

Industry **Outlook**

HEALTHCARE REGULATORY SERVICES

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DR. ASHWINI KUMAR, CEO

CLINIEXPERTS

STREAMLINING THE REGULATORY COMPLIANCE IN HEALTHCARE



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CEO

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When we look at the contemporary landscape of the Life Sciences industry, it is almost unrecognizable from what it was a few years ago. Today, economic and competitive challenges in the healthcare business are encouraging life sciences organizations to look for ways to decrease costs across operations, while focusing more on product innovation and research activities for faster turnaround times. The changing regulations, the complexity of new molecules, and the cost pressure to regulate or register products on time are some of the major factors driving Life Sciences Companies to outsource their healthcare regulatory activities. The approval process for a drug or device is time taking, expensive, complex, and documentation centric. The players in the life sciences domain need competent companies who can provide 360-degree regulatory solutions related to the strategy planning, pre-registration, registration, and post-approval changes of the product for the global market.

CliniExperts has been one such company that has been guiding its clients through numerous regulatory compliance processes in a seamless manner. CliniExperts personnel provide an exceptional perspective due to their

in-depth understanding of the regulations for the launch of the product which includes meeting compliances, testing, approval, commercialization, and post-marketing surveillance for the many global markets. The company is a leading regulatory solution provider focusing on speeding a product's entry into the market without compromising on quality; thereby contributing to the safety and health of the consumer. CliniExperts is the catalyst for all the companies who need to speed up its registration process without worrying about obstacles.

"Our experience, professional relations understanding and wealth of practical familiarity in the field, serve to ease your way through the process. With CliniExperts, you will receive expert advice, 24 hour support, practical guidance and complete technical assistance, right from the beginning till the very end of your penetration into the market", says Rashmi Verma, COO at CliniExperts.

"The use of information technology to keep all processes and development online during the registration process of drugs or devices makes CliniExperts an expert in keeping real time updates to act promptly. The three key fundamentals which comprise Regulatory compliance, Regulatory consultation and end-to-end support, have always given us an edge over our competitors", she adds.

ADAPTING TO THE CONSTANTLY EVOLVING INDUSTRY

The regulatory scenario in India, as a constantly evolving process, is undergoing rapid changes every year. Navigating this sea of applications, licenses, and keeping abreast with the latest updates for a wide variety of products and services is challenging. Getting expertise within the industry can make this process seamless and efficient. This is where CliniExperts can assist clients in negotiating and making a stand in the Indian market. CliniExperts offers multifold regulatory services for pharmaceuticals drugs, medical devices, In vitro diagnostic, biologicals, food, cosmetic and clinical trials. As a market leader in regulatory services in India for the past 12 years, CliniExperts has a deep understanding of the Indian regulatory guidelines and a dedicated team of experts who are constantly updated with all the latest regulations.

Furthermore, CliniExperts' industry veterans help in procuring the necessary licenses for registration of import or manufacture, dealer, model approval, packaging and more for weighing devices and measuring instruments. Also, the company offers authorized agent support, wherein, CliniExperts holds a valid 'Drug Wholesale License' and can act as its client's agent in India. This ensures a rapid completion of registration and launch of the products in India.

"When it comes to global regulatory services, we provide complete product lifecycle management for our clients. Right from strategizing products for specific markets, preparation and filing of appropriate documents to the Health Authorities of Regulated and Semi-regulated (Rest of the World- ROW) markets and post approval changes, we provide end-to-end support across every step in your entry into the global markets. We are helping Indian companies to register their products globally and also hand-holding them to license and in-license their products with competitive partners abroad. With a strong network of international clients, we are helping Indian partners get their products to regulated and semi-regulated markets", explains Rashmi.

SPEARHEADING THE GROWTH BANDWAGON

An MD from the prestigious AIIMS, India, Dr. Ashwini Kumar is a front-ranking Clinical Research Expert, and Founder & CEO of CliniExperts. He started his career as a Researcher in AIIMS R&D Centre, where he led pioneering research projects for frontline pharmaceutical companies. However, Dr. Kumar always sought a larger role in the Life Sciences industry. And with this, he established CliniExperts in 2009 to provide dedicated regulatory services to the industry.

"Our story began in 2009, and it was only till 2012 that we reached our 50 client's milestone. Each year brought us new achievements and highlights such as increasing number of clients, overwhelming approvals, awards bestowed

COVID-19 is disrupting global recent times, creating extreme of imported drugs and health



upon our CEO and organization along with the help of our hardworking staff that we're incredibly proud of. We also branched out to Singapore with the launching of Cosmoally and FoodSafety Mantra, which are notable achievements in such a short span of time", highlights Rashmi.

Today, CliniExperts has more than 700 esteemed clients worldwide. Determined to expand its sphere of excellence, the company has generated a clientele from over 30 countries, including US, Canada, UK, Germany, Spain, Italy, Japan, S. Korea, Switzerland, Taiwan, and many more. It envisions partnering with clients from many more countries. Over the years, there are numerous awards and recognitions that CliniExperts has been bestowed with. There are many noteworthy milestones, for instance, in the year 2014, it got featured in a compilation of '20 Most Promising Healthcare and Life Sciences Software Companies' by CIO Review. Furthermore, CliniExperts reached 200 clients in 2015 and due to its excellence in the field, Siliconindia has also recognized Dr. Ashwini as the 'Entrepreneur of the Year - 2015'.

Talking about the company's consistent growth, Rashmi states, "In 2016, we revamped our website to align with the changing market dynamics. The upgraded website provided a seamless experience to our clients. The year 2017 marked our entry to the India Market Division. We also participated in the German Medical Device Trade Mission and received

distribution on a scale unseen in
challenges for the supply chain
are products.



over 280 approvals in that year. 2018 was a stupendous year of growth for us. CliniExperts set up an office in Singapore, wherein, our research segment was established. We had also received 300+ approvals. Thereafter, we extended our growth spree to 2019 as well. We launched our Cosmoally app, initiated a blog page for food regulatory updates – FoodSafetyMantra, and also received over 350 approvals. In our quest to serve society reeling from the global pandemic, we have also successfully registered COVID-19 (coronavirus detection) kits in 2020*.

ADDING VALUE TO CLIENT'S INVESTMENTS

Ensuring that clients' requirements are met to the fullest, CliniExperts provides value-added services like business intelligence, product portfolio building, distribution set-up, and marketing & logistics solutions. All these services help clients achieve significant commercial success. Since its inception back in 2009, CliniExperts has facilitated unified and market ready outcomes which offer benchmark services for the pharmaceutical, biological & vaccine, medical device, diagnostic kit, food, nutraceutical, cosmetic, and pesticide & insecticide industries

"Going forward, we would like to transform the regulatory process with the help of information technology. We have already established multiple digital platforms to ease the understanding of regulatory compliances.



OUR EXPERIENCE, PROFESSIONAL RELATIONS UNDERSTANDING AND WEALTH OF PRACTICAL FAMILIARITY IN THE FIELD SERVE TO EASE YOUR WAY THROUGH THE PROCESS. WITH CLINIEXPERTS, YOU WILL RECEIVE EXPERT ADVICE, 24 HOUR SUPPORT, PRACTICAL GUIDANCE AND COMPLETE TECHNICAL ASSISTANCE, RIGHT FROM THE BEGINNING TILL THE VERY END OF YOUR PENETRATION INTO THE MARKET



DR. ASHWINI KUMAR,
CEO

Likewise, regulated markets have a digital database, we are similarly working on setting up a database particularly for India so as to enable faster pace and action. Our focus shall be on offering efficient and quality driven regulatory affair services to our clients and are committed to our absolute perfection and ethical correctness", concludes Rashmi. In

TOP 10 HEALTHCARE REGULATORY SERVICE PROVIDERS - 2022

COMPANY	MANAGEMENT	DESCRIPTION
Alceon Vadodara alceon.in	Atonu Dutta, CEO	Provides regulatory services to both medical devices and in vitro diagnostic devices
Arogya Legal Mumbai arogyalegal.com	Anay Shukla, Founding Partner	Assists its clients with a variety of situations ranging in various dimensions like litigation & regulatory, data protection & privacy, ethics & anti-bribery, environmental laws, and a lot more
Auxilife Scientific Services Pune auxilife.com	AM Pande, Head - Human Resources	Provides quality regulatory and scientific services to the global agrochemical industry comprising of manufacturers of pesticides, bio-stimulants and other agriculture inputs
Celegence Bengaluru celegence.com	Sonia Veluchamy, CEO	Provides a platform to support medical device manufacturers with the resource burden associated with the EU MDR and IVDR
CliniExperts New Delhi cliniexperts.com	Rashmi Verma, COO	Offers 360 Degree Regulatory Solutions to Pharmaceutical, Food, Nutraceutical, Cosmetic, Medical Device, Diagnostics Kits, Biologicals and Vaccine industries
KNORS Pharma Zirakpur knorspharma.com	Dr. Rajesh Kaushik, Director	Helps the pharma companies to implement comprehensive CAPA and prepare them for inspections from regulatory agencies like US FDA, MHRA, MFDS, EDQM and more
Maven Profcon Services Ahmedabad mavenprofserv.com	Yogesh Dad, Director	A service provider for Consultation, Audits, Trainings, GAP audits, Conformity Assessments, Various Evaluation, Documents Review and Testing
RN Pharma Consulting Pune rnpconsulting.com	Dr. Ravindra Purohit, Promoter	A Pharmaceutical Consultancy service company engaged in Formulation Development, Process Development, and Plant Design
Ross Lifescience Mumbai rosslifescience.in	Dr. Kedar Deobhankar, Managing Director	Specializes in development and evaluation of products utilized in pest management and household insecticides
Symbiorph Clinical Trialogy Ahmedabad symbiorphclinicaltrialogy.com	Siddharth Jain, CEO & Medical Device Regulatory Advisor	Provides sponsors with state-of-the-art services and support to perform clinical trials in a wide range of therapeutic areas