

Hemant Koshia - Commissioner, FDCA Gujarat



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The State of Gujarat is one of India's most culturally diverse, the birthplace of 'Father of the Nation' Mahatma Gandhi, and the only place in the world where Asiatic lions can be found in their natural habitat. It is also an economic powerhouse, with key Gujarati industries including dairy, cement, chemicals, petrochemicals, as well as pharmaceuticals. Dr Hemant Koshia, commissioner of the state's medicine regulator, FDCA Gujarat, outlines the vital role that Gujarat plays in national and international medicine supply chains, its important educational and capacity building work, and the impact of the COVID-19 pandemic on technological transformation.

Global Gujarat

Dr Koshia describes Gujarat's pharma sector as "thriving" – an assessment borne out by its 3,854 active licensed manufacturers. Many of these firms – such as Zydus Cadila – have evolved from humble beginnings to become household names.

"This success is partly due to Gujarat playing host to India's inaugural pharmaceutical college, established in 1947," explains Koshia. "We now have over 65 pharmacy schools and the industry benefits from a robust support system encompassing chemical, petrochemical, and machinery manufacturing, along with comprehensive printing, packaging, and transportation services."

The State is an extremely important pharmaceutical producer, accounting for 35 percent of India's pharma sector turnover and 28 percent of national pharma export. It also acts as a crucial cog in medical technology supply chains, with 78 percent of India's cardiac stents, 60 percent of its orthopaedic implants, and 50 percent of its intraocular lenses produced in Gujarat.

Education & Collaboration

However, ensuring that all the manufacturers within Gujarat are on top of global trends and meet global quality standards is no mean feat. Therefore, FDCA Gujarat – in addition to its role as a regulatory decision-making body – places great import on educational and training initiatives. “We engage with stakeholders across the board, both locally and internationally, on knowledge sharing and capacity building,” outlines Koshia

“Some of our key international partners include the US FDA – from whom we have hosted several visits to the State and have conducted joint inspections with – as well as the UK MHRA, the Bill & Melinda Gates Foundation, and the WHO.” He continues, “In addition, we recently organised training programs for state drug control officers in collaboration with NIPER-Ahmedabad and National Forensic Science University (NFSU)-Gandhinagar. All of these efforts are aimed at boosting the quality and reputation of our companies, and ultimately providing better and more effective medicines and technology to patients.”

COVID: A Technological Turning Point

For regulatory bodies across the world, the COVID-19 pandemic was watershed moment.

Regulators had to move more quickly than ever to fast-track trials and testing for therapeutics and vaccines, which necessitated the uptake of various digital workarounds and new technologies.

The same was true in Gujarat, as Dr Koshia elucidates. “During COVID, the demand for injectables skyrocketed, but the standard testing times meant that ordinary people were waiting too long for much-needed treatments. We therefore adopted a rapid microbiological testing system, which allowed for product quality assurance to be conducted more quickly, significantly reducing the testing duration from 14 days to just three hours.”

Looking Forward

While Gujarat, and India, have built their global pharma reputation on the price and volume of their chemical generic offering, Koshia admits that “the future of the pharmaceutical industry is shifting towards biologics, moving away from traditional chemistry-based approaches. The significant uptake of biologic COVID-19 vaccines over the past few years is just one clear example of this trend.”

Rather than perceiving this global shift as a threat, Koshia is keen to underline Gujarat’s potential to contribute to it. “The Indian government’s forthcoming R&D policy, aimed at incentivizing research and development within the pharma sector, is set to boost the industry’s financial performance significantly, offering exciting prospects for both large and small companies,” he notes. “We have the experience, the footprint, the governance, and the ambition to leverage the opportunities ahead and forge a new path for pharmaceuticals in Gujarat.”

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