Focus Compliance & Validation Services

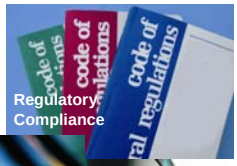
Capabilities Summary

www.FocusCVS.com

Focus Compliance and Validation Services, a division of Focus Environmental, Inc., is dedicated to providing regulatory compliance, validation, training and process engineering services to FDA regulated industries. We offer our clients a unique blend of technical expertise, regulatory compliance insight, and practical hands-on operating experience. **Focus has the qualified resources to meet your project needs in the most cost-effective manner**.

DEMONSTRATED PROFESSIONAL QUALIFICATIONS

Focus offers its clients a high level of experience. Focus personnel have extensive hands-on experience with pharmaceutical, medical device, biotechnology operations, chemical, petrochemical, metallurgical, and general manufacturing industries. **Our professional expertise and experience allows us to identify and implement the best solutions for our clients' specific applications.**



FOCUS COMPLIANCE & VALIDATION SERVICES

PROFESSIONAL EXPERTISE:

- Computer Systems Validation
- Regulatory Affairs and GXP Compliance
- Validation & Qualification
- Part 11 (Electronic Records and Signatures)
- Risk Management and Risk Assessment
- Training
- Process Engineering
- Documentation Management Systems

FOCUS COMPLIANCE & VALIDATION SERVICES

Focus supplies services and innovative solutions to FDA regulated industrial clients including pharmaceutical, medical device, and biotechnology manufacturing organizations in the following areas:

- Regulatory Compliance
- Computer Systems Validation
- Validation & Qualification
- Auditing
- Training
- Process Engineering

REGULATORY COMPLIANCE SERVICES

Focus regulatory compliance specialists work closely with the FDA to ensure our clients have the latest information available and can quickly assess the impact of regulations.

Focus provides the following services:

- Vendor/Supplier Qualification and Certification Programs
- Good Documentation Practices and Documentation Control Programs
- 21 CFR Part 11 (Electronic Records and Signatures) Training and Remediation
- Assessment and development of CAPA – Corrective & Preventive Action programs
- Quality Systems and Validation Training
- Auditing and Gap Assessments
- FDA Mock Inspections
- FDA Pre-Approval Inspections
- Risk Analysis/Risk Management
- Change Control
- International Regulations
- Quality and Statistical Tools
- Design Control Programs
- FDA Regulatory Submissions
- GXP Compliance

COMPUTER SYSTEMS VALIDATION SERVICES

Focus personnel have experience with computer systems validation activities and can provide services for the full range of validation deliverables, from Validation Plans through Validation Summary Reports. Services Include:

- User Requirement Specification
- Functional Detailed Descriptions
- Automated Processes
- Network/IT Infrastructure
- Software Imbedded Devices
- Traceability Analysis
- CSV Master Planning
- Configuration/Change Management
- Software Validation and SDLC
- Computerized Systems
- Part 11: E-records and E-signatures

VALIDATION & QUALIFICATION SERVICES

Focus has experience managing and executing projects ranging from stand-alone automated equipment and systems to start-up, commissioning and validation of new facilities. We can document that the equipment and systems operate as designed and specified prior to start of formal validation activities. Services include:

- Policy and Procedures Deployment
- Validation Gap Assessments
- Validation Master Planning
- Protocol Development and Execution
- Documentation Management (EQ, DQ, IQ, OQ, PQ, and Final Reports)
- Change Control
- Commissioning and Startup Programs
- Facilities and Utilities Qualification
- Process Validation
- Revalidation and Re-qualification
- Validation Life Cycle Methodology

CORPORATE ON-SITE TRAINING/SEMINARS

Focus Compliance and Validation Services personnel are speakers and presenters in the pharmaceutical, medical device, and biotechnology industries. Training classes are custom designed to be "hands-on" and interactive with the participants. In this manner, the participants receive direct guidance to specific questions regarding their jobs and responsibilities. Specific regulatory compliance and process validation issues pertaining to your facility are addressed as part of the program.

TRAINING TOPICS INCLUDE:

- Introduction to Process Validation for Device/ Pharmaceutical Manufacturers
- 21 CFR Part 11 - Electronic Records and Signatures
- 21 CFR Part 210/211 - cGMP Training for Pharmaceutical Manufacturers
- 21 CFR Part 820 - Quality System Training for Medical Device Manufacturers
- Regulatory Compliance and Submissions
- Design Controls and Process Validation
- Computer Systems Validation & Qualification
- Vendor/Supplier Certification & Qualification
- Equipment Qualification – DQ/IQ/OQ/PQ and Factory Acceptance Testing
- Establishing & Maintaining Change Control Programs
- Corrective and Preventative Action & Root Cause Analysis
- Failure Investigations
- Current FDA Inspection Strategies and Enforcement Trends
- Auditing Quality Systems, and Documentation

FOCUS HISTORY

Established in November 1988, Focus has successfully completed projects for the pharmaceutical, medical device, biotechnology, chemical, explosives, petrochemical, metallurgical, textiles, and general manufacturing industries. These projects have been conducted throughout the United States, Puerto Rico, and more than 10 countries.

NATIONAL REPUTATION

Focus personnel are highly skilled in performing the wide range of services that are required for FDA regulated industries.

ADDITIONAL INFORMATION

For additional information about Focus' capabilities, send an e-mail to Focus Compliance & Validation Services at info@focuscvs.com or visit Focus' web-site at www.focuscvs.com.

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