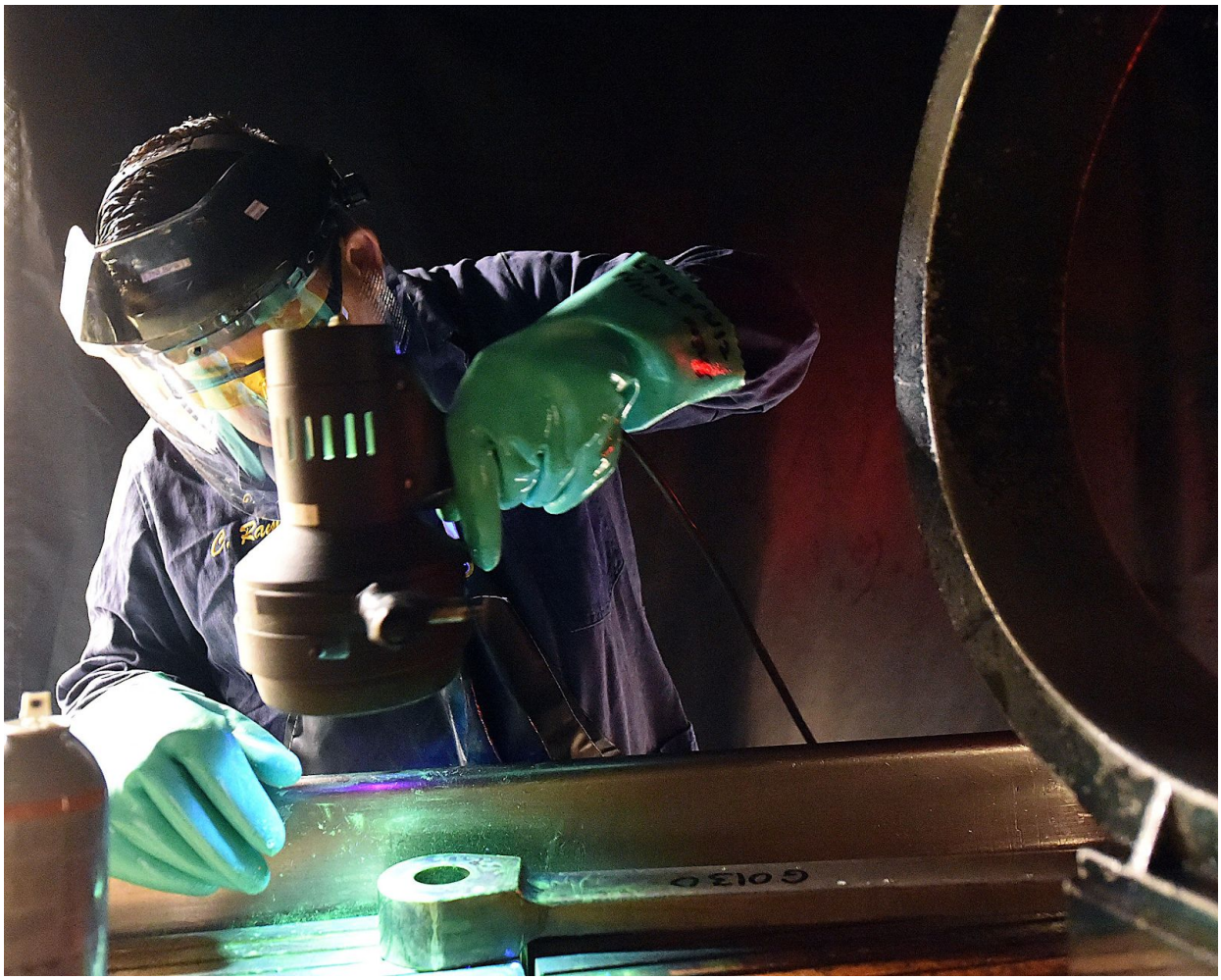
CETEC ERP

White Paper

CFR Part 11 - Validation in Cloud SaaS ERP Systems



History Of CFR Part 11

Most computer systems validation standards that medical device, food and beverage, and life sciences companies must comply with today were drafted around the assumptions and constraints of older technology and archaic models of software delivery and maintenance. For example, FDA's "CFR Part 11" requirements for electronic signatures and validation was released over two decades ago in 1997. The most recently updated "General Principles of Software Validation" guide was released in 2002, half a decade before the first iPhone was ever sold.

Since 2002, technology has moved enterprises rapidly toward web-based applications. Delivering ERP as a SaaS model introduces some fundamental changes to the problems older validation standards were attempting to address; newer technologies like automated unit testing present opportunities to automate testing and validation requirements. In this white paper, we'll discuss how quality standards like CFR Part 11 come to bear on newer "SaaS" models of software delivery.

Software Test Plan: ERP System Validation & Risk Management

The basic thrust of the CFR Part 11 is to require some exercise of validation to occur in concert with even the most minor of software code changes or upgrades. The term "validation" effectively represents a test to verify a program's ability to produce accurate or expected *outputs* provided given *inputs*.

Traditionally, with older and less configurable software systems, companies would purchase a system outright, and software "changes" or upgrades were extraordinarily expensive, and therefore infrequent, and because infrequent, therefore predictable.

With newer SaaS models of software, upgrades are centralized and distributed to end users seamlessly. SaaS-based software releases are inexpensive, streamlined, and therefore frequent, and if not *continuous*. Cetec ERP, for example, provides new releases and upgrades roughly on a three month release schedule.

Continuous Validation: A Burden Or Benefit?

The benefits of continuous software innovation are obvious enough. But, in view of the validation requirements of CFR Part 11, if software changes are constantly occurring, then the burden of validating those changes becomes constant as well. Thus, a dilemma. How can Medical Device and Life Sciences and Food & Beverage companies have their cake and eat it too? How can they enjoy both the benefits of the SaaS / cloud based ERP without crumbling under the overhead of formal validation for every change?

Modernization: A New Era For Automated Testing & Validation

Fortunately, along with newer models for software delivery like SaaS, the process of testing and validation has seen "quantum leaps" of technological innovation as well.

Today, modern software quality assurance best practices dictate automated unit testing to be written and executed in lockstep with the development of software features and

functionality. This effectively has replaced older models for software installation methods and procedures. (For a full treatment of automated unit testing best practices and software validation fundamentals in the modern software world, check out this website - http://softwaretestingfundamentals.com/unit-testing/).

At Cetec ERP, we leverage state-of-the-art "continuous integration" and "continuous deployment" technologies to build and install any new updates to Cetec ERP.

Continuous Integration (CI) and Continuous Delivery (CD) represents the practice of building and testing the application on each update. By working in small increments, errors are detected earlier and promptly resolved. Once integration is complete and all tests have passed, we add Continuous Delivery (CD) to automate the release and deployment process.

Use of CI/CD can make more frequent and reliable releases. We use Continuous Integration and Delivery (CI/CD) to automate the whole process of software updates:

1. Install project dependencies.
2. Run unit tests.
3. Build a Docker image.
4. Push the image to Hub.
5. Kubernetes deployment.

Reference: *https://thenewstack.io/a-step-by-step-guide-to-continuous-deployment-on-kubernetes/*

Front-End Testing: Automating Click-Through Validation Of Software Inputs/Outputs

Historically, a common exercise in software validation portfolios for CFR Part 11 was for a human to manually click through the links and modules of the software, e.g. testing through end-to-end transaction life cycles, work orders, and inspections, to prove the software's capability to produce expected outputs given specified inputs.

This has been an area of extraordinary innovation as well. Cetec ERP employs a technology called "Cypress", whose slogan is: "*The web has evolved. Finally, testing has too.*" Cypress allows you to develop libraries of scripts that act as *bots* to click their way through pathways required in the software to accomplish certain functions, testing inputs and recording outputs along the way.

Check out this video of Cypress running front-end web-site tests:

https://www.varvet.com/images/posts/2018-03-21-how-cypress-will-make-you-love-frontend-testing/cypress-run.gif

Streamlining Your CFR Part 11 Validation Portfolio with SaaS-based QMS and ERP

At Cetec ERP, we publish the results from our backend and frontend automated testing for you to access directly within the interface of your Cetec ERP application. Theoretically, and end user could copy these tests and results into a separate “controlled” document (and even store those documents as controlled revs within Cetec ERP controlled document repositories!)

Historically, compliance with CFR Part 11 meant shouldering the overhead of manually validating test transactions and their results, or paying a third-party to do so, representing a classic example of how regulation, however well intended, can discourage innovation.

With modernized and automated unit testing practices, and the transparent deployment of their results to all Cetec ERP users, our vision is to go above and beyond the standards of manual validation protocols. Our hope is that government regulators, certification bodies, and auditors would be very pleased to see automatic unit testing suites covering extensive validation points for both faster programmatically driven testing, more accurate and comprehensive validation, and less overhead for companies.

Additional Details Regarding CFR Part 11

Note: Cetec ERP recommends that you have a test structure in place to validate necessary processes dictated by your auditor any time a new release occurs (e.g. when Cetec ERP does new releases every 12 weeks, we release first to your "beta" environment a few weeks before "live"). We do not assert that published unit tests and results within the application constitute what qualifies as FDA approved. We would envision that our automated test writing inputs/outputs would represent a piece of your validation portfolio.

Furthermore, it's also important that you and your FDA / CFR Part 11 auditor understand that upgrades happen fluidly and consistently, and that our releases are occasions for more major changes, not restrictions on when changes will be deployed. For more information on this, please see below "installation method and installation procedure" section.

Notably, we may deploy unit tests on what we would consider the most business critical actions and transactions across the ERP system. However, what's still missing from this is an FDA auditor to sign off on whether the range of actions being tested/logged by the unit test suites have sufficiently broad/through coverage.