

Pharmaceutical Solutions

Object Technologies CEM, Inc. is committed to providing computer systems validation and regulatory compliance services for the pharmaceutical industry. Our work with computer and automated systems, including compliance with the U.S. FDA's 21 CFR Part 11, is well known throughout the industry. Object Technologies' has a dedicated group of engineers and consultants focused on industry guidelines and regulations. Our services include a full range of products, automated tools, validation services and procedures to help enable compliance to 21 CFR part 11 and the EU Annex Part 11. We leverage our expertise to provide systems, tools, policies and procedures for compliance. Object Technologies can help you achieve and maintain a competitive advantage by:

- Developing state-of-the-art solutions for compliance
- Identifying specific actions necessary to become compliant
- Automating software validation process
- Implementing automated tools for validation and validation management
- Meeting validation schedules and critical path
- Minimizing the effort required for on-going regulatory compliance
- Improving operational efficiency

Object Technologies CEM, Inc. has validation expertise and experience with all types of computer systems in the pharmaceutical industry. We can assist you in defining and implementing your requirements involving computer systems by providing the following services:

- Minimizing the effort required for on-going regulatory compliance
- Improving operational efficiency
- Determination and prioritization of your computer system validation requirements (risk analysis and risk based approach)
- Creating a system validation master plan and defining roles and responsibilities
- Defining system requirements and specifications (user requirements and functional specifications)
- Defining system design requirements and specifications (software and configuration specifications)
- Documentation and testing of systems (test plans, test scripts, execution, failure report, traceability matrixes and test summaries)
- Computer validation training
- Software vendor audits
- System implementation and project management
- Prospective and legacy system validation
- Electronic record/electronic signature compliance (21 CFR Part 11)

Object Technologies CEM, Inc. provides expertise and assistance in computer system validation by applying proven, efficient solutions based on current industry standards. Through the use of risk analysis tools, we can define the scope and focus of your computer system validation effort. Defining and justifying the end point of each computer system validation project is key to managing the scope and thereby the project plan of computer system validation.