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Public procurement frameworks could place greater emphasis on validated performance and lifecycle value rather than country of origin or lowest initial price alone.

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As India looks to strengthen domestic capabilities in life sciences, localisation is increasingly moving beyond manufacturing towards R&D, technology development and resilient supply chains. DSS Takara Bio India, a supplier of molecular biology products and solutions, is expanding its localisation strategy, with plans to broaden manufacturing capabilities, strengthen India-based R&D and support emerging areas such as genomics and molecular diagnostics. The company recently marked 15 years in India, with more than 100 molecular biology reagents and enzymes manufactured locally. In this interview with BioSpectrum India, Harkaran Dhingra, CEO, DSS Takara Bio India discusses the company's manufacturing roadmap, indigenous product development, quality benchmarks and India's export potential.



DSS Takara Bio India (DTI) has spoken about deepening localisation. How do you define localisation beyond simply manufacturing products in India?

For DSS Takara Bio India, localisation goes well beyond the final assembly or packaging of imported components. It encompasses the entire value chain: local R&D, technology transfer, indigenous development of products, manufacturing of critical raw materials and enzymes, quality assurance, application development, technical support and supply chain resilience.

DTI has already established end-to-end manufacturing capabilities for four key molecular biology enzymes, from raw material to finished product, with an annual capacity exceeding 20 million units. We have also localised nearly 80 Takara Bio catalogue products through technology transfer and independently developed close to 40 products through our in-house R&D capabilities.

True localisation should ultimately enable India not only to manufacture established products but also to develop technologies locally, build a strong ecosystem of domestic suppliers, solve India-specific scientific and diagnostic challenges, and create products capable of serving global markets.

Which product categories have the greatest potential for indigenous manufacturing over the next five years?

PCR enzymes, master mixes, nucleic acid extraction products and molecular diagnostic reagents offer significant near-term potential because they are foundational technologies used across research, clinical diagnostics, agriculture, food testing and biopharmaceutical development.

There is also considerable potential in lyophilised PCR reagents, which can improve product stability and simplify distribution; automation-compatible sample preparation solutions; specialised reagents for genomics and next-generation sequencing; and application-specific products for areas such as antimicrobial resistance surveillance, oncology and infectious disease testing.

Over time, India can also develop greater capabilities in advanced enzymes, RNA-related workflows, gene-editing reagents, cell and gene therapy research products and other high-value inputs currently dependent on imports. India has the scientific talent, expanding market and manufacturing base required to build these capabilities at scale.

What manufacturing capabilities or product lines does DTI plan to add next?

Our expansion roadmap focuses on progressively increasing both the breadth and technological sophistication of products manufactured in India. Current capabilities include PCR-related enzymes and master mixes, nucleic acid extraction kits and customer-specific dispensing in different formulations and volumes.

The next phase includes expanding our portfolio of locally manufactured extraction products, developing lyophilised or LyoReady PCR master mixes and building automation-compatible sample preparation solutions. We also intend to develop

application-oriented products for molecular diagnostics, genomics, NGS and other emerging research areas.

An important part of this roadmap is indigenous product development. Several products developed by DTI's R&D team have been submitted to Takara Bio Japan for evaluation and potential inclusion in the global portfolio. Successful qualification would allow these products to be manufactured in India and supplied internationally through Takara Bio's distribution network.

How is DTI ensuring that Indian-made products meet international quality benchmarks?

Quality is central to our localisation strategy. DTI established its quality management systems early in its manufacturing journey, achieved ISO 9001 certification in 2017 and obtained ISO 13485:2016 certification in 2023 for the design, development, manufacturing and marketing of IVD molecular biology reagents.

Our manufacturing processes are supported by defined controls, product validation, batch-level quality assessment and documented quality systems. Technology-transferred products must demonstrate the required consistency and performance before being released for domestic or international supply.

We are also strengthening process automation, manufacturing controls and validation capabilities as the portfolio expands. In parallel, DTI operates a validated cold-chain distribution system that enables temperature-sensitive products to be delivered reliably across India. Validated cold-chain packaging for up to four days, combined with typical delivery timelines of 24-48 hours, helps ensure product integrity throughout distribution. These systems help ensure that quality is maintained not only during manufacturing but throughout the product's journey to the customer.

How is DTI building confidence in locally manufactured products?

Confidence is built through performance, consistency and evidence. Indian-made products must demonstrate that they can perform reliably alongside established international alternatives in real laboratory workflows.

We combine rigorous product validation with application support, demonstrations and direct engagement with researchers, clinicians and diagnostic laboratories. Our pan-India presence, comprising nine regional offices, dedicated sales and technical teams, channel partners and a customer base of more than 4,000 institutions, allows us to support users closely before and after product adoption.

Products manufactured in India have also been supplied to Takara Bio Japan and incorporated into its global supply chain since 2014. This international acceptance provides strong evidence that products manufactured in India can meet global expectations. During the COVID-19 pandemic, DTI supplied more than five million PCR reactions' worth of master mixes and custom-dispensed products while maintaining an average lead time of two to three weeks, further demonstrating our ability to deliver quality products reliably at scale.

DTI also benefits from Takara Bio's more than 100 years of scientific expertise and technology know-how transfer, ensuring products are developed and manufactured to globally accepted standards. In addition, critical raw materials are sourced from approved global suppliers and undergo rigorous lot-to-lot consistency testing before acceptance.

How is DTI aligning its manufacturing strategy with high-growth sectors?

Our strategy is increasingly driven by complete applications rather than individual reagents. Genomics, molecular diagnostics, cell and gene therapy, single-cell analysis, spatial biology and RNA therapeutics require highly consistent reagents, robust sample preparation, automation compatibility and strong technical support.

DTI is therefore expanding local capabilities in enzymes, PCR reagents, nucleic acid extraction and application-specific workflows while drawing on technologies available across the wider Takara Bio group. Our objective is to connect locally manufactured foundational products with advanced global technologies and adapt them to the requirements of Indian laboratories.

We are also deepening collaboration with academic institutions, hospitals, biotechnology companies, pharmaceutical organisations and diagnostic laboratories so that future products are developed around actual scientific and clinical requirements.

Does DTI see India becoming an export hub for molecular biology reagents?

Yes. India has the potential to become an important global manufacturing and innovation hub for molecular biology products, provided it continues to invest in quality systems, specialised talent, R&D and dependable supply chains.

Our export journey began in 2014, when reagents equivalent to nearly 10 million reactions were supplied to Japan. Exports have continued since then, with India-manufactured products entering international markets through Takara Bio's global distribution network.

Our immediate opportunity is to expand this established model: manufacture more globally qualified products in India, increase the contribution of India-developed products and serve international demand through Takara Bio's existing network. Japan and other markets served by the Takara Bio group represent meaningful opportunities, particularly where customers require globally benchmarked quality, scalable manufacturing and greater supply chain resilience.

What additional policy or ecosystem support would accelerate localisation?

Government initiatives have created important momentum, but molecular biology manufacturing requires a specialised ecosystem. Greater support for domestic development and scale-up of critical enzymes, biological raw materials and high-value reagents would help reduce dependence on imports.

Shared validation infrastructure, translational grants, industry-academia development programmes and easier access to pilot-scale biomanufacturing facilities could help promising technologies move from the laboratory to commercial production. Predictable and time-bound regulatory pathways are equally important, particularly for molecular diagnostic products.

Public procurement frameworks could also place greater emphasis on validated performance and lifecycle value rather than country of origin or lowest initial price alone. Finally, workforce development programmes in bioprocessing, quality systems, regulatory science and molecular diagnostics would strengthen the specialised talent base required for sustainable localisation.

Strengthened regulatory oversight and clear assessment criteria for genuinely India-manufactured components are also essential to accelerating localisation. Increased awareness among end users and regulatory authorities regarding the distinction between truly indigenous products and repackaged or white-labelled offerings would encourage authentic domestic manufacturing. Such measures would support the development of a complete local supplier ecosystem, improve supply chain resilience and reduce import dependency.

What role does DTI envision playing in India's life science ecosystem by 2030?

By 2030, we envision DSS Takara Bio India as a major bridge between global biotechnology innovation and India's scientific, manufacturing and clinical capabilities.

Success would mean substantially expanding the number and sophistication of products manufactured in India; increasing indigenous enzyme and raw material capabilities; developing more products through local R&D; and supplying a growing portfolio of India-made products to international markets.

It would also mean becoming a stronger scientific partner to academic institutions, biotechnology and pharmaceutical companies, hospitals and diagnostic laboratories. We aim to support emerging fields including genomics, precision medicine, single-cell and spatial biology, RNA therapeutics, antimicrobial resistance and cell and gene therapy through technology access, education, technical expertise and collaborative development.

Our ambition is to progress from "Make in India" to "Develop in India and Make in India for the World", demonstrating that India can contribute not only scalable manufacturing capacity but also globally competitive innovation, scientific expertise and technology development to the life sciences ecosystem.

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