

Validation Services – Regulated Industries

Panacea Technologies Inc. has been providing validation services to the regulated industries for over 10 years. Our strength is our internal processes that result in solutions that cater to our clients varied regulatory needs and provide ongoing support to ensure full regulatory compliance. Panacea is also in the process of becoming ISO 9000 certified.

Depending on the project, we can provide any combination of Process Design, Automation and Validation Services.

Validation Services Provided

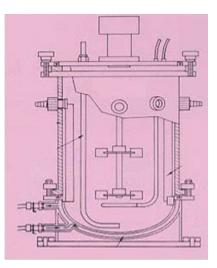
- Corporate and Departmental Level SOPs and Standards Development
- Validation Master Plan Development
- Vendor and Periodic Audits
- Establishing a risk based regulatory framework
- Risk / Impact Assessments
- 21 CFR Part 11 Gap Analysis and remediation
- Requirements Specifications Development (URS, FRS, etc.)
- Software Design Documents Development
- Qualification Protocols Development and Execution (IQs, OQs, PQs etc.).
- Requirements Traceability Matrices Development
- Summary Reports

Internal Validation Tools

Panacea has a variety of internal tools that greatly reduce the cost and increase the quality of the validation effort.

- Validation Studio for DeltaV Generates Validation Documents automatically from a DeltaV Configuration
- Project Studio Generates Validation Documents from a variety of SCADA and PLC software
- **Protocol Scripting Language** A simple scripting language that generates MS-Word tables with standard Expected and Actual Results Columns

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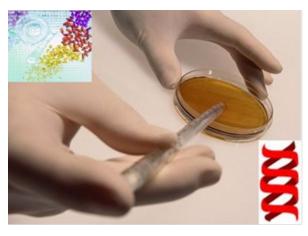


PAT and Risk Based Validation

Panacea has assisted various clients improve their product quality and reduce process variability by implementing PAT techniques and adopting a risk based regulatory framework based on scientific and engineering principles.

Realize Your Potential

Proven FDA audit sustainable Validation services through a powerful combination of skilled resources, technological competencies, and functional skills, enabling clients to improve the reliability of process critical applications and minimize



downtime due to regulatory necessities. Panacea has served many Fortune 500 clients in the areas of QA, validation, process improvement, test automation, test planning and execution. Our proven testing methodologies help reduce validation costs and significantly shortens schedules, resulting in faster return to production or time-to-market in order to maximize quality and production goals.

About Panacea Technologies

Panacea Technologies Inc. is a Process Control and Automation solutions company headquartered in Montgomeryville, PA with offices in East Greenbush, NY, Boston, MA, and Gaithersburg, MD. Panacea has been delivering cutting edge software solutions and services to our clients since 1996.

It is our mission at Panacea Technologies Inc. to provide our customers a competitive advantage by providing superior design, implementation, software, and management strategies to best leverage their automation and validation investments. Panacea Technologies' success is attributed to the confidence clients have in our technical know-how, diligence, and dependability.

Contact Panacea Technologies Headquarters at (267) 421-5300 or at <u>sales@panaceatech.com</u> to order or to schedule a personalized product overview.