BMJ Group

Medical device manufacturing in emerging markets

Business Report

India | China | Brazil | Pakistan | South Africa

UK International Development
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International Trade Centre

Executive Summary

Emerging markets have become increasingly important in medical device manufacturing as companies seek lower production costs, faster access to growing healthcare demand, and more resilient supply chains. It is an industry that operates globally and is thus driven by complex and competing factors, in particular regulation and trace demands[1]. International trade continues to grow, being roughly worth 140-160 billion USD in 2000 and an estimated 675 billion USD in 2024. The market is truly international as development often happens in one market, manufacturing in another and usage somewhere different again.

This report looks briefly at the manufacturing potential and regulatory landscapes of India, China, Brazil, Pakistan, and South Africa, which now account for a significant portion of the global medical device supply. Manufacturing decisions in this sector are inseparable from regulation; a product's commercial value depends on securing the necessary licenses, maintaining an ISO 13485-certified quality management system, and ensuring patient safety through design and reliability. Beyond simple documentation, a robust manufacturing strategy must integrate ethical labour practices, tackling modern slavery and occupational hazards and environmental sustainability, particularly as global buyers like the NHS prioritise net-zero ambitions and climate-resilient procurement.

Commercially, these five territories offer distinct profiles: China and India lead in industrial scale and technical depth for high-volume exports, while Brazil serves as a high-commitment domestic stronghold with a stable ten-year authorisation window. Pakistan remains a specialised hub for cost-effective, low-complexity surgical instruments, and South Africa functions as a strategic regional gateway for the Sub-Saharan African market. For stakeholders, success depends on a staged launch sequence, beginning with lower-risk devices to build local regulatory capability and a proactive commitment to the Environmental, Social and Governance (ESG) standards that are increasingly becoming a prerequisite for participation in the global healthcare economy.

1. Purpose and Scope

This report provides a brief overview of India, China, Brazil, Pakistan, and South Africa as locations for medical device production, as they now account for a significant portion of global supply. The focus is not only on current manufacturing and future potential, but on the regulatory requirements that affect manufacturing establishment, compliance cost, human and environmental impact.

2. Why Regulation Matters in Manufacturing Strategy

In the manufacturing and exporting of medical devices, manufacturing decisions cannot be separated from regulation. There is limited value in a product if a company cannot secure the required manufacturing license, maintain an accepted quality-management system, or if it has to undergo lengthy registration, increasing the time it will take for the product to hit the market. Overseas manufacturers also have to be aware of the regulations in the country to which they intend to export, to allow the product to be procured. In addition, it is imperative for importing countries to understand these regulations and whether the imports meet the regulatory frameworks of their country. However, regulation is not just about time to market and guaranteeing the right documentation has been approved; it is also importantly about ensuring patient safety, quality and efficacy, uniformity and reliability, building and maintaining trust[2].

Patient safety

Patient safety is paramount. Any instrument that makes contact with a patient must comply with the appropriate regulations in order to protect the patient[3]. Patient safety in surgical device manufacturing depends on strong quality systems, safe design, effective decontamination, regulatory oversight, and post-market monitoring. Internationally, ISO 13485:2016[4] is the main quality-management standard for medical devices. It now forms part of national regulations, for example, the US Food and Drug Administration's (FDA) Quality Management System Regulation (QMSR) incorporates ISO 13485:2016 by reference, reinforcing lifecycle controls in design and production[5].

"ISO 13485 is intended for any organization involved in the design, production, installation, and servicing of medical devices and related services. It can also benefit suppliers and external parties that provide product, including quality management system-related services to such organizations".

The risk of poor-quality devices is that they can fail in use, such as breakage or fragmentation, leaving unretrieved device fragments in the patient and creating further risks that may require intervention. In addition, safety also depends on instruments being designed for sterilisation and reuse where applicable, thus maintaining their robustness. In the UK, a document entitled in the UK, Health Technical Memorandum 01-01[6] provides guidance on the management and decontamination of surgical instruments used in acute care, providing an understanding to manufacturers of what instruments need to withstand.

Another aspect of safety to be considered in the design and manufacture of medical devices is the prospect of human error when using an instrument. Both the FDA and MHRA emphasise that manufacturers should identify use-related hazards early and design devices to minimise user error/ risk and patient harm[7]. These requirements sit within wider regulatory systems such as the EU Medical Device Regulation (EU) 2017/745[8], which sets a medical devices regulatory framework that works to safeguard public health and safety while supporting market competitiveness. This extends to device safety, performance, labelling, clinical evidence, and post-market surveillance. Similarly, in regard to surveillance of medical device performance, in the UK, the MHRA Yellow Card scheme supports ongoing reporting of adverse incidents and emerging device risks once products are in use[9]. This enables a feedback loop to prevent further problems.

Labour practices

Labour practices and environmental impact are other aspects of regulation that cannot be ignored and for which specific standards exist in the UK. The UK government clearly outlines expectations of tackling modern slavery in government supply chains by outlining that in global procurement, tackling modern slavery requires a risk-based and proportionate approach that goes beyond collecting supplier policy statements. In practice, this means assessing whether a contract is higher risk because of the sector, workforce profile, geographic exposure, or underlying commodities, and then reflecting that risk in procurement design, supplier selection, and ongoing contract management. Higher-risk procurements may require deeper supply-chain mapping, more targeted supplier due diligence, stronger contractual controls, and closer monitoring of labour practices, particularly where subcontracting, agency labour, or overseas sourcing are involved. The emphasis is on embedding modern slavery considerations throughout the procurement cycle and working with suppliers to improve practices and protect workers where issues arise, with contract termination used only as a last resort[10].

The health and safety of workers manufacturing medical devices is equally important, but often an underexamined issue within global procurement. This is true within both emerging markets and LMICs, where the core occupational risks are similar across manufacturing and may include exposure to chemicals, plastics, solvents, metals, sterilisation agents, repetitive assembly tasks, poor ventilation, inadequate personal protective equipment, and weak enforcement of occupational health standards[11]. These risks are often heightened where supply chains rely on subcontracting, temporary labour, informal work arrangements, or factories operating under cost pressure and tight delivery timelines, with severity shaped by local regulatory capacity, enforcement, and the maturity of workplace safety systems. As a result, responsible procurement should consider not only product quality and price, but also whether suppliers have effective systems for worker protection, including safe machinery, training, incident reporting, chemical handling controls, working-hour safeguards, and independent monitoring of labour and health-and-safety conditions[12,13].

There are **regulatory frameworks** relevant to the health and safety of workers manufacturing medical devices, but they are typically within national occupational

health and safety law, chemical-safety regulation, and supply-chain due diligence requirements rather than specifically in medical device product regulation. However, there are key international reference points such as the International Labour Organisation (ILO UN department), who promote social justice and international human and labour rights. For example, the ILO Convention No. 155 on occupational safety and health sets a general framework for ensuring a safe and healthy working environment, and ILO Convention Nos. 170 and 177 do the same regarding chemicals at work, covering the management of hazardous chemicals and employer responsibilities for chemical safety[14]. This is especially relevant to medical device manufacturing, where workers may handle a number of hazardous substances such as disinfectants, sterilants, solvents, metals, plastics, and where risk control measures such as ventilation, closed systems, training, safe storage, and medical surveillance are important[15].

Overall, the implication is that worker protection in medical device production is governed mainly through broader workplace safety, chemical management, and responsible sourcing frameworks, while medical device regulation itself is generally more focused on product safety, quality, and market approval.

Environmental practices

The environmental impact of medical device production in emerging markets includes the direct and indirect pressures created across the product lifecycle, particularly through energy use and greenhouse-gas emissions, water consumption, chemical use, air and water pollution, and plastics and packaging waste. These impacts arise from raw material extraction, manufacturing, sterilisation, assembly, transport, and disposal, and may be worsened where environmental controls and waste infrastructure are weak[16, 17]. Medical products and supply chains are a major source of health-sector emissions, which is why sustainability is becoming a strategic issue for both regulators and buyers[18]. In response, health systems and manufacturers are placing greater emphasis on climate-resilient procurement, reduced hazardous substance use, and more circular approaches such as eco-design, resource efficiency, and improved end-of-life management[19, 20]. The NHS has subsequently developed a roadmap to enable suppliers to work toward the NHS net zero ambitions between now and 2030.

3. Regulatory and Commercial Assessment by Country

3.1 India

The healthcare sector has not only become one of India's largest sectors, it is also one of the most commercially promising manufacturing locations, combining a large healthcare market with a formal and increasingly comprehensive regulatory system[21]. As documented by the Central Drugs Standard Control Organization (CDSCO), India, all medical devices in India are regulated under the Drugs and Cosmetics Act, 1940 and the Medical Devices Rules, 2017[22]. This established framework gives manufacturers a defined pathway for licensing and classification, but also means there is an understanding that compliance planning is built in from the start.

From a business standpoint, India's advantage lies in its breadth, as it is well suited both to companies seeking to build local production for domestic demand and to those looking for a manufacturing base with growing export potential[23]. Whilst the market is expanding and there is a regulatory framework in place, the operational detail involved in classifying products correctly, navigating the CDSCO process, and keeping pace with amendments and implementation notices is a challenge. For investors, this means India is attractive, but only with strong regulatory execution and disciplined product-by-product planning[24].

3.2 China

China has the most developed and industrially mature medical device framework among the five countries reviewed. The National Medical Products Administration (NMPA) is responsible for the regulation of medical devices, drugs and cosmetics[25]. They have a tiered structure of classification of devices, which reflects both sophistication and complexity. With regard to manufacturing, China offers an established ecosystem for components, engineering, scale, and technical capability, with the advantage of clear documentation discipline and a more demanding regulatory culture. NMPA continuously refines production and registration rules, creating a framework that remains active and evolving.

Commercially, China is robust for companies that are prepared to support a mature compliance function and that need scale, technical manufacturing depth, or high-volume production capability, as its medical device system combines a stringent, class-based regulatory framework with a large and sophisticated industrial base[26].

3.3 Brazil

Brazil is a significant market, but one where regulation has major implications for investment timing and cost. The Brazilian Health Regulation Agency (ANVISA) is for the regulatory framework for medical devices. The Collegiate Board Resolution, RDC No 751 (Sept 2022) outlines the marketing authorisation processes and confirms that authorisations are valid for ten years[27], giving manufacturers a practical planning horizon following approval.

ANVISA upholds a system of good manufacturing practice (GMP), ensuring consistency and quality control. Whilst all types of medical devices need to be of good standard, III and IV medical equipment require manufacturers to hold a valid ANVISA GMP certificate. ANVISA accepts the protocol for applying for GMP certification as part of a registration filing, but final approval depends on publication of the GMP certification.

This model does make Brazil attractive for companies willing to invest in a locally compliant operating model. It is less attractive for organisations looking for a quick entry into higher-risk product categories, because the compliance obligations can affect timelines and cost of capital. However, whilst strong in pharmaceutical exports, the medical export market in Brazil is growing, with 2025 seeing an export value of approximately $255 million, mainly to the US, Switzerland, Spain, Mexico, Colombia[28].

3.4 Pakistan

In Pakistan, the manufacture, import and export of medical devices is regulated by the Drug Regulatory Authority of Pakistan (DRAP) under the Medical Devices Rules, 2017. Local manufacturers are required to obtain a Medical Device Establishment Licence, and a Production Quality Management System Certificate (ISO 13485) where applicable, tying local manufacturing regulation to licensing and to quality-system compliance and product-specific approval.

This regulatory framework also matters for exporting from Pakistan because it helps establish whether a manufacturer is export-ready, although DRAP approval on its own does not grant access to foreign markets. In practice, holding an establishment licence, maintaining ISO 13485 documentation, and securing enlistment or registration provide part of the compliance foundation that overseas buyers and foreign regulators often expect when assessing suppliers. Pakistan's manufacturing regulation should be understood not only as a domestic legal requirement, but as part of the quality and credibility infrastructure that supports export competitiveness. A foundation of export has clearly been built using this framework as Pakistan has an established export base in surgical and medical instruments, reported as USD 444 million[29] in exports in FY 2023–24. The City of Sialkot has enormous relevance here as it is responsible for the production of 99% of this export to the global supply.

3.5 South Africa

South Africa can be characterised as an emerging market for medical devices, although its main strategic value lies in its role as a regulated regional gateway into Southern and Sub-Saharan Africa markets. The South African Health Products Regulatory Authority (SAHPRA) regulates the licensing of medical device establishments and the registration of medical devices, including requirements for manufacturer, distributor, and wholesaler licences, as well as authorised representative arrangements[30]. South Africa has a more formal regulatory structure than many neighbouring markets, as SAHPRA requires evidence of ISO 13485 certification (requirement for international market access[31]) on renewal for manufacturers and distributors. This strengthens its appeal for firms seeking a compliant Africa-facing base.

South Africa is still quite reliant on imports of medical devices, although the South African MedTech Master Plan[32] outlines the strategic objective over the next three years, to cultivate a robust and globally competitive MedTech sector. Central to this growth is the empowerment of Small and Medium Enterprises (SMEs) to serve as a primary supply engine for both domestic healthcare needs and international export markets. South Africa is best understood as an emerging medical device market with a relatively developed regulatory framework, continuing import dependence, and growing importance as a regional manufacturing and distribution hub.

4. Comparative Business Implications

The five countries outlined clearly present different regulatory-commercial profiles. **India and China** have broader manufacturing programs because they combine scale with increasingly formal regulatory structures. China is the more mature industrial base, but also the more procedurally demanding. India is more flexible for certain lower-risk categories and offers strong long-term potential for domestic manufacturing growth. **Brazil** is attractive, where there is commitment to building a substantial compliant presence in a major domestic market and a clearly emerging export market. It seems to be more suitable for firms with long-term intent than for those testing the market with limited regulatory infrastructure. **Pakistan** may be commercially interesting for selective low-cost production, particularly for lower-risk products. Its market and regulatory system are narrower than those of India or China, and success depends more heavily on handling establishment licensing well and using the right local authorised structure. **South Africa** is less about being a mass-manufacturing platform based on cost alone, but has distinct value as a regional regulatory anchor. For companies with existing approvals in reference jurisdictions, the reliance route may improve the attractiveness of South Africa as part of an Africa-entry strategy.

For the above, it is notable that for domestic-market manufacturing, India, China, and Brazil are the strongest options because each combines a regulatory structure with substantial market opportunity. For export-oriented manufacturing, China and India are more compelling because of scale and industrial depth, while Pakistan may be useful for selected low-complexity categories where cost matters more than ecosystem breadth. For a regional gateway model, South Africa has the clearest strategic fit.

Another important strategic consideration is launch sequencing. In all five countries, lower-risk products usually create a more manageable entry point than higher-risk devices. Companies that begin with simpler products can establish their local quality and regulatory capability before moving into product categories that trigger GMP certification, more extensive registration review, or greater post-market obligations. This staged approach is especially relevant in Brazil, India, and Pakistan.

5. Conclusion

The production of medical devices in emerging markets is not simply a search for lower manufacturing costs. It is a strategic decision shaped by regulatory architecture, quality-system obligations, market-access rules, and the ability to scale operations without repeated compliance disruption. The five countries reviewed here all offer opportunities, but they do so in different ways. It is more complicated than a generic cost comparison. The first decision should always be product classification, because class drives the licensing, filing, registration, and quality-system burden in each jurisdiction. Failing to resolve classification early is likely to distort timelines, planning, and launch expectations.

Regulations aside, the importance and impact of patient safety and the human and environmental impact of production should not be overlooked.

Ultimately, the regulation of medical device production in emerging markets must transcend product safety to address the critical intersection of labour rights, occupational health, and environmental sustainability. While medical device-specific regulations focus on clinical efficacy, worker protection is governed by a complex web of national laws and international standards, such as ILO Conventions, which are vital in mitigating the risks of chemical exposure and modern slavery prevalent in high-pressure supply chains. As global entities like the NHS move toward net-zero targets by 2030, procurement strategies are evolving from simple policy collection to active, risk-based due diligence. Consequently, a proficient and competitive MedTech industry must now demonstrate a dual commitment to both "product quality" and "process integrity," embedding eco-design and ethical labour practices into the core manufacturing lifecycle to ensure long-term viability in a climate-conscious global market.

Suggested further reading

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