Good Manufacturing Practices Industry 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 domestic and international regulatory services to industries under FDA oversight including in-depth expertise and guidance in the areas of Good Manufacturing Practices (GMPs), Good Laboratory Practices (GLPs), Good Clinical Practices (GCPs), and Good Documentation Practices (GDPs) for all FDA regulated industries. EAS conducts compliance assessments and mock FDA inspections for manufacturers, packagers, distributors, Own Label Distributors, contract manufacturers, laboratories, Research & Development facilities, Contract Research Organizations and more. Our seamless approach helps organizations navigate the many regulatory requirements for compliance with quality management and system development. Whether your firm is involved with the manufacturing, packaging, distribution of products; ingredients and additives; or is a testing or research laboratory facility; EAS is committed to helping you understand, meet and sustain compliance with the FDA's numerous technical requirements.

- ✓ EAS GMP Expertise Includes:
  - » Assessing the Facility, Quality Systems and Procedures (Gap Analysis)
  - » Mock FDA inspections
  - » Contractor Audits (Manufacturers, Packagers, Distributors and Laboratories)
  - » Own Label Distributor GMP Compliance
  - » FSMA Compliance
- ✓ Quality System Development
- ✓ Corrective and Preventative Action (CAPA) Plans and Implementation
- ✓ Standard Operating Procedure (SOP) Writing and Training
- ✓ Quality Agreement Preparation
- ✓ FDA compliance training including:
  - » GMP/GLP/GCP/GDP
  - » How to Manage FDA Inspections
  - » Laboratory Compliance
  - » Investigatory Systems
- ✓ Laboratory Operations Including:
  - » GLP/GMP/GDP Compliance
  - » Method Development, Validation and Transfer
  - » Specification Development for Raw Materials, Packaging Components, In-Process Materials, Intermediates and Finished Products
  - » Stability Program Development
  - » Out of Specification (OOS) Procedures and Implementation
- ✓ Regulatory Remediation
  - » 483 Observation Responses
  - » Warning Letter Responses
  - » Consent Decree Remediation
  - » Meetings with FDA
  - » Expert Witness Services

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