

AI Management System for Pharmaceutical GxP Environments


AI Validation


AI Supplier Governance


AI Audit Readiness


Regulatory Engagement

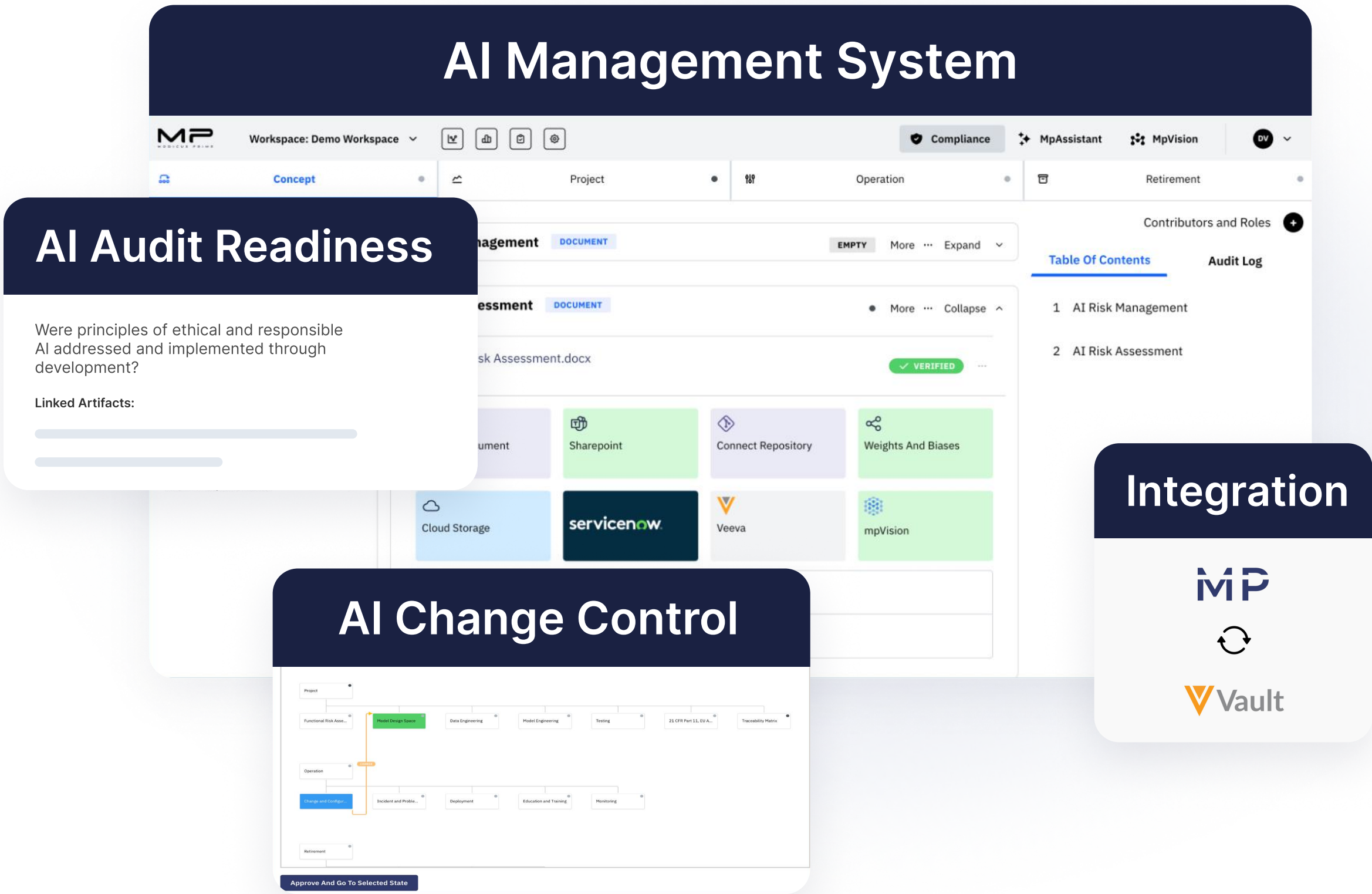

AI-in-GxP Applications

Who We Are

Modicus Prime ensures pharmaceutical companies’ AI applications are audit-ready with the AI Management System. We safeguard regulated organizations from FDA, EMA, and other health authority observations and warning letters for Inappropriate AI Usage. We are the trusted partner for organizations navigating the complexities of scaling AI into GxP environments, validating AI systems and suppliers, maintaining AI Audit Readiness, meeting auditor expectations, and staying ahead of evolving regulatory expectations.

The Need

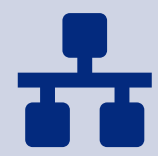
-  Compliantly scale AI into GxP operations
-  Validate AI systems and suppliers
-  Scale AI governance across the enterprise
-  Maintain AI audit readiness
-  Manage AI change control and performance monitoring
-  Prepare for regulatory inspections
-  Keep pace with evolving AI regulations



System Capabilities


AI validation


AI supplier assessments


AI validation infrastructure


AI change control and monitoring

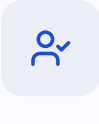

AI audit readiness


Integration with QMS and data tooling

What We Offer

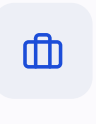
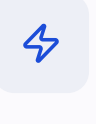


Software

-  AI Validation Infrastructure
-  AI Supplier Assessments
-  AI-in-GxP Applications

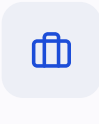
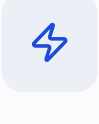


Education

-  AI Validation Workshops
-  Workforce Upskilling
-  AI Audit Readiness



Regulatory Support

-  Audit Readiness Playbook
-  Engagement with Regulators
-  Co-author Industry Guidelines



For additional information or to schedule a demo or on-site AI Validation Workshop, contact info@modicusprime.com for availability.