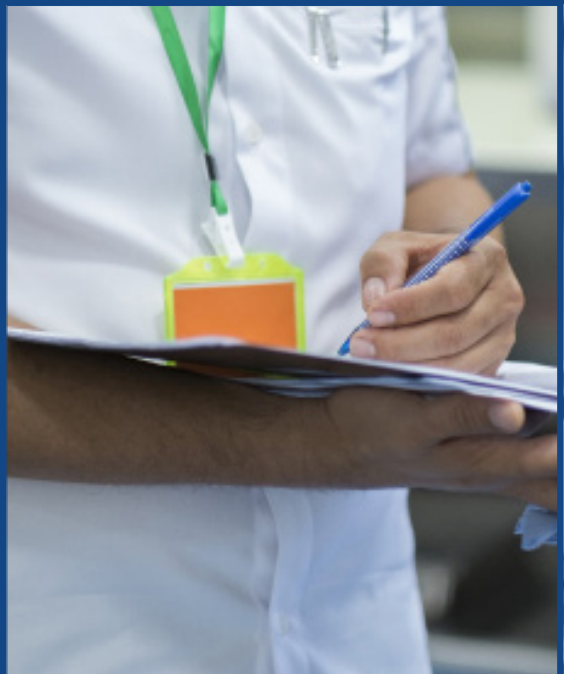
EAS Consulting Group
A Certified Group Company

Regulatory Consulting Services

So The World Can Trust In What It Consumes™












Regulatory Consulting Services

So The World Can Trust In What It Consumes™

EAS Consulting Group, as part of the Certified Group of companies, merged with Food Safety Net Services (FSNS) to become the global leader in testing and regulatory solutions for FDA and USDA regulated industries.

Originally founded in 1960, EAS Consulting Group has more than 50 years of experience assisting clients in developing regulatory strategies, implementing quality assurance programs, filing regulatory submissions and ensuring compliance with FDA regulations. Employing a unique team of former FDA officials and industry experts, EAS offers unparalleled expertise with many consultants having more than 30 years of FDA experience.

Mission Statement

Our mission is to provide quality regulatory advice and service and to represent the best interests of our clients in an ethical, timely, and cost-efficient manner.

Location

EAS Consulting Group's headquarters are located just outside of Washington, DC, in Alexandria, Virginia.

Our History

1960

Former FDA Associate Commissioner **Arthur A. Checchi** founds firm.

1985

Former FDA Director of Regional Operations Anthony Celeste acquires and operates company as **AAC Consulting Group**.

1994

After 30 years, **Edward A. Steele** retires from CFSAN at FDA and joins **AAC** as Vice President.

2001

AAC is acquired by Kendle International. Mr. Steele named President of AAC.

2006

Mr. Steele acquires Food, Dietary Supplement, and Cosmetic consulting divisions and establishes **EAS Consulting Group**.

2012

Dean Cirotta becomes partner, President and COO, expanding Dietary Supplement, Pharma, Device and Tobacco services.

2019

EAS is acquired by **Certified Laboratories**, expanding capabilities for both brands in laboratory testing and comprehensive consulting services.

PRESENT

EAS continues to successfully support FDA and USDA regulated industries with 12 staff and over 200 Independent Consultants.

About Us

Our network of 200 independent consultants together with our dedicated staff enables us to provide comprehensive consulting, training, and auditing services ensuring proactive regulatory and quality compliance. With our vast expertise in FDA's and USDA's policies and enforcement, EAS is the proven choice for assistance with regulatory and quality consulting solutions. We'll help you develop compliant quality and manufacturing procedures, policies and systems that are best for your business.

EAS serves the Food, Drug, Dietary Supplement, Medical Device, Tobacco, Veterinary, Hemp/CBD, and Cosmetics industries. Our team provides assistance with labeling and claims safety and safety substantiation, preparation of highly technical submissions, overview and preparation of requirement documents and procedures such as Standard Operating Procedures (SOPs), Good Manufacturing Practice (GMPs), Response to FDA 483s and Warning Letters, remediation and consent decrees, recall assistance, import issues, US Agent services and more. EAS also provides regulatory support for law firms including expert witness services, as well as insurance firms as part of a mergers-and-acquisitions due diligence review.

- Regulatory Strategies
- Training
- Recall Assistance
- FDA Enforcement Actions
- Due Diligence Assessments
- Insurance Assessments
- SOP Assistance
- Submission Assistance
- GMP Compliance
- Facility and Laboratory Audits
- Mock FDA Inspections
- US Agent Services
- Import Entry Assistance
- Registrations and Listings
- Product Labeling
- Marketing Claims
- Electronic Records
- Quality System Implementation
- Virtual Consulting Services

Meet Our Team

Dean Cirotta
President, EAS Consulting Group and Executive Director of Regulatory Affairs, Certified Group

Shelly Blackwell
Senior Director for Dietary Supplement and Tobacco Consulting Services

Lisa El-Shall
Senior Director for Pharmaceutical and Device Consulting Services

Tim Lombardo
Senior Director for Food Consulting Services

Victoria Pankovich
Manager, Regulatory Services

Jeb S. Hunter
Senior Regulatory Consultant

Mark Moen
Senior Regulatory Consultant

Industries Served



Food

Numbering more than 100 FDA and USDA food regulations, EAS has the depth and breadth of expert consultants to support any regulatory or food safety need. Our team specializes in all types of regulatory services related to food production and processing and has unique capabilities with beverage (including bottled water), seafood, produce, infant formula, medical foods, all forms of dairy products as well as animal feed and pet foods.



Dietary Supplements

EAS provides expert consulting services to dietary supplement manufacturers and brand owners for adherence to the Dietary Supplement Health and Education Act (DSHEA), the associated current Good Manufacturing Practices (21 CFR 111) and labeling requirements outlined in 21 CFR 101, as well as other applicable guidances and regulations.



Cosmetics

Our team provides consulting services to the cosmetic industry regulated under the authority of the Federal Food Drug & Cosmetic Act, Modernization of Cosmetics Regulation Act of 2022, and the Fair Packaging and Labeling Act. While the FDA is developing GMP requirements, it is imperative to ensure safe production and distribution, including co-packers, of these products.



Pharmaceuticals

EAS provides a variety of FDA regulatory services to the Rx and OTC pharmaceutical industry. Our team of pharmaceutical regulatory experts provide assistance with quality management system development and strategies, GMP/GLP/GCP assessments, Mock-FDA inspections, regulatory submissions, and more, all to help your organization succeed in this complex and competitive regulatory environment.

Industries Served



Medical Devices

Did you know there are approximately 1,700 types of generic devices with 19 medical specialties in three regulatory classes of devices based on risk? Whether your product is a class I, II or III device, EAS can provide assistance with your 510(k), Premarket Approval, IDE, QSR audit, US Agent, product or facility registration or the filing of petitions, exemptions, and responding to warning letters or FDA form 483s.



Tobacco and Nicotine

EAS is an industry leader in tobacco and nicotine consulting, ensuring compliance with FDA regulatory requirements outlined in the Family Smoking Prevention and Tobacco Control Act (TCA) of 2009 and the subsequent Deeming Rule of 2016 that applies 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. EAS also provides guidance to ensure adherence to the forthcoming Tobacco Product Manufacturing Practices (TPMPs) in the proposed 21 CFR 1120.



Hemp and CBD

As States begin to legalize and regulate the cannabis industry, important considerations must be addressed. One of these is the development and implementation of GMPs and a quality system that meets the state regulations. While not all state regulations are the same, some are similar to the food industry and others more like dietary supplement and pharmaceutical GMPs, the expectation across the board is that facilities throughout the supply chain will have these systems and be closely monitored.



Veterinary

EAS offers on-site assessment services for pet food, pet supplement, animal feed and animal drug manufacturers and distributors. Our highly skilled independent consultants provide solutions to your CVM and AAFCO regulatory challenges, offering a seamless approach to submissions, development of GMPs, evaluation of ingredients and labels, and more.

Our Services

Consulting

EAS serves the industries of Human and Animal Food (including USDA), Pharmaceutical, Dietary Supplement, Medical Device, Tobacco and Nicotine, Veterinary, and Cosmetics.

Submissions

EAS provides assistance with submissions for all FDA industry products and facilities. Our team can lead your company through the process of obtaining necessary background data, pre-meetings with the Agency, preparation and filing of the submission, and act as a conduit between the Agency and the sponsor during the review process.

Auditing

Our team offers comprehensive auditing services from desk-reviews of documents, policies, and procedures, to in-depth mock-FDA and USDA inspections and 3rd party audit gap assessments for firms of all sizes. These audits provide pertinent details of both strengths and weaknesses within a firm and further the ability to meet all FDA expectations.

Training

EAS is proud to be your training partner providing compliance learning opportunities in a variety of FDA and USDA-focused areas. From public seminars and in-house customized trainings to web-based e-learning and presentations at industry events, we offer a variety of interactive learning opportunities to meet your specific training needs.

Legal Support

EAS Consulting Group provides regulatory assistance, expert witness, expert testimony, and due diligence services to law firms and in-house counsel. Our vast network of professionals offers unparalleled technical support and expert guidance in all areas of FDA regulatory compliance.

Additional Services

US Agent and Imports

21 CFR Part 11 Guidance and Validation Services

Agricultural Marketing Services (AMS)

Animal and Plant Health Inspection Service (APHIS)

Certification Preparation Support Services

Color Additive Petitions (CAP)

Consent Decree Resolution

Due Diligence, M&A Insurance Support

Expert Witness and Legal Support

FDA 483/Warning Letter Remediation

Food Additive Petitions (FAP)

Food Contact Notifications (FCN)

Food Fraud

Food Safety Modernization Act Services (FSMA)

Foreign Supplier Verification

FSMA Produce Safety

Generally Recognized As Safe (GRAS)

GxP Industry Services: Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP), Good Clinical Practices (GCP), Good Documentation Practices (GDP)

National Organic Standards Board (NOSB)

New Dietary Ingredient Notifications (NDIN)

Process Authority Reviews

Product Development, Reformulation, and Labeling

Recall Assistance

Retail Food Protection

USDA Notice of Intended Enforcement (NOIE)/Notice of Suspension (NOS)

Learn With Us

Seminars and Webinars

EAS is proud to host training seminars and webinars on topics of great importance to FDA regulated industries. The detailed technical knowledge of EAS Senior Directors and Independent Consultants sets us apart from the competition and EAS frequently offers trainings to provide a regulatory overview of hot topics that enable greater industry understanding.

In-Person Training

Don't see the specific topic or training you're looking for on our upcoming schedule? Allow us to provide in-house or live virtual training seminars for your facility, tailored to the specific training needs of your team.

On-Demand Webinar Library

Our most popular webinars are also available to view as complimentary resources on the EAS Consulting Group website.

Speaking Engagements

EAS exhibits and speaks at industry conferences around the world. Check our website for a list of upcoming events where we invite you to stop by our exhibitor booth or attend one of the technical sessions delivered by EAS representatives.

Visit easconsultinggroup.com to subscribe to our monthly EASeNews and Drug & Device Corner digital newsletters.

Certified Group
Laboratory Testing | Regulatory Consulting



So The World Can Trust In What It Consumes™



The Certified Group Philosophy

Certified Group is committed to delivering innovative, scientific solutions and expertise plus quality testing our customers can feel confident in – "So The World Can Trust In What It Consumes.™"

Our network of 30+ North American and European laboratories serves the food and beverage, dietary supplements, cosmetics, OTC, tobacco/nicotine, cannabis, and hemp industries.

Certified Laboratories
A Certified Group Company

EAS Consulting Group
A Certified Group Company

FSNS
A Certified Group Company

Labstat
A Certified Group Company

Certified Laboratories

Cosmetic, OTC & Supplements Services

- First-to-Market Innovation
- Consistent, Compliant Testing
- Direct-Connect to Technical Experts

Certified Laboratories and FSNS

Food & Beverage Services

Testing Capabilities

- Microbiology Testing
- Chemistry Testing
- Contract Research
- Import Detention Testing

Labstat

Tobacco, Nicotine & Cannabis Services

Testing Capabilities

- Analytical Chemistry
- In Vitro Toxicology
- Microbiology
- Full-Suite Regulatory Testing

While EAS provides regulatory support, guidance and solutions to the FDA regulated industries, EAS is not a law firm and therefore is not engaged in rendering legal advice. The Work Product and information that EAS provides to its clients does not, and is not intended to, constitute legal advice. Please contact your attorney to obtain advice with respect to any particular legal matter.