

QA EDGE, INC.

SOLUTION11 XL™



The FDA has cited firms for not demonstrating record integrity and validation of spreadsheets.

Solution11 XL™ offers a solution to enable Part 11 compliance of spreadsheets by adding the capabilities of security, audit trails and electronic signatures directly in MS Excel.

In an educationally-charged workshop, discover how to match your spreadsheet compliance efforts to FDA's Part 11 expectations. You'll also learn the steps needed to avoid being sited for not demonstrating compliance of your spreadsheets.

You'll be introduced to Solution11 XL™, an impressive new tool which makes spreadsheet compliance easy and affordable. With our personalized web demos and one-day workshop, you'll see first hand how easy Solution11 XL™ is to operate.

An add-on to Microsoft® Excel 97, Excel 2000, and Excel 2002, Solution11 XL™ enables spreadsheets to be produced which are compliant with the 21 CFR Part 11 rule.

Solution11 XL™ ensures authenticity and integrity of Excel spreadsheets via a system of user identification, audit trail, e-signature, encryption and a unique document database.

SOLUTION11 XL™ PROVIDES:

- **A secure and protected environment for Excel files**
- **Easily installed networked solutions**
- **Simple and intuitive use**
- **New spreadsheet generation and brings legacy Excel spreadsheets into compliance**
- **Full user access control (User ID, Password, 4-User Levels, Time-out)**
- **Template, macros and add-in support**
- **Unique export facility for signed spreadsheets**
- **Full development lifecycle documentation**



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Solution11 XL™ provides compliance to the rule:

- All changes to Quality worksheets are recorded in an encrypted audit trail. This includes all changes to the content of the cells, addition of worksheets, electronic signatures, and document management activities.
- All system events (e.g. start-up and logging in, errors and security violations) are logged to a system audit trail.
- Documents, together with their audit trails and signature records, can be printed as hard copy or exported electronically for submission to third parties, such as FDA, for inspection.

The process to software compliance is easy:

The Best Ways To Evaluate Solution11 XL™	
ACTIONS	BENEFITS
1 Schedule a personalized demo of Solution11 XL™ over the web.	<ul style="list-style-type: none"> • Observe a thorough demonstration of this easy-to-use product • Get your specific questions answered at a convenient time without leaving your desk
2 Decision: If you feel confident in evaluating Solution11 XL™, go to Step 4. If not, review the following.	<ul style="list-style-type: none"> • You can decide if you have enough information to proceed with an evaluation. If your organization has not discussed all of the issues surrounding spreadsheet compliance, the workshop is a good arena to facilitate these discussions.
3 Request a one-day workshop, held at your location, which covers: <ul style="list-style-type: none"> • Solution11 XL™ functional training • Spreadsheet validation and Part 11 compliance issues • Process controls for spreadsheet record integrity • The validation of Solution11 XL™, completed by QA Edge, Inc. • Professional installation of Solution11 XL™ in a test/evaluation environment <p>Savings: Save 50% off the workshop fee if scheduled within 30 days of the web demo!</p> <p>100% money-back guarantee if not satisfied.</p>	<ul style="list-style-type: none"> • The workshop provides a framework for everyone to discuss, debate, and agree upon spreadsheet compliance strategies and implementation tactics specific to the organization • Participants receive SOPs and templates for control of spreadsheets which speeds compliance • Participants can usually decide right then and there if Solution11 XL™ is right for the organization without wasting any more time • Provides a focused approach to elicit requirements and conduct a thorough in-house evaluation
4 Install Solution11 XL™ within a test/evaluation environment and conduct an in-house evaluation for up to 30 days.	<ul style="list-style-type: none"> • Use company spreadsheets and put the software through the paces of actual use
5 Make the decision: Is Solution11 XL™ right for your organization? If not, end the evaluation, obtain clarification or make requests for enhancements. If Solution11 XL™ is the right solution, there is only one more step toward spreadsheet compliance.	<ul style="list-style-type: none"> • You decide if Solution11 XL™ offers valuable benefits versus the costs for acquisition and implementation.
6 Determine licensing, support and implementation requirements. <ul style="list-style-type: none"> • Licensing is based on concurrent users and you can have 1½ named users for each concurrent user. 	<ul style="list-style-type: none"> • Services can be tailored to your specific needs to get users up and running quickly

Solution11 XL™ is a networked solution supplied in packages of 10, 25, 50 and 100 licenses. Stand-alone licenses are also available. It operates with Microsoft® Windows NT, 2000, and XP operating systems.

For more information, please contact James Pace, 800.459.3363, Ext. 30.



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