kinapse
a SYNEOS HEALTH company

US Agent & Official Correspondent (OC) Services

All non-U.S. Food, Beverage, Dietary Supplement, Medical Device or Drug companies who wish to market products in the USA must have a designated US Agent. The appointed US agent can be a US resident or maintain a place of business inside the USA. The role involves managing all communications with the FDA, coordinating regulatory submissions, drug establishment registration and updates, product listings, compliance and facilitating inspections.

Why Outsource?

Our experienced US agents understand the importance and scope of this role and ensure they are always fully aware of the current regulations and guidelines. It is important to ensure confidentiality of your business information and no potential conflict of interest by engaging an agent dedicated to supporting you and your products. In addition, you can benefit from utilising multiple regulatory services with one provider to support all of your US activity.

Services Offered

Assistance in FDA correspondence and meetings by reviewing and responding to all communications from the FDA including emergency communications in relation to drugs or devices to be imported into the USA.

Facilitating all US submissions including IND filing and pre IND meeting requests, NDA, BLA, ANDA, NADA and ANADA as well as prior notification filings as required for dietary supplements and food category products.

Pre-assigned eCTD number requests, eCTD Submission including electronic safety submissions.

Facilitate scheduling inspections of client's facilities and CMOs.

Initial registration of a new Establishment and processing of annual FDA Establishment registrations including the eDRLS, FDA Unified Registration and Listing System (FURLS), update to registration information and listing records to ensure accuracy.

Provision of US regulatory guideline updates to clients to ensure compliance.

Use of FDA systems and tools to support controlled correspondence, field alert reports, PLAIR requests, citizen's petitions, and GDUFA program fee updates.

kinapse a SYNEOS HEALTH company Advantages

Experienced group of professionals acting as US agents supported by our India, EU and US based teams offering round the clock support to our clients.

FDA correspondence and regulatory activities are undertaken professionally and confidentially.

Competitive and consolidated pricing.

Solution tailored to each client's needs.

High level of US focused regulatory expertise across the product lifecycle including clinical product development and commercial aspects.

Ensure successful lifecycle maintenance and monitoring of regulatory compliance of US marketed products.

Support future business plans for growth.

Contact Us:

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