
MEDICAL DEVICE & PHARMACEUTICAL
REGULATORY CONSULTANTS FROM ASIA
Asia.
Business Outlook
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Dr. Ashwini Kumar
CEO
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CLINIEXPERTS
INDIA
ASPIRING TO BE ASIA'S GO-TO HEALTHCARE REGULATORY CONSULTANT
$30

COVER STORY

Asia Business Outlook TOP 10 MOST PROMISING MEDICAL DEVICE & PHARMACEUTICAL REGULATORY CONSULTANTS FROM ASIA 2023

CLINIEXPERTS

ASPIRING TO BE ASIA'S GO-TO HEALTHCARE REGULATORY CONSULTANT

The Asian medical device and pharmaceutical regulatory consulting sector is witnessing dynamic growth. There has been an increase in healthcare standards and awareness, especially after the pandemic outbreak. Healthcare regulations have also become stricter across the continent, which has increased the demand for consulting in this industry. Population boom across Asia is also a reason why the continent needs strict regulations and premium healthcare products and services. To meet these needs, products are being imported from the developed markets.

However, when it comes to seamless, end-to-end fulfilment of regulatory processes, importers and manufacturers alike often feel under-served. Their major pain-points are, clarity on the requirements for approvals, product life cycle management, resourceful experts who can meet the challenges of procuring approvals, and nonetheless, a constantly upgraded knowledge and information base. These challenges are magnified in India, where the regulatory framework at both the central and state levels creates variations in approval requirements for new and generic products.

Enter CLINIEXPERTS. With its highly experienced team and robust processes in place, the consultant is ideally positioned to emerge as a go-to address for speedy and seamless fulfilment of all regulatory processes across India, and across product categories. Post-pandemic, the company is spreading wings to serve the Asian markets with its expanded service portfolio.

Overcoming Challenges

In an interaction, the Director of the company underlined the problems faced by clients. The exhaustive documentation required for various filings, include technical files, quality management system documentation, and other long-tailed mandates. Then there are tons of Excel data files in cases of clinical trials. Generating, organizing, and managing these documents can be a Herculean task. Every regulatory approval and licensing requires custom strategy and documentation; the guidelines are strict and uncompromising. CLINIEXPERTS has in place expert teams who handle these complex tasks with speed, proficiency, and accuracy. As a result, filings are error-free and immaculate. Approvals are hassle-free. Furthermore, medical device and pharmaceutical regulations can differ across regions, requiring companies to navigate varying standards and requirements when expanding their market presence. In order to address this challenge, we have invested in region-specific market intelligence and regulatory expertise. We have made sure that these "templatized" frameworks are end-to-end, spanning market research, proactive collaboration with regional regulators, filings, follow-up, and final approvals. CLINIEXPERTS is known to deliver speedy regulatory approvals, taking care of lifecycles independently.

Going after growth

As India onsets on a rapid reforms drive, its healthcare regulatory landscape is evolving rapidly and touching global benchmarks. While this is very welcome, the industry dynamics are fluid and sometimes volatile. A client attempting to "do it all" on its own may falter at various stages, resulting in complications, costly delays,

and clogging of business pipelines. "At CLINIEXPERTS, we understand these pain points and have developed comprehensive solutions. Our experienced teams guide clients through the complexities and make the solutions simple, smart, and speedy. We are known to significantly cut the downtime of product and business launches, thereby aligning the regulatory process with the client's overall business plans", says Dr. Ashwini Kumar, CEO. He further adds, "This fusion of 'approvals' and 'operations' can be credited to our experience-based ability to plan and execute successful regulatory strategies. That is why we are emerging as the go-to address (for all stakeholders). As we expand to other markets, our call of duty is, 'Innovate, and renovate what you cannot innovate.' This recognition by your magazine (shortlisting in the Top 10 promising Medical Device and Pharmaceutical Regulatory consultants from Asia 2023) is inspiring and motivating for us to do better every day."

> "CLINIEXPERTS is India's leading regulatory solution provider, offering 360 degree regulatory support for successful product launches for our clients globally"

Explaining the company's ethos funnelling its growth, Rashmi Verma, COO, says, "Team spirit and team effort are central to CLINIEXPERTS' ethos. Our 'people potential' has manifested into 'people power' because we value each team member's contribution as inevitable to the company's growth." She adds after a thoughtful pause, "This is why our growth is sustainable. Last year, we launched our Bengaluru operations, and we have plans to cross the country's shores soon. All thanks to Team CLINIEXPERTS. And I want to add, we have merged technology with talent to offer the best of both the worlds to our clients. We have incorporated cutting-edge technology in our people-managed processes to make the entire regulatory experience trouble-free, error-free, and speedy. The latest in-house software for tracking regulatory updates and managing regulatory information are but just a couple of examples in this direction, and we will continue to invest in the best and the latest technologies, to be the numero uno."

Not surprisingly, CLINIEXPERTS takes its collaborative spirit to the clients too. "This is an essential part of our package", as Rashmi observes, and adds, "We co-own the projects, and we co-create outcomes. We don't work as external consultants, but align and match our capabilities with those of our clients much like an internal team. The results are there for all to see."

Going forward

Dr. Ashwini Kumar, while talking about future plans, says, "The 2019 medical device and healthcare reforms have ushered India into a trajectory of rapid growth and evolution as a global industry hub. The regulatory and compliance sector is growing at double-digit rate. The domestic as well as overseas players are keen to have their share of what I call "India's decade," and this is true of all the peripheral and associated domains such as hospitals, telemedicine, medical tourism, clinical trials. The overall picture is very optimistic, and we are here to provide anything and everything in regulatory affairs that will empower India to be a global medical device and healthcare supplier. I look forward to new cross-border partnerships as we grow beyond Bengaluru!" ABO

Asia Business Outlook **TOP 10 MOST PROMISING**

MEDICAL DEVICE & PHARMACEUTICAL REGULATORY CONSULTANTS FROM ASIA 2023

01

AMS Pharma Regulatory Consultants
Pakistan
ams.business

A health care & pharmaceutical consulting company assisting the clients acquire imports of pharmaceutical raw materials, pharmaceutical equipment, laboratory equipment, medical devices and other products

02

Bio-standards
Saudi Arabia
bio-standards.com

A regulatory representative specialising in product registration with the saudi food & drug authority (SFDA) and local markets access for international manufacturers of medical devices and pharmaceuticals

03

Clini Experts
India
cliniexperts.com

A regulatory solutions provider serving the drugs, medical devices, biological, IVDs, neutraceuticals, food, and cosmetic industries

04

Dossier Solutions & Services
India
pharmadossiers.com

A comprehensive regulatory consultancy company providing solutions to maintain their competitive advantage from early stage of product development to through out the life cycle of the product

05

Masuu Global Solutions
Dubai
masuuglobal.com

A provider of 360° pharma regulatory and quality service company offering expert consulting services & cutting-edge software solutions to streamline all your pharma regulatory & quality processes

06

Pharmazone
China
pharmazones.com

A highly focused GxP compliance and regulatory affairs service oriented company that supports the toughest GxP compliance and regulatory affairs challenges

07

PharmXl
India
pharmxl.com

A life sciences consulting company offering end to end product development consulting services including regulatory affairs, pharmacovigilance, clinical trials and medical writing services to the clients

08

ReClin Pharma Services
India
reclinpharma.com

A service provider which offers regulatory affairs services, impurities supply, technical writing and translation services to pharmaceutical companies and clinical research organizations (CRO)

09

Rocky Scientific
Malaysia
rockyscientific.com

An expert medical device company providing assistance for the company which need to be certified with good distribution practice for medical device (GDPMD), ISO 13485 : 2003 and also medical device registration assistance in malaysia

10

Synerrv Group
Singapore
synerrv.com

A service provider for complete solution on pharmaceutical product dossier registration, regulatory affairs support and its marketing, with rich experience in product selection, dossier compilation, registration of the product, post registration marketing on various models