FDA Validation Protocols and Services for QAD

Comprehensive Validation Services

By strict adherence to FDA regulations and sound communication practices, we will help you plan and meet your validation goals.

Validation Rational

FDA Regulations direct compliance with regulatory requirements for the validation and maintenance of computer systems used to manage, control and track the manufacturing and distribution of device and pharmaceutical products. The validation of QAD Enterprise Applications will be managed using Strategic's proprietary Software Validation Master Plan (SVMP), tailored specifically for your company.

The Installation Qualification (IQ) Protocols, the Operational Qualification (OQ) Protocols and the Performance Qualification (PQ) Protocols will provide documented verification that all key aspects of the software were installed, operate, and perform respectively in accordance with design requirements.

A Traceability Matrix, Risk Analysis, and a Final Report will be generated with conclusions and recommendations.

Markets Served

Strategic serves the Life Sciences industry including: pharmaceutical, medical device, nutraceuticals and biotechnology companies.

Our clients include drug and vaccine developers, generic houses, hospital equipment manufacturers, contract sales organizations, engineering companies, fulfillment companies, clinical research, device manufacturers including implantables and control system manufacturers.

Validation Services Include

Documentation Development

Installation Qualification (IQ) Protocols

Operational Qualification (OQ) Protocols

Performance Qualification (PQ) Protocols

Software Validation Master Plan (SVMP) Development

21 CFR Part 11 Compliance Services

> "By choosing an ERP that is designed to simplify validation and Strategic with considerable experience in this area, Vita-Tech was able to implement QAD including validation in just 90 days."
>
> - Toni Clubb
> CFO
> Vita-Tech International

> "Strategic was instrumental in Cepheid's upgrade. Our project had a tight schedule and by using Strategic, everything was completed on time including our 21 CFR Part 11 compliance."
>
> - Kristine Tang
> Enterprise Programmer
> Cepheid

VALIDATION MODULE PROTOCOLS INCLUDE:

- Security
- Routings
- Quality Management
- Distributed Orders
- Service & Support Management
- Physical Inventory
- Product Change Control
- Work Orders
- Shop Floor Control
- Item Attributes & Quality
- Sales Orders
- Compliance
- Inventory Control
- Item-Site Master Records
- Purchasing
- Formulas
- Processes
- Advanced Repetitive
- Product Structures
- eSignatures

QAD VALIDATION TOOLKIT INCLUDES:

- Computer Software Validation Plan
- Functional Requirements
- Risk Analysis
- Operational Qualification Protocol/Test Scripts
  - Distribution
  - Master Files
  - Manufacturing
- Traceability Matrix
- Baseline Configuration
- Data Migration Protocol
- Systems Stress Test Protocol
- Final Validation Report

Product Availability and Pricing

The FDA Validation Protocols and Services for QAD are available today. Please contact your Strategic sales representative today to learn more.

Sales Contact

sales@strategic.com

1-800-433-7174

Strategic helps companies achieve their corporate goals with the application of enterprise technology. We specialize in providing proven solutions for a full range of enterprise applications including ERP, CRM, Regulatory Management and Corporate Performance. Strategic works with start-ups, multinationals and market leaders to implement their systems on time and on budget, helping them maximize the value of their enterprise technology.

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