Validation Boot Camp is not designed for the feeble or fainthearted. This intensive, five-day, educationally-charged session covers Computer Validation and 21 CFR Part 11 from "soup to nuts".

SEMINAR BENEFITS

- Hosted by industry professionals who have trained thousands in Computer Validation and regulatory compliance

- Provides up-to-date information on FDA's expectation for Part 11 and Computer Validation

- Includes the processes for completing the deliverables – learning the right questions to ask to receive the needed content

- Provides examples of what not to do and the most common mistakes made

- Includes a complete set of SOPs and templates in electronic format

- Introduces Solution11 XL™ – used in the classroom exercises for Microsoft® Excel Part 11 compliance

On-site Benefits:

- Eliminates your staff's travel cost and reduces off-site time

- Contents and supporting materials are customized to match your specific regulatory challenges

- We'll craft a schedule that meets your company's timetable

This rigorous, information-packed five-day training session covers Computer Validation and 21 CFR Part 11 from "soup to nuts".

Workshops, designed for 2-12 participants:

- Enable attendees to execute immediately after completion of session

- Allow participants the opportunity to ask the tough questions and get solutions to difficult problems in a relaxed environment

- Provide ready-to-use SOPs, templates, and reference materials to get you going right away

- Encourage everyone to use the same vocabulary which is key to any project's success

Whether presented on-site at your facility or attended in our Wilmington, DE location, QA Edge industry professionals will provide real-world strategies to avoid costly mistakes through a diverse range of Computer Validation and 21 CFR Part 11 solutions.

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QA EDGE, INC.

COMPUTER VALIDATION BOOT CAMP

Enjoy the benefits of being part of a five-day, educationally-charged training session on 21 CFR Part 11.

QA edge

Your Edge in Software Quality

This in-depth course covers the entire process of Computer Validation including FDA, cGMP, and Part 11 backgrounds; GAMP, Risk, and GERM Industry Standards; User Requirements, Validation Planning and Design Control; Test Planning and Execution; Production SOPs, Validation Report and Change Control.

Complete Computer Validation training, from beginning to advanced concepts, is offered in this rigorous course. It's also designed for a more advanced audience – delving deeper, explaining the process for completing deliverables.

**UNPRECEDENTED
BOOT CAMP GUARANTEE**

If you are not fully satisfied with the contents of this rigorous, five-day session, you will receive a full refund.
NO QUESTIONS ASKED.

Does your company struggle to identify the right Computer Validation boundaries distinguishing compliant and non-compliant efforts? Are you experiencing avoidable rework? Possibly you even view validation as a necessary evil.

If so, you can close your company's Computer Validation and Part 11 gap while meeting FDA's requirements by investing in our Computer Validation Boot Camp, an intensive, five-day workshop – led by one of the nation's leading validation experts, Joseph Schenk, President and CEO of QA Edge, Inc.

Questions and open interaction fill the classroom which is why class size is strictly limited to 2-12 participants.

You and your associates will learn how to:
- Take immediate action – preventing costly errors
- Create documentation that directs projects toward meeting cost, schedule and quality goals
- Employ validation efforts to manage risk
- Streamline your projects resulting in enhanced profitability to your technical initiatives

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During class exercises, your instructor will utilize **Solution11 XL™**, an innovative and simple software tool that enables spreadsheet compliance for your Part 11 regulatory initiatives. You'll discover, first-hand, how this easy-to-use tool demonstrates the Part 11 compliance concepts of security, audit trails and electronic signatures.

Choose the time and location that best suits your company's schedule. Our QA Edge validation team hosts monthly public sessions in our Wilmington, DE location or they will bring this educationally-charged session to your facility. Thousands of attendees, from leading Pharmaceutical and Medical Device firms, have benefited from their advanced concepts and industry know-how.

If held at your facility, training and supporting materials will be customized to more closely meet your company's specific, organizational requirements. Scheduling can also be segmented allowing participation three days one week and two days the following or one day a week for five consecutive weeks.

Allow us to craft an agenda to specifically meet your regulatory needs and timetable.

DELIVERABLES:

Attendees will receive training certificates, paper and electronic copies of slides, SOPs (SLC SOP, SLC Guideline, Coding Standards), Templates (Risk Assessment, URS, Validation Plan, Design Review Memo, Test Plan, Test Script, Traceability Matrix, Technical Specification, Validation Report, Revalidation Form, System Audit Report), and reference manuals.

Boot Camp participants also receive a copy of the industry's best-selling book, *Computer Validation: The 100 Worst Mistakes You Can Make*.

FREQUENTLY ASKED QUESTIONS:

Q. What makes the training worth the investment?
A. The course is presented by leading industry professions having taught thousands in Computer Validation and Part 11. If held at your facility, your travel costs are eliminated and off-site time reduced. The course also provides a **100% Money-Back Guarantee** if you are not satisfied – no questions asked!

Q. We cannot commit to five consecutive days. Can the course be segmented?
A. Definitely. If held at your facility, we can schedule training for three days one week and two days the following or one day a week for five consecutive weeks. Contact us for customized pricing.

Q. We'd like to learn more about Solution11 XL™ for implementing Part 11 compliance and demonstrating record integrity for Excel spreadsheets. Is this possible without taking the Boot Camp?
A. Of course. We have a one-day course covering the exciting features of Solution11 XL. Call for more details.

Q. What other training services do you provide?
A. We provide access to experienced trainers to augment your training staff, delivering a consistent message using your materials. Check the Training section under the Services tab on our website, **www.QAedge.com**, for additional training opportunities.

Click here for registration form

Intensive, five-day, session:

Day 1 – Background on FDA & cGMPs, Part 11 and Computer Validation
- Regulatory Background & cGMPs
- Scope of 21 CFR Part 11
  - Computer Validation
- GMP Good Document Practices
- FDA Compliance Activities
- Part 11 Compliance Strategy
  - Part 11 Assessment Exercise
- Review

Day 2 – Industry Standards: GAMP, Risk, and GERM
- Overview of Good Automated Manufacturing Practices (GAMP 4)
- Overview of Good Electronic Records Management (GERM)
- Risk Management
  - Risk Exercise

Day 3 – User Requirements, Validation Planning and Design Control
- Background
- URS Process
- Requirements Management
- User Requirements for Part 11
- Validation Planning
- System Design Specifications
  - Design Reviews
  - Coding Standards
    - Source Code Review
  - Configuration Management

Day 4 – Test Planning and Execution
- Test Processes
  - Review Test Plan Template
  - SAT/IQ/OQ/PQ
  - Test Metrics
  - Use of Testing Tools
  - Classic Testing Mistakes
- Part 11 Test Scripts

Day 5 – Production SOPs, Validation Report, and Change Control
- Production Control SOPs
  - Infrastructure Qualification Planning
- Validation Report
- Change Control
- Summary Question & Answer