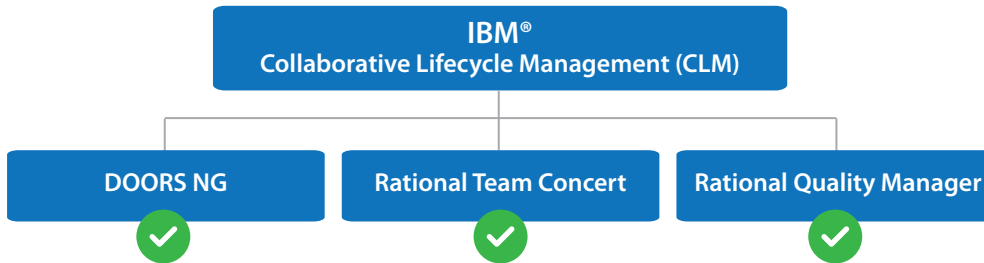




CertTech Tool Qualification Solutions

The Cost Effective Solution -
Tool Qualification for Regulated Industries



Are YOU Ready for Qual?

Software tool qualification is one component of a project’s overall safety plan. The most direct approach to qualification for project managers and developers is to utilize tools that are already qualified or that have a qualification solution. The IBM CLM Suite (DOORS NG, RTC and RQM) now fits that category. Tool qualification verifies that a software tool is performing in the end user’s environment as it was designed to perform. This is not a Quality Assurance activity but rather a feature-based process that systematically ensures that the software tools satisfy their intended use when utilized in the development of functional safety products.

CertTech’s Tool Qualification Solutions for the IBM CLM Suite provide a huge step forward in compliance with regulatory directives. Our solutions can be provided as a product for the user to implement, combined with our implementation services for on-premise integration, or can be provided as a cloud-hosted managed service offering via our partnership with Clear Object.

Features	Benefits
Updated with each new CLM release	Eliminates your need to maintain internal solutions, reducing overall soft costs.
Includes the necessary artifacts for regulatory compliance	The deliverables fully support Medical, Automotive and Aerospace industries reducing your burden for regulatory submittals.
Provides extensible architecture	Customization to meet any specific needs beyond the base platforms can be added reducing specific project costs.
Support from experienced, independent experts	Alleviates ongoing concerns as particular validation issues or topics may arise.

Why Do This?

It’s REQUIRED BY FEDERAL LAW and regulatory guidelines:

MEDICAL –
From Section 820.70 (i) of the Code of Federal Regulations, Title 21
“When computers or automated data processing systems are used as part of production or the quality system, the manufacturer shall validate computer software for its intended use according to an established protocol.”

From IEC 62304 Table C.3
“Suitably validated tools and PROCEDURES shall be selected and identified to implement each RISK CONTROL measure. The tools and PROCEDURES shall be appropriate to assure that each RISK CONTROL measure satisfactorily reduces the identified RISK(S).”

AUTOMOTIVE --
From ISO 26262-8:2011 Clause 11.2
The criteria used to determine if tool qualification is required include the following:
“the possibility that the malfunctioning software tool and its corresponding erroneous output can introduce or fail to detect errors in a safety-related item or element being developed, and the confidence in preventing or detecting such errors in its corresponding output.”

AEROSPACE --
From DO-178C section 12.2.1
“Qualification of a tool is needed when processes of this document are eliminated, reduced, or automated by the use of a software tool without its output being verified as specified in section 6.”
“The purpose of the tool qualification process is to ensure that the tool provides confidence at least equivalent to that of the process(es) eliminated, reduced, or automated.”

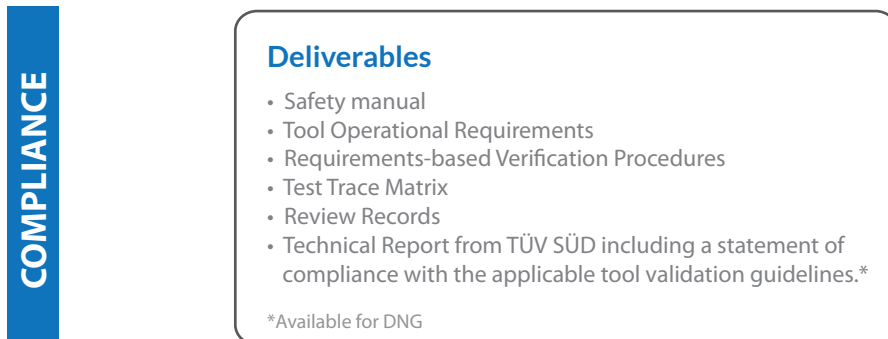
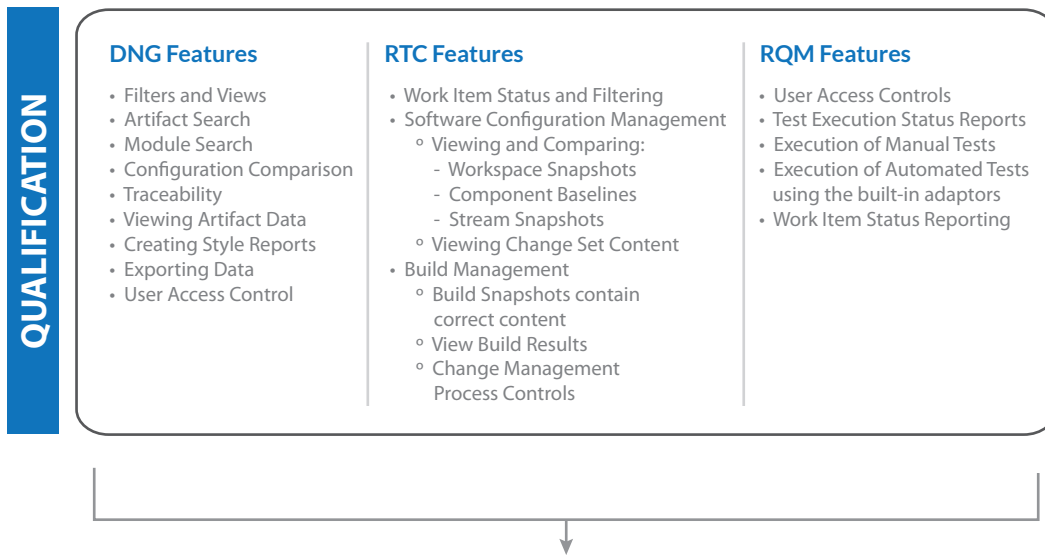
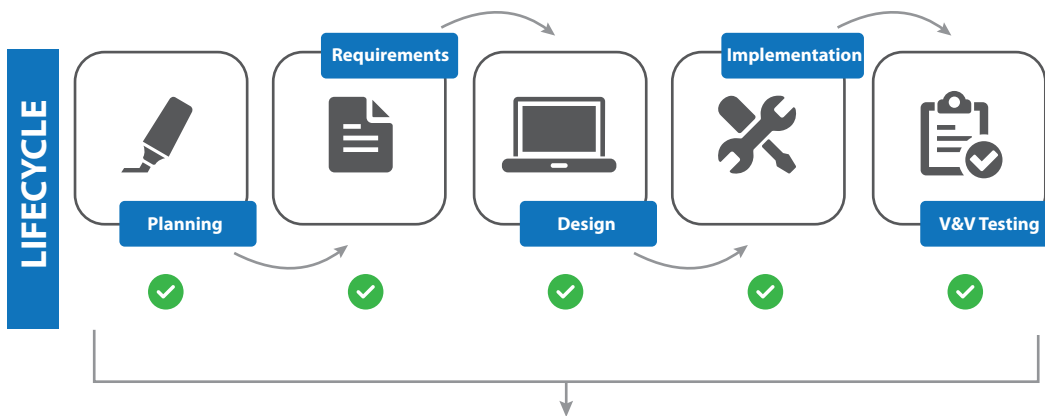


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What Do YOU Get?

A qualified tool solution that impacts every step of the development lifecycle and delivers the artifacts that you need for compliance.



Who Benefits?

Engineering Staff

Keep your team focused on the development and testing aspects of a project. Let's face it – with tight time constraints, tool qualification worries are often left to the end of a project. Our solutions confront tool validation right up front, alleviates worries and keeps the team focused on the development efforts.

Management, QA and Compliance Officers

Leveraging our solutions, while the end deliverables will still carry your branding - all of the heavy lifting is done for you. Each new version of the CLM Suite will be reviewed by us, requirements documentation and tests updated, and compliance documentation delivered to you. This results in overall reduced projects costs and improves your time to market.

CertTech's Qualification solutions provide a solid foundation for achieving formal qualification for software tools that are used as part of the development process in highly regulated industries like automotive, aerospace and medical.

Numerous Fortune 500 companies are already leveraging the Qualification solutions provided by CertTech - saving them time and reducing overall project costs.