inflectra

EBOOK

Bridging Speed, Quality, and Compliance in Life Sciences

aws PARTNER

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The Market Shift: Faster Delivery, Higher Stakes

Life sciences and healthcare teams are under pressure.

They must launch new digital products fast and still meet every FDA, EMA, and ISO requirement.

Across pharma, hospital systems, and medical device manufacturers, teams are building more software than ever including medical devices, patient systems, healthcare applications, and wearable technologies.

Most still rely on spreadsheets and manual validation.

Teams spend up to 40% of project time* preparing audit documents instead of building what matters.

To keep up, leading organizations are leaving behind disconnected tools.

They're moving to connected lifecycle platforms that bring quality, development, and compliance together for speed, transparency, and confidence.

Source: The $100M documentation problem

From Validation to Visibility

Validation proves that systems and software work as intended, safely and in line with regulations like GxP and FDA 21 CFR Part 11.

In many teams, it's still a one-off task done before audits. Evidence is tracked by hand.

Traceability is rebuilt every time.

Modern teams take a new approach: continuous validation.

Every requirement, test, and approval stays linked in one place. Evidence builds itself as the work happens.

This shift turns validation into visibility and delivers real-time traceability into what's tested, what's approved, and what's ready for release.

How Leading Life Sciences Teams Work Today

The best life sciences and healthcare teams no longer see compliance as an event.

It is part of how they work every day.

These teams connect quality, development, and testing in one system.

Validation happens as projects move forward.

Traceability builds itself. Audits become a review, not a fire drill.

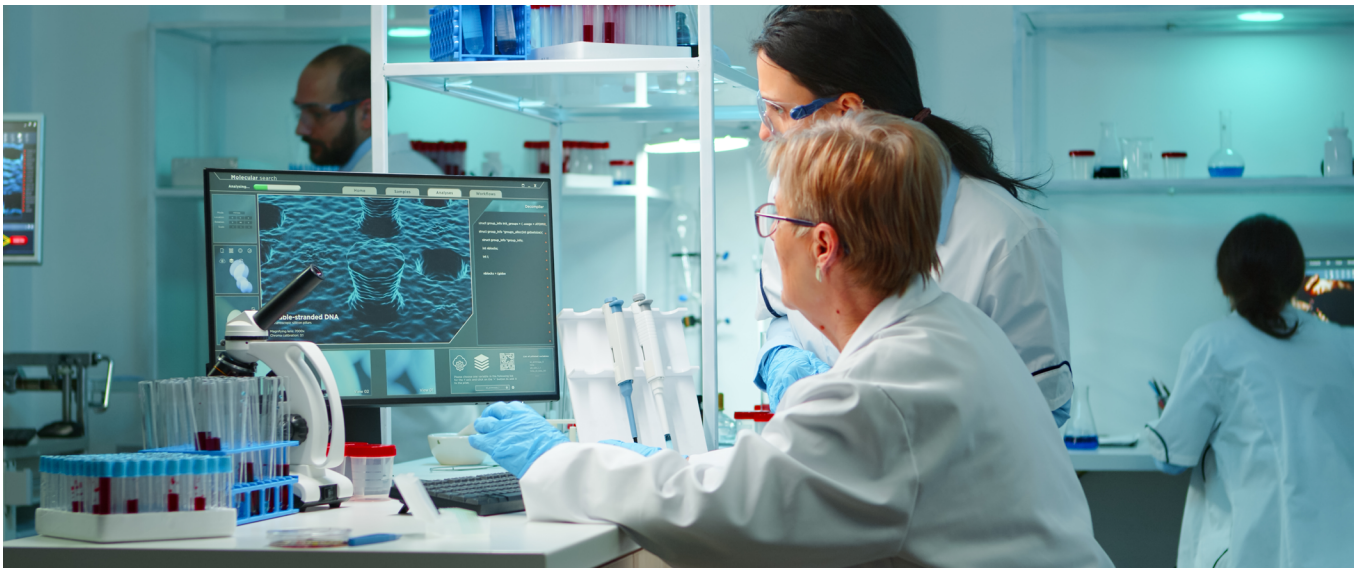
Inflectra has seen this shift across global organizations.

By embedding compliance in daily workflows, teams save time and reduce risk.

Managers gain confidence that every product, release, and record meets GxP and FDA expectations.

Connected lifecycle management creates both speed and control.

It gives QA, validation, and IT leaders the visibility they need to deliver safe, compliant software faster.



Lifecycle Management in Action

Real organizations are already proving that connected lifecycle management works.

Leica Biosystems brought validation, development, and global teams together on AWS. With centralized requirements and testing across Germany, India, and China, they improved collaboration, gained full traceability, and reduced audit prep to one hour.

USDM uses Inflectra to validate enterprise platforms like Google Drive, Box, and OneDrive for regulated use. This ensures data integrity and audit readiness at scale.

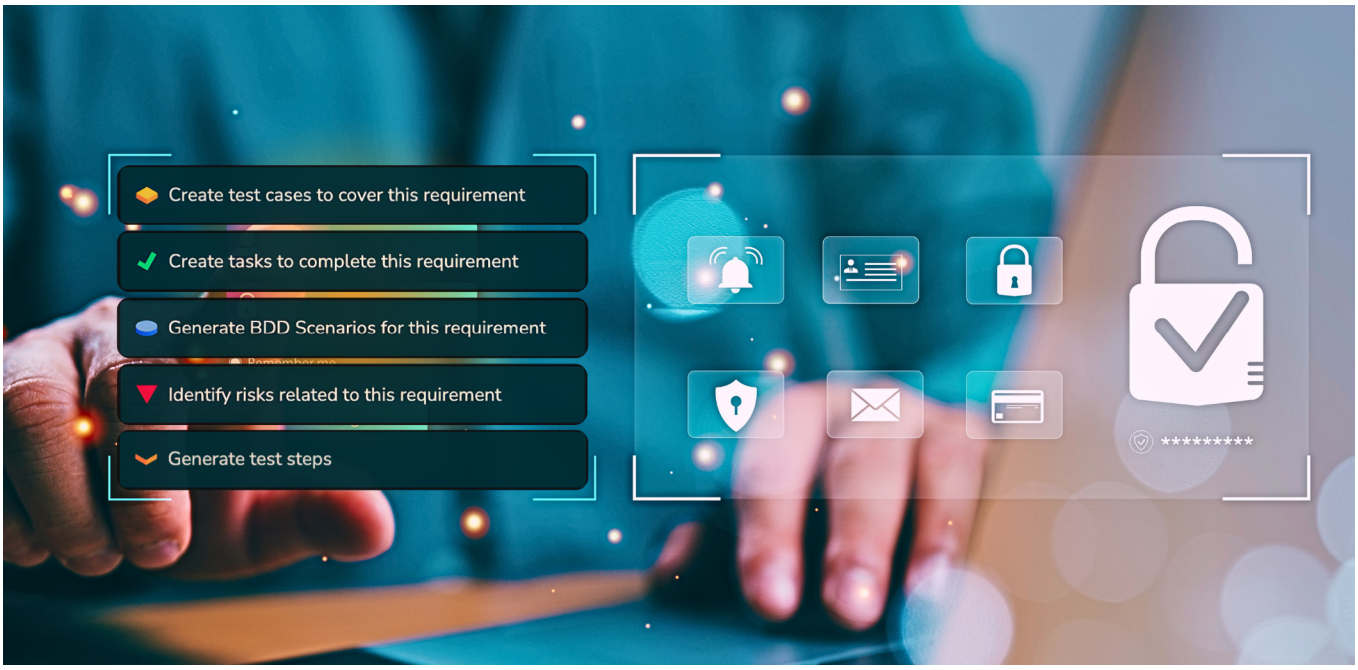
When lifecycle data and compliance live together, organizations deliver faster and stay audit-ready at any moment.

How AI is Reshaping Validation

Artificial intelligence is transforming how life sciences teams build and validate software.

Inflectra's agentic AI, built on Amazon Bedrock, brings automation and intelligence into every part of the lifecycle.

It can create and run tests from natural language requirements, identify risks early, and capture validation evidence automatically.



With AI built into the process, teams validate and release faster while maintaining complete compliance. Quality, traceability, and documentation stay consistent across the lifecycle.

Inflectra is using AI to help teams spot compliance risks early, prepare for audits faster, and stay aligned with evolving GxP standards. Working with AWS, Inflectra makes these capabilities available today to life sciences organizations everywhere.

Always Audit-Ready, Always in Control

Continuous compliance gives teams something they rarely have today. Certainty.

- Every requirement, test, and decision is connected.
- Every change is captured.
- Every release has a clear, traceable history.

Leaders know exactly where projects stand.

QA and validation teams can focus on quality instead of chasing documents.

Audits become faster, smoother, and far less disruptive.

When the entire lifecycle lives in one place, organizations move with speed and confidence.

This is what Inflectra and AWS deliver for healthcare and life sciences teams working in regulated environments.

Start Your Journey to Continuous Compliance

With connected lifecycle management, teams move faster while staying aligned with FDA and GxP expectations.

- Validation becomes part of the work.
- Audits become predictable.
- Quality stays at the center.

Now you can take the next step

Explore the Healthcare & Life Sciences Brief

Learn how teams manage testing workflows and improve traceability.

Download

See Inflectra and AWS in Action

Get a personalized demo tailored to your team's needs.

Request Demo