



# FDA Auditing of Computerized Systems and Part 11

*EduQuest's most popular course for more than 15 years*

## 3-Day, Hands-On Part 11 Compliance and Inspection Readiness Training From the Same Instructors Who Trained the FDA and Health Canada

Keep your company's safe from FDA's stepped-up enforcement in two areas directly impacted by Part 11 and computer systems validation:

1. Data integrity, especially in clinical and manufacturing environments, and
2. Supplier quality assurance

Receive expert advice from ex-FDA senior officials and industry authorities hired to train FDA's own field inspectors to investigate and interpret CSV and 21CFR Part 11 compliance. This course is based on a program EduQuest developed at FDA's request to train agency field investigators, analysts and compliance staff on Part 11 rules and the inspection of computerized systems. Included will be a complete update on FDA's Part 11 "tag-along" inspection initiatives.

### You'll learn:

- Which validation deliverables the FDA expects and what they should contain
- Why so many compliance 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
- Part 11 rules for electronic records and signatures
- Paper vs. electronic? Ensuring electronic data correlates to paper records
- Key principles of computerized system validation
- Change control and configuration management
- Ensuring audit trails and secure data access and transfer
- Evaluating software vendor compliance claims
- Current status of Part 11 – revisions, rewrite or abandonment
- How to prepare for the FDA inspector – using a simulated inspection with real-world scenarios

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### Course Curriculum:

- FDA and Computerized System Validation
  - Which validation deliverables the FDA expects and what they should contain
  - Why so many compliance dollars and resources are wasted on ineffective or inadequate validation
  - How the FDA defines a systems risk, plus mitigation strategies you can deploy
- FDA Guidance on Part 11 Scope and Application

- Part 11 rules for electronic records and signatures
- Paper vs. electronic? Ensuring electronic data correlates to paper records
- Why data integrity is critical with or without Part 11
- Current status of Part 11 – revisions, rewrite or abandonment?
- Computerized System Development Model and Methods
  - Proven techniques for developing compliant software
  - Change control and configuration management
  - Data and information resources
- Key Principles and Techniques for Computerized System Validation
  - Five pillars required for effective CSV, including: system management and monitoring, system change management, vendor management and CSV methodology management
  - Keys to maintaining your systems in a validated state
  - How to identify, document and report computerized system validation deviations
  - Ensuring audit trails and secure data access and transfer
  - Applying CSV to various types of systems, including legacy systems
  - Evaluating software vendor compliance claims
- Regulatory Enforcement – Overview and Recent Trends
  - Top validation errors cited in FDA enforcement actions
  - Proactive steps to avoid CSV and Part 11 Form 483s and warning letters
- Workshop: Simulated Inspection of Computerized System Development
  - How to prepare for the FDA inspector – using a simulated inspection with real-world scenarios
  - Learn how to apply effective auditing techniques

## About Your Course Instructors:



**Martin Browning** is the President and Co-Founder of EduQuest, Inc., a global team of FDA compliance experts based near Washington, D.C. Martin has more than 30 years of regulatory experience at the FDA and as a highly sought-after advisor to industry. His 22-year career at FDA included work in the field offices as an investigator and as a senior manager in the Office of Regulatory Affairs at FDA headquarters. He capped his FDA career by serving as a special assistant to the Associate Commissioner for Regulatory

Affairs. He also served as vice chair of FDA's electronic record and signature working group, where he helped draft the original 21 CFR Part 11 regulations. In addition, Martin served as the chair of the U.S. government's ISO 9000 committee and was a member of the FDA committee that developed the medical device Quality System Regulation (QSR).

At EduQuest, Martin helps clients solve problems related to FDA regulation, quality assurance, software and systems engineering, and compliance auditing, including the assessment of vendors and outsourced operations. His specific experience also includes quality systems design, system design assurance and verification, and the validation of biopharmaceutical and device systems, processes and software. Martin was named Speaker of the Year in 2004 by the Institute of Validation Technology (IVT) and has received dozens of other awards from the FDA, DIA, ASQ, and other organizations.



**Gordon B. Richman** is Vice President of Strategic Compliance Consulting and the General Counsel of EduQuest. He joined the company in January 2002. Gordon brings a unique background and over 20 years of regulatory, legal, and corporate management experience

to EduQuest, including more than 10 years in increasingly responsible senior management positions with leading pharmaceutical and medical device companies, first as Director of Worldwide Quality Strategy in GlaxoSmithKline's Global Manufacturing and Supply operations, and then as Vice President of Regulatory Compliance at Fisher & Paykel Healthcare and Vice President of Regulatory Affairs at Masimo Corporation.

Previously, Gordon spent several years in FDA regulatory practice with major law firms in Washington, D.C., where he advised and defended pharmaceutical and medical device companies on a broad range of FDA regulatory issues. He has a broad base of experience in the complex, cross-functional issues faced by the FDA-regulated industries, including matters that span across manufacturing and supply, research and development and information technology.



**Denise Dion** is a Senior Regulatory Consultant with EduQuest. She spent 18 years of her career with the FDA, where she served as an Office of Regulatory Affairs (ORA) headquarters' authority on agency-wide inspections and investigations. She developed many of FDA's inspection guidance and training materials, including serving as the primary editor of the *Investigations Operations Manual (IOM)*. Denise was the primary contact for interpretation and request for changes and additions to the IOM. In addition, she was one of the authors and trainers of the Quality System Inspection Technique (QSIT). For her EduQuest clients, Denise provides regulatory guidance and regularly conducts facility audits to assess compliance with drug, medical device and biologics regulations.



**Janis V. Olson** is a senior validation consultant with EduQuest. Previously, she worked at 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, writing and updating SOPs, and reviewing computer validation documentation. Janis was on the PDA task force that wrote the Generation Electronic Records Management (GERM) 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.



## Register today to reserve your free copy of the ValidationVault™ Resource CD

Receive the **ValidationVault™ Resource CD** – an electronic reference library of FDA compliance resources – **free** with your Boot Camp attendance. A \$295 value, the Resource CD gives you desktop access to a treasure-trove of FDA laws, regulations and guidance; 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 FDA's Investigations Operation Manual, relevant Title 21 CFR regulations, a complete library of FDA guidance documents related to validation and Part 11, key ICH guidelines, and much more.

### **ValidationVault™ Resource CD Table of Contents**

- Unabridged text of laws enforced by FDA
- Unabridged text of key regulations enforced by FDA – Title 21 CFR
- Library of FDA Guidance Documents related to computerized systems, software, electronic records/signatures and other automated systems
- FDA warning letters related to automated systems used for GxP compliance
- International Guidance Documents and guidelines (including PIC/S, GHTF, ICH, and EudraLex)

### **To Register or Get More Details:**

Email Cece Bland at [Info@EduQuest.net](mailto:Info@EduQuest.net) or call 301-874-6031.

Tuition to the public course is \$2795, with discounts for teams of 5 or more. Combine this course with either the 1- ½ day course on Quality Risk Management for FDA Compliance or the 1- ½ day CAPA Clinic, and you'll save \$310 on the combined course tuition.

Training also can be offered on-site, where and when you want it. Request a price quote from [ClarenceDanielson@EduQuest.net](mailto:ClarenceDanielson@EduQuest.net)