



CliniExperts

The go-to team for India's healthcare regulatory affairs management

“ This Delhi-based consultancy is emerging as a gateway to India's healthcare regulatory affairs management. From medical devices to pharmaceuticals, biologicals, cosmetics, food, Nutraceuticals and vaccine product approvals, and much more, the company has provided end-to-end clinical and regulatory compliance services to over 900 domestic and India-entrant foreign companies. Unwavering commitment to benchmarking India's regulatory compliance deliverables and bringing them on par with international standards of excellence is the reason behind the company's steady scaling.”

Dr. Ashwini Kumar, CEO

In 2009, a medical post-grad from AIIMS decided to take a plunge into the underserved regulatory compliance industry, after a brief stint as a researcher at his alma mater. Jargons like start-ups, entrepreneurship, hustle, and bootstrapped venture were not yet in vogue then, but this ambitious youngster with fire and fuel in his belly did it all – He toiled tirelessly to manifest his vision into a small company and named it CliniExperts. Dr Kumar focused on quality of deliverables, reliability, and seamless execution of the full-stack services that he offered. Soon, his name became synonymous with trusted compliance partnership, and the knocks on his door became persistent and frequent. From then

till now, the rise and rise of CliniExperts has positioned it as the leading name for anything and everything in healthcare compliance and India entry.

Drivers of success

When asked about his secrets of success, Dr Kumar circles the partnership approach and ownership of work, “*We don't behave or work as external consultants; we (rather) take a partnership stance and bond with the client as one team. This creates seamless and satisfactory outcomes. Also, we own up our work. We consider any assignment as our own, and work to our bestest capabilities.*” At that, Rashmi Verma, COO and Dr Kumar's wife chips in, “*I think the constant deepening of our knowledge and information basins has earned us respect and confidence. In regulatory contexts, India is a continent. With the dynamics of 29 states and 7 union territories at play, compliance is a volatile potpourri. We invest heavily in our resources and knowledge verticals. As a result our solutions have always been cutting-edge.*”

CEO Dr Ashwini Kumar says a partnership approach and ownership of work have driven the scale and scope of CliniExperts' success.

The brimming services bucket

As a multi-solutions service, CliniExperts covers the full spectrum of deliverables – regulatory affairs management with government and nodal agencies including CDSCO, FSSAI, NPPA, ICMR, WPC, BIS, DGFT, DSIR, CBN and the DoT. Overseas, the company's outreach extends to the US, EU, Japan, S Korea, Australia, Canada, Singapore and RoW. Its niche domains include end-to-end regulatory and compliance management of medical devices, in vitro diagnostics, drugs & biologicals, cosmetics, food, CRO, legal metrology, wireless planning and coordination, and even insecticides and pesticides.

For foreign clients, CliniExperts offers authorized

agent services and assist them in identifying marketing partners/distributors for their pan-India launch. Post-launch, the company also provides ongoing marketing intelligence and growth identifiers. And for forward-looking clients, the company provides strategic roadmaps and hands-on collaboration for future growth and expansion.

CliniExperts also assists companies in setting up manufacturing facilities and obtaining the required licenses. These facilities adhere to the manufacturing best practices, and hence their products are world-class.

Ethics and accountability

Because of the deep and intense knowledge-base, and proven resourcefulness across the labyrinths of stakeholders, CliniExperts is able to offer seamless, hassle-free services that are otherwise a Herculean task in the dynamic Indian market. This, without an iota of compromise on ethics or accountability. As Dr Kumar says, “If it's not right, it has no value. Integrity is our 1-word article of faith. We continue to remain front-of-mind for the aspiring India entrants due to our reputation as a no-nonsense, sincere, and 110% trustworthy service provider. Also, we are ethics-driven. We operate from a high moral ground and never stoop, cut corners, or take shortcuts. As a result, our clients are in a default win-win situation. Our solutions are sustainable and water-tight.

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CEO Dr Kumar

Digital transformation – Work in rapid progress

With digitalization becoming all-pervasive, what are CliniExpert's vision and initiatives? Ms Verma, an acclaimed IT professional, says, “*We are going all out to transform digitally. Our bucket list includes diverse actionable strategies such as regular updates on regulatory affairs on our website, live project tracking, AI-based mapping of regulatory changes impacting product lines, building a vibrant digital community with multiple stakeholders and interest groups, constructing a robust regtech archetype offering 3600 services to the regulatory and compliance ecosystems, and last but not the least, evolving our resource base with a kickass content calendar.*” Bingo! And what was her proud moment in terms of digital disruption? Ms Verma says – “*We developed a mammoth database of the Indian regulatory provisions. This has come as a big relief for the industry stakeholders desperate for accurate and latest regulatory information.*”

With so much going on at CliniExperts, the team is full of josh and verve. The vibes are positive and passionate, and the commitment to become India's go-to regulatory affairs consultancy is stronger than steel. There's no stopping team CliniExperts!