

### Another Satisfied Client:

“The **Fit for Purpose** consulting engagement by QA Edge’s staff helped us identify and organize a measured, pragmatic response to what has been an overwhelming task: ensuring the compliance of scores of diverse systems...”

“They compared various assets, validation and calibration lists to look at the systems in order to capture one overall compliance picture while providing recommendations for the future.”

A Phase III Clinical Biopharma Firm

### Fit for Purpose™ Benefits

This process provides a defense that the system is a high quality system and, if need be, is on the road to compliance. It also:

- Jump starts a computer compliance program
- Is more efficient and costs less
- Provides quick justification for continued use of the system in production

### Five Essential Results:

- Monitors progress
- Increases speed
- Ensures consistency
- Enables you to build and share a knowledgebase in order to leverage system description, test script, and procedural assets that can be used for similar systems
- Closes the loop to ensure Change Control is in place and that the path to full compliance for the high-risk systems is in place

At stake is the approval and launch of your pipeline products as well as your firm’s good reputation. You can utilize the **Fit for Purpose** process to head off potential problems.

Take the next step by leveraging QA Edge’s most knowledgeable and experienced professionals who have successfully performed this **Fit for Purpose** process - providing our clients the advantages needed in meeting FDA’s regulatory requirements.

We are so confident in our team’s abilities in 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.*



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## Legacy System Validation

**Confusing**  
•  
**Complicated**  
•  
**Changing**

**There is no longer a need to agonize over validating your firm’s legacy systems**



**Computer Compliance  
Made Easy**

You face challenges, daily, to insure your regulated systems meet FDA's scrutiny and unclear guidelines with one looming question:

### How much validation is enough?

**You face additional challenges if your firm has:**

- Legacy systems that have not been properly validated
- Met with failures, delays and wasted expense when applying prospective system validation standards to retrospectively validate legacy systems
- Conducted checklist assessments that failed to generate actionable information

To relieve that stress, QA Edge has developed a tested methodology to assess and create a computer compliance baseline - **Fit for Purpose™**.

You can now insure your company is in regulatory compliance using our **Fit for Purpose** process. This thorough assessment provides documented evidence that your computer systems are accurate, reliable and fit for use.

#### A Proven Success Story:

"The **Fit for Purpose** validation documentation plan has proven to be worth its weight in gold. It has allowed us to assemble the various pieces of our validation documentation into the format expected by our many pharmaceutical client companies."

"Recent audits by pharmaceutical clients of the validation documentation processed under the **Fit for Purpose** scenario have yielded excellent results."

CRO, St. Louis MO  
Director QA/RA

The **Fit for Purpose** process is more than a checklist-based assessment, but less than a full SLC validation. It charts an in-depth roadmap which puts the system on a path to achieve full compliance in a timeframe which is appropriate for your defined risk and business needs.

It also provides a documented baseline to give your firm a defensible position, should you be under FDA scrutiny, which describes why the system should remain in production. The **Fit for Purpose** process is simple and repeatable for added value.



Avoid the ramifications of not complying with FDA regulatory requirements. This plan provides the results you need to keep your budgetary and manpower objectives in line.

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### QA Edge's **Fit for Purpose™** 12-Step Process

Utilizing our proven **Fit for Purpose** process will enable you to meet the intensified FDA push for better computer systems validation using our 12-step plan:

1. Proceduralize the **Fit for Purpose** process by creating or modifying your firm's procedures/SOPs using the system-lifecycle validation process of new systems
2. Create a system inventory of your firm's suspected regulated systems
3. Assemble your key players who know the system and its history
4. Determine the risk and applicability of Computer Validation and Part 11 for your systems that could be deemed incidental to the creation of records
5. Document the conclusions, update the system inventory, stop analysis for this system and move to your next one
6. Study your system's support/maintenance history, lifecycle of regulated records, and all available validation documentation
7. Prioritize and develop a schedule and budget to complete your **Fit for Purpose** analysis for all qualified regulated systems
8. Using the **Fit for Purpose** template, write a detailed description for your system
9. Utilizing limited testing, focused on record integrity using the **Fit for Purpose** templates and ready-made scripts, write a customized test plan with scripts
10. Implement low-cost, rapid stop-gap measures to improve your level of compliance
11. Develop a **Fit for Purpose** report documenting if your system has achieved full compliance. If it has, write the validation report. If not, write a **Fit for Purpose** report which outlines a path to achieve full compliance.
12. Begin to execute your Change Control action plan as changes and compliance needs warrant