Danlaw's Mx-Suite Tool Qualification Kit

A cost-effective solution for achieving formal tool qualification in highly regulated industries

Highlights

- Provides formal tool qualification for Mx-Suite and support for TCL (tool confidence level) determination
- Includes necessary artifacts for regulatory compliance
- Significantly reduces qualification costs
- Improves time to market by eliminating manual verification steps
- Increases confidence and assurance of regulatory compliance
- Provides extensible architecture
- Support available from experienced, independent verification and validation experts

Many regulatory agencies require that any software tool used to tailor the safety life-cycle must be qualified to ensure that the tool is functioning correctly for the intended purpose. One such automation tool is Mx-Suite.

CertTech's Tool Qualification Kit (TQK) provides a solid foundation for achieving formal qualification of Mx-Suite used as part of your development process in highly regulated industries such as automotive, aerospace and medical.

Understanding the challenge of formal tool qualification

Formal tool qualification enables the tool functionality to be trusted as true and correct, eliminating the need for costly, time consuming and recurring manual review and analysis of the tool outputs.

The qualification process generally involves industry specific documentation such as a safety manual, software tool qualification report, definition of operational requirements, verification of the requirements and maintaining the tool artifacts in a suitable configuration management system.

The process includes detailed analysis of the tool use cases and specific features that are relied upon to achieve compliance with the regulatory guidelines.

For complex tools, this can take hundreds and sometimes thousands of man-hours to accomplish. Additionally, the qualification package must be updated as new versions of the tools are released.

Leverage the benefits of a COTS solution

Out of the box, the Tool Qualification Kit provides all of the documentation that will be needed as the necessary artifacts for compliance. This documentation is essential because the overall goal is to show complete transparency for the qualification process.

The TQK includes the following artifacts:

- Safety manual
- Tool Operational Requirements
- Requirements-based Verification Procedures
- Test Trace Matrix
- Technical Report from TÜV SÜD including a statement of compliance with the applicable tool validation guidelines.

The kit also includes a set of automated test sequences that are run against the Mx-Suite components installed in the customer environment. The successful results along with the tailored artifacts listed above characterize the package that is required as evidence of compliance for the regulatory agency.

Gain Extensive Feature Coverage

CertTech engineers have determined the critical tool features that require qualification and that provide the most benefit to the end users.

The qualified feature set includes:

- Project Settings
- Signal Behavior
- Signal Dictionary
- Transitions and Triggers
- Test Case Manipulation
- Scenario Operation
- Project Logging and Formal Reports
- Pass/Fail Judgments (including Data Blocks, signal patterns & triggers)
- Test Harness Interface
- Transforms (basic SW signal processing & connector)
- Requirements Traceability
- Regression Testing
- Min/Max Ranges

CertTech's TQK is based on an extensible architecture. Additional features can be added upon request.

Save time and money

By eliminating the need for manual verification, the kit provides tremendous value to companies across a wide variety of safety and mission critical industries where rigorous product development processes demand the highest levels of assurance.

With the newer functional safety standards like ISO 26262 and DO-178C, there is specific information requiring the use of 'qualified tools' for verification and validation (V&V) activities. The Mx-Suite TQK meets this specific need for the Mx-Suite tool.

If you are using Mx-Suite as part of your development process in highly regulated industries, check out the TQK for Mx-Suite — a powerful, cost-effective alternative to manual verification.

About CertTech

CertTech has extensive experience in regulated industries and functional safety standards and thoroughly understands the requirements for using qualified tools specified by standards such as ISO 26262 (Automotive), DO-178C (Aerospace), IEC 62304 (Medical).

CertTech also has extensive experience providing high quality V&V services in a variety of regulatory environments, including formal qualification of software development and verification tools used to increase efficiency of the product development and certification processes.

CertTech's team of engineering professionals provides innovative products, systems and services in support of the development of advanced technology products. The Mx-Suite TQK is yet another example of CertTech's commitment to bringing reliable, cost-effective solutions to the industries we serve.

For more information

To learn more about Mx-Suite TQK, please contact:

Mark Anderson,
manderson@certtech.com
Director of Business Development
913-814-9770

www.certtech.com

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