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One and a Half-day In-person Seminar:

Quality Control Laboratory Compliance - cGMPs and GLPs

By: **Robert C Fish**, Consultant, EAS Consulting Group, LLC

Location: March 29-30, 2018 | San Francisco, CA

SPEAKER

Robert C Fish, Consultant, EAS Consulting Group, LLC

Mr. Fish has been providing independent consulting services since 2003, joining EAS Consulting Group, LLC in November 2006. Prior to that he started work for AAC Consulting Group, Inc. (AAC) in April 1995 after serving 33 years with Food and Drug Administration (FDA). The last 6 years of that service he held the position of Director, Division of Field Investigations (DFI). He was responsible for general policy and guidance for the Agency's domestic and international investigation activities. He also managed the foreign inspections' operations. Prior to that position, Mr. Fish was Director of Compliance at the Nashville District Office for 8 years and was also a Supervisory Investigator at the Nashville District Office for 8 years. Mr. Fish began his career as an investigator in the Minneapolis District Office in 1962, and subsequently served as an Investigator at the Grand Rapids Residence Post and the Detroit District Office. Mr. Fish is experienced in all aspects of FDA regulated products. He has expertise in compliance matters and Current Good Manufacturing Practice Regulations (GMPs) as they relate to pharmaceutical, dietary supplements, tobacco, device, and biologics manufacture. Further, Mr. Fish is ISO 9000 Lead Assessor Trained and is an AFDO Certified HACCP Instructor.

LEARNING OBJECTIVES

Key goals of the conference will include learning:

- The basics of FDA law and regulations governing QC laboratories responsible for testing research materials, components of FDA-regulated products, and finished FDA-regulated products (pharmaceuticals, biologics, medical devices, cosmetics, and foods).
- Laboratory organization, personnel qualification and training requirements.
- Documentation and record-keeping requirements, including e-records and data integrity.
- Sample integrity requirements.
- Management and control of stability (shelf-life) studies
- Analytical methods verification and validation.
- Management and control of laboratory instruments.
- Management and control of laboratory supplies.
- Proper conduct of laboratory investigations.
- Consequences of laboratory non-compliance.

COURSE DESCRIPTION

FDA inspection and oversight of quality control (QC) laboratories are essential elements of the agency's evaluation of the compliance status of regulated companies representing multiple industries - pharmaceuticals, biologics, medical devices, as well as foods and cosmetics - as well as the contract QC laboratories which service these industries. Lack of compliance can result in severe regulatory actions, criminal liability, fines, and the inability to obtain product approvals.

This course will examine the fundamental requirements for all QC laboratories subject to FDA inspection, recent trends from FDA inspection reports and enforcement actions.

In addition, this course will include a list of relevant regulations and guidelines and demonstrate how quality control and quality assurance personnel can monitor industry practices to stay "current" with FDA requirements (cGMPs and GLPs).

AGENDA

DAY ONE (8.30AM – 4.30PM)

Registration Process: 8:30 AM - 9:00 AM
Session Start Time: 9:00 AM

I. Basics of FDA law and regulations for QC laboratories

A. What is adulteration?
   1. Pharmaceuticals
   2. Biologics
   3. Medical Devices
   4. Foods
   5. Cosmetics

B. What is CGMP?
   1. Pharmaceuticals
   2. Biologics
   3. Medical Devices
   4. Foods
   5. Cosmetics

C. What is GLP?
D. What is AIP?
E. Contract Laboratories
F. FDA inspection methodology

II. Laboratory Organization

A. Organization
B. Personnel qualification and training

III. Documentation and record-keeping requirements

A. Standard Operating Procedures
B. Analytical Methods
C. Raw data (notebooks, print-outs)
D. Document management (change control, retention)
E. Part 11 (electronic records and signatures)

IV. Sample integrity requirements

A. Sample collection
B. Sample delivery, handling, disposition
C. Retain samples

V. Stability (shelf-life) studies

A. Organization and management
B. Storage units
C. Analytical methodology

DAY TWO: (8.30AM – 1.00PM)

VI. Analytical methods verification and validation

A. Protocols
B. Tests
C. Documentation

VII. Management and control of laboratory instruments

A. Qualification
B. Calibration
C. Maintenance

VIII. Management and control of laboratory supplies

A. Standards
B. Reagents, chemicals

IX. Proper conduct of laboratory investigations

A. Out-of-specification results
B. Out-of-norm results
C. Root cause analysis
D. Documentation

X. Consequences of laboratory non-compliance

WHO WILL BENEFIT

Senior directors, managers, supervisors and those who have responsibility for ensuring that QC laboratory operations and practices comply with current good manufacturing practices and good laboratory practices.

- Quality Assurance
- Quality Control
- Research & Development

TESTIMONIALS

"Speaker is very knowledgeable. Glimpses "behind the curtain" in to the FDA are quite valuable in my opinion. ComplianceOnline has a broad catalog of professional advancement opportunities."

- Manager, Quality Control, Quanterix Corporation

"The seminar was very informative for the cGMP course over multiple areas (drug, device and food). The open forum for questions and discussions was very valuable. Registration process for the seminar with ComplianceOnline was easy. Details of the course content were helpful. There was quick communication of required materials from ComplianceOnline after the registration."

- Quality Assurance Coordinator, Procter & Gamble

"Speaker was informative. Contract laboratories topic was most valuable to me. Location was great. ComplianceOnline staff was excellent in resolving the registration issues with hotel."

- Research & Development, Estée Lauder Companies

"This seminar had a lot of excellent and useful information which will be beneficial for achieving compliance in our organization quality program. ComplianceOnline is very good at communicating and working with me."

- Quality & Safety Compliance Manager, Alaffia

"Speaker was very informative, interesting and nice. All topics were important to me. Nice hotel and I was happy I had a copy of slides prior to make notes on."

- Research & Development, Estée Lauder Companies

"Overall it was good seminar. ComplianceOnline was very good at email communication prior to the seminar."

- Quality Control Supervisor, International Flavors & Fragrances Inc.

"The instructor was very knowledgeable and lab auditing topic was most valuable to me."

- Food Safety and Quality Coordinator, The Raymond-Hadley Corporation

"It was good seminar. All topics were valuable to me. It was good review of cGMP."

- Quality Control Analyst, Fagron

"Overall it was good seminar. Informal conversation with other attendees was beneficial."

- Manager Quality Engineering, Nuskin Products, Inc

"The instructor was outstanding and very knowledgeable and shared great examples which really clarified the application of course material."

- Sr. VP Operations, Hologic Gen-Probe

"Great experience, very valuable. The instructor gave lot of great examples."

-- Sr. Director QC, Hologic Gen-Probe

"Some of the anecdotes were useful, all were entertaining and informative in the general/public policy/historical sense. The ComplianceOnline responded promptly to questions."

- Quality Control Manager, ProZyme, Inc.

"The instructor was experienced and knowledgeable."

- QA/QC Manager, Nellson Nutraceutical

"Sample SOPs were a good idea."

- QA Manager, Specialty Silicone Fabricators, Inc.

"'Side notes' brought up by the presenter was interesting."

- QC Lab Manager, Usana Health Sciences

"The presenter was extremely versatile/knowledgeable across the GxPs."

- GxP Vendor Compliance Management, AbbVie Laboratories

"The presenter has a lot of experience in a variety of areas and shared stories and examples that helped in better understanding and were interesting."

- Lab Manager, PaxVax, Inc.

"The presenter was very knowledgeable and the presentation was excellent."

- Associate Professor, University of Miami

"The instructor was knowledgeable and experienced."

- Quality Control Manager, Earthrise Nutritionals

"Seminar provided broad overview of what the FDA is looking for during lab inspections."

- Senior Scientist, Clorox Services Company

"The instructor had so much experience and gave lot of examples that make the information easy to understand."

- Scientist I, ViaCyte, Inc

"I had registered for a seminar but unfortunately I was not able to attend. The company was very understanding and extremely helpful. I plan on attending a future event soon."

- Director of Regulatory Affairs, Nickell Physician & Pharmacy Services