FDA FSMA Produce Safety Services

Specializing in FDA Regulatory Matters

EAS Consulting Group

A Certified Group Company

EAS Consulting Group provides a broad range of Produce Safety regulatory consulting services both domestically and for growers and companies exporting into the US market.

EAS Consulting Group, LLC understands the unique and complex challenges related to building and maintaining written and implemented procedures as well as processes and practices to prevent the introduction of known or reasonably foreseeable biological hazards into produce. The US FDA has placed imported and domestically grown produce near the top of its list for causing illness outbreaks in the US, with many of these outbreaks occurring based on inadequate agricultural controls, health and sanitation controls, harvesting controls, packing and warehouse controls and as well as traceability controls.

EAS has the expertise and capability to advise domestic and foreign produce growers, importers, packing houses, produce warehouses and shipping companies on the US Produce Safety and related regulatory requirements. These EAS services can range from questions that can be answered via simple phone calls to highly time-sensitive and urgent problems such as a company and its produce being placed on an FDA "Import Alert" list, prohibiting any entry of produce into the US. In order to minimize regulatory issues with FDA, EAS can conduct an on-site assessment of the grower's Good Agricultural Practices (GAPs) as well as evaluation of the produce packing house or produce warehouse for compliance with Good Manufacturing Practices (cGMPs). EAS can determine whether your commercial farm, harvesting, packing and/or warehouse facilities meet FSMA's Produce Safety requirements for GAP and GMP programs.

Choose EAS for:

- ✓ On-site FSMA Grower, Warehouse and Packing House Produce Safety Readiness Assessments
- ✓ Desk Review of Written GAP Plan for Growers
- ✓ Desk Review of Written Food GMP Practices for Produce Warehouses and Packing Houses
- ✓ Building Grower Written GAP Plan addressing:
  - » Produce Safety
  - » Worker Health, Hygiene, and Training
  - » Soil Amendments
  - » Wildlife, Domesticated Animals, and Land Use, Agricultural Water including Postharvest Handling Sanitation
  - » Building Warehouse/Packing House Written Food GMP Plan
  - » Labeling Compliance
- ✓ Hazard Analysis and Risk-based Preventive Control (HARPC)
- ✓ Business continuity, emergency planning, food defense and food fraud
- ✓ Produce Safety Training

EAS Consulting Group
easconsultinggroup.com
(571) 447-5500

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 full spectrum of consulting services to the produce industry. Our consultants have spent their professional careers either working at State regulatory agencies, FDA, USDA or working in industries regulated by the States and FDA. It is this first-hand experience and expertise that sets EAS apart from others in this industry.

Consulting Services

Whether the question is safety, contract manufacturer compliance, internal or supplier auditing procedures, quality systems, or FSMA challenges, EAS has experts to help. Our team of labeling experts; scientists with medical, nutrition, chemistry, microbiology and toxicology backgrounds; and compliance officials with detailed knowledge of federal/state regulations as well as import requirements and compliance procedures will provide the expert guidance you need for important regulatory requirements.

FSMA Auditing Services

EAS provides FSMA Readiness Assessments which consist of a thorough company review and assessment of which FSMA rules must be met, which documents, policies and procedures require updates as well as a regulatory pathway for meeting detailed demands of FSMA.

The CDC and FDA model Food Code provides the framework of food regulatory requirements across the USA. Each state may adopt all or portions of the Code as well as add supplemental regulatory requirements. In addition, states may have adopted earlier versions of the model code. The end result is a patchwork of food regulatory requirements across the USA. The EAS team understands this and can assist in developing unifying practices/standards that are applicable state to state. EAS can also assist in regulatory compliance and supplier qualification requirements.

Produce Safety Plans

Providing safe produce to customers and consumers can be accomplished by implementation of a comprehensive Food Safety Plan. This is dependent up food safety practices being implemented in the field, during harvesting, washing, packing and shipment. FDA requires a Food Safety Plan not only for the produce growers, but for produce packing houses and wholesale warehouses. Gaps in a Plan often lead to recalls, destruction of product and foodborne disease outbreaks. EAS can utilize the extensive produce experience of its Independent Consultant, industry Good Agricultural Practices (GAP) and Good Manufacturing Practices (GMPs) and FDA regulatory requirements to assist in building a comprehensive Produce Food Safety Plan. EAS can assist you in making sure your company is prepared for the inevitable FDA inspections.

Labeling and Claims

FDA has established specific requirements as to how food and dietary supplements must be labeled and has defined what they consider to be allowable claims for these products. EAS Independent Consultants helped develop these regulations and has an "insiders" perspective on how the Agency interprets them. Our consultants are available to review current and proposed labeling for formatting, nutrition information, and assist you in developing claims that will comply with FDA requirements. Our consultants can also assist in designing studies that will substantiate the claims made for your product.

On-Site Assessments of GAP & GMPs/Quality Systems

EAS has former FDA, USDA and state investigators, laboratory personnel and industry quality experts available to conduct GMP/Quality Systems audits of your suppliers, contract manufacturing and laboratory facilities to assess compliance with applicable FDA and state regulatory requirements as well as established best practices. We are available to conduct gap assessments of these facilities to let you know what improvements are needed to become fully compliant with FDA and state requirements. Our assessments are thorough and complete. You will receive a detailed report outlining your current level of compliance with each section of the GMP rule, along with our recommendation as to what needs to be done to bring identified deficiencies into compliance.

Recall Readiness

Recalls are a unique challenge for the industry since products are either one step away from the consumer or the consumer has already purchased the recalled product. Both FDA and the states conduct recall effectiveness checks. EAS can evaluate your recall plans and assist in developing, executing and evaluating a simple to complex mock recall.

Custom Training Programs

EAS takes pride in our ability to conduct training courses tailored to meet the needs of your organization. Whether the training takes place in-house with a customized agenda, or you travel to one of EAS public trainings, our consultants, former FDA, USDA, state and industry experts, will provide a thorough analysis and review of the current industry regulations. Students who have attended our programs have found EAS trainings to be unique, in that they have an opportunity to ask former regulators questions that simply cannot be addressed by other training organizations.

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EAS Consulting Group, LLC
1700 Diagonal Road, Suite 750
Alexandria, Virginia 22314
(571) 447-5500

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