Global Supply Chain Report

Summary

Electric Vehicle

Solar PV

Apparel

Medical Device

February 2025

HKUST LI & FUNG
SUPPLY CHAIN INSTITUTE

Medical Device

Embracing Multipolarity: Post-COVID Evolution of Global Medical Device Supply Chain

Executive Summary

The global medical device market is currently experiencing a period of remarkable growth and transformation, featuring a convergence of demographic shifts, technological advancements, and shifting market dynamics. Projections indicate a substantial increase in market size from US$518.5 billion in 2023 to an estimated US$886.8 billion by 2032, reflecting a robust compound annual growth rate (CAGR) of 6.1%, according to Fortune Business Insights. This growth is underpinned by a multitude of factors, including the aging global population, rising healthcare expenditures, and the increasing prevalence of chronic diseases worldwide.

The US and Germany play pivotal roles in shaping the medical device industry.Meanwhile, China is emerging as a significant player, implementing reforms like centralized procurement and attracting foreign investments to bolster its market presence.

The COVID-19 accelerated changes in the medical device supply chain. Pre-pandemic challenges like cybersecurity, counterfeiting, and recalls on defective designs were compounded by the COVID-19 disruptions, including manufacturing delays, supply shortages, and logistical hurdles due to lockdowns and travel restrictions. Healthcare facilities worldwide faced strain, leading to increased nurse turnover. Healthcare providers embraced remote patient monitoring amidst a shift to decentralized care. This crisis also prompted a reassessment of practices, emphasizing the importance of diversification and decentralized manufacturing to enhance resilience against future challenges.

Currently, the global medical device supply chain faces a complex landscape shaped by geopolitics, regulations, cost management, chip shortages, cybersecurity, and sustainability. Geopolitical tensions, including the Russia-Ukraine war, the Gaza war, and China-US trade tensions, force companies to reassess their sourcing strategies. Regulatory compliance is

crucial, with the medical device industry operating under stringent oversight from bodies like the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA). Early alignment with regulatory and quality strategies is vital to prevent production delays.

Effective cost and operation management are essential to ensure efficiency, sustainability, and competitive pricing in the medical device supply chain. Advanced medical devices often require additional components like chips and sensors, necessitating careful cost analysis and strategic procurement practices. However, chip shortages have posed significant challenges, as medical device makers compete with automakers and electronics manufacturers for chips. Delays in medical device production due to chip shortages jeopardize patients' well-being, unlike delays in consumer electronics or automotive industries.

Technological advancements in fields such as artificial intelligence (AI), robotics, and 3D printing are revolutionizing healthcare delivery, enhancing efficiency, and enabling more patient-centric care. However, these innovations also pose challenges such as cybersecurity threats and data privacy concerns. With cybersecurity emerging as a central concern in the medical device domain, collaborative efforts between device manufacturers and healthcare providers are essential for safeguarding patient data and mitigating the cybersecurity risks.

Sustainability has emerged as a focal point for the medical device industry. Despite operational and regulatory challenges, implementing eco-friendly practices, reducing carbon emissions, and promoting ethical sourcing are becoming integral components of supply chain strategies in the industry. Sustainable supply chain practices not only align with corporate social responsibility goals but also enhance brand reputation, attract environmentally conscious consumers, and drive long-term business value.

Currently, reshoring, nearshoring, and offshoring are common strategies employed to boost efficiency, reduce costs, and improve responsiveness to market demands. By embracing technology, forming alliances, and adopting sustainability, firms can navigate supply chain complexities and thrive. Reshoring entails bringing production back to the home country, often motivated by factors like escalating labour expenses abroad, quality control concerns, and supporting the local economy. Nearshoring involves moving production to geographically close countries, offering benefits such as lower transportation costs, quicker lead times, and cultural alignment. Countries such as Mexico, Costa Rica, Puerto Rico and the Dominican Republic are emerging as preferred nearshoring production bases for the US medical device market due to skilled workforces and proximity. Meanwhile, offshoring to countries with lower labour expenses remains popular for cost efficiency and global access. China and India stand out as key growth markets for medical device companies and are attracting international investments for medical technology innovation and manufacturing, driven by supportive government policies.

China is rapidly emerging as an important player in the global medical device supply chain, closing the gaps with leaders like the US and Germany. Chinese firms are extending their global footprint through setting up subsidiaries and research centres in the US and the EU. Meanwhile, India's medical device sector is rapidly evolving, backed by government initiatives and rising foreign investments. The Indian government has lowered device registration fees to enhance access to advanced medical devices and have streamlined clinical trial processes, simplifying market entry for manufacturers.

In short, the medical device industry is at a pivotal juncture, navigating a landscape characterized by rapid technological advancements, changing demographics, and evolving regulatory frameworks. The disruptions caused by the COVID-19 has also highlighted the importance of formulating a resilient medical device supply chain. All these challenges are compelling industry players to reevaluate their supply chain and locational strategies, as well as to carefully consider partner collaboration and decentralized manufacturing in the long term.

I. Introduction

The worldwide medical device market, with a valuation of US$518.5 billion in 2023, is forecasted to increase from US$542.2 billion in 2024 and to US$886.8 billion by 2032, displaying a 6.3% compound annual growth rate (CAGR), according to Fortune Business Insights. Numerous factors contribute to this growth, such as:

- The World Bank projects that by 2025, 22% of the global population will be aged over 60, predominantly residing in developed nations. [2] The aging population worldwide is increasing the need for ophthalmic and orthopedic procedures due to age-related conditions. Instances like osteoarthritis are on the rise, particularly in developed countries. In addition, unhealthy lifestyle behaviours are contributing to the prevalence of chronic diseases like obesity, heart disease, and diabetes, leading to a surge in diagnostic and surgical procedures. Some aging individuals face challenges from inactivity and poor diet. Globally, the growing number of surgical procedures, particularly orthopedic, cardiac, and neurological surgeries, is fueling the expansion of the medical device market, especially in minimally invasive and general surgery segments. [3]
- The expansion of the global medical device market is additionally shaped by macroeconomic elements like GDP growth, healthcare spending, and governmental actions. Nations with strong economies and increased healthcare expenditures typically boast a more sophisticated and progressive medical device market. Moreover, rising middle-class populations in emerging economies are demanding more affordable and accessible healthcare solutions, driving market growth.
- Countries with favourable regulations and reimbursement systems are attracting more investment and innovation in the medical device sector. Government initiatives focused on digital healthcare and improved healthcare infrastructure are also contributing to market growth.
- Last but not least, rapid advancements in technology such as miniaturization, artificial intelligence (AI), robotics, and data analytics are revolutionizing medical devices, making them more precise, efficient, and patient-centric. Also, improved access to health data is enhancing healthcare ecosystems.

[2] Condon, A. (2022). *The evolution of the smart home health hub.* https://galendata.com/the-evolution-of-the-smart-home-health-hub/

[3] Fortune Business Insights. (2024). *Medical Devices Market.* https://www.fortunebusinessinsights.com/industry-reports/medical-devices-market-100085

These key factors shape the decisions of global medical device manufacturers, guiding their strategic choices in selecting locations, enhancing operational efficiency, and navigating regulatory complexities.

This report first covers a comprehensive overview defining medical devices and technology. Following this, it delves into the impact of COVID-19 pandemic on the medical device market, analyzing the disruptions and adaptations spurred by the global crisis. It then explores the factors shaping the supply chain of medical devices, including challenges and opportunities. The report also investigates the phenomena of reshoring and nearshoring in the context of medical device manufacturing, examining their implications on industry dynamics. Furthermore, it assesses the performance of major manufacturing countries in the production and export of medical devices. Finally, the report concludes with a summary of key findings and future outlook of the sector.

II. Medical devices and technology

The medical device industry is a vital intersection of healthcare and technology, dedicated to supporting medical practices, improving diagnostics and treatments, and enhancing patient care. This sector broadly consists of two main types of medical devices: those crucial for life support and those intended for emergency medical care settings.[4]

Section 201(h) of the Food, Drug and Cosmetics Act of the US defines medical devices as instruments, apparatus, machines and their component parts and accessories *'intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease,… or intended to affect the structure or function of the body … and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes'*.

In practical terms, the medical device market can be categorized into different groups, such as therapeutic area, product type, end-user, and geographical location. Key therapeutic areas span from cardiology and orthopedics to diagnostics and neurology. When considering product types, the market encompasses cardiovascular devices, orthopedic devices, diagnostic imaging, in-vitro diagnostics, minimally invasive surgery tools, wound management products, diabetes care equipment, ophthalmic devices, dental devices, nephrology tools, general surgery equipment, and other related items. [5]

Regarding end-users, the market is divided into hospitals, clinics, and patients along with their caregivers. Hospitals currently dominate this sector due to the increasing number of outpatient and inpatient visits for diverse surgical procedures and treatments. Clinics are anticipated to exhibit substantial growth in demand for medical devices in the foreseeable future – This growth is primarily fueled by patients' growing preference for specialized care and effective treatment options available in clinic settings. Hospitals and clinics are adopting innovative technologies to enhance patient care and streamline operations[6]. For instance,

---

[4] Dhilawala, A. (2022, June 6). *The new normal supply chain challenges and strategies for medical device manufacturers.* https://galendata.com/the-new-normal-supply-chain-challenges-and-strategies-for-medical-device-manufacturers/

[5] Fortune Business Insights. (2025, January 20). *Medical Devices Market.* https://www.fortunebusinessinsights.com/industry-reports/medical-devices-market-100085

[6] Condon, A. (2023, October 9). *5 trends shaping the future of advanced medical devices.* https://galendata.com/5-trends-shaping-the-future-of-advanced-medical-devices/
Newton, E. (2023, May 17). *Smart Hospitals: Five Technologies Upgrading the Industry.* https://medtechintelligence.com/feature_article/smart-hospitals-five-technologies-upgrading-the-industry/

- **Medical robotics.** Robotic surgery, from its inception in 1996, has evolved into a new industry standard. Recent advancements included improved surgical robots, leading to fewer complications, reduced pain, and quicker recovery. Examples like the MicroPort Navibot demonstrate how these robots enable minimally invasive procedures and aid in rehabilitation, offering targeted support to patients. Surgeons guide procedures while robots execute precise movements, facilitating less invasive surgeries and smoother recoveries. Additionally, robots play a crucial role in telemedicine, allowing surgeons to operate remotely, expanding access to specialized care.
- **Minimally invasive surgery.** Miniature medical devices are transforming healthcare by enabling minimally invasive procedures in surgery and remote health monitoring. Equipped with advanced technologies like robotics and AI, these tiny devices improve patient comfort, reduce recovery times, lower infection risks, and enhance outcomes. For instance, they are revolutionizing tumor diagnosis. Also, smaller, more durable cardiac devices such as pacemakers and defibrillators can offer continuous monitoring for improved care of patients with heart conditions.
- **Data-driven diagnoses.** AI and machine learning (ML) algorithms are transforming healthcare by analyzing medical data, improving diagnostics, and tailoring treatments. They enable early disease detection, predict outcomes, and optimize care strategies. For example, Google's machine learning model can detect conditions like heart disease early. AI also aids in interpreting medical images such as X-rays, MRIs or CT scans and personalizing treatment plans, enhancing effectiveness and minimizing potential side effects in patient care.
- **3D printing of medical devices.** The integration of 3D printing in healthcare facilitates innovation and customization throughout the medical devices’ lifecycle. It enables rapid prototyping, accelerating device development and concept validation. In the market, custom implants and prosthetics are crafted for individual patients, enhancing fit, comfort, and functionality in various procedures. Surgeons utilize 3D-printed anatomical models for surgical planning, enhancing precision and reducing risks through realistic representations of patient anatomy.
- **Automated patient monitoring.** Continuous patient monitoring, facilitated by technologies like AI and Internet of Things (IoT), ensures quality care round the clock. Innovative systems, such as AI-driven computer vision algorithms, monitor elders and patients with dementia for safety. These algorithms analyze live video feeds, alerting caregivers and emergency services to signs of distress. This automated monitoring enhances patient care pre- and post-hospitalization.

Hospitals and clinics are driving a groundbreaking shift in healthcare by embracing cutting-edge technology to deliver safer, more efficient, and individualized care. Technological innovations are reshaping medical norms globally, promising better patient outcomes.

III. Overview of the global medical device market

The medical device market is experiencing global expansion, with significant developments in emerging countries. According to Statista[7] as shown in Table 1, the US, a longstanding leader in medical devices, commanded a sizeable 34.2% share of the global market in 2022, which is projected to reach 34.9% by 2029. China, holding the second position in 2022, accounted for 7.4% of the total market size in 2022, which is projected to expand to 8.3% by 2029. Germany and Japan, occupying the third and fourth spots in 2022, captured 6.5% and 5.8% of the total. In 2029, Germany is expected to grow to 7.2% of the total, while Japan is estimated to slightly shrink by 0.1 percentage point in 2029. The rest of the world maintained a significant share, comprising 46.0% in 2022 and decreasing slightly to a projected rate at 44.0% by 2029. These changes highlight the dynamic nature of the global medical device market and the evolving competitive landscape across various regions.

Table 1: Size of major medical device markets

	2022		2024 estimate		2029 estimate	
	Revenue (US$ billion)	% of world	Revenue (US$ billion)	% of world	Revenue (US$ billion)	% of world
US	160.1	34.2%	181.0	35.6%	233.5	34.9%
China	34.6	7.4%	37.6	7.4%	55.7	8.3%
Germany	30.5	6.5%	38.2	7.5%	48.1	7.2%
Japan	27.2	5.8%	29.0	5.7%	38.0	5.7%
Rest of World	215.5	46.0%	222.2	43.7%	294.5	44.0%
Total	467.9	100%	508.0	100%	669.7	100%

Source: Statista

In terms of retail sales of medical devices, the US market in 2021 generated US$143.6 billion, up by 6% year-on-year (yoy), according to the US Census Bureau.[8] The strong performance was fueled by factors such as the increasing geriatric population, rising adoption of minimally invasive procedures, and a surge in sports and road accidents, according to Grand view research[9]. The US medical technology (sometimes referred to as medical devices according to the International Trade Administration, ITA[10]) manufacturers are highly competitive internationally across many product categories. The US-based medical technology companies prioritize research and development (R&D), driven by the short

[7] Statista. Retrieved July 18 & December 10, 2024

[8] US Census Bureau. https://shorturl.at/fYZRS

[9] Grand view research. (2024). *U.S. Medical Device Manufacturers Market Size Report, 2030.* https://www.grandviewresearch.com/industry-analysis/us-medical-device-manufacturers-market

[10] The International Trade Administration, US Department of Commerce. Industry Overview of Medical Technology Industry. Retrieved August 1, 2024, from https://www.trade.gov/selectusa-medical-technology-industry.

product lifecycle of 18-24 months and the need to integrate new features and cutting-edge technologies to enhance patient care.

According to a MERICS report[11] published in 2023, the European market is poised for a modest growth rate, influenced by regulations like the EU Medical Device Regulation (MDR) and the In Vitro Diagnostic Regulation (IVDR). However, the region's well-established infrastructure, increasing healthcare expenditure, and adoption of advanced diagnostic and treatment devices are expected to drive steady market growth. A particular focus on shifting medical care to home settings and the introduction of portable medical equipment by global and domestic players will further support market expansion. According to Germany Trade & Invest (GTAI), Germany stands out as the largest European market, followed by France, the UK, Italy, and Spain.

The medical device market in China is poised for substantial growth, with projections indicating a revenue of US$37.6 billion in 2024, up from US$34.6 billion in 2022, led by cardiovascular devices with an estimated volume of US$4.1 billion in 2024, according to Statista. The growth of China's medical device market is mainly driven by the country's large and aging population. Strong economic expansion, escalating healthcare expenditure, healthcare reforms, and a growing middle class further boost the sector's expansion. Government initiatives such as policies, tax incentives, and streamlined regulations also support the market growth.

It is noteworthy that the adoption of digital health technologies such as wearables and telemedicine is on the rise in China's medical device market, facilitating remote health monitoring and personalized care. According to a study prepared by PTL Group[12], Chinese medical AI startups captured a significant 33% of global venture capital funding in 2020, with investments in the sector growing at an impressive CAGR of 86% from 2017 to 2021, totaling US$3.7 billion. Forecasts indicate robust growth for China's healthcare AI, with an expected CAGR of 52.8% by 2028.

Japan's medical device market remains one of the largest globally, driven by various factors such as its aging population and the rise in chronic and lifestyle diseases among patients. This trend is expected to fuel further expansion in the market. The impact of the COVID-19 pandemic highlighted the importance of innovative healthcare products, including the integration of digital technologies, which are anticipated to contribute to market growth.

---

[11] Brown, A., Chimits, F., Groenewegen-Lau, J., Gunter, J. and Sebastian, G. (2023, November 20). *Investigating state support for China's medical technology companies.* MERICS. https://merics.org/en/report/investigating-state-support-chinas-medical-technology-companies

[12] PTL Group. (2024 May 16). The Booming Medical Equipment Market in China: Trends, Drivers, and Opportunities. https://www.ptl-group.com/blog/the-booming-medical-equipment-market-in-china-trends-drivers-and-opportunities

According to the ITA's calculation[13], Japan's medical device market size in 2021 amounted to US$40.2 billion, consisting of the local production value of US$23.7 billion and imports of US$25.6 billion minus exports of US$9.1 billion.

India's medical device market size in 2022 was US$11 billion, according to the National Medical Devices Policy 2023[14]. The government has set an ambitious growth target for the sector to reach US$50 billion by 2030, representing a robust growth trajectory with a projected CAGR from 2022 to 2030 at approximately 19.4%. The country's anticipated growth is expected to be fueled by increased investments in R&D, a growing middle-class population, and a range of government initiatives such as the Production-Linked Incentive Scheme, Ayushman Bharat (a health insurance program), "Startup India" (support for startup ventures), and "Make in India." Recent regulatory changes have lowered device registration fees to enhance access to advanced medical devices and have streamlined clinical trial processes, simplifying market entry for manufacturers. Additionally, global market players are increasingly focusing on expanding their direct presence to meet the rising demand for medical devices in India.

Medical device markets emerging in Latin America, the Middle East, and Africa also demonstrate a significant growth owing to the rapid evolution of healthcare infrastructure, escalating disposable incomes, and an amplified emphasis on healthcare quality. The influx of global market players into these regions is expected to drive this growth further.

First, the medical device market in Latin American countries reached US$35.5 billion in 2023. The market is estimated to grow continuously to US$50.6 billion in 2029, according to Statista[15]. Brazil leads the market in the region, followed by Mexico and Colombia. The surge in chronic diseases, the rise in middle-class, and the availability of skilled labour are pivotal factors propelling growth in the Latin American medical device sector. However, evolving regulatory guidelines in Latin American countries to align with the US and EU standards have increased the complexity of foreign registration approvals. Despite this, certain countries in Latin America offer expedited approval pathways for devices already approved by the US Food and Drug Administration (FDA) or the European Conformité Européenne, CE-marked.

Second, the size of medical device market in the Middle East amounted to US$11.0 billion in 2023 and is estimated to grow with a CAGR of 3.9% from 2024 to 2030, according to Grand

[13] The International Trade Administration, US Department of Commerce. Industry Overview of Medical Technology Industry. Retrieved August 1, 2024, from https://www.trade.gov/selectusa-medical-technology-industry

[14] Rao A. (2024 April 10). *The MedTech Industry in India: Outlook and Growth Drivers.* India Briefing. https://www.india-briefing.com/news/india-medtech-industry-outlook-growth-31918.html/

[15] Statista. 2024. *Revenue of the medical devices market in Latin America from 2017 to 2029*. https://www.statista.com/forecasts/1450116/indicator-revenue-medical-devices-medical-technology-market-latin-america

View Research[16]. Factors fueling the market growth include aging populations, increases in medical expenditure, improved healthcare infrastructure, advancements in medical technology, and a surge in lifestyle-related diseases like diabetes, cancer, and cardiovascular ailments. Turkey, Saudi Arabia, and the United Arab Emirates are the major medical device markets in the Middle East, primarily due to individual governmental initiatives driving healthcare markets and fostering new business opportunities.

Last but not least, the market revenue of the African medical device market totaled at US$8.9 billion in 2023 and is projected to grow with a CAGR of 6.7% from an estimated US$9.3 billion in 2024 to US$12.9 billion in 2029, according to Statista[17]. The significant market expansion stems from the rise in chronic diseases and acute illnesses, alongside aging populations. Due to Africa's diversity and insufficient healthcare infrastructure and skilled professionals, developers are focusing on creating innovative, cost-effective medical devices tailored to African requirements. Meanwhile, African countries are also developing locally manufactured medical devices to reduce their reliance on imports from China and other countries. Collaborations with global firms and technology transfers will continue to be pivotal for developing the African market.

In summary, the US maintains a leading position in the global medical device market, poised to increase its market share, followed by China which shows substantial growth potential. The global market growth is driven by aging population, increased R&D investments, mergers and acquisitions, advancements in technologies, and surging demand for medical device products in emerging regions such as Latin America, Asia Pacific, the Middle East, and Africa, alongside established markets like North America, Europe, and Japan.

---

[16] Grand View Research. Middle East Medical Devices Market Trends. https://www.grandviewresearch.com/industry-analysis/middle-east-medical-device-market

[17] Statista. (2024). Medical Devices – Africa. https://www.statista.com/outlook/hmo/medical-technology/medical-devices/africa

IV. Impact of COVID-19: Catalyst for Change

Prior to the COVID-19 pandemic, numerous governments were either reducing public health budgets or maintaining it at a steady level while struggling with escalating expenditures on chronic illnesses among their aging populations. However, during the pandemic, governments faced with the challenge of orchestrating a comprehensive pandemic response within the already strained budgets, pushing healthcare systems and infrastructures to their limits. The looming economic downturn in post-COVID-19 era will further intensify the strain and underline the urgency for substantial reforms.

1. Supply chain disruptions

The medical device supply chain encountered a variety of challenges even before the COVID-19 pandemic, including issues related to cybersecurity, counterfeiting, and recalls on defective designs. The onset of the pandemic in early 2020 further brought about significant disruptions across the supply chain, such as overloaded healthcare facilities worldwide, manufacturing delays, supply shortages, and logistical issues due to lockdown and travel restrictions. The impact of the pandemic touched every aspect of healthcare, highlighting the critical need for stockpiling essential medical components and equipment to prepare for surges in demand. The crisis has also shed light on deficiencies in medical device manufacturing processes, including a lack of transparency in the supplier network, rigid planning cycles, and difficulties in scaling production swiftly.[18]

A report by the Health Industry Distributors Association (HIDA) in March 2023 revealed that 93% of the surveyed healthcare organization executives are still grappling with product shortages[19]. The current situation underscores the need for a more strategic and forward-thinking approach to managing critical supply chains in the healthcare sector. Strategies such as reviewing process flows between plants, increasing multipurpose plant deployments in different locations, and expanding outsourcing partnerships with custom manufacturers can enhance flexibility and resilience.

More importantly, embracing new technologies within manufacturing facilities can significantly enhance agility and efficiency. Innovations, such as digital 3D printing, wearables, sensors, and smart automation solutions like Tulip, empower operators to achieve higher performance levels and reduce quality issues. Additionally, advancements in

[18] Kearney. (2020, June 5). *It is high time to make medtech supply chains ready for the future.* https://www.kearney.com/industry/health/article/-/insights/it-is-high-time-to-make-medtech-supply-chains-ready-for-the-future

[19] Nadeau, K. (2024). *Future of Healthcare supply chains: An in-depth analysis.* https://www.ghx.com/the-healthcare-hub/supply-chain-future-healthcare/

maintenance technologies, including preemptive and remote maintenance capabilities, have proven to be invaluable in ensuring operational continuity and minimizing disruptions. [20]

2. Demand for more off-site alternatives

Since the start of the COVID-19 pandemic, there has been a significant increase in nurse turnover in the US, with nearly 80% of nurses reporting staffing shortages, as indicated by a 2022 survey of over 2500 registered nurses conducted by the National Nurses United[21]. Skilled nursing facilities have experienced declines in employment, partly attributed to concerns related to the pandemic and burnout, particularly in countries heavily impacted by the virus. A collaboration among global nursing associations has revealed that the global nursing workforce numbered around 28 million in 2022, with a projected need for an additional 13 million nurses by 2030 to address escalating demands. In parallel, healthcare providers are increasingly adopting remote patient monitoring and other solutions[22] as a response to the pandemic, reflecting a broader trend towards decentralizing healthcare services.

(a) Remote patient monitoring

The global medical device market is witnessing a surge in the adoption of telemedicine and remote patient monitoring technologies, driven by the need for alternative healthcare delivery methods. These technologies encompass connected devices, telemedicine platforms, mobile health applications, and innovative sensors that can be worn on the skin to track biometrics. Smart clothing equipped with biometric sensors is also emerging as a tool to collect health data and synchronize with patient and healthcare provider apps, facilitating remote patient monitoring and personalized care delivery.

In addition, the advent of 5G networks is revolutionizing healthcare by enabling real-time communication among medical devices, healthcare professionals, and data centres. This advancement is particularly beneficial for telemedicine, remote surgeries, and the rapid exchange of extensive medical datasets. For instance, the Mayo Clinic demonstrate the shift towards remote patient monitoring solutions. The remote monitoring kits include essential tools like blood pressure cuffs, thermometers, pulse oximeters, and cellular-enable tablets, allowing patients to transmit vital health data to healthcare professionals in real-time for improved care management.

---

[20] Kearney. (2020, June 5). *It is high time to make medtech supply chains ready for the future.* https://www.kearney.com/industry/health/article/-/insights/it-is-high-time-to-make-medtech-supply-chains-ready-for-the-future

[21] Galen Data. (2022, September 12). *5 Top Post-Pandemic Priorities for Global Healthcare Leaders.* https://galendata.com/5-top-post-pandemic-priorities-for-global-healthcare-leaders/

[22] Condon, A. (2022, June 20). *The evolution of the smart home health hub.* https://galendata.com/the-evolution-of-the-smart-home-health-hub/

(b) Wearable devices

The COVID-19 pandemic and growing health concerns have driven a surge in demand for wearable devices across various sectors. These devices, ranging from fitness trackers in the consumer market to outpatient monitoring tools, track vital signs, monitor physical activity, and offer valuable health insights, with advancements in AI algorithms enhancing their role in preventive care and early disease detection. A ValuePenguin survey revealed in March 2022 that 45% of the US population use fitness trackers, and around 69% are open to wearing these devices for health insurance discounts.[23]

Companies like Apple, Samsung and Amazon are tapping into the medical device realm. Amazon's Alexa is making its way into households as a digital family member, introducing new services like *Alexa Together* designed to aid families in remote elderly monitoring and care. Best Buy's acquisition of *Current Health*, an at-home tech care startup, further highlights the growing intersection of technology and healthcare.

(c) Pre-diagnosis

Patients and consumers are increasingly inclined towards self-diagnosing certain health conditions without physically visiting a doctor. For example, COVID screening tests serve as a significant catalyst for the expanding market of at-home health testing. Quest Diagnostics projects that the consumer-driven health testing sector could surpass a value of US$2 billion by 2025.[24] Other segments within the at-home testing market encompass food allergies and nutrition, disease screening, heavy metals testing, genetic testing, as well as hormones and hormonal imbalance assessments.

In short, the COVID-19 pandemic has exposed vulnerabilities in global healthcare systems, including supply chain disruptions and workforce shortages. Post-COVID economic downturns amplify these issues, prompting necessary healthcare reforms. Enhancing supply chain resilience through process flow reviews, diverse manufacturing, and collaborations is crucial. Also, the shift towards more off-site healthcare alternatives redefines healthcare engagement, reflecting operational efficiency enhanced through the adoption of technologies.

---

[23] DeMarco, J. (2022, April 18). *Nearly 70% of Americans Would Wear a Fitness Tracker/Smartwatch for Discounted Health Insurance*. https://www.valuepenguin.com/fitness-tracker-smartwatch-health-survey
[24] Galen Data. (2022, September 12). *5 Top Post-Pandemic Priorities for Global Healthcare Leaders.* https://galendata.com/5-top-post-pandemic-priorities-for-global-healthcare-leaders/

V. Other factors shaping the supply chain of medical devices

Even after the COVID-19 threats have diminished, global supply chain of medical devices continues to face persistent risks. Medical device firms must embrace adaptive supply chain risk management to excel in the volatile post-pandemic landscape. Rising pressure on cost and quality accelerates this evolution, yielding a more intricate, technology-centered, and sustainable system.

1. Geopolitical factors

Geopolitical risks, such as armed conflict, sanctions, and trade tensions, have the potential to disrupt transportation, trade processes, and regulatory approvals for medical device products. This geopolitical volatility could result in shortages of essential manufacturing components for medical devices. Such disruptions may lead to increased costs, delays in product availability, and could compromise product safety and effectiveness.

The current global landscape presents a myriad of threats impacting various sectors. For example, the ongoing conflict in Ukraine has disrupted traditional containership routes in the Black Sea, resulting in heightened shipping costs between Europe and Asia and shortages of product parts. Similarly, the war in the Gaza region has disrupted container ship traffic through the Suez Canal, forcing vessels to divert routes around Africa. This diversion not only increases time and distance for shipping but also contributes to rising costs. Moreover, the Panama Canal, serving as an alternative route, encounters challenges such as water depth restrictions due to drought, leading to additional fees and decreased ship transits.[25] Ultimately, these disruptions pose significant risks to public health.

In addition, trade tensions between China and the US amplify risks, potentially resulting in abrupt tariffs and import complexities. The Section 301 tariff increases, unveiled in September 2024, range from 25% to 100%, covering items like respirators, facemasks, syringes, and needles imported from China. These increases will affect US-China medical device trade starting from 2025.[26] On 1 February 2025, the Trump administration announced to impose a 10% additional tariff on all China's imports[27], which is expected to impact medical device trade. According to GlobalData's Medsource Database, 75% of US-

[25] LMA Consulting Group. (2024). Medtech's Supply Chain: Global Risks Driving Regional Manufacturing. https://www.lma-consultinggroup.com/medtechs-supply-chain-global-risks-driving-regional-manufacturing/

[26] Bond. D, Solomon, M. and Saccomanno, I. (2024, September 17). *United States Finalizes Section 301 Tariff Increases on Imports from China.* White & Case LLP. https://shorturl.at/a2EMk

[27] White house. (2025, February 1). Fact sheet: President Donald J. Trump imposes tariffs on imports from Canada, Mexico and China. https://www.whitehouse.gov/fact-sheets/2025/02/fact-sheet-president-donald-j-trump-imposes-tariffs-on-imports-from-canada-mexico-and-china/

marketed devices are produced abroad.[28] Any additional tariff hikes in Chinese medical devices may hinder exports from China to the US, leading to higher costs, supply chain disruptions, and retaliatory tariffs, potentially impairing the US medical device market.

In the rapidly evolving global landscape, the medical device industry faces the risk of disruption if it relies on limited sources for critical raw materials and goods. Proactive measures are essential to mitigate risks and ensure the continuous availability and quality of medical device products. Strategies such as diversifying manufacturing bases, collaborating with local manufacturers and stakeholders, and stockpiling essential parts are vital. Companies may consider localizing operations to offset risks and uncertainties amid geopolitical turmoil. Adaptation and strategic planning are essential for navigating these complex challenges in the current global environment.

2. Chips shortage

In the medical device sector, semiconductor chip scarcity is a critical concern. Medical device makers compete with automakers and electronics manufacturers for chips, constituting a mere 1% of the total chip supply[29]. The industry's demand for chips is set to double from 2021 to 2028[30]. The delays in the production of vital medical devices such as ventilators, imaging machines, and pacemakers due to chip shortages jeopardize patients' safety and well-being. With a few Taiwanese companies dominating advanced chip production, countries like the US are reassessing their reliance on a vulnerable global supply chain in this crucial industry.

3. Cybersecurity

In an era marked by widespread digitization, the IoT, and the integration of AI in the medical device industry, the imperative for robust data security measures has never been more pressing. The technological evolution has rendered modern devices increasingly susceptible to cyber threats, posing potential risks to patient safety and the seamless functioning of healthcare operations. Moreover, the entry of wearable devices into the healthcare landscape has introduced a fresh set of cybersecurity challenges. Ensuring the secure

[28] GlobalData. (2024, November 23). *Impact of Trump tariffs on US medical device market.* https://finance.yahoo.com/news/impact-trump-tariffs-us-medical-181049944.html
[29] Dhilawala, A. (2022, June 6). *The new normal supply chain challenges and strategies for medical device manufacturers.* https://galendata.com/the-new-normal-supply-chain-challenges-and-strategies-for-medical-device-manufacturers/
[30] Murray, B. and Bradley, S. (2021, September 23). *The Semiconductor Chip Shortage Hits Medtech: Strategies to Build Resilient Supply Chains.* AdvaMed. https://www.advamed.org/2021/09/23/the-semiconductor-chip-shortage-hits-medtech-strategies-to-build-resilient-supply-chains/

transmission of personal data from these devices is essential to safeguard patient information and prevent breaches that could compromise patient well-being.

The 2017 WannaCry attack stands as a stark reminder of the tangible repercussions of cyber threats on healthcare entities.[31] This incident underscored the critical need for stringent cybersecurity measures to uphold the integrity of patient data within the interconnected supply chain. Another case in point is the July incident in 2024, involving CrowdStrike[32], a prominent cybersecurity firm. An inadvertent software update triggered a significant IT outage, disrupting healthcare services across multiple institutions. This event highlighted the vital importance of meticulous software management and cybersecurity practices in preventing unforeseen consequences that could disrupt healthcare operations and compromise patient care.

As cybersecurity emerges as a central concern in the medical device domain, collaborative efforts between device manufacturers and healthcare providers are essential to safeguard patient data and mitigate the risks associated with cyber threats. The device manufacturers should integrate strong encryption, authentication protocols, and regular software updates to tackle data weaknesses. Healthcare institutions should enforce strict access controls to prevent data breaches and unauthorized access to patient information. And it is essential to educate healthcare professionals and consumers on cybersecurity best practices and potential threats. By embedding cybersecurity considerations from the design phase and adhering to best practices, the safety, integrity, and effectiveness of medical devices can be ensured within an increasingly interconnected healthcare ecosystem.[33]

4. Stringent regulations

The medical device industry operates under stringent regulatory oversight from bodies like the US Food and Drug Administration (FDA), European Medicines Agency (EMA), and other national authorities, enforcing guidelines for product safety and efficacy[34]. These regulations, like the FDA's proposed Medical Device Quality System Regulation Amendments and the EU's Medical Device Regulation (MDR), govern approval, clinical trials, and post-market surveillance[35].

---

[31] Slabodkin, G. (2022, February 28). *Medtech, hospitals on alert for cyberattacks after Russia's invasion of Ukraine.* https://www.medtechdive.com/news/medtech-hospitals-alert-cyberattacks-russia-ukraine/619486/

[32] Vogel, S. (2024, July 19). *CrowdStrike outage hits US hospitals.* https://shorturl.at/qhg80

[33] Condon, A. (2023, October 9). *5 trends shaping the future of advanced medical devices.* https://galendata.com/5-trends-shaping-the-future-of-advanced-medical-devices/

[34] Rajbhandary, S. and McLeod, D.P., Five trends to watch in the medical device industry. *Mercer Capital*. Retrieved August 1, 2024, from https://mercercapital.com/article/five-trends-to-watch-in-the-medical-device-industry/

[35] Nadeau, K. (2024). *Future of Healthcare supply chains: An in-depth analysis.* https://www.ghx.com/the-healthcare-hub/supply-chain-future-healthcare/

In the US, the FDA mandates clearance for most devices, while low-risk ones can exempt from this requirement. The EU requires CE-Mark certificate for market entry, indicating that a product has met EU's safety, health and environment standards. The EU MDR introduces additional costs and surveillance obligations, impacting companies in the region.[36] Countries such as Japan, Canada, and Australia follow similar robust regulatory frameworks.[37] Meeting diverse directives can escalate compliance complexity and costs for manufacturers. Medical device manufacturers should follow the regulations and device quality standards requested by the respective governments to prevent any delay when they apply for market entry approvals.

5. Cost and operation management

Effective cost and operation management are essential in the medical device supply chain to ensure efficiency, sustainability, and competitive pricing. Advanced medical devices often require additional components like chips and sensors, necessitating careful cost analysis and strategic procurement practices to manage operational expenses effectively. Moreover, medical device manufacturers have encountered substantial hurdles in their supply chain operations in recent years, grappling with disruptions and rising costs stemming from factors like inflation and supply chain complexities. These difficulties have particularly affected segments such as cardiovascular, coronary and peripheral vascular products, and neuromodulation and biologics. As a result, manufacturers are compelled to refine and streamline their manufacturing processes.[38]

- Medtronic, a key player in the medical device sector, underwent significant restructuring in 2024, optimizing its global operations and supply chain. The company consolidated manufacturing sites, suppliers, and distribution centers across 134 countries. By prioritizing strategic suppliers and implementing efficiency measures, Medtronic aims to boost profitability and operational efficiency. This restructuring focuses on cost reduction, working capital optimization, and integration of automation and forecasting systems.

---

[36] Awasthi, P. and Stanick, J. (2021). *The rise of global medical technology.* https://www.healthtechireland.ie/wp-content/uploads/2021/01/The-rise-of-global-medical-technology-White-Paper-1.pdf

[37] Panwar, A. (2021, September 30). *Medical Device Manufacturing: Five Challenges in Maintaining Compliance.* https://medtechintelligence.com/column/medical-device-manufacturing-five-challenges-in-maintaining-compliance/

[38] Banga, B. Medtronic tackles supply chain challenges in a bid to return to profitability. *Medical Technology.* Retrieved August 1, 2024, from https://medical-technology.nridigital.com/medical_technology_mar24/medtronic_tackles_supply_chain_challenges_in_a_bid_to_return_to_profitability

- Baxter International Inc. announced to close its Alabama plant as part of a US$300 million cost-saving plan in December 2023.
- GE Healthcare Technologies, Inc. is working on streamlining its operations, investing in digital manufacturing solutions such as the IoT and data analytics to monitor its production chains in real-time. This will enable the company to optimize inventory management, reduce downtime and enhance product quality.
- Johnson & Johnson, Inc. is striving to optimize its operations using cutting-edge technologies such as automation, data analytics, and AI in a bid to improve product quality and reduce manufacturing costs.
- Philips is investing in smart manufacturing solutions to strengthen device traceability and streamline supply chain management.

6. Sustainability

Healthcare, a significant industry with a substantial carbon footprint, is under scrutiny for its environmental impact. Medical products, including disposables and technology-based devices, contribute one-third of healthcare's carbon emissions and most of the waste generation. Various strategies exist to reduce waste, for example, Mölnlycke and NewGen Surgical have launched various products made of biobased materials, including surgical gloves, drapes, and staplers. Also, Johnson & Johnson introduced a compact battery-operated device for traumatology and small bone surgeries, equipped with a wide array of attachments and accessories, allowing multiple devices to be used with the same reusable ancillary equipment. Switching to renewable energy sources in production, minimizing scrap through process redesign, opting for sustainable transport options, and reducing packaging waste are key steps. [39]

However, some medical device companies face substantial challenges in implementing sustainability measures due to commercial, operational, and regulatory hurdles. For example, transitioning to biobased materials presents uncertainties regarding performance, regulatory compliance, and potential environmental impacts like land use and material degradability. Also, changes in materials and design might necessitate costly requalification by regulators, prompting device companies to focus sustainability efforts only on new products. Hospitals, on the other hand, resist reducing single-use items in favour of multiuse products due to concerns about staff time, sterilization logistics, and patient and staff safety.

To mitigate the concerns and efficiently manage end-of-life medical devices, it would require innovative solutions involving partnerships among industry competitors, hospitals, logistics

[39] Wurzer, C., Surtevall, E., Tziambazis, E., Goldader, J., Hardin, E.M., Gerecke, G., Nayak, S., and Hansmann, L. (2024 March 22). *Medtech's Path to a Circular Future.* BCG. https://www.bcg.com/publications/2024/medtech-path-to-circular-future

providers, decontamination services, and recyclers. Streamlining processes such as automated waste sorting and incentivizing take-back programs require collaborative design and cost-effective strategies. For instance, Resourcify, a circularity solutions provider based in Germany, has developed a recycling application and platform to streamline the coordination of waste management efforts involving various vendors and types of waste.

Last but not least, regulatory flexibility is also essential, as existing restrictions on recycling contaminated waste hinder sustainability efforts. Countries like France, Italy, and Austria have strict regulations against reprocessing, underscoring the need for regulatory innovation to enable reprocessing businesses to become profitable and reduce healthcare costs for hospitals.

VI. Nearshoring: A trend on the rise

The medical device supply chain faces persistent global disruptions, urging manufacturers to pursue proactive strategies. Medical device companies can enhance their agility and resilience by leveraging reshoring and nearshoring strategies. By prioritizing suppliers in proximity to care delivery sites, organizations can reduce logistical complexities and enhance supply chain efficiency. The onset of the pandemic accelerated the adoption of nearshoring and reshoring strategies, primarily driven by the need for stable and efficient logistical systems. Some governments restricted exports and prioritized domestic production during the pandemic, leading to supply chain disruptions and extended lead times.

Proximity to primary markets enables quicker responses to customer demand, facilitating faster distribution and improved customer service. Apart from boosting supply chain resilience and shortening product design cycles, reshoring and nearshoring initiatives offer greater control over processes and adherence to quality standards.

On one hand, the integration of automation and advanced technologies like 3D printing and AI has reduced the importance of labour expenses. On the other hand, escalating labour costs in traditional offshoring hubs have made these hubs less appealing. Moreover, rising logistics costs from distant offshoring hubs, including expenses in transportation and inventory carrying, have also lead to a surge in reshoring and nearshoring strategies.[40]

Besides, it is noteworthy that regulatory compliance is a critical consideration in medical device manufacturing. Nearshoring often simplifies compliance procedures as nearshoring countries often have similar regulatory frameworks and legal systems, thereby reducing the complexities associated with adhering to diverse regulations in offshore operations. Conversely, offshoring can introduce challenges related to regulatory compliance due to varying regulatory frameworks across different countries, potentially increasing the risk of non-compliance and associated penalties.

Nearshoring and onshoring have gained prominence in North America's healthcare sector due to factors like transit delays, tariff implications, and the sourcing of medical-grade materials domestically. The resurgence of semiconductor manufacturing in the US signifies a shift towards reshoring chip production. Central American countries are favoured for their skilled workforce, robust technical education systems, and the accelerating trend of nearshoring amidst the disruptions caused by the COVID-19 pandemic.

[40] Grawford, M. (2022, July 1). *The big shift: nearshoring trends in medtech manufacturing.* https://www.mpo-mag.com/issues/2022-07-01/view_features/the-big-shift-nearshoring-trends-in-medtech-manufacturing/?widget=listSection

A few years ago, 3M revamped its supply chain logistics to mitigate production disruptions. The company shifted to a regional manufacturing strategy, producing goods in North America for the US market and in Asia for the Asian market. Many industry giants such as Johnson & Johnson, Medtronic, GE Healthcare, and Cardinal Health are also transitioning to a regional manufacturing approach by diversifying away from China to Central America to minimize disruptions. Costa Rica is attracting companies like Abbott Laboratories and Boston Scientific Corp, while Puerto Rico and the Dominican Republic are emerging as preferred destinations for nearshoring in medical device manufacturing. [41] This trend underscores the strategic advantages and increasing reliance on nearshoring and contract manufacturing in the medical device industry.

In sum, location strategic decisions play a pivotal role in shaping supply chain efficiency, market responsiveness, and cost-effectiveness. Careful evaluation of these strategies, aligning with organizational goals, market demands, and regulatory requirements, is vital for navigating global supply chain complexities and ensuring sustained growth and competitiveness in medical device manufacturing.

[41] LMA Consulting Group. (2024). *Medtech's Supply Chain: Global Risks Driving Regional Manufacturing.* https://www.lma-consultinggroup.com/medtechs-supply-chain-global-risks-driving-regional-manufacturing/

VII. Performance of Major Manufacturing Countries

1. Global market leaders

(a) The US

According to the *Report to the Congress: Medicare and the Health Care Delivery System* by Medical Payment Advisory Commission (MEDPAC) in June 2017[42], the US medical device industry encompasses a broad array of products, making it challenging to define precisely. Estimates of its size vary, with studies by organizations like the ITA, Congressional Research Service, BMI Research, and the Advanced Medical Technology Association suggesting different figures for US spending on medical devices. For example, the ITA reported that the US serves as the world's largest market for medical technology, representing approximately 40% of worldwide sales. International trade plays a crucial role in the US medical device industry, with a substantial proportion of US production being exported (35% to 40%) and a similar proportion being imported for domestic consumption[43]. Overall, the medical device industry's share of total US healthcare spending is approximately 5% to 6%, estimated by the Advanced Medical Technology Association.[44]

The North American Industry Classification System (NAICS) categorizes the medical device industry of the US into six subsectors as shown in Table 2, defined by the US Economic Development Administration and the ITA's Office of Health and Information Technologies[45]. In 2021, the total retail sales of these six manufacturing sectors were US$143.6 billion, up by 6.0% yoy, with an employment of over 333,000 persons. The industry is distributed across the US, with notable concentrations in California, Indiana, Massachusetts, and Minnesota. During the same year, the annual payroll of the six sectors reached US$27.5 billion, up by 4.9% yoy.

---

[42] Medicare Payment Advisory Commission. (2017). *Report to the Congress: Medicare and the Healthcare Delivery System.* Chapter 17. https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun17_ch7.pdf

[43] The International Trade Administration, US Department of Commerce. *Industry Overview of Medical Technology Industry.* Retrieved August 1, 2024, from https://www.trade.gov/selectusa-medical-technology-industry

[44] Donahoe, G.F. (2021, June). *Estimates of Medical Device Spending in the United States. Advanced Medical Technology Association.* https://www.advamed.org/wp-content/uploads/2021/12/Estimates-Medical-Device-Spending-United-States-Report-2021.pdf

[45] The International Trade Administration, US Department of Commerce. (2022). *An Overview of the U.S. Medical Devices and Biopharmaceutical Industries.* https://tinyurl.com/3bdjufkz

Table 2: US's medical device market in 2021

	Total Retail Sales in the US (USD billion)	Yoy growth	Number of employees	Yoy growth
339112: Surgical and Medical Instrument Manufacturing	38,034,768	10.1%	113,217	3.1%
339113: Surgical Appliance and Supplies Manufacturing	38,591,473	7.3%	78,934	-1.1%
339114: Dental Equipment and Supplies Manufacturing	5,025,761	20.8%	14,247	1.9%
325413: In-vitro diagnostic substance manufacturing	18,079,972	6.3%	32,597	5.7%
334510: Electromedical and Electrotherapeutic Apparatus Manufacturing	36,005,776	0.6%	81,767	-6.4%
334517: Irradiation Apparatus Manufacturing	7,833,465	-1.8%	12,389	-7.7%
Total Sum	143,571,215	6.0%	333,151	-0.6%

Source: US Census Bureau[46]

The US houses some of the world's leading medical device manufacturers like Medtronic, Stryker, GE Healthcare, Johnson & Johnson, Boston Scientific Corp, Baxter, Abbott, and others. However, some of the medical device giants experienced a slight downturn due to the COVID-19 pandemic and postponement of certain surgical arrangements. For instance, Medtronic experienced a decrease in revenues from US$30.6 billion in the fiscal year 2019 to US$28.9 billion in the fiscal year 2020, as a result of revenue drop of cardiac & vascular group, minimally invasive therapies group, restorative therapies group and diabetes group, according to the company's annual report[47]. Conversely, the pandemic had a beneficial effect on the drug delivery device sector owing to the increased medical requirements related to the pandemic.

Currently, the US medical device manufacturing industry is poised for expansion, driven by the increasing global presence of industry participants and strategic divestitures from existing operations. Through acquisitions and partnerships, US-based medical device manufacturers can access diverse markets, broaden their customer base, and stimulate innovation. For example, in February 2023, Abbott's acquisition of Cardiovascular Systems, Inc. marked a significant move in the cardiovascular device industry, with an estimated

46 US Census Bureau. Retrieved August 29, 2024, from https://shorturl.at/fYZRS
47 Medtronic. Annual reports. Retrieved August 1, 2024, from https://investorrelations.medtronic.com/annual-meeting-reports

acquisition value of US$890 million[48]. Similarly, in July 2023, 3M's investment of US$468 million to expand its healthcare facility in Brookings, South Dakota, aimed to bolster its footprint in the region and meet local healthcare needs.[49]

Some players strategically divested from their existing operations to strengthen their positions in other sectors. Baxter International Inc. continued to restructure the company by streamlining nine business segments into four. In May 2023, the company finalized the sale of its BioPharma Solutions business to Advent International and Warburg Pincus in a cash transaction valued at US$4.3 billion. Furthermore, the company announced In August 2024 to sell its Vantive kidney care business to Carlyle Group with a value of US$3.8 billion.[50] As mentioned in section V.5, many other players in the US also refined and streamlined their operations processes, so as to boost efficiency.

In addition, the US plays a crucial role in foreign direct investment (FDI) within the global medical device sector, according to GlobalData's FDI Projects Database[51]. The US led the way as the primary investor supporting FDI projects in medical devices throughout 2019 and 2020, followed by Germany. US investors actively invested in numerous projects across Costa Rica, France, Germany, Ireland, Mexico, the UK, the Netherlands, China, and Belgium.

On the other hand, during the years 2019 and 2020, the US was the second-largest global destination for receiving medical device FDI. It notably drew the majority of projects concerning manufacturing, R&D, headquarters, as well as logistics and warehousing functions. Furthermore, the US served as the number one destination for medical device FDI from Germany.

Following President Donald Trump's inauguration as the 47th US president on 20 January 2025, he decided to withdraw the US from the World Health Organization (WHO), citing concerns over the organization's management of the COVID-19 pandemic[52]. Despite this decision, the President announced on 25 January 2025, that he would reconsider the move[53]. Concurrently, Trump's administration paused research-grant evaluations, travel, and training for scientists associated with the National Institutes of Health (NIH). This suspension

---

48 Kelly, S. (2023, February 9). *Abbott to pay $890M to acquire CSI, gaining atherectomy device*. https://shorturl.at/xYn1r

49 3M News Center. (2023). *Brookings, S.D., plant to begin multi-million-dollar expansion*. https://news.3m.com/Brookings-S-D-plant-to-begin-multi-million-doll

50 Grand view research. (2024). *US Medical Device Manufacturers Market Size Report, 2030.* https://www.grandviewresearch.com/industry-analysis/us-medical-device-manufacturers-market

51 Karadima, S. (2022, May 17). *FDI in medical devices: The state of play.* Investment Monitor. https://www.investmentmonitor.ai/sectors/lifesciences/fdi-medical-devices-state-of-play/?cf-view

52 Maxmen A. (2025, January 24). *What a US exit from the WHO means for global health.* CBS News. https://www.cbsnews.com/news/trump-withdraw-who-global-health/

53 Bose, N. and Singh, K. (2025, January 26). *Trump says he may consider rejoining World Health Organization*. Reuters. https://www.reuters.com/world/us/trump-says-he-may-consider-rejoining-world-health-organization-2025-01-25/

of NIH activities has sparked apprehension within the healthcare community, raising uncertainties about the future of health research and innovation in the US[54]. Overall, these decisions are anticipated to have a far-reaching impact on the public health sector, affecting the US's engagement in global health collaborations and impeding joint efforts to tackle health challenges on an international scale.

(b) Germany

In 2022, Germany ranked as the largest European medical technology market, with a combined revenue of 43 billion euros from the medical devices and in vitro diagnostics segments, according to Germany Trade and Investment. During the same year, the German medical technology sector registered 1,391 patents with the European Patent Office, showcasing the industry's commitment to driving innovation in healthcare.

The German Medical Technology Association (BVMed) reported that German medical device manufacturers generated over 38 billion euros in turnover in 2022, marking a 5.5% year-on-year increase and accounting for 26.4% of the entire European market. The growth was fueled by a positive domestic market outlook and robust export performance. When considering all small and micro-enterprises within Germany, the overall sales of the industry surpassed 47 billion euros. Among the 1,450 companies with over 20 employees, around 93% are small- and medium-sized companies with 20 to 250 employees. [55]

In 2022, around two-thirds of the revenue of the German medical device sector, amounting to 25.8 billion euros, was generated from international markets. While the US remains the single biggest market of Germany, followed by China, a significant portion of German medical device exports stays within Europe. Germany's advanced infrastructure and its central European location position the country as an ideal production base for serving neighbouring European markets.

In the German medical device sector, cardiology, diagnostics, oncology, neurology, and surgery emerged as the most innovative areas, as highlighted by a 2020 BVMed survey[56]. Renowned for its innovation, the German medical technology industry actively drives medical advancements, allocating approximately 9% of its revenue to R&D. Germany hosts about 50 cluster networks focused on medical technology, aiming to foster ongoing innovation in R&D and manufacturing by connecting companies, hospitals, universities, and

---

[54] Kozlov, M. (2025, January 23). *'Never seen anything like this': Trump's team halts NIH meetings and travel.* Nature. https://www.nature.com/articles/d41586-025-00231-y

[55] Germany Trade and Invest. *The Medical Technology Industry in Germany.* Retrieved August 1, 2024, from https://www.gtai.de/en/invest/industries/healthcare-market-germany/medical-technology

[56] Germany Trade and Invest. (2022). *Medical technology clusters in Germany.* https://www.gtai.de/resource/blob/64176/0b820ca68223cf736433b4eb60d921c9/20221019_FS_MedTech_WEB.pdf

research institutions. Dedicated cluster management teams assist in securing funding for collaborative R&D projects, offer shared facilities, and coordinate educational programs for network members.

According to GlobalData's Project Database[57], Germany stands out as a pivotal hub for medical device FDI during 2019 and 2020, attracting a substantial share of projects in this sector. Hosting approximately 20% of the medical device projects announced or initiated globally during 2019 and 2020, GlobalData reported that Germany solidified its top position for attracting medical device FDI. Noteworthy investors from countries such as Switzerland, China, and the US were prominently involved in funding ventures within Germany's medical device industry. Additionally, Germany's appeal extended to hosting projects in various business functions, with a particular emphasis on sales, administration, and marketing activities. Together with the US, the two countries claimed the top positions in both inbound and outbound FDI charts, constituting 33% of global FDI inflows and 39% of outflows in medical devices during the years 2019 and 2020.

Between the first quarter of 2019 and the second quarter of 2024, Siemens Healthineers, a Germany-based medical device company, emerged as the most active greenfield investor in the global medical device sector, as per GlobalData [58]. The primary recipients of these investments were the US, Colombia and France. Other notable investors in the global medical device sector include B. Braun, another German company, along with other US firms such as Medtronic, Boston Scientific and Stryker.

[57] Karadima, S. (2022, May 17). *FDI in medical devices: The state of play.* Investment Monitor. https://www.investmentmonitor.ai/sectors/lifesciences/fdi-medical-devices-state-of-play/?cf-view

[58] GlobalData. (2024, September 19). *Most active FDI companies in the medical devices industry.* Investment Monitor. https://www.investmentmonitor.ai/data-insights/active-fdi-companies-medical-devices-industry/?cf-view

2. Rising giants

(a) China

China's medical device sector exhibits a diverse landscape with players of varying sizes, including prominent firms like Mindray and United Imaging which are actively expanding globally, as well as smaller enterprises with more localized operations. China's presence in the global medical device market is evolving, with notable impacts on established players like the EU and the US.

According to MERICS report[59], in 2021, China surpassed the US in catheter exports and approached EU levels, and overtook both regions in syringe exports. Moreover, China is challenging the EU and the US in X-ray technology exports to middle-income markets, narrowing the export gap to regions like Africa and Southeast Asia.

Despite China's status as a major market player, its outreach remains focused primarily on domestic market and select regions such as Russia, North Africa, and the Middle East. The country's growing presence at global events like the Medlab Middle East conference signals a proactive push to showcase innovative technologies and solutions. Chinese companies like Vazyme, Tianlong, and Fapon are highlighting cutting-edge products in areas like biotechnology, nucleic acid extraction, and diagnostic systems, setting the stage for increased international engagement in the medical device industry.

The rise of Chinese medical device exports can be attributed in part to traditional competitive strengths, bolstered by substantial state aid that Chinese firms receive domestically. Since the COVID-19 pandemic, China has increasingly underscored the importance of its localization strategy in the medical device sector. The government's initiatives to revamp the nation's medical system and develop domestic markets have propelled a swift localization trend, reshaping competitiveness and influencing international trade dynamics.

Chinese government initiatives such as "Made in China 2025" and the 14th Five-Year Plan emphasized the localization strategy to support domestic medical device companies and promote the use of domestically manufactured products. Government schemes like "In China for China" and "In China for Global" highlight China's commitment to both local and international markets. Domestically produced items benefit from advantages in government procurement, faster approvals, and lower costs, making them more competitive in the market. Government support includes grants and loans from the Innovative Medical Device

[59] Brown, A., Chimits, F., Groenewegen-Lau, J., Gunter, J. and Sebastian, G. (2023, November 20). *Investigating state support for China's medical technology companies.* MERICS. https://merics.org/en/report/investigating-state-support-chinas-medical-technology-companies

Assessment office, particularly for areas like diagnostic imaging and cardiovascular implants. Reimbursement reforms and standardized tendering processes also help boost the competitiveness of domestic firms. Chinese companies are advancing up the value chain, competing not only in the budget and mid-value segments, but also in the high-end markets of certain medical equipment. [60]

In the domestic medical device market, competition of homegrown Chinese medical device companies continues to escalate as they move up the value ladder. Armed with entrepreneurial vigor, financial backing, market acumen, and agility, domestic players are rapidly expanding their product lines, introducing fast-follower products, and outpacing multinational corporations (MNCs) in certain categories. Notably, local companies have pioneered advancements like transcatheter aortic valve replacements and laboratory automation systems, capitalizing on local preferences and gradually gaining market share across various segments. They have significantly expanded their market share in the local market, surpassing 50% in product categories like medical imaging, orthopedic, and cardiovascular devices.[61]

With a solid foundation in the domestic market, these companies are now venturing beyond China, intensifying competition globally.[62]

- Mindray Medical has set up subsidiaries and offices in the US, with R&D centers in key locations like Silicon Valley, Seattle, and New Jersey. They are developing a cross-system medical product innovation platform and have partnered with major Group Purchasing Organizations in the US, expanding their reach to around 10,000 medical institutions. Additionally, Mindray has established branches in France and forged partnerships with local healthcare institutions. In Asia, they have signed agreements for academic exchanges and collaborations, enhancing medical innovation.
- United Imaging Healthcare has strategically collaborated with German company ITM Isotopen Technologien München AG to enhance precision healthcare imaging, covering radiopharmaceuticals, image processing, patient workflow, and management.
- Lepu Medical plans to establish a wholly-owned subsidiary in Malaysia for manufacturing and marketing medical devices.

[60] Campbell, I. and Campbell, S. (2024, May 1). *China in the global medtech industry: Equal parts promising and uncertain.* https://www.meddeviceonline.com/doc/china-in-the-global-medtech-industry-equal-parts-promising-and-uncertain-0001
[61] McKinsey. (2023, September). *Medtech pulse: Thriving in the next decade.* https://shorturl.at/Jn57L
[62] Deloitte. (2024, February). *Insights into Chinese medical device companies going global – popular target markets overview and key success factors.* https://www2.deloitte.com/content/dam/Deloitte/cn/Documents/life-sciences-health-care/deloitte-cn-lshc-chinese-medical-device-companies-going-global-en-240221.pdf

- Shanghai Moge Biotechnology has partnered with ALPS Medical Centre Malaysia to drive advancements in healthcare and biology, aiming at fostering cooperation among members of the Regional Comprehensive Economic Partnership (RCEP) in the healthcare sector.

In short, China's medical device market is experiencing a shift towards innovation, with the country transitioning from being a recipient to an innovator of medical technologies. The market is expected to grow significantly, presenting opportunities for MNCs to tap into this innovation.

MNCs are increasingly considering China as a hub for medical device innovation, with avenues such as licensing products invented in China to complement their portfolios. Major international medical device companies are also intensifying their localization efforts by manufacturing products in China to better cater to local market demands. [63]

- Medtronic's collaboration with the Changzhou National High-tech Industrial Development Zone underscores its focus on manufacturing, research, and innovation in China. The company is establishing a local R&D and manufacturing hub in Shanghai to produce cardiovascular products.
- Boston Scientific introduced an intravenous ultrasound imaging product in Shanghai for global distribution, in line with its long-term vision of revolutionizing healthcare through innovative solutions and improving patient outcomes worldwide with cutting-edge technology.
- Philips aims to achieve 100% made-in-China products for specific segments.
- Danaher has heavily invested in a new diagnostics R&D and manufacturing facility in Suzhou and aims to domestically produce 80% of its products sold in China.
- Siemens Healthineers is progressing with localizing entire product lines as part of Siemens's China localization strategy.

Besides, acquisitions and mergers with Chinese medical device companies are also on the rise. [64] For instance, in 2022, Boston Scientific, a US-based medical technology, secured a controlling interest in Acotec, a China-based vascular interventional treatment device company, integrating a range of cardiovascular intervention devices manufactured in China.

In sum, China's healthcare ecosystem is witnessing rapid innovation. Government actions aimed at upgrading the nation's healthcare system and nurturing local markets have triggered a rapid shift towards local production, transforming competitiveness and impacting global trade dynamics. On one hand, competition within the Chinese medical device

---

[63] Campbell, I. and Campbell, S. (2024, May 1). *China In The Global Medtech Industry: Equal Parts Promising And Uncertain.* https://www.meddeviceonline.com/doc/china-in-the-global-medtech-industry-equal-parts-promising-and-uncertain-0001

[64] McKinsey. (2023, September). *Medtech pulse: Thriving in the next decade.* https://shorturl.at/Jn57L

industry is on the rise with domestic firms advancing to higher value segments, starting from the domestic market and expanding internationally, thereby heightening global competition. On the other hand, MNCs are quickly adapting to China's market dynamics, emphasizing efficiency, agility, and omnichannel engagement to succeed. Staying abreast of evolving policies, which range from local manufacturing regulations to data privacy laws, is crucial for operational compliance and success in the China's medical device market.

(b) India

India's medical device market size in 2022 was US$11 billion, according to the *National Medical Devices Policy 2023*[65]. India heavily relies on foreign suppliers for its medical devices, importing around 80% of its equipment, according to the ITA[66]. This dependency is especially notable for advanced technologies like cancer diagnostics, medical imaging, ultrasonic scans, and polymerase chain reaction technologies. Imports are on the rise, fueled by leading hospital chains such as Max, Hinduja Group, Fortis, and Apollo, that are enhancing healthcare infrastructure and boosting India's medical tourism sector, which is now valued at around US$9 billion.

Medical devices in India are regulated by the local government under the *Drugs & Cosmetics Act* (D&C Act) in 1940, which categorizes them as "drugs". In July 2022, the Ministry of Health and Family Welfare introduced the *New Drugs, Medical Devices, and Cosmetics bill* to replace the D&C Act.[67] This new legislation aims to enhance safety, efficacy, and compliance with international standards for medical devices, drugs, and cosmetics to be imported, produced, and sold within India. The draft bill is slated for presentation in parliament sessions. Upon approval by the Parliament, the new bill will establish regulations governing medical devices, pharmaceuticals, and cosmetics across the country.

India's domestic medical device sector faces hurdles such as inadequate infrastructure, high financing costs, and limited R&D investments. To address these challenges, the Indian government has implemented strategic initiatives such as the Production-Linked Incentive (PLI) Scheme and the Medical Devices Parks Scheme to catalyze the industry's expansion.[68]

The PLI Scheme for Promoting Domestic Manufacturing of Medical Devices was launched in March 2020 to stimulate local manufacturing and attract capital. The PLI scheme, spanning

[65] Rao A. (2024, April 10). *The MedTech Industry in India: Outlook and Growth Drivers.* India Briefing. https://www.india-briefing.com/news/india-medtech-industry-outlook-growth-31918.html/

[66] The International Trade Administration, US Department of Commerce. *India -Country Commercial Guide.* Retrieved August 1, 2024, from https://www.trade.gov/country-commercial-guides/india-healthcare-and-life-science

[67] Matai, A. (2024, January 4). *Navigating a new era: India's drugs, medical devices, and cosmetics bill.* https://www.financialexpress.com/business/healthcare-navigating-a-new-era-indias-drugs-medical-devices-and-cosmetics-bill-3354345/

[68] Rao A. (2024, April 10). *The MedTech Industry in India: Outlook and Growth Drivers.* India Briefing. https://www.india-briefing.com/news/india-medtech-industry-outlook-growth-31918.html/

from 2020–2021 to 2027–2028, incentivizes selected companies with financial rewards based on incremental sales, aimed at boosting specific medical device segments like cancer care, radiology, and cardiac devices. In March 2024, the government approved 26 applicants under the PLI scheme to manufacture a range of 138 medical device products, signaling a proactive approach to support domestic manufacturing. The *National Medical Devices Policy 2023*, introduced with the aim of boosting the industry's value to US$50 billion by 2030, focuses on critical areas like infrastructure development, R&D facilitation, investment attraction, regulatory streamlining, human resource development, and brand positioning. The government aims to enhance domestic manufacturing capabilities and the industry's competitiveness.

Some local companies have begun to prioritize R&D and high-end devices. For instance,

- Meril Life Sciences, founded in 2006, boasts a wide-ranging portfolio of medical devices that encompass vascular intervention, cardiac surgery, orthopaedics, endosurgery, diagnostic devices, as well as ear, nose and throat medical devices. With a strong emphasis on innovation, the company obtained the CE-mark for 'Myval,' its transcatheter heart valve.
- Skanray Technologies, headquartered in Mysuru and established in 2007, specializes in developing diagnostic X-Ray systems, surgical C-arms, electrocardiograms devices, and patient monitoring systems. The company's commitment to innovation is underscored by its extensive IP, boasting over 80 patents and more than 50 CE/FDA certified medical devices.[69]
- Primary Healthtech Pvt. Ltd., a startup established by the Indian Institute of Technology (IIT) Guwahati alumni, launched MobilabTM, a Point-of-Care Testing (POCT) device designed for the early detection of different chronic illnesses, in October 2023.[70]
- S3V Vascular Technologies Ltd, situated in Mysore and specializing in neurovascular devices for stroke treatment, secured a series B funding round in March 2024. The funding will facilitate the establishment of a manufacturing facility for neurovascular devices in Mysore. The company intends to seek US FDA and European approvals, aiming to export its devices to Asian, Middle Eastern, and East European markets.[71]

---

[69] KPMG. (2023, October). *From volume to value – Fostering research and innovation in India's medical device industry.* https://assets.kpmg.com/content/dam/kpmg/in/pdf/2023/10/from-volume-to-value.pdf

[70] India Brand Equity Foundation. (2024). Medical Devices Industry Analysis. https://www.ibef.org/industry/medical-devices-presentation

[71] Medical Buyer. (2024, March 15). *S3V Vascular Technologies secures Rs 300 crore in Series B funding*. https://medicalbuyer.co.in/s3v-vascular-technologies-secures-rs-300-crore-in-series-b-funding/

According to a KPMG report published in October 2023, India's medical device sector accounted for a 1.5% share of the global market but is poised for significant growth, presenting lucrative opportunities for investors [72]. FDI in India's medical device sector has been on the rise, reaching US$3.4 million in the period of April to December 2022, up from US$1.9 million in the period of April 2021 to March 2022. Major international players are making substantial investments in India, underscoring the country's attractiveness as a hub for medical technology innovation and manufacturing. For instance,

- In March 2024, Medtronic announced a US$350 million investment to establish the Medtronic Engineering & Innovation Center in Hyderabad, set to become one of the largest R&D facilities globally outside the US. This funding will advance technologies in surgical procedures, implants, robotics, imaging, and navigation.
- Omron Healthcare, a renowned Japanese personal healthcare products corporation, disclosed plans in May 2024 to build a device manufacturing facility in Tamil Nadu, committing US$15.5 million to the endeavor.
- Siemens Healthineers is poised to invest US$179.7 million by 2025 to inaugurate an innovation hub in Bengaluru. In a collaboration initiated in August 2023, Siemens partnered with India's Manipal Academy of Higher Education to facilitate a research collaboration in the medical field, focusing on cutting-edge technologies such as immersive experiences, cybersecurity, AI, and data analytics.
- The French diagnostics specialist BioMérieux is in the process of establishing a laboratory at Kasturba Medical College in Manipal.
- Boston Scientific inaugurated its first facility in Gurugram in 2016, and then extended its presence in India by launching a second R&D center in Pune in 2022. This move solidifies India's status as the company's second-largest R&D center globally outside the US. [73]
- Stryker inaugurated a neurovascular research facility at its Global Technology Center in Gurugram, with a particular focus on developing treatments for brain strokes.

In summary, India's medical device industry is undergoing a period of rapid transformation and growth, supported by government initiatives, increased foreign investment, and strategic policy interventions. The sector's potential for expansion and innovation presents promising opportunities for global investors and stakeholders. The increased focus on R&D, infrastructure development, and regulatory facilitation is poised to position India as a key player in the global medical technology landscape, boosting healthcare outcomes and driving economic growth of the country.

---

[72] KPMG. (2023, October). *From volume to value – Fostering research and innovation in India's medical device industry.* https://assets.kpmg.com/content/dam/kpmg/in/pdf/2023/10/from-volume-to-value.pdf
[73] Rao A. (2024, April 10). *The MedTech Industry in India: Outlook and Growth Drivers.* India Briefing. https://www.india-briefing.com/news/india-medtech-industry-outlook-growth-31918.html/

3. Selected nearshoring manufacturers for the US market

Medical device manufacturers have traditionally outsourced operations to low-cost countries like China, Malaysia, Thailand, and Vietnam to leverage inexpensive labour[74]. However, rising labour expenses in those countries have diminished this cost advantage. Moreover, global events such as the COVID-19 pandemic, climate change, natural disasters, trade conflicts, and geopolitical tensions have tested supply chains like never before. Medical device manufacturers are now more inclined to shorten supply chains and drive down operational costs through regional manufacturing strategies. This shift is driven by the need for better cost control and meeting evolving customer demands. In response, over the past decade, US companies have increasingly turned to nearshoring in Mexico, Central America, and the Caribbean to mitigate risks and enhance resilience.

(a) Mexico

Mexico's medical technology market has exhibited consistent growth. According to Statista, the market stood at US$6.4 billion in 2019, rising to US$7.7 billion in 2022, reflecting a CAGR of 6.4%. Looking forward, Statista anticipates a substantial expansion, projecting the market to reach US$12.3 billion by 2029.[75] Mexico's healthcare sector is evolving rapidly, with increasing investments and technological advancements driving further expansion in the industry.

Mexico stands out as a prominent player in the global medical device manufacturing landscape, ranking as the top exporter of medical devices to the US and the 8th largest producer of medical devices worldwide.[76] The country hosts a thriving medical device sector comprising over 2,500 specialized companies, with key production hubs in states like Chihuahua, Tamaulipas, and Baja California. Notably, Tijuana in Baja California shines as a major North American manufacturing center, benefitting from its close proximity to San Diego's National Biotech Cluster, fostering R&D collaborations across the border.

As a nearshoring production base for the US market, Mexico offers a skilled labour force, favourable demographics, and a reputation for upholding high-quality standards in medical device manufacturing. Renowned global industry players such as Medtronic, Johnson &

---

[74] Bamber, P., Fernandez-Stark, F., and Taglioni, D. (2020, May 12). *Four reasons why globalized production helps meet demand spikes: The case of medical devices and personal and protective equipment.* World Bank Blogs. https://blogs.worldbank.org/en/developmenttalk/four-reasons-why-globalized-production-helps-meet-demand-spikes-case-medical

[75] Statista. Retrieved July 18, 2024, from https://www.statista.com/outlook/hmo/medical-technology/worldwide

[76] Malottky, S. (2023, January 25). *4 Reasons Mexico's Medical Device Industry is Attracting Interest, Investment.* https://www.americanindustriesgroup.com/blog/4-reasons-mexicos-medical-device-industry-is-attracting-interest-investment/

Johnson, Stryker, Philips, and Siemens have recognized Mexico's capabilities, with facilities compliant with stringent regulatory requirements like FDA, CE, and ISO 13485 certifications.

Amidst a global shift towards agile and diversified supply chains, Mexico's appeal increases as companies seek to reduce reliance on Chinese manufacturing. Reshoring operations to Mexico presents an attractive proposition with labour cost savings averaging around 20% compared to China, positioning the country as both a cost-effective and quality-driven manufacturing base for medical devices.

While border states like Baja California and Chihuahua boast strong manufacturing capabilities, proximity to the US border entails higher operational costs and intensified competition. Wage levels near the border can be up to 50% higher compared to central Mexico. President Lopez-Obrador's efforts to elevate minimum wages annually, with increments of 15-20%, have uplifted income levels across the country, with border areas experiencing even steeper rises.

Nevertheless, manufacturers have a lot of options within Mexico. Guanajuato, a state located in central Mexico, emerges as a prime location for global medical device manufacturing. Three main strengths contribute to its appeal, including its robust manufacturing heritage, favourable demographics, and strategic positioning.

Guanajuato emerges as a cost-effective alternative, offering competitive labour costs without compromising on quality. Leveraging its established manufacturing background across diverse industries, the region hosts a skilled workforce adaptable to the needs of medical device manufacturers. The region's population has steadily increased over the past two decades, with a median working age of 29. The allure of a dynamic, cosmopolitan environment coupled with year-round pleasant weather in the Bajio region, where Guanajuato is situated, attracts a skilled workforce. In response to private sector demands, Guanajuato's government is ramping up support for manufacturers through financial incentives and educational programs.[77]

Besides, the Guanajuato International Airport, a major transportation hub, facilitates visits for overseas investors and clients and the city's international engagements. Guanajuato's central location also aligns with major trucking routes, intersecting the country's busiest highways.

For companies venturing into manufacturing in Mexico for the first time, a key challenge often arises from the unfamiliarity with the country, including understanding Mexico's regulatory landscape concerning compliance, customs procedures, import/export protocols,

[77] MedTech Intelligence. (2023, October 25). *Ask the Expert: Four Key Reasons Medical Device Manufacturers Should Be Looking at Mexico.* https://medtechintelligence.com/feature_article/ask-the-expert-four-key-reasons-medical-device-manufacturers-should-be-looking-at-mexico/

human resources practices, facility requirements, supply chain intricacies, and more. For example, achieving the Certification of the Authorized Economic Operator program (known in Mexico as OEA Certification), which allows for expedited and less rigorous customs assessments for cross-border shipments, can be a lengthy process spanning two to three years. Additionally, navigating Comisión Federal para la Protección contra Riesgos Sanitarios, COFEPRIS, the regulatory body of Mexico responsible for ensuring the quality of medical devices, can be as complex as navigating the FDA. To sidestep these obstacles, companies should collaborate with an experienced partner in Mexico with a proven history of not just facilitating market entry but also providing ongoing support essential for a successful and profitable venture.

The US-Mexico-Canada Agreement (USMCA) trade agreement, effective since July 2020, has catalyzed growth and investment in Mexico's medical device industry by enhancing regulatory alignment and facilitating smoother import processes for medical and pharmaceutical products. However, after maintaining a zero tariff for a couple of years, the US President announced on 1 February 2025 the decision to impose a 25% tariff on all imports coming from Mexico. Two days later, the President paused this tariff decision on Mexico for 30 days. This suspension is delaying an immediate onset of a trade war between the two neighbours, suggesting potential trade uncertainties that could harm the economies of all parties involved in the future. [78]

(b) Costa Rica

Costa Rica, a small country with a population of five million, has achieved remarkable success in nearshore production, with medical devices emerging as the country's primary exports. This strategic shift reflects Costa Rica's focus on the life science and medical device sectors in its export strategy. Positioned as a rising star in biomedical exports, Costa Rica's medical device manufacturing sector showcases a diverse range of high-quality products, highlighting the country's export prowess and growth in the industry. [79]

Costa Rica's transition from an agriculture-based economy to a manufacturing-focused one, particularly in the medical device sector, can be attributed to several key factors. In response to the debt crisis of the 1980s, Central American countries shifted towards an export-oriented development strategy, moving away from import substitution models. Costa Rica

---

[78] Garcia, D.A. and Martinez, A.I. (2025, February 3). *Mexico vows retaliation to Trump tariffs without detailing targets*. Reuters. https://www.reuters.com/world/americas/mexican-president-orders-retaliatory-tariffs-against-us-2025-02-02/ &
Garcia, D.A., Hunnicutt, T. and Ljunggren, D. (2025, February 4). *Trump pauses tariffs on Mexico and Canada, but not China*. Reuters. https://www.reuters.com/world/us/trump-says-americans-may-feel-pain-trade-war-with-mexico-canada-china-2025-02-03/
[79] Alfaro, L. (2024, April 22). *Biomedical Exports and Costa Rica: The Great Reallocation of Global Supply Chains.* https://revista.drclas.harvard.edu/biomedical-exports-and-costa-rica-the-great-reallocation-of-global-supply-chains/

embraced this shift by establishing free trade zones, offering tax incentives, and liberalizing trade policies to attract foreign investment and promote export-driven manufacturing operations. A skilled workforce, strategic location bridging North and South America, stable political environment, and attractive investment incentives have propelled the transformation, positioning Costa Rica as a significant player in the global medical device market.

The country has signed multiple free trade agreements (FTAs) with the US, peer countries in Central America, and various nations in Europe and Asia. The Central America-Dominican Republic free trade agreement (CAFTA-DR), effective from January 2009, facilitated the modernization of Costa Rican laws concerning intellectual property, insurance, telecommunications, and distribution agreements. This FTA also streamlined the trade of medical devices among the participating countries by establishing standards and regulations[80]. In fact, the strong partnership between Costa Rica and the US in nearshoring efforts is bolstered by decades of trade relations rooted in historical initiatives and treaties. From President Kennedy's Alliance for Progress Initiative to President Reagan's Caribbean Basin Initiative, and the CAFTA-DR under President Bush, these collaborations have solidified the bond between the two nations. With the US being Costa Rica's dominant trade partner, accounting for over 40% of trade activities and a significant source of medical tourism of Costa Rica, these connections are invaluable for both countries. Bilateral trade between Costa Rica and the US in the medical device sector has exceeded US$300 million, emphasizing the deep economic ties of the two nations in this industry.

In addition, Costa Rica has engaged in other regional trade agreements, including the Association Agreement between the EU and Central America (AACUE), which took effect for Costa Rica in October 2013. With the EU eliminating 99% of its tariffs on industrial goods and fisheries, Central America is committed to granting duty-free access to all industrial products and fisheries by 2025[81]. Furthermore, a collective FTA involving the European Free Trade Association (EFTA) countries (Switzerland, Iceland, Liechtenstein, and Norway), Costa Rica, and Panama took effect in 2014. Specifically for Costa Rica, the country enjoyed duty-free access for 98.7% of its exports to the EFTA countries, covering a range of agricultural products and industrial goods. Conversely, 93.3% of exports from the EFTA states to Costa Rica will immediately benefit from tariff elimination[82].

---

[80] Villarreal, A. (2022, July 22). *Dominican Republic-Central America-United States Free Trade Agreement (CAFTA-DR)*. Congressional Research Service. https://crsreports.congress.gov/product/pdf/IF/IF10394
[81] European Commission. *EU-Central America Association Agreement.* Retrieved December 23, 2024, from https://trade.ec.europa.eu/access-to-markets/en/content/eu-central-america-association-agreement
[82] CR Business Book. *Costa Rican Trade Policy.* Retrieved December 23, 2024, from https://www.crbusinessbook.com/politica_comercial_eng.html#gsc.tab=0

As part of the country's broader investment portfolio, Boston Scientific's Costa Rican journey began in 2004 with its Heredia facility focused on endoscopic devices. In 2009, the company expanded to Coyol, becoming the first medical device company in Costa Rica with dual locations. In 2012, Boston Scientific established a leading R&D centre in Heredia, progressing to advanced devices. In 2019, a commercial office in San José further extended Boston Scientific's reach to Central America, emphasizing patient care. Following the acquisition of Baylis Medical in 2022, a Cartago site was opened, making Boston Scientific the first with three Costa Rican manufacturing facilities. This growth continued with the establishment of another site in Cartago in early 2025, showcasing ongoing expansion and commitment of the company in Costa Rica.

Besides Boston Scientific, Costa Rica hosts over 80 medical device companies today, including industry leaders like Baxter, Medtronic, Allergan, and Hologic. From 2017 to 2023, the sector displayed robust growth, with employment rising from 22,399 to more than 55,000 positions, demonstrating resilience and continuous advancement. In 2023, the country's medical device exports have significantly expanded, and precision and medical equipment accounted for 42% of the country's total exports, marking a significant rise from 26% in 2017[83]. Major medical device export items of Costa Rica include orthopedic implants, surgical instruments, cardiovascular devices, diagnostic imaging equipment, and disposables, while major medical equipment export items cover hospital beds, patient monitoring systems, surgical lights, anesthesia machines, and more.

In short, the medical device industry in Costa Rica has thrived due to its strategic location bridging North and South America, cost-effective and skilled workforce, favourable investment environment, open economic policy and free trade agreements. As the sector continues to evolve, Costa Rica is poised to become a significant nearshoring manufacturing and R&D location for the US medical device market.

[83] LATAM FDI. (2024, December 12). *Why Are Costa Rican Medical Device Exports Growing So Rapidly?* https://latamfdi.com/costa-rican-medical-device-exports/

VIII. Conclusion and Future Outlook

The global medical device market is expanding rapidly, with significant advancements unfolding in emerging markets. The landscape is evolving dynamically, driven by key players worldwide. The US and Germany play pivotal roles in shaping the medical device industry. Meanwhile, China is emerging as a significant player, implementing reforms like centralized procurement and attracting foreign investments to bolster its market presence.

The impact of COVID-19 has catalyzed transformative shifts in the medical device supply chain. Pre-pandemic challenges like cybersecurity, counterfeiting, and recalls on defective designs were compounded by the COVID-19 disruptions, including manufacturing delays, supply shortages, and logistical hurdles due to lockdowns and travel restrictions. This crisis prompted a reevaluation of practices and the need for diversification and decentralized manufacturing. Decision-making in the medical device supply chain is complex, influenced by multifaceted factors such as geopolitics, regulations, cost management, chip shortages, cybersecurity, and sustainability.

Amidst the evolving landscape, the pandemic has underscored the importance of collaboration and data exchange among stakeholders like suppliers, distributors, and healthcare providers to strengthen supply chains. Transparent communications on inventory levels and demand forecasts can bolster supply chain resilience in times of disruption. Medical device companies should prioritize investing in software and data analytics, collaborate with technology firms to meet evolving consumer demands, as well as ensure data security, data privacy, and intellectual property protection. In addition, cutting-edge technologies like AI, ML, IoT, data analytics, robotics, and 3D printing are elevating the industry's innovative capabilities. These technologies are reshaping healthcare delivery, making it more efficient and patient-centric. Wearable devices integrated with cloud-based data and analytics are also revolutionizing diagnostics, monitoring, and treatment.[84]

In addition, strategic decisions around reshoring, nearshoring, and offshoring are pivotal in shaping supply chain efficiency, responsiveness, cost-effectiveness, and regulatory compliance. Thoughtful evaluation and implementation of these strategies empower companies to enhance operational flexibility, anticipate emerging healthcare trends, and navigate the intricate global medical device manufacturing landscape with resilience and competitiveness.

[84] Damicis, J., Tranmer, A., and Otterby, D. (2024, February 2). *Innovation and investment driving US medical device industry growth.* https://camoinassociates.com/resources/medical-device-industry-growth/

Reshoring entails bringing production back to the home country, often motivated by factors like escalating labour expenses abroad, quality control concerns, and supporting the local economy. Nearshoring involves moving production to geographically close countries, offering benefits such as lower transportation costs, quicker lead times, and cultural alignment. Countries like Mexico, Costa Rica, Puerto Rico and the Dominican Republic are emerging as preferred nearshoring production bases for the US market due to skilled workforces and proximity.

Meanwhile, offshoring, which involves outsourcing to countries with lower labour costs, persists as a prevalent tactic for companies seeking cost savings and global opportunities. China and India stand out as key growth markets for medical device companies and are attracting international investments for medical technology innovation and manufacturing, driven by supportive government policies. China is also rapidly emerging as an important player in the global medical device supply chain, closing the gaps with leaders like the US and Germany. Currently, Chinese medical device companies are actively expanding their global reach by setting up subsidiaries and research centres in the US and the EU, as well as offices and manufacturing facilities in Southeast Asia.

India's medical device industry is undergoing a period of rapid transformation and growth, supported by government initiatives, strategic policy interventions, and increasing foreign investment. The government has lowered device registration fees to enhance access to advanced medical devices and have streamlined clinical trial processes, simplifying market entry for manufacturers. Global market players are also increasingly interested in expanding their direct presence in India.

In summary, the medical device industry is at a pivotal juncture, navigating a landscape characterized by rapid technological advancements and evolving regulatory frameworks. The disruptions caused by COVID-19 have highlighted the importance of formulating a resilient medical device supply chain, which revolves around innovation, technology, sustainability, and global health challenges. A shift towards predictive, personalized, data-driven healthcare solutions, collaborative partnerships and decentralized manufacturing is poised to shape the future trajectory of the industry.

Our Global Supply Chain Analysis by Industry

Electric Vehicle

Charged Up: The Rise of Electric Vehicles and the Race for Critical Minerals and Components

View

Solar PV

Chasing the Sun: Will the Global Solar Supply Chain Find New Horizons?

View

Apparel

Beyond Borders: The Global Landscape of Apparel Supply Chains and China's Evolving Role

View

Medical Device

Embracing Multipolarity: Post-COVID Evolution of Global Medical Device Supply Chain

View

Authors:

Helen Chin
Head
helenchin@ust.hk

William Kong
Manager
williamkong@ust.hk

Wendy Weng
Manager
wendyweng@ust.hk

Sophie Zhang
Manager
sophiezhang@ust.hk

Winnie Lo
Manager
winnielo@ust.hk

Chang Ka Mun
Executive Director
changkamun@ust.hk

HKUST Li & Fung Supply Chain Institute

The HKUST Li & Fung Supply Chain Institute accelerates the creation, global dissemination, and practical application of new knowledge and technologies for managing supply chains. Jointly established by international research university HKUST and supply chain industry leader Li & Fung, the Institute engages in collaborative research, exchanges, professional development and executive education to drive real-world impact across the region and globally, while contributing to Hong Kong's development as a multinational supply chain management center.

HKUST LI & FUNG
SUPPLY CHAIN INSTITUTE