KNORS PHARMA SOLUTIONS

NAVIGATING COMPLIANCE TURBULENCE IN PHARMA WITH OPTIMAL PRECISION


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The pharmaceutical market is under growing pressure as governments all over the world tighten regulation and enforcement. The presence of frequent quality audits and non-conformance citations is a serious threat and usually leads to operational halts. Furthermore, domestic manufacturers are facing the issue of being unprepared to take risk-based inspections (RBI), struggling to deal with old systems, and are resistant to foreign expertise. This causes a chronic weakness in standard operations, jeopardizing sustainability, exportability, and profitability in the face of global requirements of high standards of GMP.

Knors Pharma Solutions, led by Dr Rajesh Kaushik, enables the clients to overcome these challenges by undertaking proactive interventions in a customized setting. Through independent gap assessments, third-party audits, and pre-inspection preparations, the firm can detect weaknesses early. This enables the implementation of corrective and preventive measures (CAPA) to reduce regulatory citations.

Empowering Compliance & Innovation in Pharmaceutical Consulting

In the fast-changing pharmaceutical industry where strict laws and regular audits demand strict adherence, Knors Pharma Solutions stands as a key partner to manufacturers across the globe. The firm has evolved into a strong consultancy with a team of professionals with different expertise and has operated for clients in Europe, North America, Latin America and Asia. The firm has been performing audits across the globe; India, Australia, Malaysia, Indonesia, Thailand, China, Taiwan, Korea and the Middle East. Having over 500 audits for drug products, drug substances, Raw materials, Medical Devices, Cosmetic Ingredients, Biologicals, Packing materials, Laboratories (R&D and Analytical) with more than a decade of experience, the firm has earned recognition in its audit reports, which are regularly endorsed by regulatory agencies when their clients are audited.

Third-party audits and gap assessments are the most fundamental products of the firm, which is aimed at preventing non-conformities before they are hit by the regulatory scrutinizing process. This is especially crucial with the updated Schedule M set for implementation by December 2025. "As pharmaceutical consultants, we identify non-conformities early, helping manufacturers minimize citations and ensure sustainable growth", states Dr. Rajesh Kaushik, Director & Managing Partner, Knors Pharma Solutions.

In addition to the audits, the firm offers extensive training and workshops to qualify teams in terms of quality assurance, control, and regulatory matters. It believes training of the working staff and subject matter experts (SMEs) on real issues can enhace the operational excellence and minize the non-conformities. Its training programe is tailored based on the maturity level of QMS of the site and personnel competence considering the live examples.

KNORS regulatory department deals with regulatory filings; Drug Master Files (DMF) and Dossiers for finished dosage forms. The firm is propelled forward by innovating the solutions for pharmaceutical industry. In 2023, it established KNORS Scientific Research Private Limited, an R&D laboratory staffed with PhD and MSc chemists. These experts specialized right from process and product development, technology transfer to commercial scales, and analytical research. This promising project contributes to R&D-driven strategies, both biotechnological startups and contract research organization (CRO) services, generating concrete outcomes such as smooth exports and profitability. The USPs of the firm, such as professionalism, integrity, and continuous and constant assistance, stand out with auditors with 20-35 years of experience, including IRCA certified leads.

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Expanding Presence in Regulatory Markets

The firm is on the path of revolutionary growth. Dr Kaushik has a vision of Knors becoming the top professional pharmaceutical consultants powerhouse of India, a leader in the realm of global regulatory markets. The core of this roadmap is to expand global partnerships. The firm intends to serve clients in high regulatory centers and establish strategic partnerships with entities in Europe and in the U.S. This will enhance its position as a connection between its local business and the demands of the foreign market to streamline compliance and access to the market. The firm plans to expand globally by leveraging its relationships with European auditing firms and direct customers in North America and Canada. This strategy aims to reduce the company's vulnerability to regular risk-based inspections (RBIs), which have led to closures of noncompliant units in recent years.

The firm is further exploring biotechnology so as to drive the needed innovation. Over the next few years, Knors will nurture an independent start-up as a Contract Research Organization (CRO) in the biotech industry. Under the guidance of a team of PhDs and MSc chemistry graduates, this program fosters innovative thinking—from producing working standards to developing R&D-driven strategies. It aims to help clients achieve sustainable profitability in export markets.

Adding to this, the firm also plans to enter into materials management, which improves supply chain resiliency in response to changing requirements under compliance. These solutions solve fundamental client pain areas: constant audit preparation, identification of gaps, and corrective measures (CAPA). With proactive consulting budgets, the domestic players will be able to prevent non-conformities, as Dr Kaushik advises, and transforms regulatory challenges into growth opportunities.

With the firm growing, it will not only be able to ensure compliance but also long-lasting customer happiness, which will make it an essential partner in the high-stakes game of pharma. The firm will transform the role of consulting and make it innovative and, with a vision on leadership, the industry will be vibrant in the years ahead. PO