When the FDA comes knocking, will your inspection be a success? YES — when you have the same training the agency gives its own investigators.

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- **FDA Auditing of Computerized Systems and Part 11/Annex 11: How to Ensure Data Integrity, Security and Compliance throughout Your Enterprise**
- **Managing & Auditing Supplier Quality: FDA Expectations, Global Standards, and Real-World Solutions**

*The course location is accessible from three major airports (Baltimore-Washington International, Washington Dulles International, and Washington Reagan National) and two Interstate Highways (I-70 and I-270).*

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# FDA COMPLIANCE BOOT CAMP 2018

**COURSE 1: FDA Auditing of Computerized Systems and Part 11/Annex 11: How to Ensure Data Integrity, Security and Compliance throughout Your Enterprise**

**DAY 1 | Monday, May 14**

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:30 a.m. – 8:45 a.m.</td>
<td><strong>WELCOME AND CLASS INTRODUCTIONS</strong></td>
</tr>
<tr>
<td>8:45 a.m. – 10:30 a.m.</td>
<td>Regulatory Framework for Computerized Systems: Introduction</td>
</tr>
<tr>
<td>10:30 a.m. – 10:45 a.m.</td>
<td><strong>BREAK</strong></td>
</tr>
<tr>
<td>10:45 a.m. – 12:15 p.m.</td>
<td>Part 11 and Annex 11: Analysis and Comparison of Key Requirements</td>
</tr>
<tr>
<td>12:15 p.m. – 1:00 p.m.</td>
<td><strong>LUNCH BREAK</strong></td>
</tr>
<tr>
<td>1:00 p.m. – 2:30 p.m.</td>
<td>What Auditors Need to Know about Software Development &amp; Computerized System Validation</td>
</tr>
<tr>
<td>2:30 p.m. – 2:45 p.m.</td>
<td><strong>BREAK</strong></td>
</tr>
<tr>
<td>2:45 p.m. – 4:30 p.m.</td>
<td>Planning and Executing Audits for Computerized System Validation</td>
</tr>
<tr>
<td>4:30 p.m. – 5:00 p.m.</td>
<td>Introduction to Mock FDA Audit Scenarios</td>
</tr>
<tr>
<td>5:00 p.m.</td>
<td><strong>ADJOURN DAY ONE</strong></td>
</tr>
</tbody>
</table>

**DAY 2 | Tuesday, May 15**

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:30 a.m. – 9:00 a.m.</td>
<td>Mock FDA Audit Scenario #1: Highly Configurable System; Group Review of Documents; Preparation of Audit Questions</td>
</tr>
<tr>
<td>9:00 a.m. – 10:15 a.m.</td>
<td>Questions &amp; Answers/Discussion of Scenario #1</td>
</tr>
<tr>
<td>10:15 a.m. – 10:30 a.m.</td>
<td><strong>BREAK</strong></td>
</tr>
<tr>
<td>10:30 a.m. – 12:15 p.m.</td>
<td>Questions &amp; Answers/Discussion of Scenario #1, continued</td>
</tr>
<tr>
<td>12:15 p.m. – 1:00 p.m.</td>
<td><strong>LUNCH BREAK</strong></td>
</tr>
<tr>
<td>1:00 p.m. – 2:00 p.m.</td>
<td>Wrap-Up of Scenario #1: Lessons Learned and Key Take-Aways</td>
</tr>
<tr>
<td>2:00 p.m. – 2:30 p.m.</td>
<td>Introduction to Mock FDA Audit Scenario #2: Vendor-Hosted Learning Management System (LMS)</td>
</tr>
<tr>
<td>2:30 p.m. – 2:45 p.m.</td>
<td><strong>BREAK</strong></td>
</tr>
<tr>
<td>2:45 p.m. – 3:15 p.m.</td>
<td>Mock FDA Audit Scenario #2: Group Review of Documents; Preparation of Audit Questions</td>
</tr>
<tr>
<td>3:15 p.m. – 5:00 p.m.</td>
<td>Questions &amp; Answers/Discussion of Scenario #2</td>
</tr>
<tr>
<td>5:00 p.m.</td>
<td><strong>ADJOURN DAY TWO</strong></td>
</tr>
</tbody>
</table>

**DAY 3 | Wednesday, May 16**

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:30 a.m. – 9:30 a.m.</td>
<td>Wrap-Up of Scenario #2: Lessons Learned and Key Take-Aways</td>
</tr>
</tbody>
</table>

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"Great job! I will watch for other EduQuest courses."
COURSE 2: Managing & Auditing Supplier Quality: FDA Expectations, Global Standards, and Real-World Solutions

DAY 4 | Thursday, May 17

7:30 a.m. – 8:30 a.m. | REGISTRATION & CONTINENTAL BREAKFAST
8:30 a.m. – 10:30 a.m.
The Big Picture: FDA and ISO Requirements for Managing Suppliers
- Why supplier management is a high priority at FDA
- FDA’s regulatory authority and enforcement tools
- Inter-relationship of ISO and FDA requirements
- Introduction to FDA’s 7 subsystems of a compliant Quality System

Contracting with Suppliers: Establishing Expectations and Accountability
- Three types of processes you should never hand off to a third party
- Vendor qualification: tips for selecting suppliers who have a culture for compliance
- How to define and document each party’s responsibilities
- Monitoring and auditing provisions to include

10:30 a.m. – 10:45 a.m. | BREAK
10:45 a.m. – 12:30 p.m.
Role of a Quality System in Managing Suppliers
- Crucial elements your Quality System must include
- Quality management principles under ISO
- Definitions of key terms and concepts
- Incorporating suppliers into your CAPA program

Integrated Auditing Techniques
- Differences between auditing and monitoring – know which is appropriate when
- Setting realistic goals and strategies for supplier quality audits
- Linking the mindset of FDA inspectors with your auditing SOPs and techniques
- Objective Evidence: recognizing the gold standard of auditing and compliance

12:30 p.m. – 1:15 p.m. | LUNCH BREAK
1:15 p.m. – 3:30 p.m.
Tips and Requirements for Auditing Management Control
- Management responsibility and reviews: the core of FDA’s expectations
- What to include in your quality policies and procedures
- Role of internal audits… and the critical importance of audit follow-up
- Examples of FDA Warning Letters citing management control failures

Tips and Requirements for Auditing CAPAs and Non-Conformances
- What FDA looks for in your CAPA system
- Potential sources of CAPA information
- Auditing non-conforming materials, complaints, and MDRs
- Examples of FDA Warning Letters citing CAPA and root cause investigation failures

3:30 p.m. – 3:45 p.m. | BREAK
3:45 p.m. – 5:30 p.m.
Tips and Requirements for Auditing Production and Process Control
- Importance of Device Master Records and Device History Records for effective design transfer
- FDA expectations for process control and validation
- How responsible are you for ensuring adequate training at your suppliers?
- Examples of FDA Warning Letters citing Process Control failures

Tips and Requirements for Auditing Records, Documents, and Change Control
- FDA rules for electronic records and signatures
- Expectations for validating computerized systems
- Critical importance of audit trails
- Examples of FDA Warning Letters citing documentation and change control failures

5:30 p.m. | ADJOURN DAY ONE

DAY 5 | Friday, May 18
7:30 a.m. – 8:30 a.m. | CONTINENTAL BREAKFAST
8:30 a.m. – 10:30 a.m.
Tips and Requirements for Auditing Facilities and Equipment Control
- Documenting and calibrating inspection, measurement and testing equipment
- Tools and techniques for monitoring contractor validation programs
- Role of environmental monitoring
- Examples of FDA Warning Letters citing Equipment Control failures

Tips and Requirements for Auditing Material Control
- Documenting supplier status and establishing purchasing SOPs
- Acceptance activities: ensuring incoming products meet specifications
- Traceability: documenting units, lots and batches
- FDA expectations for material shipping, labeling, handling and storage
- Examples of FDA Warning Letters citing Material Control failures

10:30 a.m. – 10:45 a.m. | BREAK
10:45 a.m. – 12:30 p.m.
Tips and Requirements for Auditing Design Controls
- Differences between design verification and design validation
- Defining and documenting essential design inputs and outputs
- Ensuring accurate transfer of product design to production
- Examples of FDA Warning Letters citing Design Control failures

Regulatory Enforcement: The Consequences of Non-Compliance
- Helping your suppliers prepare for an inspection or audit
- Can you shield your audit reports from FDA?
- Responding to 483s and Warning Letters
- Latest FDA enforcement priorities and targets

Course Exam (Self-Test; Open Book)
12:30 p.m. | ADJOURN CLASS
YES! Sign me up for the FDA Compliance Boot Camp 2018

☐ Training Course #1: FDA Auditing of Computerized Systems and Part 11/Annex 11: How to Ensure Data Integrity, Security and Compliance throughout Your Enterprise
   Monday - Wednesday, 8:30 a.m. to 5:00 p.m.
   $2,995

☐ Training Course #2: Managing & Auditing Supplier Quality: FDA Expectations, Global Standards, and Real-World Solutions
   Thursday, 8:30 a.m. to 5:30 p.m., Friday, 8:30 a.m. - 12:30 p.m.
   $1,595

Save $695 by registering for Track A!

☐ Track A: Combination of Courses 1 and 2
   $3,895
   Training Course #1: FDA Auditing of Computerized Systems and Part 11/Annex 11: How to Ensure Data Integrity, Security and Compliance throughout Your Enterprise
   Monday - Wednesday, 8:30 a.m. to 5:00 p.m.
   Training Course #2: Managing & Auditing Supplier Quality: FDA Expectations, Global Standards, and Real-World Solutions
   Thursday, 8:30 a.m. to 5:30 p.m., Friday, 8:30 a.m. - 12:30 p.m.

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To reserve your room, call the hotel at the number below. Be sure to tell the hotel Code EDUQM1 to qualify for the reduced rate. Only reservations made by the reservation cutoff date are offered the special rates, and space is limited. Hotels may run out of discounted rates before the reservation cutoff date. Room cancellations within 72 hours of the date of arrival or “no-shows” will be charged for the first night’s room with tax.

Dates/Location:
May 14-18, 2018
Hilton Garden Inn Frederick
7226 Corporate Court, Frederick, MD 21703
(240) 566-1500 or (866) 909-6090
www.frederick.stayhgi.com
Room rate: $122, per night plus tax
(Please mention discount code: EDUQM1)
Reservation cut-off date: April 30, 2018

TUITION:
Tuition of $3,895, $2,995 or $1,595 includes all course materials, lunch, refreshments, and the opportunity to learn and interact with some of the top FDA compliance experts in the nation.

CANCELLATIONS/SUBSTITUTIONS:
Cancellations received before the beginning of a course will be subject to a refund according to the following schedule and rates: A 95% refund will be provided for cancellations received up to 6:00 PM EST, 10 business days in advance of the course start date. If less than 10 business days-advance notice is provided, the refund amount will be reduced to 50%. Substitutions are permitted with prior notification to FDAnews. Individuals requesting to change course location less than 10 business days in advance of the course will be charged a $500 administrative fee. No-shows will be charged the full amount. FDAnews reserves the right to cancel the courses and is not responsible for any airfare, hotel, or other costs incurred by registrants.

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Fax: +1 (703) 538-7676
Phone: Toll free (888) 838-5578 (inside the U.S.) or +1 (703) 538-7600
Mail: FDAnews, 300 N. Washington St. Suite 200
Falls Church, VA 22046-3431 USA
ABOUT YOUR INSTRUCTORS

**Martin Browning**, course leader, president and co-founder of EduQuest, 2004 IVT Speaker of the Year, capped a 22-year FDA career as a special assistant to the associate commissioner for regulatory affairs. As vice chair of the electronic record and signature working group, he helped draft the original 21 CFR Part 11 regulations. He also served as the chair of the U.S. government’s ISO 9000 committee, and was a member of the committee that developed the medical device quality system regulation. EduQuest was hired by the FDA to train its field investigators, analysts and compliance staff on Part 11 and inspection of computerized systems.

Martin will be joined at FDA Compliance Boot Camp 2016 by other members of the EduQuest training team — computer and compliance experts with extensive FDA experience, plus decades more experience in engineering, software, quality, validation and manufacturing positions with leading FDA-regulated companies.

**Janis Olson**, vice president of regulatory and quality services with EduQuest. Previously, Janis worked at the FDA for more than 22 years, where among other responsibilities she conducted domestic and international inspections of FDA-regulated companies. Currently, Janis helps clients comply with GxP regulations worldwide. She also helps companies prepare for FDA inspections through training, reviewing computer validation documentation, and writing and updating SOPs. Janis was on the PDA task force that wrote the Good Electronic Records Management documents and has served as chair of the PDA industry advisory board for audits of computer system suppliers. She was an instructor for EduQuest’s national FDA training program on Part 11 and has written web-based training on computer system validation and Part 11.

**Sharon A. Strause** is a national authority on computer systems validation and a member of EduQuest's global consulting and training team. She has more than 20 years of experience in the pharmaceutical and medical device fields, including seven years in the Quality Assurance Division at McNeil and Johnson & Johnson Merck Pharmaceutical. Since 2004, she has been a consultant to the life science, consumer product, and software development industries. Previously, she worked 15 years at McNeil Consumer & Specialty Pharmaceuticals, a Johnson & Johnson Company. For seven of those years, she managed the Quality Sciences and Compliance Document Control Group that established standards, policies and practices for documentation at McNeil and Johnson & Johnson Merck Pharmaceutical.

WHO SHOULD ATTEND

- Quality assurance/quality control
- Research and development
- Validation
- Information technology/transfer
- Electronic records
- Software development
- Regulatory affairs
- Internal auditing
- Document management
- Vendor management
- Laboratory information management systems
- Software and computerized systems procurement
- Clinical trial data

ATTENDEES WILL LEARN

- What FDA investigators are trained to look for … which systems they inspect first … which problems get the most scrutiny
- Self-auditing techniques to use before the investigators call
- How to identify and implement corrections, corrective actions and preventive tools
- How to perform a computerized system validation
- How to choose the right risk management tools and methodologies for your organization

“Excellent, knowledgeable, interesting instructors.”

“One of the best training [courses] I ever attended.”