
AVEVAWORLD
ACCELERATE INDUSTRIAL INTELLIGENCE

Continuous Validation for AVEVA CONNECT 2.0

Enabling GxP Confidence for Life Sciences Industrial Intelligence

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Why This Matters Now

Industrial intelligence is moving faster than traditional validation.

Cloud & AI Adoption

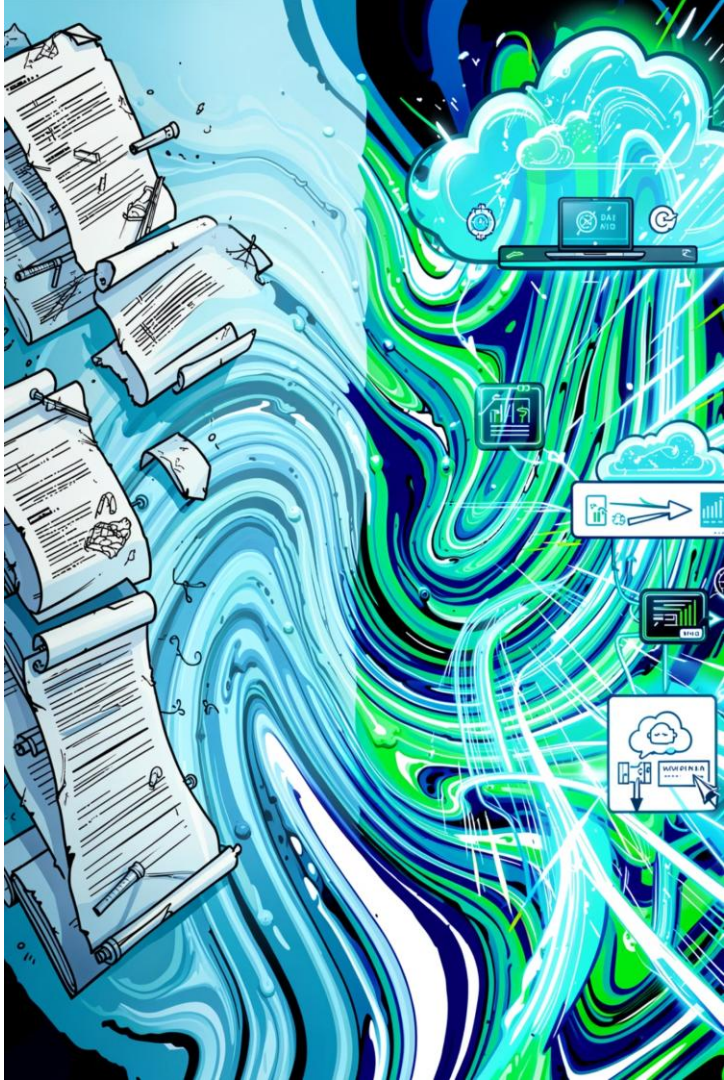
Life sciences companies are rapidly adopting cloud platforms, data analytics, AI, and connected manufacturing workflows at unprecedented speed.

Outdated Validation Models

Traditional validation approaches were designed for slower, release-based software environments — they were never built for continuous platform evolution.

The Opportunity

Move from document-heavy, periodic validation to **evidence-driven continuous validation** that keeps pace with modern industrial intelligence platforms.



The AVEVA CONNECT Opportunity

CONNECT gives life sciences companies a foundation for unified industrial intelligence.

Open, Vendor-Neutral Platform

AVEVA describes CONNECT as an open, vendor-neutral, cloud-based platform that integrates industrial data, models, applications, AI, and analytics.

Real-Time IIoT Integration

CONNECT collects real-time data from IIoT devices and remote assets, aggregates edge and multi-site data, and integrates analytics and AI across the ecosystem.

Life Sciences Opportunity

For regulated manufacturers, this creates enterprise-wide visibility, contextualized manufacturing data, and dramatically faster decision-making capabilities.

The Regulated Adoption Gap

> The adoption question is not only *'Can CONNECT do it?'* but *'Can we trust it in GxP use?'*

What Regulated Customers Need

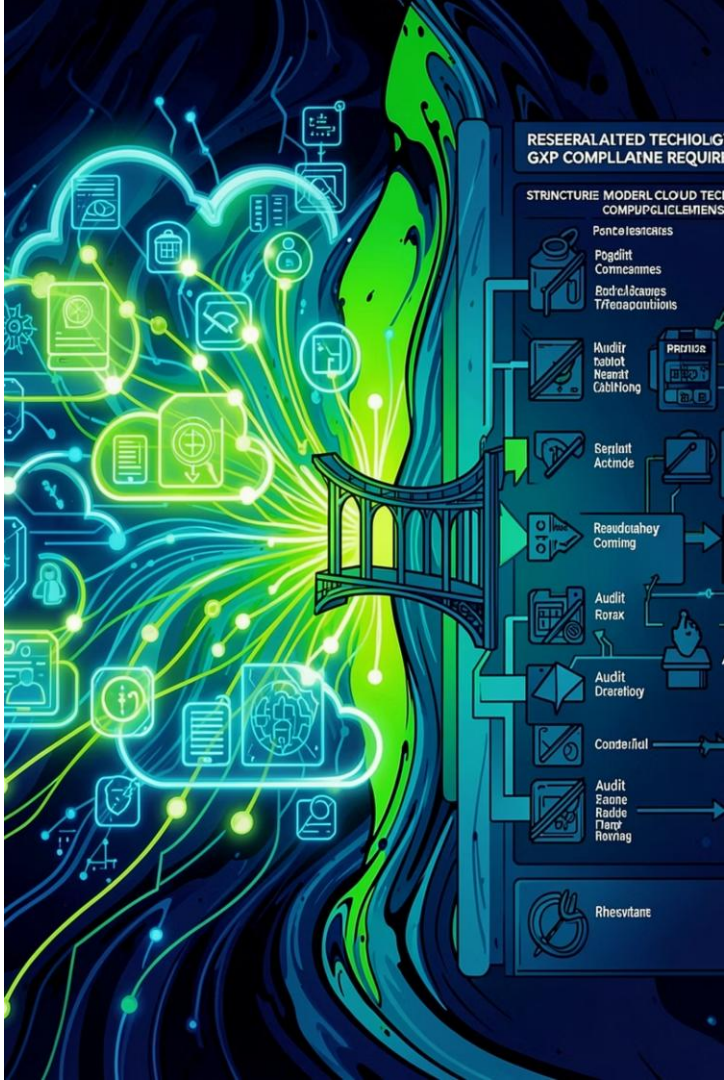
- Clarity on intended use and system boundaries
- Access control and identity management evidence
- Audit trails and data integrity assurance
- Testing evidence and change impact documentation
- Ongoing validated state maintenance

Highest-Risk Areas

The highest-risk areas are not simple connectors — they are **analytics, predictions, workflows, alerts, and automated actions** that may influence production or quality decisions.

The Solution: Use-Case-Driven Validation

A use-case-driven approach allows **lighter assurance** for monitoring use cases and **stronger scripted assurance** for predictive or automated actions.



xLM + AVEVA Partnership Vision

Goal: Establish xLM Continuous Validation for AVEVA CONNECT 2.0

1

Assess

GxP audits of AVEVA CONNECT SDLC and cloud infrastructure

2

Remediate

Module review and Part 11 / Annex 11 gap remediation

3

Baseline

Validation environment setup and automated validation packages

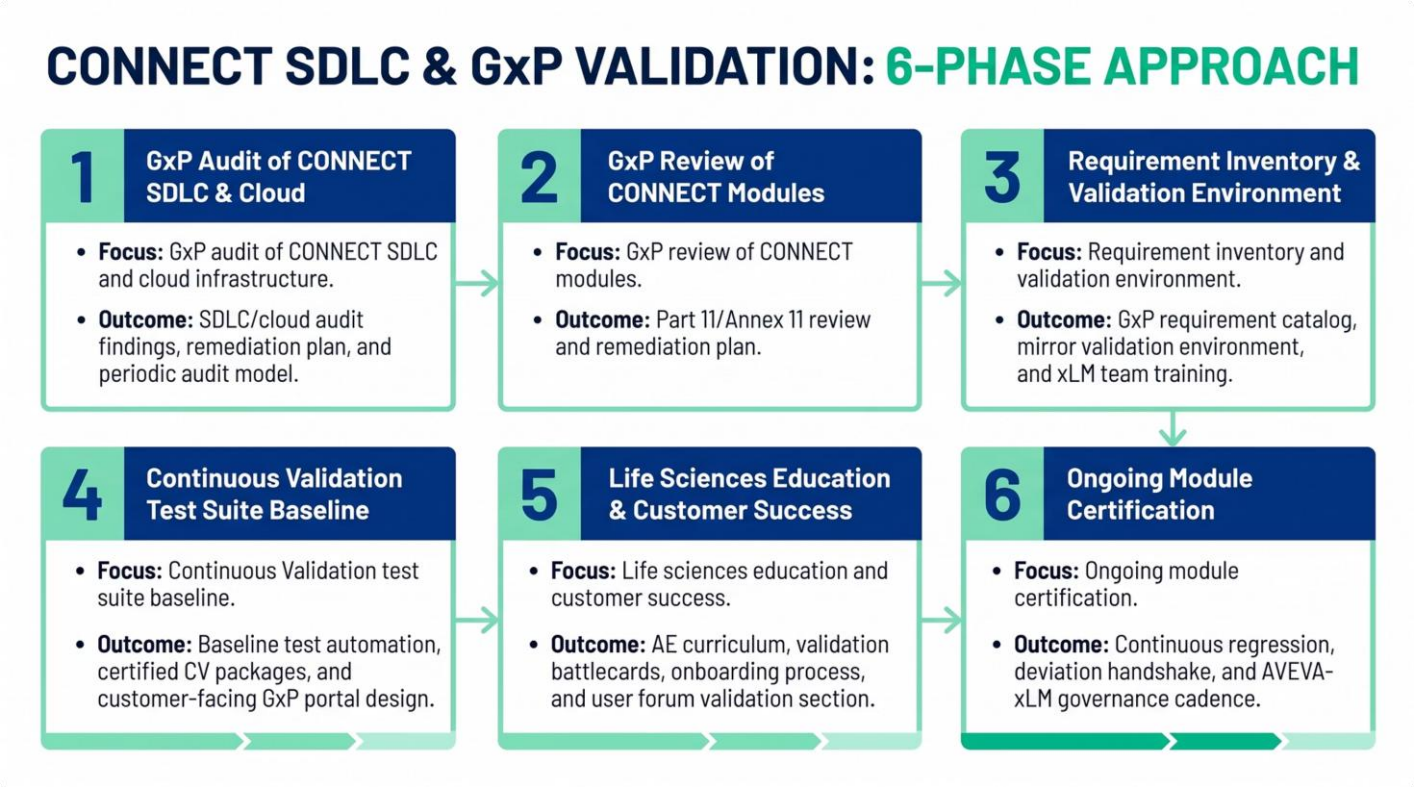
4

Certify & Sustain

Customer success enablement and ongoing certification cadence

xLM proposed a six-phase approach for Continuous Validation of AVEVA CONNECT — creating a full lifecycle model from initial audit through perpetual certification.

Six-Phase Roadmap



This is an ambitious Validation Package when compared any other major Platform vendor. There is no match in terms of depth and breadth of this effort.
Bottomline: Reduced risk for the end customer. The end customer can leverage to take a more focused "instance" validation approach.

Current Status

Where We Are Today

1

Phase 1 — Almost Complete

GxP audit of AVEVA CONNECT SDLC, cloud infrastructure, remediation planning, and periodic audit model development.

NEAR COMPLETE

2

Phase 2 — In Progress

Reviewing CONNECT modules from 21 CFR Part 11 and Annex 11 perspectives to identify gaps and define remediation actions.

IN PROGRESS

3

Phase 3 — Planned

Planned after CONNECT 2.0 GA. Includes module requirement inventory, a validation environment mirroring pre-production, and xLM team training.

PLANNED

4

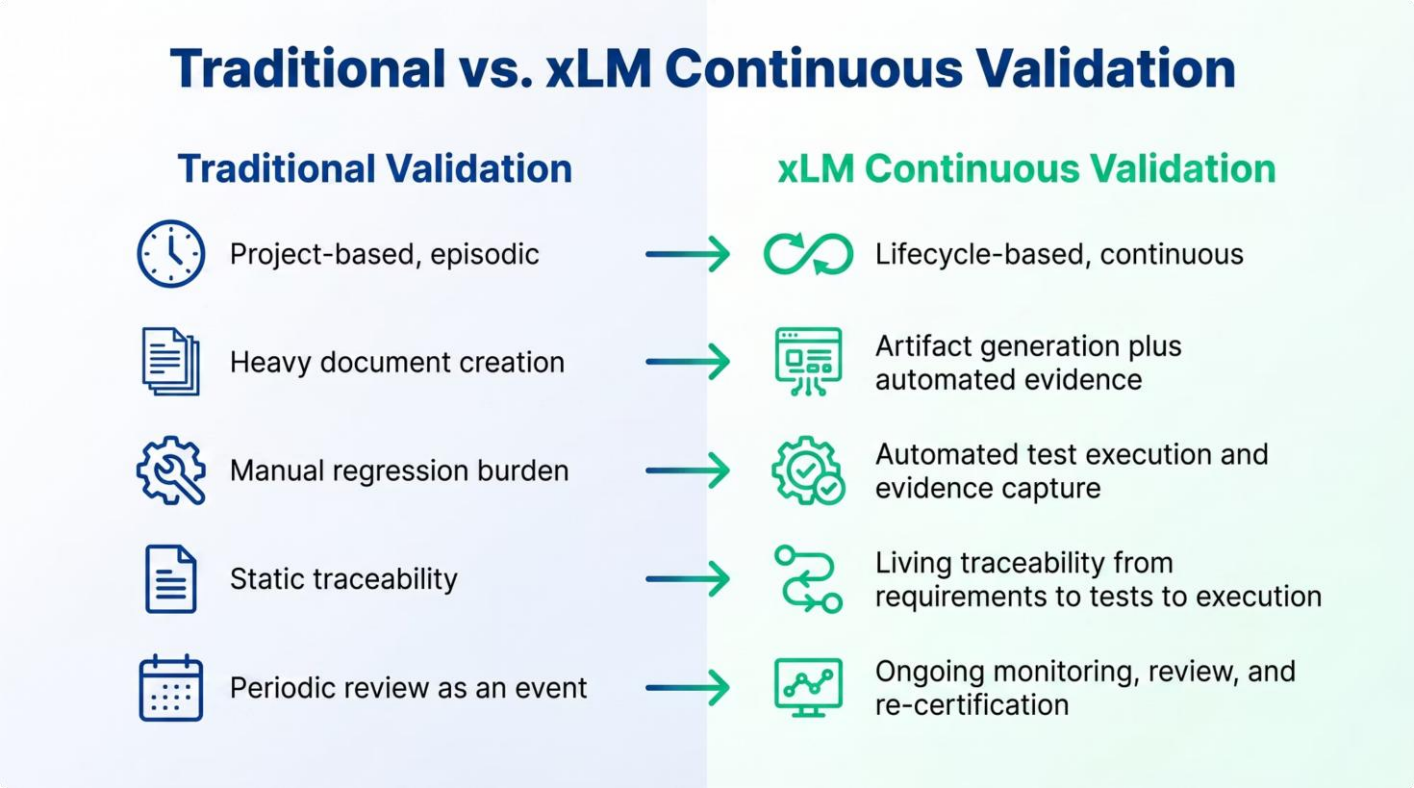
Phase 4 — In Progress

Continuous Validation artifacts are actively being developed for CONNECT CDS 2.0, establishing the baseline test automation suite.

IN PROGRESS

Validation Model

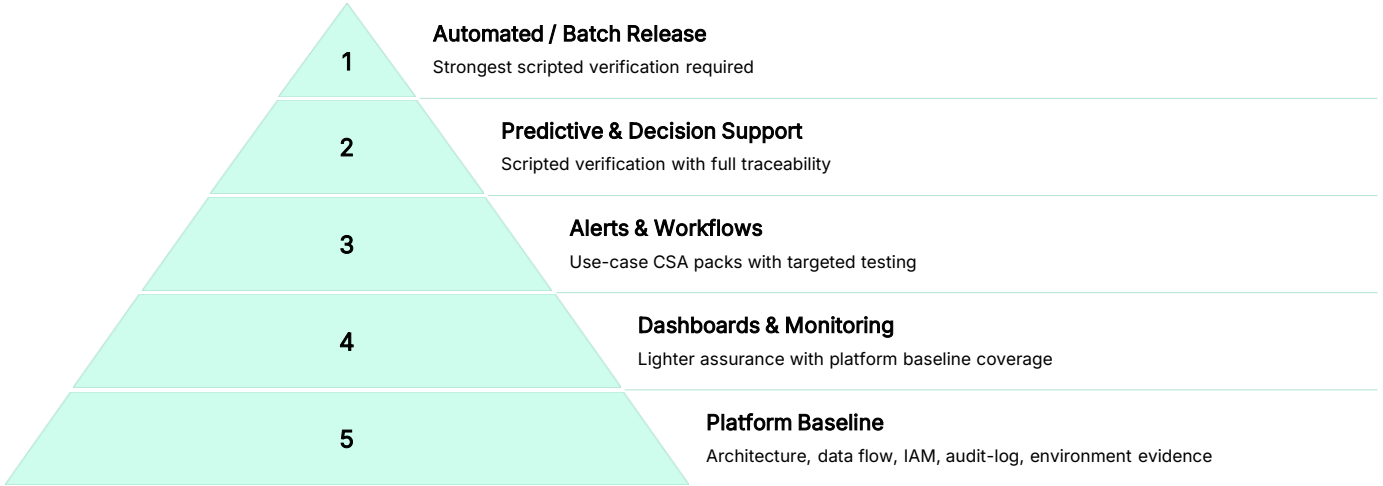
From one-time validation to continuous validation



xLM has extensive experience validation many platforms: **Veeva, MasterControl, Tracelink, ServiceNow, Cognite, SAP, PowerBI, Azure/AWS. etc**..

Risk-Based CSA Logic: xLM's model for CONNECT 2.0 Product Validation

> Validate by intended use, not by platform label.



A platform baseline covers architecture, data flow, connector inventory, IAM design, audit-log configuration, and environment-specific installation evidence. Use-case CSA packs are then layered on top for each GxP-relevant application.

⚠ **"By allowing manufacturers to leverage principles such as risk-based testing, unscripted testing, continuous performance monitoring, and data monitoring, as well as validation activities performed by other entities..., the computer software assurance approach provides flexibility and agility in helping to provide assurance that the software maintains a validated state..."**

"Because the computer software assurance effort is risk-based, it follows a least-burdensome approach, where the burden of validation is no more than necessary to address the risk."

- FDA (Computer Software Assurance for Production and Quality Management System Software: Guidance for Industry and Food and Drug Administration Staff, Feb 3, 2026)

CONNECT 2.0 Validation Package

What a CONNECT 2.0 CV Package Includes

Validation Plan & CSA Strategy

Defines scope, risk classification, and the overall approach to computer software assurance for the CONNECT deployment.

System Boundary & Architecture Specification

Documents the system boundary, data flows, integration points, and infrastructure components within scope.

Access & Roles Specification

Defines user roles, access controls, and identity management configuration aligned to 21 CFR Part 11 and Annex 11 requirements.

Requirement Inventory & Traceability Matrix

Living traceability linking GxP requirements to test scripts and executed evidence records.

Automated Test Scripts & Executed Evidence

Scripted test cases with captured execution evidence, supporting both initial validation and continuous regression.

Deviation Log, Periodic Review & Re-Certification

Deviation management workflow, remediation tracking, and a structured periodic review and re-certification package.

This End User Validation Package can be built on xLM's Continuous Validation CONNECT Package. The focus can be on Configuration Management and Automation Testing focused on Critical Workflows and Integration Points.

"Because the computer software assurance effort is risk-based, it follows a least-burdensome approach, where the burden of validation is no more than necessary to address the risk." - *FDA (Computer Software Assurance for Production and Quality Management System Software: Guidance for Industry and Food and Drug Administration Staff, Feb 3, 2026)*

Demo Setup

Live Demo: Continuous Validation Artifacts for CONNECT CDS 2.0

Demo Objective: Shows how xLM can **generate, execute, and maintain** validation evidence for CONNECT 2.0 use cases — end to end, in a live environment.

Generate

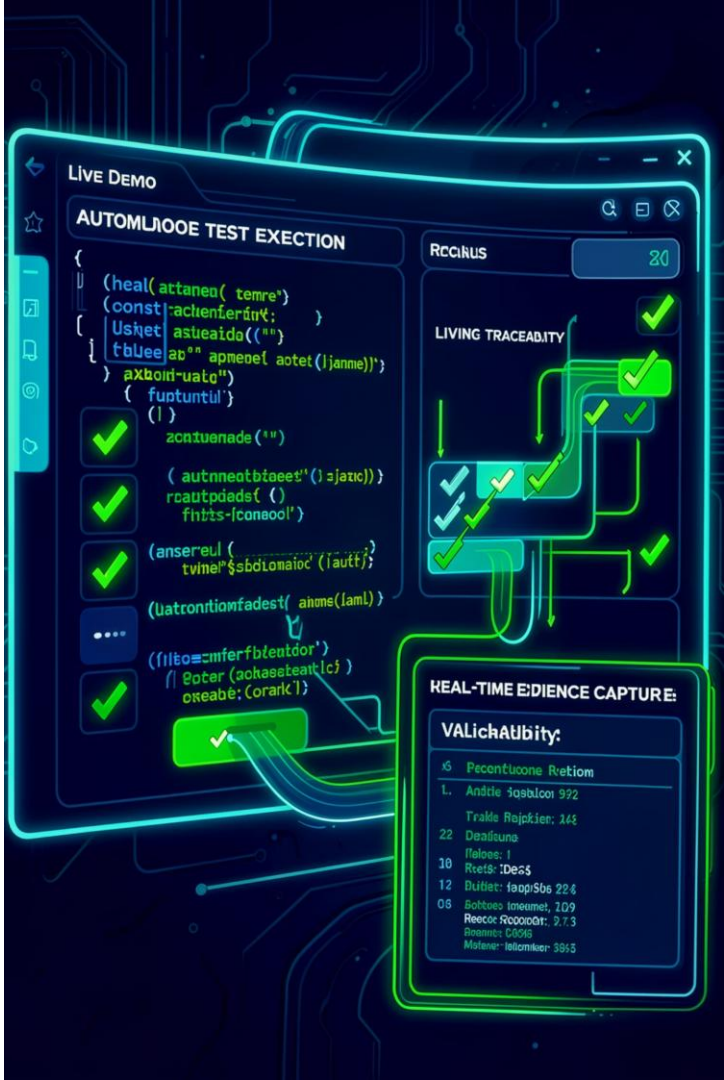
Automated creation of validation artifacts using a chat based interface.

Execute

Automated test script execution against CONNECT CDS 2.0, capturing timestamped evidence records in real time.

Maintain

Continuous regression and re-certification triggered by platform updates, with living traceability and deviation management.



Why Customers Care

Customer Value

Faster Regulated Adoption

Accelerate CONNECT adoption in regulated environments by removing validation ambiguity from the implementation path.

Reusable Baseline Artifacts

Pre-built, reusable baseline artifacts for common CONNECT modules and services reduce the cost and time of initial validation efforts.

Better Audit Readiness

Consistent, structured evidence packages that can be "confidently" leveraged to ensure organizations are always inspection-ready — not just at go-live, but throughout the platform lifecycle.

Lower Cost of Validated State

Automated regression and continuous re-certification dramatically reduce the ongoing cost of maintaining a validated state across platform updates.

Why AVEVA's Customers Benefit

xLM Partnership Value

Reducing Adoption Friction

The xLM partnership directly reduces the "adoption friction" that regulated life sciences customers experience when evaluating CONNECT for GxP use cases.

Validated, trusted evidence packages remove the single biggest barrier to enterprise deployment in regulated manufacturing.

A Life Sciences Adoption Framework

- Supports customer success after deployment through ongoing product validation updates
- Creates a structured life sciences adoption framework for CONNECT 2.0
- Helps position CONNECT as a **trusted industrial intelligence platform** for regulated manufacturing globally

Future State

The Destination: Continuously Certified CONNECT Modules

Ongoing Module Certification

Phase 6 establishes a perpetual module certification process, keeping the xLM CV suite current through QMS configuration management.

AVEVA-xLM Governance Cadence

Regular alignment cadence between AVEVA and xLM teams ensures the certification engine evolves with the platform roadmap.

100% Regression Coverage

Continuous regression execution with full coverage ensures every platform update is validated before it reaches regulated customer environments.

Deviation Handshake

A qualified deviation reporting handshake between AVEVA and xLM teams ensures rapid response to any platform change with GxP impact.

The end state is a **repeatable certification engine** that supports platform evolution and sustains customer confidence across the full CONNECT lifecycle.

Call to Action

For AVEVA Customers

Identify CONNECT 2.0 GxP use cases suitable for a pilot. Start with a monitoring or advisory use case to build confidence before expanding scope.

For Quality & Validation Leaders

Help define the evidence model that would satisfy your internal quality expectations. Your input shapes the validation package design for your organization.

For Digital Manufacturing Leaders

Start with monitoring and advisory use cases before moving into predictive or automated decision support — build the validated foundation first.

Closing

Industrial intelligence needs continuous trust.

> "AVEVA CONNECT 2.0 can be a foundation for the next generation of life sciences manufacturing intelligence. xLM Continuous Validation helps make that foundation **adoptable, auditable, and sustainable** in regulated environments."

Adoptable

Pre-built validation artifacts and a risk-based CSA approach remove barriers to regulated adoption of CONNECT 2.0.

Auditable

Consistent, automated evidence packages ensure inspection readiness at every stage of the platform lifecycle.

Sustainable

A repeatable certification engine and governance cadence keep the validated state current as the platform evolves.

cIV for CONNECT

Intelligent Validation

AWC 2026 Milan