

## Overview

iLink Systems and xLM are partnering to deliver a GxP continuous validation tool for Microsoft Apps & Services. iLink systems is a Digital Transformation company delivering solutions that help clients solve complex business and technology challenges, improve organizational effectiveness, increase business productivity, and realize sustainable enterprise value.

xLM is an established managed services software company that specializes in GxP Compliance related solutions. These solutions are cloud agnostic and rooted in automation to provide “continuous validation” managed services. The xLM client/ partner list consists of Big Pharma companies, mid-size life-sciences firms, and related technology partners.

## Value Proposition

We can validate any cloud App “continuously”. This enables customers to “GxP enable” their instances shifting focus to using the App to its fullest potential.

Our technology platform automates the GxP validation process alleviating compliance risk- related concerns – all while considerably reducing spend and increasing speed to market.

Our managed service is governed by a cutting-edge Quality Management System built on ISO 9001:2015, 21 CFR Part 11, Annex 11 and GxPs.

## What Do We Offer?

- Continuous Validation Services for Cloud Apps

## What is GxP Validation?

- Validation is providing “documented” evidence that a software performs as per its pre-established acceptance criteria while operating in its production environment with all its interfaces.
- The End Customer has the regulatory obligation to ensure any software service that directly or indirectly impacts the drug product and/or patient safety is duly “validated”.
- This can be an onerous task in the SaaS world considering the complexity of the Platform/ Apps and the velocity of changes

## Old Thinking Around Cloud Validation

- Validation costs are supposed to be high.
- Validation must be time consuming and resource intensive.
- “Old style paper-based” validation is the only validation option even for modern cloud apps.
- For Life-sciences firms, validation must be a deterrent to cloud adoption.

## Market Segment Segments & Industries

- Global Pharmaceutical / Biotech / Med Device Companies.
- Contract Manufacturing Organizations (CMO)/ Packaging Organizations (CPOs).
- Third Part Logistics Companies (3PLs).

## Differentiators

- Know-how –unmatched cloud validation and FDA GxP knowledge / expertise.
- Innovation Enabled–first of its kind, automated, continuous validation platform for Cloud Apps.
- Built for Purpose –build around requirements of Life-science companies to enable seamless consumption of periodic updates.