

QI Macros Software Validation Statement

In 2006, the QI Macros celebrated its 10th anniversary. The QI Macros have changed a lot over the last 10+ years, but one thing hasn't changed. That is our commitment to providing affordable, accurate, easy to use SPC software to quality and process improvement personnel in varying industries.

Some people confuse affordable with cheap. They then take the next leap from cheap to unreliable. It just isn't so with the QI Macros. Here's why.

How can we keep our prices so low?

The QI Macros is an add-in for Microsoft Excel. Therefore, we let Excel do all of the heavy lifting. We don't have to create and maintain a separate application.

We also keep our overhead low. We don't have a huge in-house sales staff or fancy offices and you certainly won't ever attend a conference where the QI Macros is a platinum sponsor.

How do we make sure the QI Macros are accurate?

The QI Macros were developed and are maintained using the methodology in Jay Arthur's three books on software development and maintenance:

- Rapid Evolutionary Development (Wiley 1992)
- Software Evolution - The Software Maintenance Challenge (Wiley 1998)
- Software Quality (Wiley 1994)

QI Macros output is validated using the following methods:

1. Validated by manual calculations
2. Validated against textbook examples
3. Validated against other software

The QI Macros Software Development and Testing Process

Requirements - come from three sources:

1. Customers

Our best ideas come from customers. We track requests from our technical support line, from our website comment forms and through direct conversations with customers.

Customers requesting new functionality are asked to help us identify a resource for the requested calculations that is generally accepted and well known in their industry.

2. Statistical and Quality Textbooks

QI Macros formulas and test data come from well known and generally accepted text books and publications. Resources used to validate and verify our formulas and results include:

- Juran's Quality Control Handbook (4th), McGraw Hill, NY, 1988.
- Douglas Montgomery, Introduction to Statistical Process Control (4th), John Wiley & Sons, NY, 2001.
- Montgomery Instructor Companion Site includes Data Sets Referenced in Montgomery's book
- Douglas Montgomery, Design and Analysis of Experiments (5th), John Wiley & Sons, NY, 2001.
- Engineering Statistics On Line Handbook at <http://www.itl.nist.gov/div898/handbook/eda/section3/eda33.htm>

3. Standards Bodies for Various Industries

We monitor standards bodies for various industries. When these bodies come out with new requirements they are incorporated into the QI Macros.

Examples of these groups include:

- Joint Commission on Accreditation for Healthcare Organizations (JCAHO)
- Automotive Industry Action Group - <http://www.aiag.org/Index.cfm>.
AIAG resources used include:
 - Statistical Process Control (SPC) 2nd edition, AIAG, 2005
 - Measurement Systems Analysis (MSA) 3rd edition, AIAG, 2002.
 - Production Part Approval Process (PPAP), 4th edition AIAG, 2006
 - Advanced Product Quality Planning and Control Plan, AIAG, 1995
 - Potential Failure Mode and Effects Analysis, 3rd edition, AIAG, 2001

Development

QI Macros 2006 and previous versions were written in Excel macro language. QI Macros 2007 is written in VBA Code. Releases occur on a quarterly basis and include new functionality, performance enhancements and bug fixes.

Testing

Unit and System Test: All changes to individual macros and templates are unit tested by a separate department.

Regression Testing: All changes to the macros and templates are regression tested through Excel 97-2007 in both Windows and the Macintosh environments.

Test Data

The QI Macros are validated using the test data provided with the software in c:\qimacros\testdata. You can also download the test data at <https://www.qimacros.com/testdata/>

Each test file specifies the book reference (Juran's Quality Handbook or Montgomery's Intro to SPC) used for validation. Gage R&R template was verified against AIAG MSA Version 3.

The QI Macros have been independently verified by several healthcare and manufacturing organizations.

Validation Data and Expected Results

We used a subset of the test data mentioned above to create a validation test file. You can download the validation data set and expected QI Macros results with comparisons to Minitab and other resources at the following links:

- Validation Test Data- at <http://www.qimacros.com/validation-test-data.xls>
- Expected Results and Comparison to Minitab and Other Resources at <http://www.qimacros.com/pdf/QIMacros-test-results.pdf>

Formulas

QI Macros formulas can be viewed at <http://www.qimacros.com/formulas.html>

Technical Support - Users can contact us about technical questions in a variety of ways:

- **On-line** - View our tech support page and frequently asked questions at <http://www.qimacros.com/techsupport.html>
- **Call** 888 468 1537 or 303 756 9144 - Monday thru Friday between 8:00 am and 5:00 pm Mountain time
- **Email** lifestar@rmi.net - please attach a spreadsheet of your data and the QI Macros results.

Questions regarding the QI Macros are always free. However, we charge a \$95 fee for Excel and SPC coaching (up to 1/2 hour).

Bugs

If you find a bug, we will fix it and send you a corrected file at no charge.

QI Macros Statement About 21CFR Part 11

21 CFR 11 requires that spreadsheet templates and data that are saved or updated over time:

1. Be Validated
2. Be Secure from unauthorized changes
3. Have an audit trail of changes

Validation: The QI Macros and templates have already been validated against numerous examples from a wide variety of texts. See further discussion above.

Security and Audit Trail: The QI Macros are written to run in native Excel, so they do not supply any of these features other than what Microsoft Excel supplies.

We recommend that you purchase a separate package to manage these key aspects of compliance for Excel. Consider: Data Compliance System (DaCS) from Wimmer Systems and ABB: <http://www.spreadsheetvalidation.com>.

Once you have this Excel add-in installed, you can:

1. Run the QI Macros charts on your data or
2. Open and update the QI Macros templates or
3. Run the Anova analysis tools on your data
4. and then save it as an Excel workbook under DaCS control.