Validation Engineering & FDA Compliance

Validation. Compliance. Confidence.

Why Validation Matters—and Why Deaton Engineering Is Your Ideal Partner

A robust validation program not only ensures regulatory compliance—it sets your organization apart in a competitive market. Effective validation confirms that systems perform as intended, guarantees that products meet the highest standards of quality and safety, and significantly reduces the risk of FDA 483 observations.

At Deaton Engineering, we specialize in helping clients succeed across the full spectrum of validation challenges—whether you're launching a new process, upgrading legacy equipment, or preparing for an audit. We leverage a risk-based, Total Quality Approach rooted in current Good Manufacturing Practices (cGMP), which allows us to deliver results even in the most complex environments.

Deaton is committed to engineering-driven solutions. Our validation projects are executed by experienced engineers—not technical writers—who deeply understand your systems and processes. We take the time to assess every interrelated system to develop documentation that stands up to regulatory scrutiny and supports long-term compliance.

Validation is not just a checkbox—it's a continuous improvement tool. From process equipment and control systems to full facility validations, our team is equipped to prevent compliance issues or help remediate them when they occur. With Deaton, you gain a partner committed to quality, compliance, and operational excellence.

Industries we support:

- Pharmaceuticals (oral solid dose, injectables, APIs)
- Biopharmaceuticals (cell and gene therapy, biologics)
- Medical Devices (diagnostics, software-based systems)
- CDMOs and CMOs
- FDA- and EMA-regulated research labs and startups

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DEATON ENGINEERING
YOUR VISION, OUR PRECISION

A Risk-Based Approach to Validation Services

Validation Master Planning (VMP)

- Development of compliant, risk-based Validation Master Plans
- Defines scope, systems impact, scheduling, roles, and responsibilities
- Regulatory strategy built for successful inspections

Commissioning & Qualification (FUSE CQV)

- Full lifecycle qualification: DQ, IQ, OQ, PQ
- Utility qualification: Clean Steam, WFI, HVAC, Compressed Air, etc.
- Equipment qualification: Autoclaves, Bioreactors, Cleanrooms, etc.
- Installation and start-up support

Automated Process Control Systems (APCS)

- Control systems and Building Management Systems (BMS)
- SCADA, PLCs, and DCS qualification
- Verification of alarm management, audit trail, user access, and data integrity

Risk-Based Assessments & Gap Analysis

- System impact assessments
- GMP criticality ranking
- Remediation strategies for legacy or undocumented systems
- Data integrity assessments

Regulatory Inspection & Audit Readiness

- Inspection readiness assessments
- Support for FDA/EMA audits
- 483/CAPA response support and remediation execution

Computer System Validation (CSV)

- Validation of GxP-relevant software applications
- Aligns with GAMP 5 guidelines and 21 CFR Part 11
- Services include:
  - User Requirements Specification (URS)
  - Risk assessments and traceability matrices
  - Test planning and execution (IQ/OQ)
  - Audit trail and electronic signature verification
  - Validation reporting and change control support
- Systems: LIMS, QMS, ERP, MES, Document Management Systems, e-Logbooks, and cloud/SaaS platforms

Protocol Development & Execution

- Development of IQ, OQ, PQ, FAT, SAT, and custom protocols
- Execution of validation activities with clear, audit-ready documentation
- Deviation management and change control coordination

SOPs & Quality Document Support

- Creation, revision, and harmonization of SOPs
- Development of validation templates and standardized documentation
- Onboarding and training of QA/QC and operational personnel

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CERTIFIED DASSAULT SYSTEMES PROFESSIONAL