ThinSpring

Validation Consulting

As with all of our products and services, ThinSpring Validation Consulting Services supports our clients by helping them achieve their goals by providing multitalented, compliance knowledgeable people.

ThinSpring personnel focus on meeting your project's milestones to stay on schedule and on budget. Our approach to providing validation services is adaptable to fit each client's procedural needs and regulatory mandates.

With expertise and in-depth knowledge on both technological and regulatory fronts, ThinSpring, uses its "risk-based" approach to systems validation to identify and implement appropriate levels of validation where needed and as required. ThinSpring provides a cost effective and robust validation solution that is suitable for both GxP and Non-GxP systems alike.

This "risk-based" approach to validation follows both industry and regulatory best practices adding value to our clients' current compliance processes. ThinSpring Validation Consulting Services has built a solid reputation in the field of computer systems validation by offering services that are tailored to meet our clients' existing validation and regulatory compliance needs. We also assist, as needed, by assisting in the modification of those existing processes to create a best of breed validation solution that will stand up to audit scrutiny by any regulatory agency or group.

Non-GMP Computer Systems Validation:

- Validation Project Management
- Prospective, Concurrent, & Retrospective Validation
- Document Templates for Validation Deliverables
- Preparation of Validation Strategies and Plans
- Developing Validation Documentation, such as Protocols, Test Scripts, and Reports
- Execution Validation Protocols (IQ, OQ, PQ)
- Result Analysis & Documentation
- Evaluation/Assessment of Validation Documents
- On-Site Compliance Training Programs & Speaking Engagements
- Auditing internal Computer Validation Practices
- Performing quality system analysis

cGMP and Regulatory Compliance

With national and international regulatory compliance requirements continuously changing it is difficult to keep up. ThinSpring consultants are industry experienced professionals who keep pace with ever changing regulations, as well as, the state of Industry Best Practice systems validation concepts and methods.

ThinSpring has been providing consulting services to regulated industries such as pharmaceutical, medical device, biotechnology, chemical, and consumer products since 1997 and are well aware of the ebb and flow of regulatory guidelines on a global level. With multiple harmonization efforts and the migration towards paperless regulatory submissions ThinSpring is well versed in the unique compliance challenges that Life Science companies face.

Key Features

- **GxP and Non-GxP Computer Systems Validation**
- **GxP and Other Regulatory Compliance Projects**
- **Regulatory Compliance Training**
- **SAP R/3 ERP Validation**

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Using ThinSpring's system validation approach we can leverage the FDA compliance regulations to support and achieve SOX compliance as well. This multi-track approach will provide a system validation strategy and methodology that is based on guidelines and mandates set forth by the FDA, the SEC and the IT Governance Board.

We can help you to plan, develop, and implement regulatory and compliance programs that include:
- System Design Review
- Evaluation of system compliance to 21 CFR Part 11 and other compliance guidelines
- Evaluation of system compliance to 21 CFR Part 210, 211 and 820
- Laboratory Controls
- Change Control Management
- Documentation and Control Management
- Regulatory Submissions
- GMP Drivers in Technology Transfer
- Validation Management
- Internal Audits
- Compliance Training Programs

Regulatory Compliance Training

ThinSpring Validation Consulting Services are capable of conducting training on following topics:
- Computer System Validation Principles
- 21 CFR Part 11
- Auditing for Computer-Related Compliance
- Software / Application Testing
- PDMA and Sample Accountability
- Performing validation training
- Identifying international requirements
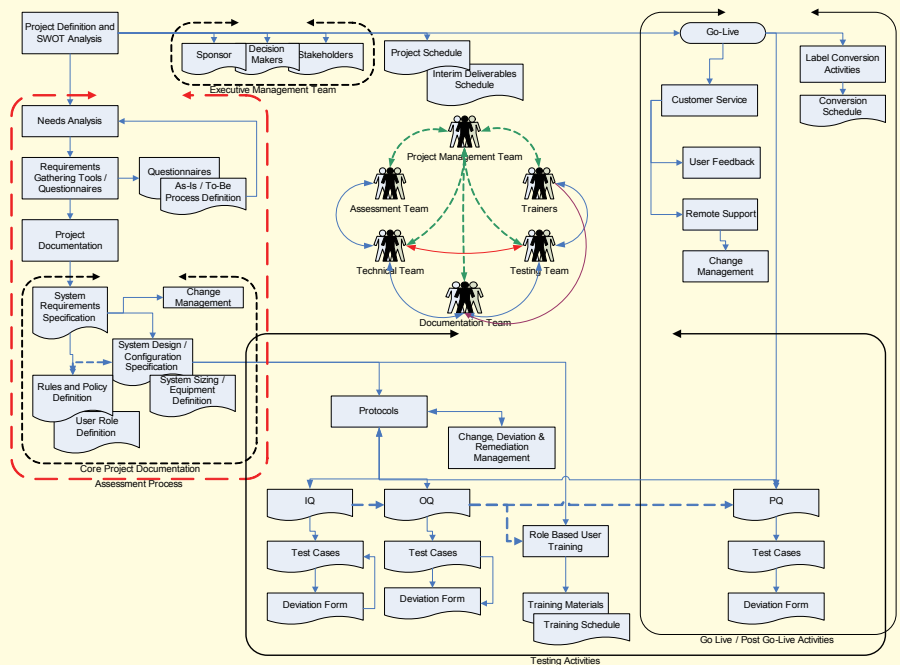
Validation Consulting Process Diagram

SAP R/3 ERP Validation

With over 10 years of SAP implementation and validation expertise and experience Thinspring Validation Services consultants, using our "risk" based approach to quality systems validation, will work with your implementation partner or our IT Department to achieve a cost effective and robust validation program that is suitable for both GMP and Non-GMP environments alike.

Our SAP R/3 validation services include:
- Validation Project Management
- Prospective & Retrospective Validation
- Document Templates for Validation Deliverables
- Preparation of Validation Strategies and Plans for both regulated and non-regulated companies
- Developing validation documentation, such as protocols, test scripts, and reports
- Executing validation qualifications (IQ, OQ, PQ)
- Test Execution, Result Analysis, & Documentation
- Evaluation/Assessment of Validation Documents
- On-Site Compliance Training Programs & Speaking Engagements
- Auditing internal Computer Validation Practices
- Performing quality system analysis
- Performing quality system analysis
- Developing cGXP related quality system requirements
- Developing validation documentation, such as validation plans, protocols, test scripts, and reports
- Identify international compliance requirements

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