DEATON ENGINEERING
Your Vision Our Precision

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Validation Engineering & FDA Compliance

Specification Development, Design, Verification, and Validation of Pharmaceutical, Biopharmaceutical, Medical Device, and other FDA Regulated Industries

A good validation program can differentiate your company from others in the industry. Successful validation practices verify that systems operate as designed, ensure that manufactured products are of the highest quality and safety, and minimize 483 findings. To meet U.S. and international regulatory requirements, your validations have to be top-notch.

Whether you are developing a new process or validating legacy equipment, Deaton Engineering can help. We understand current GMP requirements and follow the proven **Total Quality Approach** to providing engineering services. Our risk-based approach to pharmaceutical engineering is successful with even the most complex validation projects because we take the time to fully understand the process, system, or equipment and all of the systems that affect it. Our documentation packages have a proven history of satisfying FDA auditors.

We believe that validation is an integral part of continuous improvement. That is why we use engineers (not technical writers) who understand your equipment and processes. Our staff works with you to resolve issues uncovered during the validation process. We are experienced in validating process equipment, automated process control systems, and processing facilities. We can significantly reduce your likelihood of receiving a 483 or help you remedy the situation if you receive one.

A Risk-Based Approach to Validation Services

Validation Master Plans

Deaton Engineering can audit your facility's validation program, perform gap assessments, and identify the most critical systems to be addressed. We then develop a validation master plan that describes a compliance strategy, long-term schedule, personnel responsibilities, and methods to accomplish compliance goals.

System and Equipment Validation

Deaton Engineering develops installation, operation, and performance qualification protocols for all types of pharmaceutical processes, equipment, and facilities. Our validation documents thoroughly verify that the system was installed correctly and that the functionality, alarms, limits, error-handling capabilities, throughput, and other functions operate as intended.

Automated Process Control System (APCS) Validation

Deaton Engineering employs a proven risk-based approach to electronic records based upon sound logic. We define the criticality of each record, examine the entire life of a record from origin to archive, analyze functionality, define and verify security requirements, and make sure the systems provide an electronic audit trail.

Validation Engineering & FDA Compliance

- GMP, cGMP, GLP, GAMP
- System validation
- Equipment validation
- Process validation
- 483 warning letters
- Good manufacturing practices
- Good laboratory practices
- FDA compliance
- Standard operating procedures (SOP)
- User requirements specifications (URS)
- Functional requirements specifications (FRS)
- Software requirements specifications (SRS)
- Validation gap analysis
- Validation master plan
- Installation qualifications (IQ)
- Operational qualifications (OQ)
- Performance qualifications (PQ)
- Risk assessments
- Hazard analysis
- Deviation resolutions
- Traceability matrices
- Calibration management
- Factory acceptance tests (FAT)
- Site acceptance tests (SAT)
- Network qualification
- 21 CFR Part 11
- Process control system gap analysis & validation
- Software engineering & process control
- Engineering services
- Process and manufacturing equipment list