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When can India become a global gateway for the medtech industry?

31 January 2025 | Features | By Vrushti Kothari

Over 70 per cent of innovations by Indian medical technology startups are powered by digital integration, driven by a convergence of factors accelerating the industry's growth, according to a recent report by EY. Additionally, government initiatives are playing a pivotal role in positioning India as a global medtech hub. And the growing US FDA approvals is providing the required recognition to Indian medical technologies. Would these developments eventually lead to import independence for the Indian medtech sector?

The Indian medtech market, valued at $12 billion in 2023-24, is projected to reach $50 billion by 2030, with India's global market share set to grow from 1.65 per cent to 10-12 per cent over the next 25 years. Further, Indian medtech exports reached $3.8 billion in 2023-24, with the US as the primary market. Although India is still import dependent in the medtech sector, the growing number of startups in this space are moving the tailwinds in a global direction.

Over the past few years, medtech startups have emerged as trailblazers, using innovation to bridge gaps, solve pressing challenges, and unlocking new possibilities in healthcare. This growth is particularly crucial in India, where healthcare challenges include vast geographical disparities, increasing disease burdens, and affordability constraints.

For example, artificial intelligence (AI)-driven diagnostic solutions are helping healthcare providers detect diseases at earlier stages, while wearable devices are empowering individuals to monitor their health in real time. As a result, Indian medtech startups are actively integrating digital solutions such as AI, IoT, and cloud computing to democratise healthcare with portable devices, remote monitoring and screening tools.

Taking a few examples, BrainSight AI, a Bengaluru-based deep-tech neuroscience startup, is revolutionising the diagnosis and treatment of complex brain disorders through its technology platform, VoxelBox. Likewise, another Bengaluru-based startup 4baseCare is using advanced genomics and digital health technology to offer cutting-edge precision oncology solutions.

The developer of the country's first indigenous surgical robotic technology, Gurugram-based startup SS Innovations, the visionary force behind Made-in-India SSI Mantra Surgical Robotic System, has recently achieved a historic feat in Indian medical science by becoming the first and only company in India to receive Central Drugs Standard Control Organization (CDSCO) approval for Telesurgery and Teleproctoring, signifying a monumental leap in surgical robotics.

Medprime Technologies, a Thane-based medical device company focused on developing cutting-edge healthcare solutions in diagnostics, has announced the launch of Micalys, first-of-its-kind innovative AI-integrated digital microscopy platform that is set to revolutionise digital pathology in India.

"As of 2024, the number of medtech startups has surpassed 10,000, with an impressive annual growth rate of over 15-20 per cent. This expansion is a testament to the sector's ability to address critical healthcare challenges through innovative solutions, including AI, IoT, and nanotechnology integration. Government programmes such as Startup India and Make in India have been instrumental in fostering this growth, encouraging entrepreneurs to focus on affordable, high-quality medical devices", said **Dr Vishal Gandhi, Chief Executive Officer, BioRx Venture Advisors**.

The Health Ministry, in early November last year, announced the launch of a scheme to strengthen the medical device industry. With an outlay of Rs 500 crore, this scheme is a comprehensive one which targets critical areas of the medical device industry, covering manufacturing of key components and accessories, skill development, support for clinical studies, development of common infrastructure and industry promotion.

At present, this scheme is providing regulatory support for 6 technology-based startups funded by Pfizer INDovation Programme. These include- Aarca Research (diagnosing Peripheral Artery Disease), Babycue (POC device for childhood diarrhoea), Biolockey Healthworks (at-home test for cervical cancer), Brela Innovations (breast pads for women for early detection of breast cancer), RNT Health Insights (AI-assisted early gastric cancer detection software) and Utopic Tech (POC test for kidney health).

"The government has approved these startups for assistance under the research linked incentive scheme, and also approved their products for support for pre-clinical and clinical studies. We hope to see these innovations entering the market in the next 2-3 years", said Dr Arunish Chawla, the then Secretary, Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India while announcing the assistance.

Out of these startups, Chandigarh-based startup RNT Health Insights is gaining global attention as it received second US FDA breakthrough device designation for oesophageal cancer detection tool in January this year. The startup has previously received US FDA breakthrough device designation for its early gastric cancer detection tool.

Touching global heights

Besides RNT Health Insights, there are numerous medtech startups in India that are developing technology integrated products and launching them in the global market. Mumbai-based Qure.ai is transforming radiology with AI-powered medical imaging, providing faster and more accurate diagnoses. Recently it has achieved a major milestone with the 510(k) US FDA clearance for its latest AI-powered chest CT solution – qCT LN Quant. Designed to assist radiologists and pulmonologists, this advanced solution analyses lung nodules on non-contrast chest CT scans and tracks volumetric growth for precise progression monitoring. In addition, the startup has also received breakthrough device designation from the US FDA Center for Devices and Radiological Health (CDRH) for its AI-powered Tuberculosis (TB) solution, qSpot-TB.

Citing another example, Pune-based startup DeepTek's US FDA-approved platform, Augmento Enterprise, has been chosen as the national radiology AI platform, contributing to improved productivity and quality of care across public hospitals in Singapore.

Then there is SigTuple, a Bengaluru-based medtech startup that develops Artificial Intelligence (AI) powered digital microscopy solutions. The startup's path-breaking device AI100 with Shonit (Peripheral blood smear application) has received US FDA 510(k) clearance. This is the first integrated hardware and AI medical device, and the first product in AI assisted digital microscopy from India to obtain the coveted clearance and one of the handful of companies in the world to obtain it.

While the innovation level is touching the sky for our medtech entrepreneurs, these global approvals are making it easier for the products to reach different parts of the world. Simply because developing products as per globally accepted standards ensures smooth export and helps overcome technical or qualitative differences across regions and countries.

In this context, **Gaurav Agarwal, Managing Director, Innvolution Healthcare** is of the opinion, "Any startup with an eye on the future must have global regulatory approvals in its design phase. Today over a dozen Indian medtech companies have

strong international presence. I believe in the next 20 years India will corner a large chunk of medtech exports as well. With a favourable investment, regulatory and policy environment, there is an unprecedented surge in medtech startups in the country."

Sharing her perspective, **Gauri Navalkar Godse, Director and CEO- India, UE LifeSciences** said, "Indian medtech startups aren't waiting for global nods before making waves. They're leveraging India's unique strengths i.e. a massive, diverse population of over 1.4 billion, a burgeoning digital landscape with over 900 million internet users expected by 2025, and supportive government initiatives like Startup India and Make in India, to build innovative solutions first for the Indian market. This approach allows them to rapidly iterate, gather crucial real-world data from this vast user base, and scale quickly, all while directly addressing pressing local healthcare needs."

One of the very earlier players in the medtech startup space, UE LifeSciences received US FDA approval many years ago to launch iBreastExam - a handheld, mobile connected and completely wireless device which can detect tumour tissues as small as 3-5 mm while emitting no harmful radiation. For 2025, UE LifeSciences is poised to launch not one, but two groundbreaking solutions. In the first half of the year, the company is unveiling a novel triple cancer screening solution, offering early detection capabilities, and by year's end, the company will empower individuals with an at-home breast cancer screening solution.

Currently, Bengaluru-based startup Niramai has partnered with Goa-based company MolBio Diagnostics to accelerate the adoption of Niramai's AI-based non-invasive breast cancer screening solution in developing countries around the world.

"Niramai is the first Indian company to get an US FDA clearance for a medical device used for women's health. We have also received European CE approval for our Thermalytix Solution. While it is a great learning experience to go through the very rigorous US regulatory process, we have also observed that globally approved products get easily accepted in India. This strengthens the trust factor for an Indian innovation, which can otherwise take time to establish its presence in the market", said **Dr Geetha Manjunath, CEO and Founder of Niramai.**

Dr Geetha further adds, "As India's healthcare ecosystem embraces digital transformation, startups are pioneering groundbreaking solutions. But there are challenges that persist for medtech startups in India, especially in terms of funding, investments and getting good collaborative opportunities with bigger medtech players."

Still a lot more to be done

Both established entities and burgeoning startups in the Indian medtech sector are introducing innovative products that cater to local demands while aligning with international advancements. Moving forward, a great strategy would be needed for the established players to collaborate with the startups for expediting the path from ideation to market introduction.

"There is a need to connect hospitals, medtech companies, and startups, supporting critical stages such as multi-centric trials, regulatory compliance, securing scale-up funding, and facilitating product launches. For instance, KIIT TBI envisions establishing a Technology Development & Deployment Hub for molecular diagnostics, encompassing translational research, product development, validation, regulatory compliance, and skill development. A significant milestone is the creation of the Centre of Innovation in Molecular Diagnostics, a convergence platform for academia, startups, and industries. This centre, supported by Thermo Fisher Scientific, offers industry-aligned training to biotech scholars while driving product innovation in molecular diagnostics", said **Dr Mrutyunjay Suar, Chief Executive Officer, KIIT-Technology Business Incubator (TBI).**

Reflecting upon the current funding and investment opportunities in store for the medtech startups, Dr Vishal Gandhi adds, "The funding landscape for medtech startups in India has transformed significantly. Between January and November 2024 alone, venture capital investments across sectors reached $16.77 billion, with medtech being a key beneficiary. This represents a 14.1 per cent increase in value and a 21.8 per cent rise in deal count compared to the same period in 2023." He also mentions that over the past five years, investments in medtech startups have surged, with significant interest in diagnostics, AI-driven healthcare solutions, and telemedicine platforms.

Another important factor that is ensuring success of many medtech innovations in India lately is the presence of cross-functional leadership teams, where one founder can focus on the science and technology, while the other can take the commercialisation aspect forward.

As the sector matures, the focus will likely expand to include more advanced technologies, global collaborations, and regulatory harmonisation to unlock its full potential. India's journey to becoming a global healthcare hub is well underway, and the medtech startup ecosystem stands at the forefront of this evolution.

Vrushti Kothari

(vrushti.kothari@mmactiv.com)