



CQRM XD Compliance Builder with Real Time Monitoring Provides the Ability to Track changes to:

- Office/ Text Files/Any Proprietary File Type)
- Microsoft SharePoint®
- Databases (Oracle, SQL Server, MS Access)
- Any Laboratory Equipment Connected to a Windows PC Workstation
- And More...



CQRM XD Compliance Builder with Real Time Monitoring Out-of-the-Box Functionality:

- **Audit trail**
- **Electronic signatures**
- **Dashboards**
- **Email notifications**
- **Alerts**
- **Database monitoring**
- **Revision history**
- **Controlled user access**
- **Audit schema structure**
- **Multi-domain support**

Overview

Reduce Organizational Risk, Improve Compliance, and Ensure Data Integrity

Real-Time Compliance Monitoring and Data Integrity

Xybion provides a total compliance and quality management solution for companies operating in highly regulated industries. A key component of this comprehensive solution is CQRM XD Compliance Builder with Real Time Monitoring, a unique software offering that helps companies enable 21 CFR Part 11 compliance and ensure data integrity by monitoring and securing data from file systems, databases, and from Lab and manufacturing equipment.

Simply stated, CQRM XD Compliance Builder with Real Time Monitoring provides real-time visibility, enhanced control, and information security across your entire information enterprise. The solution offers complete flexibility in securing data across your managed folders and tracks data pertaining to specific users, workstations, and file types, while providing a full audit trail of all changes such as data creation, deletion or modification. CQRM XD Compliance Builder with Real Time Monitoring enables the complete monitoring of data across all your IT systems including:

- Files on your workstations or files servers
- Tables in your databases
- Any lab or manufacturing equipment

Enterprise-Wide Data Integrity

CQRM XD Compliance Builder with Real Time Monitoring provides the ability to ensure user access control, generate audit trails for all data activities, and create reports required to meet compliance mandates. These actions facilitate data integrity across IT systems such as file systems, database systems, laboratory or any manufacturing instruments. The FDA defines data integrity as a key component of 21 CFR Part 11 compliance to ensure every electronic record has completeness, consistency, and accuracy of data. As outlined by the "ALCOA" Principle, data should be:

- **Attributable**
- **Legible**
- **Contemporaneously recorded**
- **Original (or a true copy)**
- **Accurate**
- **Compliance Builder helps monitor all elements of the ALCOA Principle for ensuring data integrity and Part 11 compliance.**

21 CFR PART 11 Compliance

CQRM XD Compliance Builder with Real Time Monitoring is a cost-effective solution that provides 21 CFR Part 11 compliance with minimal system and operator changes. The system records all actions pertaining to data being secured, thus providing an independent and secure audit trail with date and time stamp and identification of the user who initiated the action. This audit trail is captured contemporaneously as the data event happens, which serves as evidence from the time raw data is created, and any subsequent data events (data addition, deletion, modification) that took place, thereby providing integrity of data and transparency.



The system has the ability to capture electronic signatures for all data events, which also helps eliminate the need to print and maintain paper records with wet signatures.

Flexible and Configurable Security Options

CQRM XD Compliance Builder with Real Time Monitoring provides complete This includes the ability to enable functionality such as managing eSignatures, user sign-offs or even setting up email alerts for specific data folders (or all folders), with no impact or interference to any application performance.

Additional security features, such as user access control, data security, full audit trail and a central data archive of all revision history, enable companies to fully secure their data to ensure data integrity and prevent unauthorized use or any data falsification.

Data and Device Agnostic Solution

Be it a file system (any file type), a database (Oracle, SQL Server or MS Access), or any lab equipment, CQRM XD Compliance Builder with Real Time Monitoring provides a one-stop, platform and instrument agnostic solution to remediate compliance challenges and ensure data integrity across an organization's entire IT system.

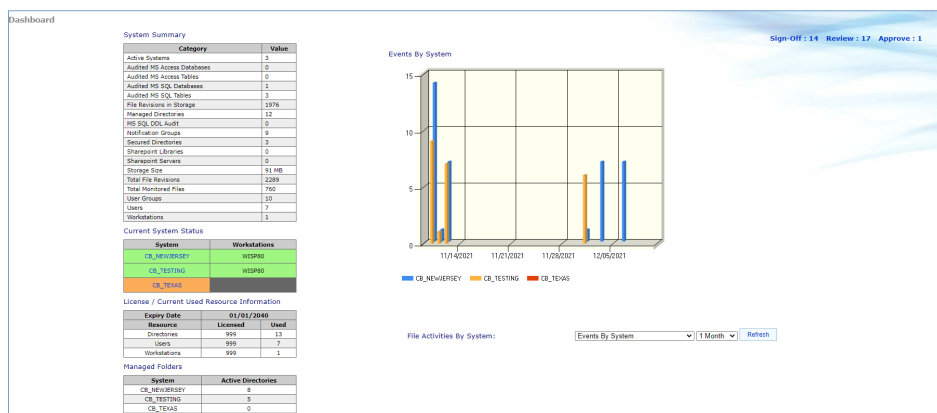


Figure 1. Dashboard provides insight into important compliance deviations, log files and events

CQRМ XD Compliance Builder with Real Time Monitoring Key Features

Comprehensive Application Security:

A comprehensive application security layer integrates seamlessly into existing security infrastructure, controlling both user administration and access to raw data. Layered security levels enable control access at both the application and file levels. Features such as sign-off authorization provide additional layers of security.

Full Audit Trail: A detailed audit trail records changes made to file-based systems, databases, and laboratory equipment. For file-based systems, users can perform full retrieval of all changes through revision history. CQRМ XD Compliance Builder with Real Time Monitoring enables comparison of file revisions for any text-based files, including Excel spreadsheets and MS Word documents. This file comparison feature is supported for databases as well.

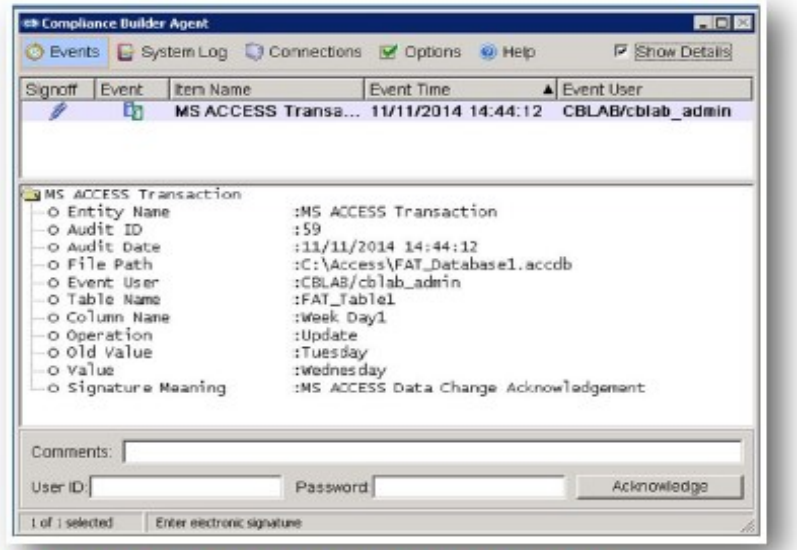


Figure 2. ComplianceBuilder supports flexible transaction monitoring on databases, including Microsoft Access.

Configurable Electronic Signatures:

For e-signatures, three levels of interaction are supported that can be configured based on customer's organization policies:

- Silent
- Acknowledgement
- Signature Confirmation

Validation-Ready Platform:

Xybion offers a comprehensive set of validation documentation templates to support the implementation and deployment of CQRМ XD Compliance Builder with Real Time Monitoring in highly regulated systems and environments. Additionally, Xybion offers comprehensive services to specifically customize validation documentation to meet a customer's unique business requirements.

The screenshot shows the 'Audit Trail Report' interface. At the top, it displays 'System: CR_NEWBERRY', 'Folder: /', 'File Name: Config...', 'Event Time Start: 11/24/2013 00:00', and 'Event Time To: 12/02/2013 23:59'. Below is a table with columns: Action, File Name, Version, Action, Size, Event Time, Modified At, Modified By, Sign-Off Modification, and Event Action. The table lists numerous file modification events, including configuration files and database-related files.

Figure 3. The Compliance Builder audit trail report consolidates all important file modification information, allowing you to prepare completely for an audit with just a few clicks.

Database Monitoring and Audit Trail:

CQRМ XD Compliance Builder with Real Time Monitoring monitors databases for structural changes, such as the addition or deletion of a column. It also monitors for change in the database records and provides a complete audit trail. Compliance Builder supports multiple databases including Microsoft® Access®, Oracle Databases, and Microsoft® SQL Databases.

Microsoft® SharePoint Monitoring and Fraud Detection: CQRМ XD Compliance Builder with Real Time Monitoring has a SharePoint module that provides capabilities designed to monitor the SharePoint library and send the appropriate notifications when document downloads from the configured library exceed the specified average usage by a user. Upon detection of any abnormality in the usage pattern, an alert email is sent to mitigate risk and allow for appropriate action from stakeholders to prevent any data leak from the system.



Multi-Domain Support:

CQRM XD Compliance Builder with Real Time Monitoring provides multi-domain support, which enables the support of a large number of systems across multiple sites and locations for a customer.

CQRM XD Compliance Builder with Real Time Monitoring Allows Customers to:

- Produce secure, computer generated audit trails of all electronic records. Time stamped change logs and audit trail reports can be created to support compliance mandates.
- Control access to key file locations and databases by restricting access based on user-profiles.
- Provide complete traceability for any data from the time raw data gets generated.
- Enable audit trail report generation based on various filters such as: by user/ by folder/ by workstation, etc. Also enable comparison of revision for all text-based files including MS Word/ MS Excel and databases.
- Enable comprehensive application level security, which integrates with any existing security infrastructure, controlling both user administration and access to raw data.

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.

