



www.ddcvalidation.com
(877) cGMP-211

Quality Services

Developing and improving quality systems are a mission-critical goal. D & D Consulting LLC recognize the importance of such systems and are ready to help you implement simple and effective solutions that address your change control, product release, corrective action, and complaint handling requirements.



Our Quality Systems services include:

- **Quality Systems Assessments:** A thorough review of your existing quality systems using our established auditing and assessment procedures will help to identify the strengths, issues, and opportunities for improvement within your quality program.
- **Quality System Design and Implementation:** Our consultants have the hands-on expertise to produce customized, simple and effective programs to implement their recommendations and meet your needs. They also have the project management skills and the ability to work with all levels of your organization to implement a comprehensive quality system.

Auditors Who Understand Your Business:

Auditing is a valuable tool for ensuring compliance with regulations, guidelines, internal standards, and industry expectations. D & D Consulting has teams of qualified auditors who have the skills and experience to uncover useful and relevant information. Our auditors are experts within the industry who understand your business, the regulations and the product development and manufacturing environment. Our team will produce a detailed comprehensive report that will identify potential problems and weaknesses and identify effective solutions to reduce the regulatory compliance risk.

Quality Services

D & D Consulting can provide the following audits and regulatory services:

- **Mock Pre-Approval Inspection (PAI) audits**
- **Compliance Audits: Evaluate the compliance of your systems and controls with cGMP/QSR regulations and implement corrective actions prior to regulatory inspections.**
- **Quality System Requirement Development**
- **Policy/Procedure (SOP) Review and Development**
- **Agency Submission Review**
- **Regulatory Inspection Support**
- **FDA 483 Response Support**
- **Change Control Program Development**
- **CAPA Development / Support**
- **Vendor/Supplier Qualification and Audits**
- **Contract Manufacturer Audits**
- **Validation**
- **Documentation Review**
- **GMP, GLP, GCP, QSR, and Part II Compliance Audits**
- **Failure Mode Effect Analysis (FMEA)**
- **Third Party Inspections**

Our Promise to You:

Our company takes pride in our expertise and responsiveness to your needs. Here are some of the qualities you will find when you partner with D & D Consulting LLC – qualities that ensure your satisfaction.

- **Expertise: Your team will be staffed with industry experts who know your business. They will be knowledgeable about the latest regulations, directives, laws, policies, and guidelines that are applicable to your products and market. They will be able to sort through the details, interpret guidelines, and make recommendations that are best suited to your organization.**
- **Quality Work: When it comes to providing Quality Consulting services, we strive in our quest for the highest quality standards that you deserve. We are detail oriented and accept nothing less than the best from our staff.**
- **Integrity: Our reputation is our business and our reputation is important to us. That is why we will never make a promise that we cannot keep and we will make sure you understand the logic behind every recommendation and action that we take.**
- **Cost-Effective Recommendations: We will always recommend the most cost-effective solution and provide you with an honest and competitive quote. We will also make sure that there is an option to meet your needs and budget.**