



DIGITAL TRANSFORMS PHYSICAL

Tool Validation Kit



Overview

For safety-critical product developers, compliance is a key concern. Regulations and industry standards governing the development of mission- and life-critical products (including medical devices, automotive and aviation embedded systems, railway applications, pharmaceutical projects, etc.) stipulate requirements on product quality, but also on the maturity of the processes and tools used during their development.

As digitalization increases the role of software in safety-critical products, the development tools supporting the engineering, coding, Quality Assurance, testing, and maintenance of software embedded in these regulated products come under growing scrutiny. In various highly regulated industries, software tools need to be qualified and validated for use in safety-critical product development.

Users of our platforms are greatly supported by our Tool Validation Kit which enables the modular verification of features for their intended use. With use cases and test cases to help tool qualification, this template helps accelerate and simplify the validation processes of our platforms for use in safety-critical product development. This kit saves you significant time and costs in the effort-intensive qualification & validation process.



Tool qualification in medical, automotive, aviation, and pharma development

In medical device development, Title 21 Code of Federal Regulations (CFR) Part 820 covers Quality System regulations, and stipulates that software tools used in the production of a device are validated. The Federal Aviation Administration (FAA) imposes similar requirements on avionics developers, while ISO 26262 stipulates that automotive developers, too, have to validate their software tools to enable their use with confidence for their intended purposes. GAMP 5 differentiates between four categories of software based on their sophistication and level of customization. The guidance requires users to take a risk-based approach in validating these software tools with different levels of rigour for each category.

Validation is mandatory whether the tool belongs to the category of SOUP (Software of Unknown Provenance) or COTS (Commercial Off-the-shelf software). Tool qualification and validation in general is based on the concept of "intended use".

Intended use limits the scope of your validation efforts to the features & use cases relevant for you. As a safety-critical product developer, you have to specify what purposes you will be using your software tools for, and validate them for those specific use cases.

Our Tool Validation Kit contains all the assets that you or any independent auditor can use to validate our product for their most widely applied intended uses. The template's contents include:

- Manual and automated test configurations, test cases, and test sets
- The most common use cases for verification
- Test cycles, manual and automated test runs

"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. All software changes shall be validated before approval and issuance. These validation activities and results shall be documented."

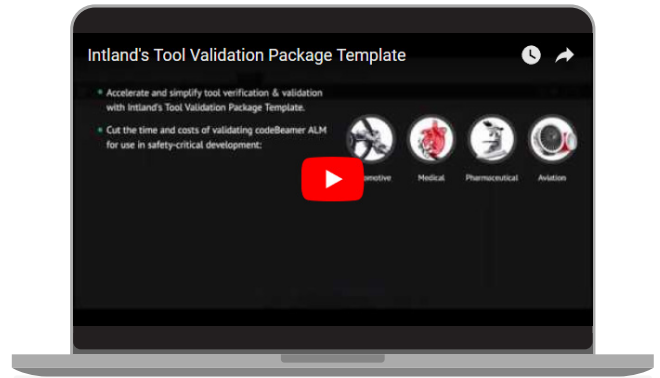
– FDA Title 21 CFR Part 820.70 (i)



Main features

Common use cases

The kit contains general use cases of our platform's features. Ranging from e-mail notifications to FDA-compliant audit trails, these use cases support the verification of features matching your intended use.



Manual and automated testing

Codebeamer's Tool Validation Kit includes test configurations, test cases, and test sets for both manual and automated testing.

Parametrized **test cases** cover a wide range of features from tracker user authentication through the association of work items all the way to document management.

Test sets contain test cases grouped to verify specific use cases. Test configurations are provided for all the general applications of our platform including popular databases and browsers.

A preconfigured **test cycle** includes detailed manual and automated test runs to cut validation effort & costs.

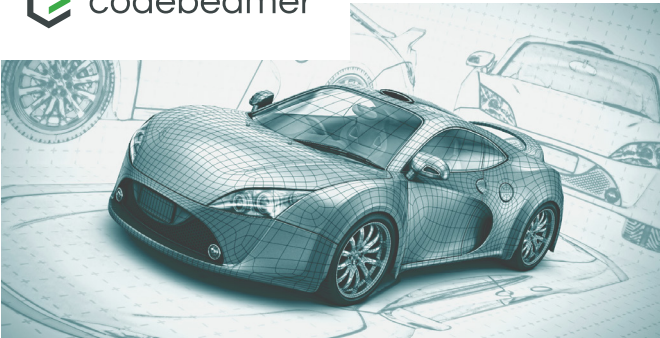
Consulting & customization

Codebeamer's Tool Validation Kit comes with consulting days and customization to help fit the use cases, environment, and other specific requirements to the audited processes.

For more information, visit

<https://intland.com/codebeamer/intlands-tool-validation-kit/>

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Validation Kits

Codebeamer's Validation Kits are valuable tools for safety-critical product development teams with regulatory compliance needs.

- **Tool Validation Kit**
Use this kit to simplify and accelerate tool qualification and validation in regulated product development.
- **Title 21 CFR Part 11 Validation Kit**
Rely on this tool to prove compliance with 21CFR11 requirements about electronic records management.