

Retail Food Protection Services

Specializing in FDA Regulatory Matters



Retailers of food, pharmacy, OTC and dietary supplements have a unique set of challenges. From supply chain and contract manufacturer management, to transportation and storage requirements; from own label product claims and marketing to Food Safety Modernization Act (FSMA) legislation, retailers are touched by every level of compliance regulation. For example under FSMA, retailers who source directly from international suppliers may shoulder the liability. Retailers also have to comply with USDA requirements such as meat labeling, packaging and testing as well as COOL requirements.

EAS Consulting Group, LLC understands the unique and complex challenges facing retailers and own label distributors. EAS is a leading provider of regulatory services to FDA and USDA regulated industries. With more than 50 years of experience assisting clients in developing regulatory strategies, implementing quality assurance programs, as well as assisting contract manufacturers in compliance with FDA regulations, EAS is poised to assist Retailers with the significant implications of FDA compliance. EAS Independent Consultants are a unique team of former State regulatory officials, FDA and USDA officials and industry experts, many of whom have more than 30 years of food, pharmacy, OTC and dietary supplement experience.

Choose EAS for:

- ✓ FSMA Readiness Assessments
- ✓ Labeling Compliance
- ✓ Contract Manufacturer qualification and compliance
- ✓ Dietary Supplement Own Label Distributor GMP Compliance
- ✓ Hazard Analysis and Risk-based Preventive Control (HARPC)
- ✓ Development of Food Safety Plans
- ✓ Auditing GMPs/Quality Systems
- ✓ Warehouse Sanitation
- ✓ SOP development for all mandatory practices
- ✓ Business continuity, emergency planning, food defense and food fraud
- ✓ FSMA Produce Rule affecting you and your raw agricultural commodity (RAC) suppliers



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 retail industry. Our consultants have spent their professional careers either working at State regulatory agencies, FDA, USDA or working in retail 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 retail 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 retail 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.

EAS Independent Consultants are experienced in both the wholesale and retail food industries. This experience is advantageous when assessing the food chain from point of receiving at your distribution center and downstream to your retail stores.

Food Safety Plans:

Protecting your food product and your brand starts with a comprehensive Food Safety Plan. FDA requires a Plan for much of the Food Wholesale industry and experts agree with the importance of a Plan. Gaps in a Plan often lead to recalls and worse, foodborne disease outbreaks. EAS can develop a Plan or review your Plan.

Business continuity is critical to survival across all business platforms. Natural disasters, intentional contamination, or food fraud can impact your operations. Minimizing any interruption of your services is vital to your brand and possibly the survival of your company. EAS can assist you in making sure your company is prepared. Our experts have first-hand experience responding to the retail sector after natural disasters and are experts in retail food defense. EAS can help your business to prevent, respond and recover from such emergencies.

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.

Auditing 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, with our recommendation as to what needs to be done to bring identified deficiencies into compliance.

Pharmacy, OTC and Dietary Supplement Assistance:

There is an advantage to a one-stop-shop consulting services through EAS. Our team of pharmaceutical, OTC and Dietary Supplement experts have the expertise up-stream with manufacturers and distributors. An EAS team approach to ensuring compliance across company and retail lines, from food to pharmacy, cosmetic to household products provides peace of mind and ease of coordination.

Recall Readiness:

Recalls are a unique challenge for the retail 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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