Presented by EduQuest in cooperation with FDAnews

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

FDA COMPLIANCE Boot Camp 2014

Validation, Data Security, Quality Risk Management, and Compliance Training

Imagine getting inside the head of a working FDA investigator — long before your next inspection. Without risking a single noncompliance penalty, you'll enjoy all the benefits of knowing what comes next — from what the agency trains its investigators to look for … to which problems face the most scrutiny. You'll even know which of your systems would be first-up for inspection. Now you can capture that compliance confidence. And it takes less than a week.

Experience a simulated investigation, pick up effective self-auditing techniques and so much more. Here's how …

Hilton Garden Inn Frederick
Frederick, MD
Oct. 20–24, 2014

FDA training now available to industry!
Get three intensive courses in one week:

- FDA Auditing of Computerized Systems and Part 11/Annex 11
- Quality Risk Management for FDA/ICHQ9 Compliance: Agency Expectations, Global Standards and Tools for Success
- The CAPA Confidence Clinic: FDA Rules for CAPA Systems, Failure Investigations and Complaint Management

Get five days of hands-on, interactive training!

Send Your Compliance Team for Maximum Benefit

Send four team members to the same course/s and your fifth member is free.

FDA Compliance Boot Camp's simulated inspection exercise is as close to the real thing as you're likely to get — until the day the FDA actually knocks on your door.

Receive the Validation Vault Resource CD — FREE with Your Boot Camp 2014 attendance.

www.compliancebootcamp14.com
(888) 838-5578 • +1 (703) 538-7600

Get five days of hands-on, interactive training!

Benefits of Attending

You'll 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

"EduQuest seminars are excellent! If you can attend, you should. I've been to several of your seminars over the years, enjoy them, and always leave with a pile of new information. If you can get your management (CxO or director-level people and IT staff) to attend, you should."
- Doug Finner, Elbit Systems

PROGRAM AGENDA

Training Course #1
FDA Auditing of Computerized Systems and Part 11/Annex 11

(24 Course Hours) Monday – Wednesday, 8:30 a.m. – 5:30 p.m.

The FDA is facing a looming crisis of public confidence in three areas directly impacted by computer systems validation — data integrity, especially in clinical and manufacturing environments, supplier quality assurance, and audit trails and change control in virtual computing environments.

Enroll your team in the ***FDA Compliance Boot Camp*** to ensure your company and its contractors and suppliers aren't in the cross-hairs of the FDA's stepped-up enforcement in these areas.

NEW FOR 2014!
Simulated Inspections of Computerized System Development and Maintenance

- ❍ **YOU BE THE AUDITOR:** Learn how to prepare for the FDA inspector – using a simulated inspection with real-world scenarios, SOPs, and personnel responsibilities
- ❍ Participate in three hands-on Mock FDA Audits:
  - ❍ Off-the-shelf but highly configurable system used for complaint management, adverse event reporting, and other quality management functions
  - ❍ Vendor-hosted Learning Management System (LMS) using cloud-based technologies
  - ❍ Hybrid in-house developed/off-the-shelf Manufacturing Execution System (MES) with complex network configurations plus change control and data monitoring challenges

You'll learn:

- ■ Which validation deliverables the FDA expects, and what they should contain
- ■ Why lots of compliance dollars and resources are wasted on ineffective or inadequate validation
- ■ How to identify, document and report computerized system validation deviations
- ■ Top validation errors cited in FDA enforcement actions
- ■ Proactive steps to avoid CSV and Part 11 Form 483s and warning letters
- ■ How the FDA defines a systems risk and mitigation strategy that you can deploy
- ■ Part 11 rules for electronic records and signatures
- ■ How to ensure electronic data correlates to paper records
- ■ Proven techniques for developing compliant software
- ■ Key principles of computerized system validation
- ■ Change control and configuration management
- ■ Ways to ensure audit trails and protect data access and transfer
- ■ How to apply CSV to various types of systems, including legacy systems
- ■ Evaluation of software vendor compliance claims
- ■ How to prepare for the FDA inspector — using a simulated inspection with real-world scenarios
- ■ Five critical pillars required for effective CSV
- ■ Current status of Part 11 — revisions, rewrite or abandonment
- ■ Why data integrity is critical with or without Part 11
- ■ Keys to maintaining your systems in a validated state

Who Should Attend?

Register today if your responsibilities include:

- ✓ 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

Receive the ValidationVault™ Resource CD — FREE with your Boot Camp registration

A $295 value, the Resource CD gives you desktop access to a treasure-trove of FDA laws, regulations and guidances, inspection protocols, warning letters and international guidelines. The CD has been designed by the **Boot Camp** instructors specifically for those involved in computerized systems validation, quality management, software development, or electronic records/signatures compliance. Included in the ValidationVault™ Resource CD are the latest versions of the relevant Title 21 CFR regulations, a complete library of FDA guidance documents related to validation and Part 11, key ICH guidelines and much more. Register today and reserve your free copy of the ValidationVault™ Resource CD.

Training Course #2
Quality Risk Management for FDA/ICHQ9 Compliance: Agency Expectations, Global Standards and Tools for Success

(12 Course Hours) Thursday, 8:30 a.m. – 5:30 p.m. and Friday, 8:30 a.m. – 12:30 p.m.

Risk management is the bedrock of FDA regulation in the 21st century. Devicemakers already scramble to keep up with international risk standards; now, new legislation on Capitol Hill may require all drugmakers to prepare quality risk management plans and conduct periodic audits of their suppliers. Companies that ignore the heightened public and legal demand for cradle-to-grave product risk management imperil their shareholders and their public reputation.

You'll learn:

- The FDA's expectations for managing people, product and process risks
- The language of risk — concepts and definitions of risk management as used by the FDA
- How to better integrate risk management with your quality system
- Regulatory foundations for risk management
- The role risk management plays in developing compliant GxP and electronic recordkeeping systems
- Proven tools for risk assessment, management and hazard control (with hands-on practice)
- The interrelationship of ISO 14971, ICH Q9, and FDA's GxP rules
- What's ahead — and why you must develop a mindset to always evaluate risks

Training Course #3
The CAPA Confidence Clinic: FDA Rules for CAPA Systems, Failure Investigations and Complaint Management

(12 Course Hours) Thursday, 8:30 a.m. – 5:30 p.m. and Friday, 8:30 a.m. – 12:30 p.m.

If your current CAPA system is disorganized, poorly documented, or not supported by thorough failure investigations, you're waving a red flag to FDA inspectors and third-party auditors. Get your quality program back on track by building — step by careful step — a robust CAPA system that meets the FDA's latest expectations. Register today and discover how an effective CAPA system can reduce your manufacturing costs, minimize product recalls, and ensure product safety and effectiveness.

You'll learn:

- The FDA's requirements for CAPA systems
- Why CAPA systems continue to be at the top of the FDA's enforcement list
- Definitions of a correction, corrective action and preventive action — and why the difference matters
- 32 important and often overlooked sources of CAPA data
- Recommended flow charts for CAPA data collection and closure
- Key elements of compliant CAPA Systems
- Picking the right CAPA tracking tools
- FDA guidance for failure investigations and root cause analyses
- How to conduct a proper failure investigation to its root cause
- FDA's trending rules — and how quality data trending helps you better manage product risk
- Lessons learned from recent FDA 483s and warning letters

To register online, visit www.compliancebootcamp14.com or call (888) 838-5578

Space is limited — Register today!

Send Your Compliance Team for Maximum Benefit

Get your compliance team up to speed in just one week!

Significant tuition discounts may be available for teams from the same company. Register four members for the same course and send the fifth member for free. You must register at the same time and provide a single payment to take advantage of the discount.

Call +1 (703) 538-7600 for details.

Receive Your Certificate of Completion

Receive documentation of your training endeavors for management and inspectors. On the last day of each course, you will be presented with a Certificate of Completion.

CONFERENCE TUITION

	Training Course #1: FDA Auditing of Computerized Systems and Part 11/Annex 11 (24 Course Hours)	Training Course #2: Quality Risk Management for FDA/ICHQ9 Compliance (12 Course Hours)	Training Course #3: The CAPA Confidence Clinic: FDA Rules for CAPA Systems, Failure Investigations and Complaint Management (12 Course Hours)
Fee	$2,795 Includes 24 hours of intensive instruction, interactive participation, training materials (presentation slides and reference material), refreshments, breakfasts and lunches Monday through Wednesday.	$1,495 Includes instruction, interactive participation, training materials, refreshments, breakfast on Thursday and Friday and lunch on Thursday.	$1,495 Includes instruction, interactive participation, training materials, refreshments, breakfast on Thursday and Friday and lunch on Thursday.
Mon.	8:30 a.m. – 5:30 p.m.		
Tues.	8:30 a.m. – 5:30 p.m.		
Wed.	8:30 a.m. – 5:30 p.m.		
Thurs.		8:30 a.m. – 5:30 p.m.	8:30 a.m. – 5:30 p.m.
Fri.		8:30 a.m. – 12:30 p.m.	8:30 a.m. – 12:30 p.m.

Save $495 by registering for Track A or B!

Select a Multiple-Course Track

Combination	Discounted Fee
Track A: Combination of Courses 1 and 2	**$3,795**
Track B: Combination of Courses 1 and 3	**$3,795**

*Lunch is provided on Thursday for attendees who sign up for either Multiple-Course Track.

To register online, visit www.compliancebootcamp14.com or call (888) 838-5578

4 EASY WAYS TO REGISTER

Please mention priority code BROCHU when registering.

By Phone: Toll free (888) 838-5578 (inside the U.S.) or +1 (703) 538-7600

By Fax: +1 (703) 538-7676

Online: www.compliancebootcamp14.com

By Mail: **FDAnews**
300 N. Washington St., Suite 200,
Falls Church, VA 22046-3431 • U.S.

LOCATION

Oct. 20–24, 2014
Hilton Garden Inn Frederick
7226 Corporate Court
Frederick, MD 21703
www.frederick.stayhgi.com
Reservations: 866-909-6090
Room rate: $119 per night, plus tax
(Please mention discount code: QUEST1)
Reservation cut-off date: Sept. 28, 2014

CANCELLATIONS AND 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.

TEAM DISCOUNTS

Significant tuition discounts may be available for teams from the same company. Register four members for the same course and send the fifth member for free. You must register at the same time and provide a single payment to take advantage of the discount. Call +1 (703) 538-7600 for details.

LOCATION

❑ **Oct. 20–24, 2014, Hilton Garden Inn Frederick — Frederick, MD**

COURSE(S)

❑ **Training Course #1: FDA Auditing of Computerized Systems and Part 11/Annex 11 . . . . $2,795**
Monday – Wednesday, 8:30 a.m. – 5:30 p.m.

❑ **Training Course #2: Quality Risk Management for FDA/ICHQ9 Compliance: $1,495**
Agency Expectations, Global Standards and Tools for Success
Thursday, 8:30 a.m. – 5:30 p.m., Friday, 8:30 a.m. – 12:30 p.m.

❑ **Training Course #3: The CAPA Confidence Clinic $1,495**
FDA Rules for CAPA Systems, Failure Investigations and Complaint Management
Thursday, 8:30 a.m. – 5:30 p.m., Friday, 8:30 a.m. – 12:30 p.m.

Save $495 by registering for Track A or B!

❑ **Track A: Combination of Courses 1 and 2 . . . . . $3,795**

Training Course #1 FDA Auditing of Computerized Systems and Part 11/Annex 11
Monday – Wednesday, 8:30 a.m. – 5:30 p.m.

Training Course #2 Quality Risk Management for FDA/ICHQ9 Compliance:
Agency Expectations, Global Standards and Tools for Success
Thursday, 8:30 a.m. – 5:30 p.m., Friday, 8:30 a.m. – 12:30 p.m.

❑ **Track B: Combination of Courses 1 and 3 . . . . . $3,795**

Training Course #1 FDA Auditing of Computerized Systems and Part 11/Annex 11
Monday – Wednesday, 8:30 a.m. – 5:30 p.m.

Training Course #3 The CAPA Confidence Clinic
FDA Rules for CAPA Systems, Failure Investigations and Complaint Management
Thursday, 8:30 a.m. – 5:30 p.m., Friday, 8:30 a.m. – 12:30 p.m.

Name _____

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❑ Check enclosed, payable in U.S. funds to **FDAnews**

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Purchase orders are also accepted. ❑ Please bill my company PO# _____

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MEET 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 2014*** 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.

Denise Dion, vice president of regulatory and quality services with EduQuest, spent 18 years with the FDA, where she served as an Office of Regulatory Affairs headquarters authority on agency-wide inspections and investigations. She developed many of the FDA's inspection guidance and training materials, including serving as the primary editor of the well-known *FDA Investigations Operations Manual (IOM)*. Denise was the primary contact for interpretation and request for changes and additions to the IOM. For her EduQuest clients, Denise provides regulatory guidance with particular emphasis on cGMPs, GCPs, quality systems, CAPA systems, risk management, bioresearch monitoring, and FDA inspections and enforcement. Denise regularly performs audits to assess regulatory compliance with drug, medical device and biologics regulations.

Janis Olson, vice president of regulatory and quality services with EduQuest. Previously, Janice 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 is on the PDA task force that wrote the Generation 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 15 years at McNeil Consumer & Speciality Pharmaceuticals, a Johnson & Johnson Company. For seven of those years, Sharon managed the Quality Sciences and Compliance Document Control Group that established standards, policies and practices for documentation. She also was responsible for computer system validation on the McNeil/JJMCP SAP project. Sharon is a member of the advisory board of the Institute of Validation Technology (IVT), and she is the editor of the Computer Validation Forum published in the Journal of Validation Technology. She received an Industry Recognition Award from IVT in 2004.

Comments from Previous Boot Camp Attendees

"Excellent, knowledgeable, interesting instructors."

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

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EduQuest is a leading provider of regulatory consulting, auditing and training services to the pharmaceutical, biologics and medical device industries.

FDAnews publishes domestic and international regulatory, legislative and business news and information for executives in industries regulated by the U.S. Food and Drug Administration.

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