The reassurance of having one of the nation's leading Computer Validation and 21 CFR Part 11 consulting firms directing and supporting you with your software regulatory compliance challenges is only a phone call away - 800.459.3363.

- **Share your frustrating software regulatory concerns**
- **Relinquish those compliance burdens**
- **Challenge us on our proven, creative, and flexible solutions**
- **Share the burden of those approaching deadlines**

PROGRAM BENEFITS

- A "friendly" audit by a certified QA Edge industry professional can expedite and possibly increase sales as well as perhaps alleviate independent audits by prospective clients
- Gaining a common vocabulary and a better comprehension of your industry's regulatory expectations enables cost-effective, targeted solutions
- A readily-accessible, independent resource, tackling those quality-related issues on your behalf, relieves those constricted deadlines and tight budgets
- Outsourcing industry professionals provides a low-cost way to augment validation expertise for your organization
- The ability to easily and rapidly respond to your clients' audits demonstrates your genuine desire to serve your clients
- A crafted, defensible position in response to perspective clients' audit findings avoids over-reaction
- Proven validation support allows you to better respond to sales objections

Contact James Pace, 800.459.3363, Ext. 30.

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QA EDGE, INC.

SOFTWARE QUALITY SUPPORT PROGRAM

One of the nation's leading Computer Validation and 21 CFR Part 11 consulting firms directing and supporting your company's regulatory efforts

Your Edge in Software Quality

QA Edge, Inc. understands the unique regulatory demands facing the Pharmaceutical and Medical Device Manufacturing industries today. Since 1994, these industry leaders, as well as the software vendors providing products and services to these firms, have benefited from our flexible and innovative solutions.

You, as well, can benefit from the regulatory experience and crafted deliverables provided over the years. The QA Edge ***Software Quality Support Program*** is backed by the skilled training and industry knowledge of our more than 35 regulatory professionals in providing:

- A one-year, fixed-price validation support program available both on-site and web-based
- A three-hour training session for developers, QA personnel, support and sales staff on Computer Validation concepts and Part 11 compliance and industry interpretations
- Assessments of outstanding historical vendor audit reports
- A "friendly" audit covering evidence of control over design, testing and consumer support
- An action plan for issue remediation
- Development of SOPs and templates, on an as-needed basis, to address the action plan
- A one-time training session, held on-site, covering SOPs and templates (may be video taped for future internal use)
- Unlimited sales support in handling objections to validation issues that arise during the sales process
- A final, "friendly" audit at the contract's completion to measure the maturity level for validation compliance
- One year of support in swiftly formulating a defensive response to any audit finding

Your company will be assigned one dedicated contact to address an unlimited number of phone and e-mail requests covering Computer Validation, Part 11, and FDA-related industry issues. This constant support will provide the reassurance needed in meeting your regulatory challenges.

Other than software quality-related SOPs and/or audit reports, specific creation or review of documents, as well as evaluation/test of products, will be billed separately. Any on-site support provided during an audit will also be billed separately.

We secure and retain the very best talent – a world class team. The broad base of their experience will provide your edge in meeting today's validation and compliance requirements.

1.800.459.3363

www.QAedge.com

We're so confident in their abilities that we offer you the industries' 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. Should FDA have an issue with any document created by QA Edge, we will immediately correct the document at our cost.

DELIVERABLES:

- An initial, "friendly" audit report
- A tailored action plan
- Training programs (intro and SOPs) including paper and electronic slides as well as supplied training records
- Customized SOPs and templates
- Unlimited e-mail and/or phone responses to validation-related questions/audit findings
- Unlimited sales support to address objections to validation issues that arise during the selling process
- End-of-the-year audit report to measure progress

All questions and e-mails will be acknowledged within 24 hours. If an answer is not readily available, a response timeframe will be provided.

Critical issues will be discussed daily until resolved.