

Compliance Builder™ File

Compliance Builder File

Compliance Builder File allows you to import existing data from laboratory instrument files, Microsoft Excel spreadsheets, and Microsoft Word documents or any other file based system. Compliance Builder File helps you quickly integrate your desktop applications with your legacy data sources, while at the same time helping you achieve 21 CFR Part 11 compliance.

Compliance Builder File detects and Monitors the following:

- Configuration files, Excel spreadsheets, Word document files, text files
- PDF files
- Graphic files
- Recipe files
- Lab instrument data files PLC Programs
- Access databases
- SAS data sets
- Any file-based system



File Audit Trail Report									
System: CR_NEWBERRY									
Folder:									
File Name Contain: 11/01/2021 00:00									
Event Time From: 11/01/2021 00:00									
Event Time To: 12/10/2021 23:59									
Actions	File Name	Revisions	Action	Step	Event time	Modified At	Modified By	Sign-off Workstation	Event Action
Compare	\\SRP01C\chem2\LOGBOOK.TXT	2	Modify	486	11/01/2021 11:16:51	11/01/2021 11:16:58	C. Buika (CBUSA)	WISPRO	Signed By C. Buika (CBUSA) on 11/01/2021 11:16:44 Sign-off Comment: Instrument configuration file has been changed
Compare	\\SRP01C\Instrument Configuration\AdvADVA.DOCXPLNRC	28	Modify	348	11/01/2021 07:16:00	11/01/2021 07:16:00	C. Buika (CBUSA)	WISPRO	Signed By C. Buika (CBUSA) on 11/01/2021 07:16:16 Sign-off Comment: File has been changed for review
Compare	\\SRP01C\Instrument Configuration\AdvADVA.DOCXPLNRC	29	Modify	348	11/01/2021 07:48:20	11/01/2021 07:48:20	C. Buika (CBUSA)	WISPRO	Signed By C. Buika (CBUSA) on 11/01/2021 07:48:45 Sign-off Comment: Instrument configuration file has been changed
Compare	\\SRP01C\Instrument Configuration\AdvADVA.DOCXPLNRC	30	Modify	348	11/01/2021 09:00:11	11/01/2021 09:00:10	C. Buika (CBUSA)	WISPRO	Signed By C. Buika (CBUSA) on 11/01/2021 09:00:19 Sign-off Comment: File
Compare	\\SRP01C\Instrument Configuration\AdvADVA.DOCXPLNRC	31	Modify	348	11/01/2021 09:34:14	11/01/2021 09:34:14	C. Buika (CBUSA)	WISPRO	Signed By C. Buika (CBUSA) on 11/01/2021 09:34:16 Sign-off Comment: File has been changed
Compare	\\SRP01C\Instrument Configuration\AdvADVA.DOCXPLNRC	32	Modify	348	11/01/2021 10:11:51	11/01/2021 10:11:51	C. Buika (CBUSA)	WISPRO	Signed By C. Buika (CBUSA) on 11/01/2021 10:11:46 Sign-off Comment: File has been changed
Compare	\\SRP01C\Instrument Configuration\AdvADVA.DOCXPLNRC	33	Modify	348	11/01/2021 10:44:52	11/01/2021 10:44:51	C. Buika (CBUSA)	WISPRO	Signed By C. Buika (CBUSA) on 11/01/2021 10:44:51 Sign-off Comment: File has been changed
Compare	\\SRP01C\Instrument Configuration\AdvADVA.CUSTOM	22	Modify	348	11/04/2021 10:12:14	11/01/2021 10:12:15	C. Buika (CBUSA)	WISPRO	Signed By C. Buika (CBUSA) on 11/01/2021 10:12:17 Sign-off Comment: File has been changed
Compare	\\SRP01C\Instrument Configuration\AdvADVA.CUSTOM	22	Modify	348	11/04/2021 10:12:45	11/04/2021 10:12:44	C. Buika (CBUSA)	WISPRO	Signed By C. Buika (CBUSA) on 11/01/2021 10:12:37 Sign-off Comment: File has been changed
Compare	\\SRP01C\Instrument Configuration\AdvADVA.DOWNLOAD	12	Modify	348	11/01/2021 09:34:20	11/01/2021 09:34:20	C. Buika (CBUSA)	WISPRO	Signed By C. Buika (CBUSA) on 11/01/2021 09:34:20 Sign-off Comment: File has been changed
Compare	\\SRP01C\Instrument Configuration\AdvADVA.DOWNLOAD	15	Modify	348	11/01/2021 15:45:06	11/01/2021 15:45:05	C. Buika (CBUSA)	WISPRO	Signed By C. Buika (CBUSA) on 11/01/2021 15:45:06 Sign-off Comment: File has been changed
Compare	\\SRP01C\Instrument Configuration\AdvADVA.DOWNLOAD	15	Modify	348	11/04/2021 17:42:09	11/04/2021 17:42:09	C. Buika (CBUSA)	WISPRO	Signed By C. Buika (CBUSA) on 11/04/2021 17:42:09 Sign-off Comment: Instrument configuration file has been changed
Compare	\\SRP01C\Instrument Configuration\AdvADVA.DOWNLOAD	14	Modify	348	11/01/2021 09:00:10	11/01/2021 09:00:10	C. Buika (CBUSA)	WISPRO	Signed By C. Buika (CBUSA) on 11/01/2021 09:00:11 Sign-off Comment: File
Compare	\\SRP01C\Instrument Configuration\AdvADVA.CODES.TXL	4	Modify	348	11/04/2021 10:12:00	11/04/2021 10:12:00	C. Buika (CBUSA)	WISPRO	Signed By C. Buika (CBUSA) on 11/04/2021 10:12:07 Sign-off Comment: File
Compare	\\SRP01C\Instrument Configuration\AdvADVA.TEST.COMPLNRC	3	Modify	348	11/01/2021 14:51:23	11/01/2021 14:51:23	C. Buika (CBUSA)	WISPRO	Signed By C. Buika (CBUSA) on 11/01/2021 14:51:27 Sign-off Comment: File
Compare	\\SRP01C\Instrument Configuration\AdvADVA.TEST.COMPLNRC	2	Modify	348	11/04/2021 17:58:40	11/04/2021 17:58:39	C. Buika (CBUSA)	WISPRO	Signed By C. Buika (CBUSA) on 11/04/2021 17:58:55 Sign-off Comment: File has been changed
Compare	\\SRP01C\Users\Public\Documents\Strator\Buick\Universal\Output\CB Demo 11042021_11_omp	1	Create	4748	11/01/2021 15:55:29	11/01/2021 15:55:11	C. Buika (CBUSA)	CR_NEWBERRY	Signed By THESETUP on 11/01/2021 15:55:11 Sign-off Comment: File has been created
Compare	\\SRP01C\Users\Public\Documents\Strator\Buick\Universal\Output\CB Demo 11042021_11_omp	1	Create	9788	11/01/2021 15:55:31	11/01/2021 15:55:29	C. Buika (CBUSA)	WISPRO	Signed By THESETUP on 11/01/2021 15:55:29 Sign-off Comment: File has been created
Compare	\\SRP01C\Users\Public\Documents\Strator\Buick\Universal\Output\CB Demo 11042021_11_omp	1	Create	2348	11/01/2021 09:42:37	11/01/2021 09:42:24	C. Buika (CBUSA)	WISPRO	Signed By C. Buika (CBUSA) on 11/01/2021 09:43:17 Sign-off Comment: File has been created
Compare	\\SRP01C\Users\Public\Documents\Strator\Buick\Universal\Output\CB Demo 11042021_11_omp	1	Create	9788	11/01/2021 09:42:40	11/01/2021 09:42:37	C. Buika (CBUSA)	WISPRO	Signed By C. Buika (CBUSA) on 11/01/2021 09:43:18 Sign-off Comment: File has been created
Compare	\\SRP01C\Users\Public\Documents\Strator\Buick\Universal\Output\CB Demo 11042021_11_omp	1	Create	6848	11/04/2021 18:45:34	11/04/2021 18:45:14	C. Buika (CBUSA)	WISPRO	Signed By C. Buika (CBUSA) on 11/04/2021 18:45:24 Sign-off Comment: File has been created
Compare	\\SRP01C\Users\Public\Documents\Strator\Buick\Universal\Output\CB Demo 11042021_11_omp	1	Create	9788	11/04/2021 18:45:35	11/04/2021 18:45:34	C. Buika (CBUSA)	WISPRO	Signed By C. Buika (CBUSA) on 11/04/2021 18:45:25 Sign-off Comment: File has been created
Compare	\\SRP01C\Users\Public\Documents\Strator\Buick\Universal\Output\CB Demo 11042021_11_omp	1	Create	3448	11/01/2021 10:12:51	11/01/2021 10:12:38	C. Buika (CBUSA)	WISPRO	Signed By C. Buika (CBUSA) on 11/01/2021 10:12:42 Sign-off Comment: File has been created
Compare	\\SRP01C\Users\Public\Documents\Strator\Buick\Universal\Output\CB Demo 11042021_11_omp	1	Create	9788	11/01/2021 10:12:54	11/01/2021 10:12:51	C. Buika (CBUSA)	WISPRO	Signed By C. Buika (CBUSA) on 11/01/2021 10:12:42 Sign-off Comment: File has been created

Being able to track the lifecycle of desired files has repeatedly enables teams to quickly resolve discrepancies saving valuable time in file forensics work and in documentation."

Compliance Builder File Features:

File Version Comparison Plug-ins You can install application specific plug-ins that enable Compliance Builder File 's "compare" functionality. You just choose the two files you want to compare, and Compliance Builder File will generate a comparison report highlighting the files' differences.

Plug-ins are available for Microsoft Excel and Word, and for any text file. Multi-platform support. Additional application specific plug-ins can be developed and delivered to suit your specific requirements.



Compliance Builder™ - File

Key Features

File change notifications occur whenever a file is added, modified or deleted in a managed directory. Compliance Builder File then issues a notification that pops up in the CB Agent window on a designated user's workstation. You can specify whether notification sign-off is required, and how long Compliance Builder File should wait before it "times out" an unacknowledged notification.

Browse Folders using your designated file-based systems for file changes: additions, deletions and modifications. Upon detecting a file change, Compliance Builder File stores the file version in a secure data repository. You have complete flexibility in setting up your "managed folders" file-monitoring program: by specific directory, by workstation or file server, or by file type. Compliance Builder File's folder manager page displays managed files and file versions in a Windows-like hierarchy. You can view or download any file, display file attributes, or run the File Compare option. File Audit Trail Report displays file changes in managed directories according to your report selection criteria: by folder, file name(s), sign-off workstation or a date/time range. Compliance Builder File audit trail report displays changes made to your managed directories' configuration and set up over a specified time period.

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.

