ENTERPRISE SOLUTIONS

RevereIT LLC offers smart solutions for its clients for all their project requirements. We provide customized implementation model that suits our client requirements. Our team is wise, creative and enthusiastic, and challenges the latest technology. RevereIT LLC is committed to providing the best resources and solutions to our clients. We maintain win-win relationships with our clients.

RevereIT has deep roots in Software Quality Assurance, Validation, Medical Devices Quality Engineering, CAPA and Project Management.

RevereIT LLC today has become a leading provider of Validation and Engineering services for the Life Science Industry.

In Medical Devices domain, we provide Device Registration, Process Validation, QMS Compliance, Quality Engineering, Risk Assessment and Mitigation, Manufacturing, Safety and Reliability and UDI services.

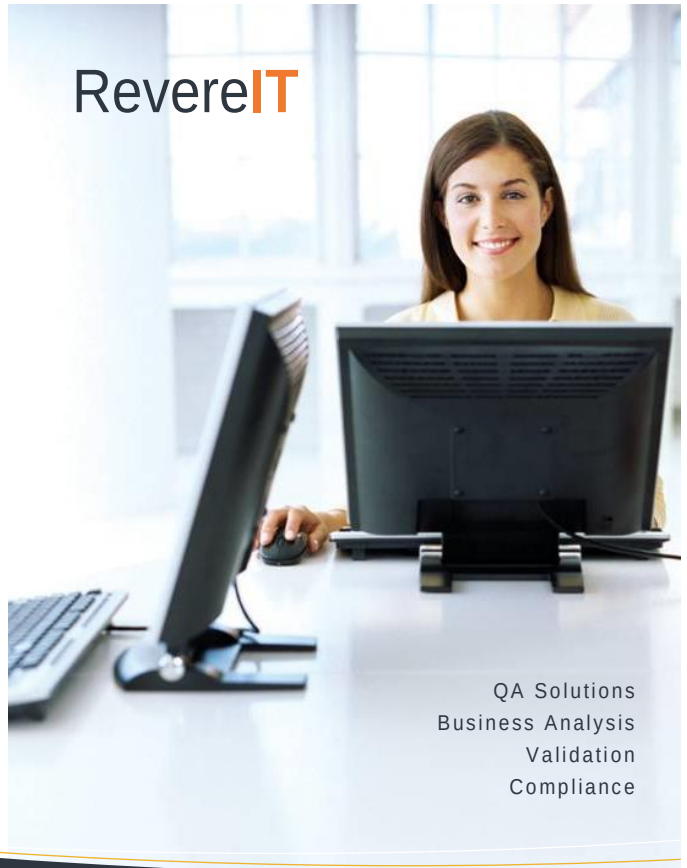
In Pharmaceutical Domain, we provide Equipment Validation, Commissioning & Qualification, Process & Cleaning Validation, Regulatory Affairs, Utilities Validation, Biologics & BLAs, Solid & Semi-Solid Dosage related services.

Technology

45640 Willow pond plz, Ste 200
Sterling, VA 20164
703-757-8000 ph
781.846.8300 fax
www.revereit.com

RevereIT

RevereIT



QA Solutions
Business Analysis
Validation
Compliance

IT solutions that work for your business.

We are efficient in leading a project-level coordinated effort; from outlining objectives to defining implementation strategy to training and follow-up.

VALIDATION SOLUTIONS

Partnering with many of the major Pharmaceutical, Biotech companies and Specialist consultancies to help them to exceed their regulatory obligations, RevereIT LLC is rapidly becoming the market leader in the recruitment of professionals in the Validation & Regulatory Compliance market.

Regulatory Compliance- Are you ready for the stringent standards and strict timelines?
RevereIT LLC can help you meet your deadline!
The pharmaceutical industry is faced with unprecedented business challenges: rising costs, reduced government reimbursement, growing consumerism, and increased government regulation, such as 21 CFR Part 11, QA/QC, Computer System Validation, HIPPA.

We hire world Class Bio Medical, Chemical, Bio-Engineering and Bio Tech Engineers

flexible solutions for your business needs

VALIDATION SOLUTIONS CLIENTS

Abbott Labs	Eisai	Novartis Pharma
Amgen	Eli Lilly	Parke Davis
Aventis Pharma	Forest Labs	Pfizer
Bayer Corp	Fresenius Medical care	Pharmion Corporation
Berlex Labs	Glaxo SmithKline	Purdue Pharma
Biogen Idec	Johnson & Johnson	Quest Diagnostics
Boston Scientific	Knoll Pharma	Ranbaxy Pharma
Bristol Myers Squibb	Merck	Roche Pharmaceutical
Celgene Corp	Medtronic	Schering Plough
CSL Behring	Monsanto	Teva Pharmaceuticals
Wyeth		

VALIDATION SOLUTIONS

Partnering with many of the major Pharmaceutical, Biotech companies and Specialists to help them to exceed their regulatory obligations, RevereIT LLC is rapidly becoming the market leader in providing QA, Validation & Regulatory Compliance market.

BUSINESS ANALYSIS SOLUTIONS

Our BA group introduces the notion of process orientation, of concentrating on and rethinking end-to-end activities that create value for customers, while removing unnecessary, non-value added work.

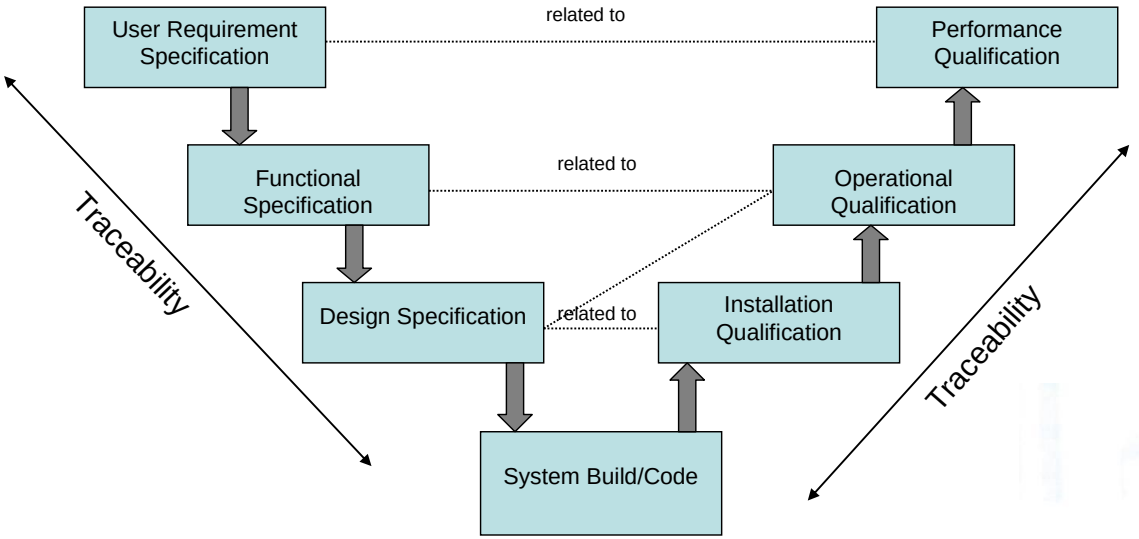
QUALITY ASSURANCE SOLUTIONS

Our Quality Assurance group provides customers with unparalleled industry experience.

By making wise IT investments and fundamental changes to business models, Organizations can reduce their costs, streamline administrative processes, empower consumers, improve quality of care and increase the speed of new discoveries to market.

WE'VE WORKED WITH A DIVERSE CUSTOMER BASE. HOW CAN WE HELP YOU?

Methodologies.



The GAMP ‘V’ Model

Our Core Competency:
Adverse Event Reporting System (AERS)
Bio-Statistical Data Analysis Systems
Calibration Systems
Change control and configuration management
Corrective Action/Preventive Action (CAPA)
Drug Safety Systems
Electronic Common Technical Document (eCTD)
Electronic Data Capture (EDC)
Electronic Document Management Systems
Enterprise Resource Planning (ERP)
Interactive Voice Response Systems (IVRS)
Laboratory Information Management Systems (LIMS)
Pharmacokinetic/Pharmacodynamics (PK/PD)
Quality Engineering
Quality Management System
Software development lifecycle
Quality assurance, control and auditing
Risk-based compliance approaches
R&D IT
Project and resource management
Process control and automation
Pharmacovigilance
Process Validation
Workflow automation

Commissioning Services
We can also provide the right level of expertise at competitive cost with our professional compliance consultants and technical writers. Our teams are well qualified in industry best practices for validation, qualification, compliance assessments, and vendor audits that cover systems and processes in all your regulated areas.

- Developing & Executing Commissioning Plans and Documents (URS, Inspection Forms, FAT, SAT, Protocols etc.)
- Vendor Audits
- Managing the commissioning activities of vendors, construction contractors, owners, and contract resources
- Executing commissioning activities for utility and process equipment systems in a manner that maximizes opportunities for leveraging with qualification activities

Quality Assurance Services
- Providing validation and testing support to CAPA system implementation projects at medical device and pharmaceutical clients
- QA/Quality Control Staff Augmentation
- Policy, SOP & Batch Record Review, Prepare & Optimization
- Quality System (QS) Development, Assessment & Optimization, Supplier Audits
- Training – FDA, GMP, QSR, DQSA, USP (795, 797), Validation etc.
- Process Validation, Risk Management
- Software Quality Assurance

Compliance and Regulatory Affairs Services
- Third Party GMP & GLP Compliance Auditing
- Mock FDA/International Regulatory Agency Inspections & PAI Readiness
- Due Diligence Compliance Inspections, Audits & Assistance
- FDA Action (483 Observations, Warning Letters, Consent Decrees) Remediation
- Training – FDA, CFR, GMP, QSR, DQSA, USP <795, 797>, Validation etc.
- Analytical Lab Equipment Validation
- Cleaning Validation
- CFR Part 11/210/211/64/801/803/820
- UDI (Unique Device Identification), Serialization