Tobacco and Nicotine Services

Specializing in FDA Regulatory Matters

EAS Consulting Group

A Certified Group Company

EAS Consulting Group, LLC is a leading provider of regulatory consulting services to the tobacco and nicotine industries assisting clients all over the World with compliance to many of the U.S. Food and Drug Administration (FDA) regulatory requirements dictated under the Family Smoking Prevention and Tobacco Control Act (TCA) of 2009 and the subsequent Deeming Rule of 2016 that apply to e-cigarettes and other electronic nicotine delivery systems (ENDS), e-liquids, next generation products, cigars, pipe and hookah tobacco, nicotine gel, and dissolvable nicotine products. These FDA requirements include assistance with Premarket Tobacco Applications (PMTAs) or Substantial Equivalence (SE) submissions for "new" tobacco products. Compliance to Current Good Manufacturing Practices (cGMPs), which will be referred to as Tobacco Product Manufacturing Practices (TPMPs) when specifically promulgated for tobacco and nicotine products, is also required at all facilities performing manufacturing, packaging, labeling, holding and distribution, and testing operations for the tobacco products.

As one of the leading FDA consulting firms in the US, EAS has extensive experience assisting clients in developing regulatory strategies, implementing quality systems, filing regulatory submissions, and ensuring compliance with applicable regulations. Employing a unique team of former FDA, USDA and state agencies 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.

Specific lists of activities:

- ✓ Preparing for TPMPs (traditionally known as GMPs)
- ✓ Training on GMPs and Quality Systems
- ✓ Quality Management System (QMS) Development and Implementation
- ✓ Inspectional Readiness Preparations
- ✓ Facility Auditing
  - » Gap Analyses
  - » Mock-FDA Inspections
  - » Supplier Qualifications
  - » Contractor Audits (Manufacturers, Packagers, Distributors, and Laboratory)
- ✓ Quality Investigations
  - » Out of Specification (OOS)
  - » Deviations
  - » Material Reviews
  - » Non-Conformances
  - » Product Returns
  - » Consumer Complaints
- ✓ Regulatory Remediation and FDA Communications
  - » Requests for Additional Information (AIs)
  - » Deficiency Letters
  - » Form 483 Observations
  - » Warning Letters
  - » Corrective and Preventative Actions (CAPAs)
- ✓ Develop Regulatory Strategies
- ✓ Facility Registrations
- ✓ Product and Ingredient Listings
- ✓ PMTA and SE Submissions Assistance
- ✓ Environmental Assessments (EAs)
- ✓ Expert Witness