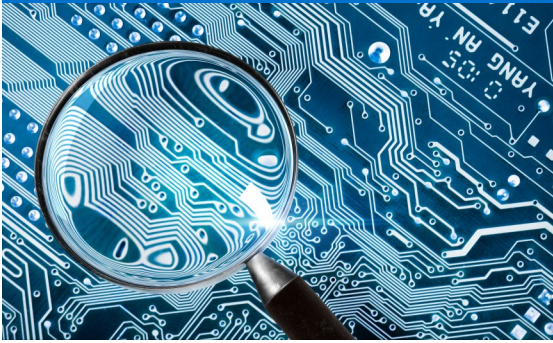




Compliance Builder Information Security is offered on multiple platforms including Microsoft® SharePoint Server®



21 CFR PART 11 Compliance

Compliance Builder Information Security is a cost effective solution that provides 21 CFR Part 11 compliance with minimal system and operator changes. The system records all actions in an independent, secure audit trail. Changes (additions, edits and deletions) are immediately reported for any authorized user prompted for a 21 CFR Part 11 compliant approval signature. The system also captures electronic signatures from authorized workstations and in accordance with Part 11 requirements, provides device and authority checks that limit access to authorized personnel. Compliance Builder Information Security supports biometric and non-biometric signatures (including PKI).

Information Security Software

Xybion provides a total compliance and quality management solution for companies operating in heavily regulated industries. As part of our total solution, we offer Compliance Builder Information Security, a unique solution that helps companies ensure they are properly monitoring all files, databases, and equipment in accordance with 21 CFR Part 11 and other regulations. Compliance Builder Information Security provides real-time visibility and information security across your entire information enterprise.

Compliance Builder Information Security is designed to help you meet the requirements set out by 21 CFR Part 11, SOX and other regulations by securing and monitoring any file-based system or application. This is accomplished through a security wrapper that can be placed around the application and file storage area and by monitoring file changes, including file creation, deletion or modification. Click the thumb to view a full size screenshot Compliance Builder Information Security offers complete flexibility in establishing your managed folder criteria by specific director, workstation, file type, or file server. Compliance Builder Information Security is designed to monitor key data sources such as:

- Files on your Workstations or Files Servers
- Tables in your Databases
- Process and Manufacturing Equipment



Compliance Builder Information Security

Security

Compliance Builder Information Security contains comprehensive application security. Integrates into your existing security infrastructure, controlling both user administration and access to raw data.

Validation-Ready

Xybion offers a comprehensive set of validation documentation templates and SOPs to support the implementation and deployment of Compliance Builder in highly regulated systems environments. We offer comprehensive services to specifically customize validation documentation to meet your unique business requirements.

About Compliance Builder

Compliance Builder is a flexible compliance software solution designed to provide real-time monitoring of 21 CFR Part 11. By generating audit trails and providing configurable electronic signatures, Compliance Builder allows you to securely track changes across all IT subsystems including file systems, databases and laboratory equipment. It can be configured to monitor any file-based system for changes, including additions, deletions, and file modifications. This is accomplished through a security wrapper that can be placed around the application and file storage area and by monitoring file changes, including file creation, deletion or modification.



About Xybion

Xybion is a leading SaaS company dedicated to providing life sciences and health systems companies with innovative software solutions to accelerate the transformation of today's inventions into tomorrow's approved medicines, devices, and diagnostic tests designed to save lives and keep employees safe. Our intelligent cloud platform and software solutions help companies accelerate digital transformation of processes, speed up innovation, optimize operations, reduce compliance risks, and achieve significant cost savings.

Xybion is serving over 160 customers in 29 countries including all the top 20 global biopharmaceutical

companies. Xybion's global scale and expertise brings employees around the world to help companies in life sciences, health systems, research institutions, and governments. We help companies digitally transform their regulated business operations. Our unique solutions focus on employee health and safety, integrated preclinical lab management, early stage drug discovery, digital lab solutions, regulatory compliance, GRC, quality management, predictive compliance, content management, and systems validation.

