





Qualified Data Systems is a global Information Technology Consultancy delivering assurance and advisory services to the Life Science Marketplace.

Our business is focused in the following areas:

- Information Management
- Compliance Solutions
- Verification and Validation
- Systems Engineering

We assist our clients as technical advisors and business partners in public and private sectors. Whether it's Business Process Engineering, Systems Integration, or Application Performance Tuning, Qualified Data Systems provides a wide array of services that are tailored to meet our customer's detailed requirements. Our partnerships and affiliations with other industry leaders extend our global reach to provide unparalleled end-to-end capabilities. Our proven delivery methodology and project management skills enable us to provide cost effective, on-time solutions that improve internal processes, product quality, and our client's competitive edge.

Qualified Data Systems concentrates its efforts in working within regulated environments as system integrators and compliance solution developers.

Our client service team has an average of 15 years of experience in industry and consists of professionals with expertise in IT Management, Quality Systems, Software Engineering, Verification & Validation Management, and Network Engineering.



Information Management

In today's fast paced business environments, an organizations ability to satisfy it clients needs is directly related to their ability to process data and make sound decisions. In order to protect your investment in quality data, our team provides Information Management Services that incorporate People, Process, and Technology in the following areas:

- IT Policy/Procedure Development, Training, and Deployment
- Business Continuity Planning
- IT Strategy Development and Implementation
- Business Process Engineering
- Total Cost of Ownership (Cost Reduction Strategies)
- Technology Contract Review (Legal Considerations)
- Change Management
- Program/Project Management
- Technology Risk Assessments
- Software Quality Management (FDA, IEEE, and ISO)
- Enterprise Application Integration
- Application Portfolio Management

Our hands-on approach allows us to effectively transfer our industry expertise while developing a deep understanding of technology solutions that address specific Life Science issues. The ability to design, build, and validate using an integrated methodology helps us deliver bottom-line business value quickly.



Compliance Solutions

Compliance for regulated industries is a strategic initiative that provides a clear marketplace advantage. Today, implementing cost effective compliant solutions that are delivered on-time and within budget is a key part of every Information Management's Strategy. QDS develops simple, systematic, sustainable solutions that include:

- Validation Package Reviews
- 21 CFR Part 11 (ERES) implementation
- Industry Best Practice Deployment (GAMP)
- Process and Procedure Development
- Periodic Computer System Audits
- Knowledge Management Tools and Training
- Supplier Quality Management
- Application Compliance Certification
- Enterprise Remediation
- Compliance Strategy
- Technology Infrastructure Compliance Certification

Our technology professionals have extensive business process expertise in manufacturing, business, and laboratory environments; and understand how to take a project from requirements solicitation to deployment through maintenance.



Verification & Validation

Quality Assurance begins early in a product's life cycle. Qualified Data Systems is committed to implementing solutions that are reliable, cost-effective, and meet our customer's expectations. In order to accomplish these goals our team works with clients to develop robust processes, procedures, and technology solutions. Our services include:

- Methodology Development
- Product Life Cycle Management
- Software Quality Engineering
- Test Engineering
- Requirements Gathering and Specifications Development
- Protocol Development and Execution
- Participation in Design Reviews
- Performance of Risk Assessment and Mitigation
- Software Supplier Audits
- Validation Maintenance Programs
- Computer Systems Validation

Our V&V professionals are experienced at all levels of business process execution. From ERP packages, to manufacturing execution systems, to plant floor SCADA Systems, our engineers and technicians are versed in industry best practices.



Systems Engineering

One of the leading contributors to organizations gaining a competitive advantage is the network infrastructure it operates. Operating a high-performance, reliable, and secure network infrastructure is imperative in today's marketplace. Our Solutions include:

- Infrastructure Assessments (Health Checks)
- Operations Management
- Design and Implementation of LAN & WAN Environments based upon Business and IT Strategy
- Implementation of Network Operating Centers for cost-effective network management and maintenance
- Capability to offer Hosted Operations through strategic partners
- Development and implementation of Service Level Agreements and online monitoring programs
- Identification and resolution of network security gaps and intrusions
- End-to-end Network Solution Integration including Strategy, Planning, Design, Build-out, Test, and Operations
- Managed Services such as security, hardware & application support, and operations

Our Infrastructure Engineers are Cisco & Microsoft certified and have extensive deployment experience ready to share with our clients.

Why QDS Consulting?

QDS provides clients with a comprehensive IT strategy and integrated compliance framework for your most business critical information assets.

We offer proven experience in rapidly implementing best-in-class systems that enable accelerated returns on investment through process improvements, cost reductions, productivity gains, compliance optimization, and risk minimization.

What sets QDS apart from the competition?

- ☑ An industry-focused business model and flexible solutions that create immediate value
- ☑ A dedicated and well trained workforce with extensive industry and technology experience
- ☑ A proven delivery methodology that is deployed consistently around the globe

Capabilities	Planning	Design	Build	Validation	Implementation	Maintenance
<i>IT Strategy</i>	•	•		•	•	•
<i>Business Process Optimization</i>		•	•	•	•	
<i>Financial Valuation</i>	•	•		•		•
<i>Systems Integration</i>	•	•		•	•	
<i>Risk Management</i>	•	•	•	•	•	•
<i>Program/Project Management</i>	•	•	•	•	•	•
<i>Validation Assessment</i>	•	•			•	
<i>Compliance Certification</i>	•	•	•	•	•	•
<i>Enterprise Remediation</i>	•	•		•	•	
<i>21 CFR Part 11</i>	•	•	•	•	•	•
<i>Computer Systems Validation</i>	•	•	•	•	•	•
<i>Infrastructure Qualification</i>	•	•	•	•	•	•
<i>Network Operations</i>	•	•	•	•	•	•
<i>Package Implementation</i>	•	•	•	•	•	•

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