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IKP Global Regulatory Forum to address challenges faced by startups and MSMEs

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Healthcare and life sciences innovations are evolving, as are the regulatory environment and national and international regulatory requirements. Indian pharmaceutical and medical device companies are increasingly becoming global in nature and manufacturing goods for worldwide markets. For commercialisation, enterprises must go through regulatory pathways, which are a complicated collection of requirements that a product, process, or activity must meet in order to be approved by a regulatory body or authority. These guidelines are often difficult to understand and implement.

The regulatory paths also differ based on the product or activity as well as the country or region in which it is regulated. Misinformation can increase the risk of product delays or rejections. In order to provide clear regulatory guidance and to develop regulatory strategies at an early stage, there is a need for dialogue and information sharing between regulatory experts and enterprises, particularly startups developing novel pharmaceutical products, devices, IVDs, APIs, digital health solutions, medical software, and many other emerging technologies

Over the last 23 years, IKP Knowledge Park (IKP) has supported innovation in a multifaceted manner through more than 25 different initiatives. One of the most recent initiatives launched is the IKP Global Regulatory Forum (IGRF), which recognises the need for regulatory support for startups. IKP established IGRF in partnership with former regulatory officials and experts to address the regulatory challenges faced by start-ups and MSMEs.

The effort is a collaboration between IKP, that has played an important role in assisting startups by providing them with the resources and services they require to develop and grow, and the JSS Academy of Higher Education and Research (JSSAHER), Mysore which has extensive regulatory expertise and offers regulatory education.

IGRF aims to assist entrepreneurs in accelerating the development and commercialisation of innovative products and technologies by reducing regulatory hurdles through effective support.

The initiative was launched on February 16, 2023 in Bengaluru, in the presence of representatives from the MSME sector, academia, startups, regulators, and government officials. At the launch event, the discussion centred around the challenges faced by regulators and business owners and how IGRF will help close those gaps.

The IKP Knowledge Park and JSS AHER agreement to promote entrepreneurs that was signed few months earlier served as the catalyst for the creation of IGRF.

The core expert committee, which will guide the activities of IGRF, was announced at the launch. The Core Experts Committee members, headed by Chairperson Dr Surinder Singh, Vice-Chancellor, JSS Academy of Higher Education & Research, and Former Drug Controller General of India, include Dr D. Roy, Ex-DDC (I), CDSCO, Govt. of India, and ex-members of state and zonal regulatory bodies, as well as experts from industry.

Additionally, the IGRF members are senior professionals who are working in close collaboration with regulatory agencies such as USFDA INO (United States Food and Drug Administration International Programs Office), MHRA (Medicines and Healthcare Products Regulatory Agency), PMDA (Pharmaceuticals and Medical Devices Agency), ANVISA, WHO, IPA, etc. IGRF's Expert Committee, with its diverse and extensive experience and knowledge in regulatory affairs from various countries and regulatory agencies, is expected to serve as an excellent resource for startups seeking regulatory guidance.

The Chairman and CEO of IKP Knowledge Park, Deepanwita Chattopadhyay, and Dr Surinder Singh, Chairman, IGRF, unveiled the IGRF logo that symbolises the colours of the universe, healthcare, and interconnectedness on a global scale.

IGRF membership is open to start-ups, academic researchers, and MSME regulatory professionals seeking regulatory assistance. IGRF will offer regulatory guidance via toolkits, templates, and guideline documents, as well as hold webinars and discuss case studies for startups. It will assist organisations, small and medium-sized enterprises (SMEs), academics, and individuals who are creating innovative products in understanding what is necessary to advance their product through the regulatory procedures.

The forum will also help regulatory agencies understand the landscape of emerging technologies through specific training programmes and interactions with startups and innovators. IKP plans to expand its services to include complete regulatory filing support, which will be a substantial advantage to startups and entrepreneurs in the life sciences and healthcare industries. IGRF members will receive regular updates and support on the regulatory front.

To get regulatory clearances both domestically and globally, startups must ensure that all information provided to regulatory agencies is precise, complete, and transparent. This involves great attention to detail as well as a comprehensive understanding of regulatory standards and processes. Seeking guidance and support from regulatory specialists, such as those available through the IKP Global Regulatory Forum (IGRF), could assist enterprises in avoiding misinformation and effectively navigating the regulatory process.

To become a member of the IKP Global Regulatory Forum, register at https://tinyurl.com/4xuz7bdm. For any questions related to IGRF, please write to igrf@ikpknowledgepark.com.