authorities. It replaces the necessity of an audit performed by ANVISA in manufacturing units of MDs.

2. The validity of the Certificate of Good Manufacturing Practices issued by ANVISA for MD manufacturers granted through MDSAP was extended from two to four years, through the publication of the RDC 850/2024.

With regards to the MDs submissions, ANVISA published the IN 290/2024, which establishes the process to leverage authorization from an Equivalent Foreign Regulatory Authority (AREE). It applies only to Class III/IV MDs and IVDs, which are subject to a more complex regulatory process in Brazil. The AREEs include the following — Australia Therapeutic Goods Administration (TGA), Health Canada, FDA and Japan Ministry of Health, Labor and Welfare (MHLW) — bringing many expectations of positive impacts as it establishes the optimized procedure for the review and decision of submissions for registration of MDs.

With this approach, ANVISA expects to have a simplification of submission analysis and better use of the workforce. These improvements are already adding value to the MDs area and the expectation is to have a 30 per cent decrease in the timeline for the risk class III/IV license approvals.

In conclusion, it is quite clear that ANVISA is aware of the existing challenges. On the other hand, their improvements show that the Agency will not spare efforts to be an innovative and reliable health authority to the whole world. Stepping into Brazil's market has its complexities, it can be challenging, however, Brazil is the largest MD market in Latin America, therefore, persistence will prove itself to be worth all the effort.

Laura Baroni is the Regulatory Affairs Analyst at Vera Rosas Group in Brazil. She will be speaking at the "Main Regulatory Issues for LATAM — How to Surf LATAM's Regulatory Issues" session on June 20 at 11am.

Guardia Virtual Revolutionizes Telemedicine in Latin America with AI and Telemetry Advances

From the United States to Argentina, the company introduces cutting-edge technologies to transform healthcare.

In an increasingly interconnected world, the need for accessible, high-quality medical solutions has become imperative. Guardia Virtual, with its innovative telemedicine software, is leading this change from the United States to Argentina, implementing the latest in Artificial Intelligence (AI) and telemetry to significantly improve patient journeys and healthcare efficacy.

Diego R. Kumorkiewicz.

How does Guardia Virtual's software benefit both patients and doctors?

"Guardia Virtual's software is an integrated solution that facilitates the latest technological advances for both patients and doctors, optimizing wait times during the overall patient journey and offering a pre-diagnosis with over 91% accuracy," stated Diego Kumorkiewicz, CEO of the company. "And these are just a few of the platform's main benefits."

What services does Guardia Virtual's system offer patients?

The system allows patients to access it from any device for immediate medical consultations and provides a pre-diagnosis through an AI-based medical avatar, ensuring each patient is guided precisely to the medical service they need at the right time. It also offers the ability to evaluate their vital signs (including ECG) through one of our affordable devices linked to the platform.

What other features does Guardia Virtual's platform include?

In addition to its accessible interface, Guardia Virtual includes medical telemetry devices that collect vital data such as temperature, blood pressure, oxygen levels, and electrocardiograms (ECG). These devices come in various forms, from home care kits to public Totems and consultation booths in remote areas, ensuring accurate diagnoses and effective patient follow-up.smartwatch detected an arrhythmia that led to the diagnosis of atrial fibrillation, saving his life and allowing early treatment. However, just a few months later, tragedy struck when a friend's stroke was misdiagnosed as a simple headache, resulting in his passing. This contrast between immediate and inadequate care underscored the need for a solution integrating advanced AI and telemetry, leading to Guardia Virtual, which connects patients with doctors for accurate diagnosis and proper follow-up.

How does Guardia Virtual address traditional healthcare challenges?

Guardia Virtual's platform not only offers an alternative to traditional healthcare, but also responds to the growing demands of a society seeking to avoid long waits and additional costs associated with in-person visits. "Our goal is to offer high-quality, convenient, and accessible healthcare, transforming the medical experience and providing a modern and effective alternative to healthcare," Kumorkiewicz explained.

"Guardia Virtual's software is an integrated solution that facilitates the latest technological advances for both patients and doctors, optimizing wait times during the overall patient journey and offering a pre-diagnosis with over 91% accuracy,"

Backed by 30 years in the medical industry, we have pioneered a new paradigm that leverages telemedicine, telemetry, and AI. We possess the requisite knowledge and qualifications to empower patients. This integrated model enhances the health experience across the entire ecosystem.
Mar del Plata, Buenos Aires. Argentina 2024

What is Guardia Virtual's vision and mission?

The company's vision is to empower healthcare, overcoming traditional barriers to offer primary and specialized care to every corner where it's needed. Guardia Virtual works continually to stay at the forefront of telemedicine trends, collaborating closely with health and technology experts to ensure the efficacy and safety of its platform

What inspired the creation of Guardia Virtual?

The company emerged from the experiences of its CEO, Diego Kumorkiewicz. In 2018, living far from an urban center, Kumorkiewicz's smartwatch detected an arrhythmia that led to the diagnosis of atrial fibrillation, saving his life and allowing early treatment. However, just a few months later, tragedy struck when a friend's stroke was misdiagnosed as a simple headache, resulting in his passing. This contrast between immediate and inadequate care underscored the need for a solution integrating advanced AI and telemetry, leading to Guardia Virtual, which connects patients with doctors for accurate diagnosis and proper follow-up.

How does Guardia Virtual see its role in the healthcare industry?

"Guardia Virtual is transforming healthcare by bridging technology and patient care, ensuring everyone has access to quality medical services at any time and place," Kumorkiewicz concluded.

For more information on how Guardia Virtual is changing the healthcare landscape in Latin America, visit :

www.guardiavirtualmedica.com

Or contact us at:

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