

Inflectra Healthcare and Life Sciences Solution Brief



The Future of Regulated Software Is Connected

Healthcare and life sciences teams are building more digital systems than ever from medical device software and patient applications to lab systems and cloud-based platforms. As delivery accelerates, expectations for FDA, GxP, 21 CFR Part 11, HITRUST, and HIPAA compliance continue to grow.

Traditional validation workflows rely on manual steps and disconnected tools, creating gaps that slow releases and increase audit risk. To keep pace, organizations need connected lifecycle systems that provide visibility across development, testing, and validation.

Connected software lifecycle management integrates requirements, testing, validation, risks, and documentation into a single workflow. It makes compliance part of everyday work, supports continuous release cycles, and ensures teams always know the state of validation.

Inflectra's Solution: Connected Lifecycle Management

Inflectra brings requirements, testing, validation, traceability, and documentation together in one platform aligned to GxP and 21 CFR Part 11 expectations. Teams can plan, execute, and document validation activities in a controlled, audit-ready system.

Key Capabilities Built for Healthcare and Life Sciences

- Streamlined validation workflows with integrated testing.
- Built-in 21 CFR Part 11-compliant signatures for regulated approvals.
- Secure, HIPAA-compliant cloud or on-premise storage for all validation artifacts.
- Unified visibility from requirements through test scenarios, execution, and results.
- Automatic, secure logs capturing all user actions, changes, and timestamps.
- AI Tools that generate test scenarios and scripts to reduce manual effort.

This connected approach gives teams full lifecycle visibility while reducing manual documentation and audit preparation.



Validation & Testing

Replace your paper-based methods with streamlined workflows and testing using our **integrated validation** solution.



Electronic Signatures

Our products include a unique, built-in **21 CFR Part 11 electronic signature** facility that is tightly integrated with our customizable workflows to ensure compliance.



Data Privacy

Keep all your project artifacts in a secure, private, HIPAA-compliant repository. Whether you choose **cloud hosting**, or prefer to install **on-premise**, we have you covered.



End-to-End Traceability

Use our platform to define your specifications, **create test plans and test scenarios**, execute manual or automated testing, and tie corrective actions to the results, with real-time reporting.



Audit Trails

Our platform automatically maintains a **secure audit log** of all actions in the system, with the user, timestamp, changes and reason all captured and stored.



Automated Validation

Save time validating your systems. Our platform includes **automation tools** that generate test scenarios and scripts directly from your running applications.

The Power of Inflectra on AWS

Connected lifecycle management is only as strong as the infrastructure supporting it. Healthcare and life sciences teams need an environment that protects sensitive data, scales with global workloads, and aligns with strict regulatory expectations. Inflectra and AWS together provide that foundation.

Inflectra manages the lifecycle, and AWS provides the secure, scalable cloud platform to run it. Together, they centralize validation, testing, and traceability while leveraging AWS' proven controls for data protection, audit logging, and global performance.



This combination helps teams modernize validation and quality processes without increasing compliance risk. Data and audit records stay protected, automation becomes easier to introduce, and teams gain the reliability they need to release software confidently.

Inflectra holds AWS Life Sciences, Generative AI, and DevOps Competencies, reinforcing its readiness for GxP-aligned development and continuous compliance at scale.

How Leica Biosystems Unified Global Validation on AWS

Leica Biosystems needed a more efficient way to manage validation and testing across global teams while meeting strict regulatory requirements. Distributed tools and inconsistent workflows made collaboration slow and audit preparation challenging.

By adopting Inflectra on AWS, Leica connected validation, requirements, testing, and incident management in one platform. Teams in Germany, India, and China worked from the same real-time information.

What Leica Achieved:

- Audit prep went from a full day to just one hour
- Requirements, tests, and results were all connected and easy to review
- Teams across regions stayed aligned with shared, real-time workflows
- AWS delivered the secure, scalable infrastructure needed for regulated work

With everything connected in one workflow, Leica can now keep compliance on track while moving new releases out faster.



The Value of Connected Lifecycle Management

Connected lifecycle management gives healthcare and life sciences teams clarity, control, and confidence. Unified requirements, tests, risks, and documentation create automatic traceability, predictable audits, and faster digital product delivery.

Inflectra on AWS extends this with secure, scalable infrastructure built for regulated environments. To see how connected lifecycle management can elevate your own workflows, you can:

Download our eBook:
Bridging Speed, Quality, and
Compliance in Life Sciences

Download

See how Inflectra and AWS
can support your validation
and compliance workflows.

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