BATCHMASTER®
Process Manufacturing Software

GMP Validation Services - Built for Compliance. Designed for Your Business.

Scalable, flexible, and transparent GMP validation support — so you can focus on your business

BatchMaster's GMP Validation Services delivers complete software validation for regulated manufacturers — ensuring your ERP and critical systems like WMS, MES, and QMS perform as intended and remain fully compliant with FDA 21 CFR Part 11, GAMP 5, and cGMP requirements.

Introduction

BatchMaster's GMP Validation Services

BatchMaster's GMP Validation Services specialize in Computer System Validation (CSV) for regulated industries, helping businesses implement, validate, and maintain software systems that are reliable, secure, and inspection ready.

Why is GMP Validation Critical?

Validation is a legal requirement in FDA-regulated manufacturing — and a core safeguard for product quality, patient safety, and business continuity.

Validation matters because it:

- Ensures systems are compliant, reliable, and secure
- Confirms software performs as intended and meets regulatory requirements
- Ensures product quality and patient safety through consistent, accurate, and traceable results
- Supports data integrity and trustworthy records
- Provides documented evidence to meet audit and inspection requirements
- Minimizes the risk of non-compliance, recalls, and penalties through a risk-based approach
- Improves operational efficiency and supports business continuity

Industries We Serve

Pharmaceuticals

Validation for batch records, formula control, and lot traceability — built for the demands of pharmaceutical manufacturing.

Nutraceuticals

Nutraceuticals Software validation ensuring compliance across ingredients, formulations, and traceability requirements.

Food & Beverage

Validated systems supporting FSMA preventive controls and end-to-end traceability compliance.

Biotechnology

Biotechnology Validation for complex, evolving production environments and regulatory submissions.

Medical Devices

Audit-ready validation of software workflows supporting quality system compliance.

Cosmetics/Personal Care

Consistent quality and compliance validation aligned with FDA cGMP standards.

What's Included in Our GMP Validation Services

Our flexible engagement models are designed for businesses of all sizes — delivering the right level of validation support, at the right time.

Complete ERP Software Validation

End-to-end ERP software validation, from User Requirements Specifications (URS) to final validation reports, fully documented and audit ready.

Validation Toolkit

Ready-to-use validation templates aligned with FDA and GAMP 5 requirements — built specifically for BatchMaster ERP.

Complete QMS Validation Services

End-to-end Quality Management System (QMS) validation ensuring your quality processes are compliant, documented, and inspection-ready.

Validation-as-a-Service (VaaS)

Ongoing validation and compliance monitoring delivered on a contract basis — ensuring your systems remain validated and audit-ready through every update, change, and upgrade.

Gap Assessments & Training

Identify compliance gaps, train your team on validation best practices, and ensure your organization stays current with evolving regulatory requirements.

The GMP Validation Lifecycle — Key Phases

Our validation lifecycle follows a structured, GAMP 5-compliant approach — ensuring every phase is executed with the right depth, at the right time, aligned with your regulatory landscape.

Discovery

On-site and off-site discovery to gather initial system information and conduct a cGMP assessment — establishing a clear understanding of your environment before validation begins.

This phase includes stakeholder alignment, GMP requirements gathering, review of existing SOPs, and initial risk assessment to define validation scope.

Planning

Gathering and documenting system information, conducting Risk Assessments, transferring your SOPs into User Requirements Specifications (URS). This phase also includes defining validation scope, preparing the Validation Master Plan (VMP), drafting Functional Requirements (FRS), and developing IQ, OQ, and PQ test scripts aligned with GAMP 5 guidelines.

Execution

Executing approved IQ, OQ, and PQ test scripts in controlled and production environments, with full documentation of results, deviations, and incident tracking.

This phase includes user acceptance testing (UAT), risk monitoring, and formal review and approval of executed validation activities.

Summary

Analyzing, approving, and archiving all results from the Execution phase — producing final documentation that is audit-ready, inspection-ready, and available to the FDA, your staff, and all relevant stakeholders.

This includes preparation of the Validation Summary Report, traceability matrix, validation certification, and secure archiving of all validation records for regulatory review.

Why Manufacturers Trust BatchMaster for GMP Validation Services

End-to-End Validation

Comprehensive support from User Requirements (URS) through Final Validation Reports — nothing left incomplete.

Multi-System Expertise

Proven experience with ERP, QMS, WMS, MES, and other critical manufacturing systems.

cGMP Regulatory Compliance

Full alignment with FDA 21 CFR Part 11, Parts 210/211, Part 820, GAMP 5, FSMA, and more.

GAMP 5-Compliant Documentation

Risk-based, audit-ready documentation that meets industry standards and withstands FDA inspection.

Flexible Engagement Models

Choose from Complete Validation, Validation Toolkit, VaaS, Gap Assessments, or Training — based on your needs.

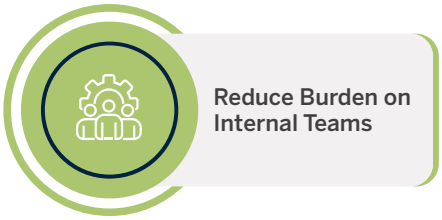
Experienced Cross-Functional Team

Deep domain knowledge across regulations, ERP systems, and regulated industry processes.

Reliable, On-Time Delivery

Strong track record of delivering validation projects on time and within budget.

What This Means for Your Business



Let's Get Started

Make Compliance a Seamless Part of Your Operations.
Partner with BatchMaster for GMP Validation Services to stay compliant, confident, and inspection-ready.

For More Information:

949.583.1646 X 2
sales@batchmaster.com
www.batchmaster.com

Contact Us Now