ComplianceOnline
The Largest GRC Advisory Network

2-day In-person Seminar:

Why is FDA at my facility, and what do I do during an inspection?

By: **Martina LaGrange**, Former FDA Investigator and FDA Compliance Officer
Shelly Maifarth, Former FDA Investigator and FDA Compliance Officer

Location 1: February 4-5, 2016 | San Diego, CA **Location 2:** April 21-22, 2016 | Chicago, IL



SPEAKERS

Martina LaGrange,
Principal, FDA Compliance Group LLC

Ms. Martina LaGrange began her career in Seattle, WA as an FDA Field Investigator. She moved back home to Denver, CO in 1996 where she completed her 14 year career with the FDA as a Medical Device Specialist.

Ms. LaGrange performed medical device, dietary supplement, pharmaceutical and clinical investigator inspections both domestically and internationally. She inspected some of the world's largest manufacturers, with 75% of inspections resulting in the issuance of a Warning Letter. She was the lead investigator on several injunction recommendations.

Ms. LaGrange was a member of the Quality System Inspection Technique (QSIT) Reengineering Team. She assisted in creating QSIT Training CD-ROM and QSIT CD Exam. She assisted in developing QSIT Training for FDA managers and compliance officers, and was a presenter on the 7/00 LIVE video downlink that trained FDA managers and compliance officers nationwide. She received Vice President Gore's Government Hammer Award for her accomplishments in the device arena. She was also part of the Medical Device EIR (Establishment Inspection Report) Workgroup, created to harmonize FDA's inspectional reports in accordance with the Mutual Recognition Agreement (MRA). She provided classroom training to FDA employees European Union authorities, Colorado Department of Health and Environment, trade groups, and professional societies.

Ms. LaGrange has been consulting in the medical device, dietary supplement, pharmaceutical and clinical investigator areas since 2003. She continues to assist FDA regulated companies in gaining compliance with the FDA regulations. Her focus includes gap analysis, quality control reviews, mock FDA audits, training, SOP development, MDR and Adverse Event Reporting.

Shelly Maifarth, RAC,
Principal, FDA Compliance Group LLC

Ms. Maifarth began her career with FDA as an investigator and microbiologist in Dallas and Denver Districts from 1972 to 1984, then served as an FDA Compliance Officer in Denver's District Office for more than 22 years. As a compliance officer, she has significant experience in the medical device, dietary supplement, food, and pharmaceutical areas. She has conducted training, reviewed quality systems and provided guidance on quality, labeling and compliance issues. Ms. Maifarth provided technical assistance and guidance to investigators and analysts within Denver District, and to state, local, and other federal agencies, including Customs (CBP), EPA, and CDC.

As the senior Compliance Officer in the Denver District Office, Ms. Maifarth received the most complex cases to determine if a company was in compliance with FDA laws, regulations and current policy. These cases were in the areas of medical device cGMPS/labeling/510(k)/PMA, dietary supplement labeling, pharmaceutical GMPS/labeling/new drug, seafood and juice HACCP, and food sanitation and labeling. She successfully completed numerous regulatory actions to bring firms and products into compliance. These actions included Warning Letters, Regulatory Letters, Seizures, Injunctions, Prosecutions, Inspection Warrants, License Suspensions and License Revocations. She provided guidance to assist these companies to come into compliance after these FDA actions.

Ms. Maifarth served as a member of the Expert Panel for National Compliance Officers Law Course, a member of Cadre and Trainer for National Compliance Law Clerk Course, and has provided training for Regulatory Affairs Professional Society (RAPS) on current FDA compliance policies on dietary supplements, drugs and medical devices.

Since beginning her career as a consultant, she has worked extensively with medical device and dietary supplement industries to assist them in achieving compliance with the requirements of FDA laws and regulations. She has coordinated meetings and successfully interacted with FDA on behalf of client firms at the Denver District, FDA Headquarters, and other district offices. She effectively coordinates communication with FDA post-audit, writes 483 responses on behalf of client firms to the FDA, and coordinates any subsequent follow-up.

Instructors are former FDA Investigator and FDA Compliance Officer, having more than 36 years of combined experience working with FDA.

LEARNING OBJECTIVES

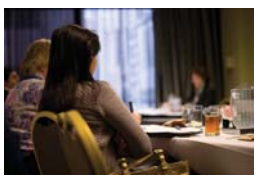
If you are looking for answer of these questions, you would certainly benefit by attending this seminar:

- Which FDA sanctions apply to you, and how to operate in compliance with FDA requirements.
- What to do when FDA knocks – step by step instructions to handle inspections.
- How to handle day by day inspection scenarios?
- What is a front room and back room? Do you need one?
- Runners and Scribes? What do they do?
- Are your SME's the right people, and are they ready/right for the job?
- Why responses to 483's and Warning Letters are critical?
- Steps for responding to 483's and Warning Letters.

COURSE DESCRIPTION

This two day course will prepare firms for a quick, productive, and efficient FDA inspection. Included are segments on FDA Law, how to prepare for the inspection, how to prepare your subject matter experts (SME's) to respond properly, and how to respond to an FDA 483 or Warning Letter. Case Studies and Templates are included.

This course begins with a high level discussion about why FDA conducts inspections and the sanctions available to FDA for those companies who choose not to comply with FDA requirements. Next, we cover what to expect during the inspection, including how to communicate with the investigators, run your front and back rooms, and present documents and records. We cover do's and don'ts, choosing your core inspection team, facilitators, Subject Matter Experts (SME's), runners and scribes. We provide tips for Executive Management/CEO's, Production area staff, Reception Area staff and what each group needs to know during an inspection. The session includes real life inspection scenarios/case studies. Participants are given real life FDA inspection scenarios and are asked to discuss how they would handle each situation. Feedback is given on how to best handle each situation and scenario. This is one of our most popular training sessions!



AGENDA

Day One: 8.30AM – 5.00PM

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

FDA Law and Inspection Training

1. FDA Management and General Training
   - a. Legal Obligations
     - i FD&C Act, § 704(a)(1), Right to Inspect
     - ii Case Law- Real life examples
       1. Section 305 Notices
       2. Indictments
       3. Convictions
       4. Debarment
       5. Consent Decree
       6. Dis-engorgement penalty
     - iii Regulatory Sanctions used by FDA
       1. Written Notices
       2. Judicial Action
       3. Prosecution (fines, jail)
     - iv Administrative Action
     - v Prohibited Acts
       1. Interstate commerce
       2. Adulteration
       3. Misbranding
     - vi Penalties
       1. Seizure
       2. Injunction
       3. Prosecution (fines, jail)
     - vii Civil vs. Criminal
   - b. Management Responsibility from FDA's view
     - i Management with Executive Responsibility defined
     - ii Expectations
     - iii Resources
     - iv Duty, Power, Responsibility

2. Front Room Back Room
   - a. Your FDA Inspection Team
     - i Inspection Team Roles
     - ii Assigning jobs on the Inspection Team
   - b. FDA Inspection SOP
     - i Initial FDA Meeting
     - ii Scribes-what are they – what do they do?
     - iii Runners- what are they- what do they do?
   - c. Front Room/Back Room
     - i Staffing
     - ii Supplying/equipping
     - iii Location
     - iv Training/Prep
   - d. Putting it all together

Day Two: 8.30AM – 4.30PM

SME training, 483/Warning Letter Response

3. SME Training
   - a. Basic Ground Rules for everyone
   - b. Role of the SME
     - i What is an SME?
     - ii SME Characteristics
     - iii How to choose effective SMEs
     - iv Off-site SMEs
     - v SME's Should:
     - vi Utilize Subject Matter Experts (SMEs)
   - c. FDA Interviews
     - i predetermined roles
     - ii How to understand and answer FDA questions
     - iii Should you use props!
     - iv What does your Facilitator do?
   - d. How to get the best out of the inspection
   - e. Say NO to…
   - f. Do's and Don'ts
4. Replying to 483s and Warning Letters
   - a. General Points to Consider
     - i FDA 483 Responses
     - ii Warning Letter Responses
     - iii What you must know about both responses
     - iv Hard copy or via the internet?
     - v Specific and Systemic Corrections
     - vi Templates to consider
     - vii Make sure…
   - b. The Response
     - i Response Cover Letter Importance Tone Who Signs
     - ii Response Body
     - iii Attachments
   - c. Templates
   - d. Let's not forget
   - e. When and How to do updates

** This training will not delve into clinical inspection issues.*
** Chicago, IL seminar on June 5-6, 2014 will be presented by Shelly Maifarth.*

WHO WILL BENEFIT

Industries

FDA regulated Industries

- Medical Device
- Pharmaceuticals

Dietary Supplements

- Food
- Med Tech

Positions/Titles

- Top and Middle Management
- Subject Matter Experts (SME)
- Quality Assurance/management
- Compliance Management
- Manufacturing
- Laboratory
- Regulatory Personnel

Types of facilities:

- Manufacturing facilities
- Private label and contract manufacturing facilities
- Distributors, warehouses
- Own label distributors, private label distributors
- Packers, Labelers
- Ingredient suppliers
- Laboratories
- Importers

TESTIMONIALS

It was a lively seminar with good real life examples and case studies. Management responsibility topic was most valuable for me because it is often missed and not addressed in other seminars. I really appreciate the way how ComplianceOnline is conducting seminars and webinars. Their training topics are always current and timely.

- Quality Assurance Manager, Nellson Nutraceutical

I like the way how seminar was informal and allowing for dialogue. We discussed practical inspection situations through class questions and case studies which will help organizations prepare for inspections. ComplianceOnline has chosen a great venue for this seminar.

- Quality Assurance Specialist, Gilead Sciences

This was an informative seminar. Provided very valuable insight into how the FDA works. Presenters' experience in real life events and interaction with the FDA is priceless.

- Director of QC and Food Safety, Dulcinea Farms, LLC

This seminar was incredibly informative and there was a good amount of interaction between the speakers and the participants. Both the instructors were highly knowledgeable and experienced and I liked their rapport with each other. Also the case studies discussed were very useful.

- Sr. QA Associate II, Ardea Biosciences

This was an interesting session with good practical information. Case studies discussed are very useful to me.

- Director Quality Assurance, Cereal Ingredients, Inc

Presenters were highly knowledgeable and conversation with other participants were very beneficial for me.

- Quality Manager, Cereal Ingredients, Inc

Seminar was very helpful and both the presenters were highly knowledgeable.

- Chief Engineer, Terumo Corporation

I really enjoyed this seminar and it was covering a wide range of topics for various industries.

- QA Manager, Trius Therapeutics

I learned a lot about process during the FDA audits, FDA's expectations and how to prepare for the audits. Good stories and experiences shared by presenters were very interesting and it was a nice team teaching method.

- Food Safety Supervisor, Paramount Farms

I really enjoyed both presenters and their field experience was shown throughout the session that was very helpful. It provided good insight in the proper demeanor to have while dealing with the FDA auditors on site.

- Quality Assurance, Paramount Farms International, LLC

This seminar provided a good understanding on FDA systems and also provided awareness on compliance issues. Case studies discussed were very useful. This seminar was well coordinated by ComplianceOnline and had a very professional approach on the entire process.

- Cody Laboratories

Martina and Shelly are very knowledgeable and as former investigators have provided valuable information and insight. Front/back room set up topic was highly valuable to me because we have an upcoming PAI and this information will help us to prepare upfront.

- QA Manager, Trius Therapeutics

Interaction among attendees and the presenters was excellent. Gained good insight on how to respond to FDA warning letters and 483s. It was a well-organized event. I am impressed with the way how ComplianceOnline has conducted this seminar.

- Supervisor, Corporate Audit, Apotex Inc.

It was an excellent resource for those companies starting the journey of preparation for FDA audits.

- Quality Assurance, Paramount Farms International, LLC

I thoroughly enjoyed this session. Instructors provided good real life examples and personal experiences.

- Quality Assurance, Paramount Farms International, LLC

It was valuable to have training from experienced and highly knowledgeable former FDA investigator and compliance officer.

- Program Manager, Medtronic

Excellent and highly knowledgeable speakers with great new ideas and approaches.

- Sr. Manager – QA, Trius Therapeutics

Registration Form

GROUP REGISTRATIONS

Send Your Team for Maximum Benefit Get your team up to speed!

2 Attendees	-	Get 10% off
3 to 6 Attendees	-	Get 20% off
7 to 10 Attendees	-	Get 25% off
10+ Attendees	-	Get 30% off

Call Toll Free +1-888-717-2436
if you have any queries.

Registration Information:

- **Register Online**. Use your American Express, Visa or MasterCard.
- Get your group to attend the seminar at a discounted price call +1-888-717-2436.
- Call +1-888-717-2436 or Fax your PO: 650-963-2556.
- Pay your check to (payee name) "MetricStream Inc" our parent company and Mail the check to: ComplianceOnline (MetricStream, Inc), 2600 E. Bayshore Road, Palo Alto, CA 94303.
- Please fill this form with attendee details and payment details and fax it to 650-963-2556

Terms & Conditions

Your Registration for the seminar is subject to following terms and conditions. If you need any clarification before registering for this seminar please call us @ +1-888-717-2436 or email us @ editor@complianceonline.com

Cancellations and Substitutions

Written cancellations through fax or email (from the person who has registered for this conference) received at least 10 calendar days prior to the start date of the event will receive a refund — less a $200 administration fee. No cancellations will be accepted — nor refunds issued — within 10 calendar days from the start date of the event. On request by email or fax (before the seminar) a credit for the amount paid minus administration fees ($200) will be transferred to any future ComplianceOnline event and a credit note will be issued. Substitutions may be made at any time. No-shows will be charged the full amount. We discourage onsite registrations, however if you wish to register onsite payment to happen through credit card immediately or check to be submitted onsite. Conference material will be given on the spot if it is available after distributing to other attendees. In case it is not available we will send the material after the conference is over. In the event ComplianceOnline cancels the seminar, ComplianceOnline is not responsible for any airfare, hotel, other costs or losses incurred by registrants. Some topics and speakers may be subject to change without notice.

Seminar Topic: Why is FDA at my facility, and what do I do during an inspection?

Date & Location: .....

Attendee Details:

Register for 3 and 4th person gets a free pass.

	Name	Title	Email
Attendee 1			
Attendee 2			
Attendee 3			
Attendee 4			

Email address (so you can receive order acknowledgements, updated news, product information and special offers)

Company Information

Organization .....

.....

Address .....

.....

City .....

State ..... Zip.....

Country .....

Phone ..... Fax .....

Payment Options

☐ Check enclosed, payable in U.S. funds to ComplianceOnline (MetricStream, Inc.)

☐ Charge to: ☐ Visa ☐ MasterCard ☐ American Express

Credit card no. .....

Expiration date .....

Total amount $ .....

Signature .....
(Signature required on credit card and bill-me orders.)

Print name.....

☐ Bill me/my company $ .....

Purchase order # .....
(Payment is required by the date of the conference.)

Please fill this form with attendee details and payment details and fax it to 650-963-2556

ComplianceOnline
The Largest GRC Advisory Network
www.complianceonline.com
2600 E. Bayshore Road Palo Alto, CA 94303
Ph: +1-888-717-2436 | Fax: 650-963-2556