

QIMacros® Software Validation Statement

In 2022, the QI Macros Software for Excel celebrated its 25th anniversary. With that, QI Macros has changed a lot over the last 25+ 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.

How can we keep our prices so low?

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?

QI Macros was developed and is 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

Some of 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 (5th), John Wiley & Sons, NY, 2005.
- Montgomery Instructor Companion Site includes Data Sets Referenced in Montgomery's book.
- Douglas Montgomery, Design and Analysis of Experiments (5th), John Wiley & Sons, NY, 2005.
- Engineering Statistics Online Handbook at: https://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:

- The Joint Commission on Accreditation for Healthcare Organizations (TJC)
- Automotive Industry Action Group https://www.aiag.org/, AIAG resources used include:
 - Statistical Process Control (SPC) 2nd edition, AIAG, 2005.
 - o Measurement Systems Analysis (MSA) 3rd edition, AIAG, 2002.
 - Measurement Systems Analysis (MSA) 4th edition, AIAG, 2010.
 - Production Part Approval Process (PPAP), 4th edition AIAG, 2006.
 - Advanced Product Quality Planning and Control Plan (APQP), 2nd edition AIAG, 2008.
 - Potential Failure Mode and Effects Analysis, 4rd edition, AIAG, 2008 & 5th Edition FMEA (AIAG & VDA FMEA 1st Edition), 2019.

Note: JCAHO uses QI Macros for Improvement Advisor Training.

Development

QI Macros 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 2013, 2016, 2019 2021, and Office 365 in Windows environments, and Excel 2019 and 2021, and Office 365 in Macintosh environments.

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

Practice Data / Test Data

QI Macros are validated using data sets loaded on your computer with the software. The data sets are loaded in your documents folder at: C:\Program Files\QIMacros\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 4.

Validation Test Macro 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 Macro and Spreadsheet of Expected Results at https://www.qimacros.com/testdata/Ql Macros Software Validation Results.zip
- Expected Results and Comparison to Minitab and Other Resources at https://www.qimacros.com/pdf/QIMacros-test-results.pdf

To run the validation test:

- Open the Validation Macro (this is an Excel file).
- Click on the "XmR" tab.
- Click on the "Run" button.
- Wait for the macro to run. It will stop a few times to ask for your input. Put in your answer and the macro will continue to run.
- Compare the results with the "QI Macros Validation Expected Results" file.

Formulas

QI Macros formulas can be viewed at: https://www.qimacros.com/control-chart-formulas/

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 https://www.gimacros.com/support/gi-macros-tech-support/
- Call 888 468 1537 or 303 756 9144 Monday thru Friday between 8:00 am and 5:00 pm Mountain time.
- Email support@qimacros.com please attach a spreadsheet of your data and the QI Macros results.

• Chat via https://www.qimacros.com/ – Monday thru Friday between 8:00 am and 5:00 pm Mountain time.

Questions regarding the QI Macros are always free. However, we charge a \$350/hour fee for Excel and SPC coaching.

QI Macros Bugs - If you find a bug within (12) months of purchase, we will fix it and send you a corrected file at no charge.

Microsoft Office Bugs - If you find a bug created by either new Microsoft service packs or due to a found Microsoft Excel bug within (12) months of purchase, we will fix it and send you a corrected file at no charge.

Jay Outher



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

Security and Audit Trail: QI Macros is written to run in native Excel, so it does 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: https://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 statistical analysis tools on your data
- 4. and then save it as an Excel workbook under DaCS control.