Pharmaceutical Services

Specializing in FDA Regulatory Matters

EAS CONSULTING GROUP

EAS Consulting Group, LLC is a leading provider of regulatory services to the pharmaceutical, medical device, food, dietary supplement, tobacco, and cosmetic industries. Originally founded in 1960, EAS has over 50 years of experience assisting clients in developing regulatory strategies, implementing quality systems, filing regulatory submissions, and ensuring compliance with all Food and Drug Administration (FDA) regulations. Employing a unique team of former FDA officials and industry experts, many with more than 30 years of experience, EAS has unparalleled expertise to assist clients with all of their consulting needs.

EAS provides a variety of FDA based regulatory services to the global Rx and OTC pharmaceutical industry. We offer a seamless approach to help your organization navigate the regulatory intricacies associated with product development, submissions, claims and labeling, manufacturing and packaging of commercial products, as well as facility and product registrations and listings. Our team of pharmaceutical regulatory experts are ready to provide assistance in; the development of filing and quality strategies, GMP/GLP/GCP assessments, Mock-FDA Inspections and reviews, quality management system development, regulatory submissions, product labeling and claims compliance, and a number of other topics that will help your organization succeed in this highly complex and very competitive regulatory environment. EAS is committed to helping the members of domestic and international pharmaceutical market understand, meet and sustain compliance with the FDA's numerous requirements in a manner that is respectful of your timelines and business drivers.

- ✓ Regulatory Strategy Development
- ✓ DMF, NDA, ANDA, NADA
- ✓ Assisting with Regulatory Compliance
- ✓ Auditing GMPs/Quality Systems
- ✓ Seminars and Onsite Training
- ✓ Label Assistance
- ✓ Cosmetic to OTC Switch
- ✓ Homeopathic
- ✓ Allopathic
- ✓ Quality Management System Support
- ✓ Registration and Drug Product Listing

EAS Consulting Group, LLC
www.easconsultinggroup.com

EAS Consulting Group, LLC provide pharmaceutical consultation services to assist you with product development and registration, GMP compliance, taking your new product through the regulatory evaluation process and obtaining marketing approval from regulatory bodies, such as the FDA.

Developing Regulatory Strategies

Our Independent Consultants have spent much of their professional careers working at FDA and/or working in industries regulated by the Agency. We have scientists with medical, clinical, nutrition, chemistry, microbiology, and toxicology backgrounds; and former compliance officials with detailed knowledge of federal/state regulations and compliance procedures. It is this first-hand experience that sets EAS apart from others in this industry. We can assist you in planning new product development, including the applicability of regulations such as the Orphan Drug rules and User's Fees; preparing submissions to the Agency; completing registration and listing forms; establishing or upgrading adverse event reporting systems; and preparing for pre-approval inspections.

Assisting with Regulatory Compliance

Whether you need assistance in the development and registration of your prescription drugs; labeling your OTC drugs; have questions about the safety of a pharmaceutical component; need advice on whether to recall a product; or advice on responding to an FDA-483 or Warning Letter, we have experts to help. Labeling issues can be particularly difficult. Our labeling experts can guide you through the different rules of labeling Homeopathic and conventional allopathic drugs; ensure that the structure/function claims are appropriate whether your product is a drug or a dietary supplement, and identify when both cosmetic and drug claims can be included in labeling certain products. Our expert consultants have advised companies on the preparation of remedial action plans, including meeting the terms of an injunction. We have also helped clients respond to hearings on detained imported products, and applications deficiency letters.

Auditing GMPs/Quality Systems

Several EAS Independent Consultants were FDA Investigators when the first pharmaceutical CGMPs were implemented, participated in the comprehensive revision of the regulations in 1978, and co-authored Application of Pharmaceutical CGMPs, which was published by the FDLI in 1997. They have performed GMP audits of large and small companies both in the United States and around the world. The audits have covered the most complicated API syntheses and the full range of OTC and prescription finished dosage forms. Such audits have been used to certify GMP compliance to FDA following injunctions. We also have experience in building ISO based quality systems that incorporate the requirements of pharmaceutical GMPs.

Seminars and Onsite Training

We pride ourselves on our ability to conduct training courses tailored to meet the needs of your organization. For example, the GMP training we offer to a manufacturer of APIs will be different than that offered to a maker of prescription drugs. Our staff will travel to your facility, providing customized training at a reasonable cost. We also conduct public training seminars at convenient locations throughout the US and abroad.

Students who have attended our programs have found EAS training to be unique, in that they have an opportunity to ask former regulators questions that simply cannot be addressed by other training organizations. Whether it is a training program on GMPs, OTC labeling, or other regulatory issues you will find these sessions to be extremely beneficial.

Label Assistance

EAS' labeling staff is highly experienced in requirements for pharmaceutical labels. With our detailed knowledge of FDA labeling requirements we can review your label for formatting, nutrition information, and claims and advise you on how to be in compliance.

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