Tobacco 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 industry assisting clients all over the World with compliance to all 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), cigars, pipe and hookah tobacco, nicotine gel, and dissolvable nicotine products. These FDA requirements include the preparation of 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 products, is also required at all facilities performing manufacturing, packaging, labeling, holding and distribution, and testing operations for the tobacco products.

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 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:

- ✓ Develop Regulatory Strategies
- ✓ Facility Registrations
- ✓ Product and Ingredient Listings
- ✓ PMTA and SE Submissions
- ✓ Environmental Assessments (EAs)
- ✓ cGMP Training
- ✓ Preparing for TPMPs
- ✓ Quality Management System (QMS) Development and Implementation
- ✓ Inspectional Readiness Preparations
- ✓ Facility Auditing
  - » Gap Analyses
  - » Mock-FDA Inspections
  - » 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)
- ✓ Expert Witness

Employing a unique team of former Food and Drug Administration (FDA) officials and industry experts, EAS offers unparalleled expertise with many consultants having more than 30 years regulatory experience and quality compliance.

EAS Consulting Group LLC provides tobacco consultation services and assistance with registrations and listings of tobacco products, TPMP compliance, manufacturing site audits and regulatory compliance training.

Regulatory Compliance

EAS offers assistance with the development of quality systems, compliance assessments of manufacturing facilities, filing of regulatory submissions and more to ensure your facility, product and labeling all meet FDA's stringent requirements for the tobacco industry. Whether ENDS products, cigars, pipe tobacco or c-cigarettes, cigars, certain dissolvables that are not "smokeless tobacco," gels, and waterpipe tobacco, EAS Independent Consultants offer the expert answers you need no matter the regulatory question.

EAS Independent Consultants are well versed in the details of The Family Smoking Prevention and Tobacco Control Act, supplemental FDA guidance and the May 2016 Deeming Rule. We monitor FDA tobacco activities and regulation development, keeping clients informed of the latest updates and thorough assessments of FDA guidance.

Registrations and Listings

EAS provides assistance with facility registration, product listings, and ingredient listings.

Mock Audits & Compliance Assessments

EAS Independent Consultants provide "compliance assessment" and "mock FDA-inspection" services to both large and small tobacco and e-cig/e-liquid companies, providing detailed analysis and reports on how your systems and procedures align with current FDA expectations and what corrective actions and enhancements you may want to consider implementing in preparation for future TPMP requirements.

Onsite Trainings

EAS takes pride in our ability to conduct training courses tailored to meet the unique needs of your organization. Our trainers, former high level FDA officials and industry executives, travel to your facility, providing customized training and a thorough analysis and review of current industry regulations. Students who have attended our programs have found EAS trainings to be unique in that that they provide an opportunity to ask former regulators questions that simply cannot be addressed by other training organizations.

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