CIMCON Software

Value from Compliance

Validation and Compliance Services

Proven Validation Methodology

www.part11solutions.com

- Risk Assessment
- Validation Planning
- User Requirements
- Functional and Design Specifications
- IQ/OQ/PQ Protocols
- 21 CFR Part 11 Remediation
- Procedures and Policies

Validation and Compliance Consulting Services

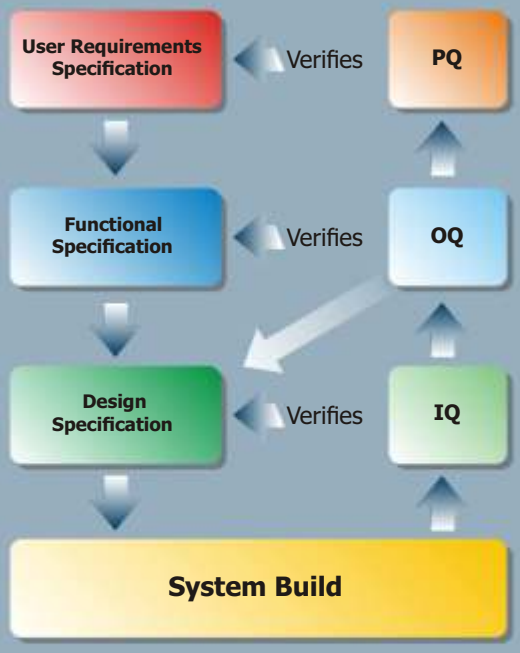
CIMCON Software (CS) is an experienced firm that provides validation and compliance consulting services that help clients achieve their business goals. CS offers a suite of validation and 21 CFR Part 11 compliance services that anticipate, define, evaluate, and solve the technological and validation issues that arise in a constantly changing environment. The firm brings to bear eighteen (18) years of experience in implementation and validation of mission-critical software systems in FDA-regulated and other industries.

CS is a recognized leader in providing compliance solutions to the FDA-regulated industry with a global client base that spans North America, Europe and Asia. CS consultants combine regulatory knowledge with technical expertise to provide solutions to issues instead of simply highlighting them. CS follows the FDA-recommended GAMP 5 methodology for all validation services. CS's validation methodologies have been developed after years of real-world field experience to ensure successful project outcomes. We strive to deliver value as an added ingredient in all our deliverables with a view to improving operations and productivity and simplifying processes with compliance as a by-product.

CS offers a wide range of services that include validation planning, risk assessments, Part 11 assessments and remediation plans, preparation of validation documents and SOPs, protocol execution, deviation resolution and training. CS regularly contributes to industry conferences, journals, tradeshows and events and is in tune with current FDA thinking and future direction.

With increasing regulatory scrutiny and requirements to comply with national and international regulations, more and more companies are moving to replace manual and paper-based processes with automated systems. Due to their experience and background, CS consultants are well equipped to qualify your systems of varying levels of complexity and help you stay compliant. CS optimizes the time and cost of validation by applying a risk-based approach to each system. CS can also provide a wide range of automated tools as part of the consulting engagement to provide you with sustainable compliance.

GAMP 5 methodology



CS has extensive experience in applying GAMP 5 Methodology across the full Life Cycle for Computer Systems Validation.

Computer Systems Validation Experience - Representative Systems

- Enterprise Resource Planning (ERP) Systems
- Laboratory Information Management System (LIMS)
- Document Management Systems (DMS)
- Adverse Event Systems
- Network Infrastructure Qualification
- Laboratory Systems
- Spreadsheet Validation
- Plant Floor Systems
- Equipment/Systems Validation
- Label Management Systems
- Manufacturing Execution Systems (MES)
- Clinical Trial Management Systems

Planning

- Master Validation Plan (MVP)
- Risk Assessment

Requirements

- User Requirements Specification (URS)

Design

- Software Design Specification (SDS)
- Hardware Design Specification (HDS)

Configuration

- Hardware Configuration Specification (HCS)
- Application Configuration Specification (ACS)

Specifications

- Functional Specifications (FS)
- Standard Operating Procedures (SOPs)

Testing

- Installation Qualification (IQ)
- Operational Qualification (OQ)
- Performance Qualification (PQ)

Reporting

- Summary Reports

21 CFR Part 11 Services

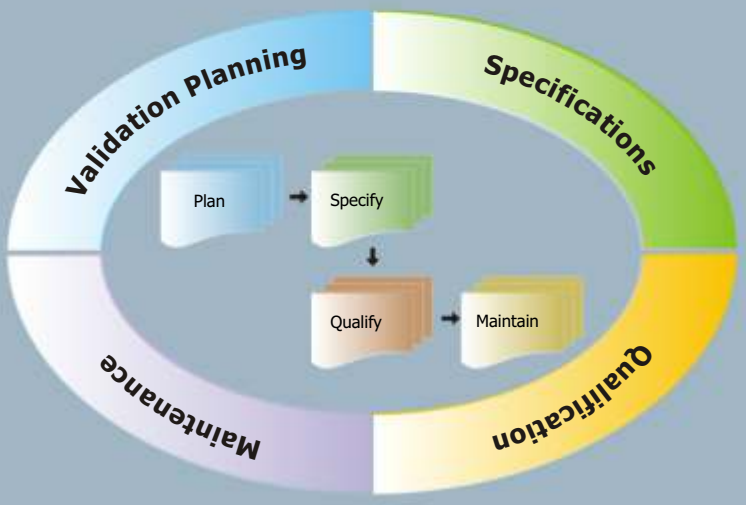
- Strategy and Planning
- System Inventory
- Gap Analysis
- Remediation
- Technical Controls
- Procedural Controls

- Source Code Reviews
- Change Management Systems
- Batch/Process Data Management System
- Database Querying and Information Retrieval in a Controlled, Part 11 Environment
- Computerized Maintenance Management Systems
- Engineering Drawing Management System
- Environmental Monitoring and Trending
- Training Systems

Validation and Compliance Services

Our Key Differentiators:

- Experience
- People
- Methodology
- Industry Participation
- Regulatory Knowledge



Validation Life Cycle

Validation Planning

- Prepare validation master plan
- Conduct Risk Assessment
- Perform Part 11 Assessment
- Specify user requirements

Specifications

- Design and configure the system
- Prepare functional and configuration specifications
- Draft procedures
- Set up configuration management

Qualification

- Verify installation
- Perform operational qualification
- Train the users
- Conduct performance qualification

Maintain

- Periodic Reviews
- Security
- Backup and Recovery
- Implement change control procedures

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