SUPPORT PRODUCTS

Books:
Computer Validation – The 100 Worst Mistakes You Can Make

Ludwig Huber's Compliance Tool Boxes:
Best Practices - FDA Inspections
Best Practices - Macros and Spreadsheets
Best Practices - Network Quality Package

CORPORATE GUARANTEE

We are so confident in our team's abilities in initially crafting the best individualized solutions for our clients that we offer the industry's only corporate guarantee:

UNPRECEDENTED CORPORATE GUARANTEE

QA Edge, Inc. guarantees that any document, authored by our staff, will pass any FDA inspection. If desired, we can be there with you during an inspection to answer any questions. In the unlikely event FDA would have an issue with any document created by QA Edge, we will immediately correct the document at our cost.

Computer Compliance Made Easy

800.459.3363 - Ext. 28
www.QAedge.com

QA Edge Solves Computer Validation and Part 11 Problems By:

- Relieving your staffing worries with qualified long- and short-term staffing
- Shortening your learning curve on risk-based approaches to Computer Validation
- Providing experienced TrackWise™ personnel
- Showing you how to lower your validation costs while adding value
- Increasing your Computer Validation skills on limited budget
- Providing SAP change control personnel

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Clayton Building – Suite 205
Wilmington, DE 19810

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Computer Validation

and Part 11

- **Staffing**
- **Training**
- **Services**
- **Support Products**

Computer Compliance Made Easy

Pharmaceutical and Medical Device leaders have improved the efficiency and effectiveness of their Computer Validation and 21 CFR Part 11 efforts by looking to QA Edge in providing innovative, proven compliance solutions. Four of the top five largest pharmaceutical firms are our clients as well as many mid-size and smaller firms. We help them all with large, complex projects as well as small assignments – delivering on-time and within budget.

SERVICES

- **Long- and Short-Term Staffing**
- **Computer Validation for Regulated Systems**
- **Assessments and Audits**
- **SAP Change Control**
- **Trackwise™ Validation Support**
- **Infrastructure Qualification**

TRAINING

- **Computer Validation Boot Camp™ (5 days)**
- **Risk Based-Approach to Computer Validation (optional 1 or 2 days)**
- **Auditing Software Suppliers (1 day)**

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QA Edge, Inc. can provide staffing for validation of computer systems in regulated environments with respect to cGMP/GLP/GCP (21 CFR 210, 211, 820, Part 11 compliance) and ISO9000.

SYSTEMS VALIDATION EXPERIENCE

- Clinical Information Systems
- LIMS
- Document Indexing/Management
- MRP/ERP (Homegrown and SAP)
- Lab Data Acquisition
- Computerized Lab Instruments
- Clinical/Medical Measurement
- Remote Data Entry / IVRS
- Data Center Control
- Records Management
- TrackWise* expertise

*TradeMark of Sparta Systems Inc

- Regulatory Publishing
- Software Controlled Medical Devices
- Software Controlled Packaging Equipment
- Software Controlled Manufacturing Equipment
- Factory Floor Control Systems
- Manufacturing Execution Systems
- Adverse Event Reporting Systems
- Supply Chain/Logistics Systems
- Drug Supply Accounting
- Imaging Systems

Testing Tools Experience:

Mercury TestDirector
Mercury QuickTest Pro
Segue & Compuware

Lab Validation Experience:

High Performance Liquid Chromatographs
Gas Chromatographs
Ion Chromatographs
Microplate Readers
UV/Visible Spectrophotometers
Atomic Absorption Spectrophotometers
Inductively Coupled Plasmas
Total Organic Carbon Analyzers
Titrators
Robotic Analyzers
Continuous Flow Analyzers
Near IR Analyzers
Data and Acquisition Servers
Chemical Inventory Management