INSTRON®

The difference is measurable®

ComplianceBuilder™ for Instron® Software | 21 CFR § 11 Compliance Solution

For Medical Device and Pharmaceutical companies, records management compliance with FDA 21 CFR § 11 is non-negotiable. ComplianceBuilder™ (CB) is a stand-alone, add-on compliance solution that can be integrated with Instron's Bluehill® Software to provide features necessary to meet the latest FDA 21 CFR § 11 regulations.

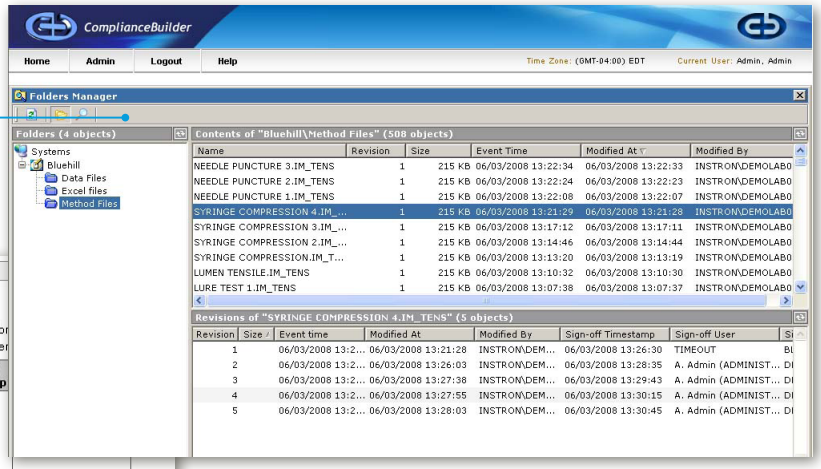
How does ComplianceBuilder Allow You to Comply with 21 CFR § 11?

- Ability to generate copies of electronic records of Bluehill test methods – including any version of that record, such as the original and most current
- Security that limits access to only authorized individuals for all Bluehill Software test methods, data files, and reports
- Secure, computer-generated, and time-stamped audit trail of all electronic records
- Unique e-signatures containing printed name, date and time, and reason for signature
- Authority checks for important operations, such as e-signatures and altering records

The ComplianceBuilder Advantage

- An electronic records storage solution, designed with full compliance in mind that provides an efficient and convenient approach to passing FDA audits and maintaining production schedules
- Secure files and documents through the use of e-signatures
- Restrict accessibility based on user-profiles
- Allows you to search electronic data to find specific records and identify issues quickly
- Electronic records reduce your costs through savings on paper, printers, and maintenance and administration time
- Storage of records on a single server allows you to maximize valuable work space and reduce costs associated with physical storage and maintenance

Previous versions of any Instron sample or method file can be restored through the ComplianceBuilder file management system.



File Audit Trail Report

System: **Bluehill**
Folder:
File Name Contains:
Event Time From: **06/01/2008 00:00**

File Name	Revision	Action	Size (KB)	Event Time	Modified At	Modified By	Sign-Off Timestamp
DemoLab09XP\\C:\Documents and Settings\All Users\Documents\Instron\Bluehill\Output\MDM DATA.ID_TENS	1	Create	0.064	06/03/2008 10:11:53	06/03/2008 10:08:10	INSTRON\DEMOLAB09	
DemoLab09XP\\C:\Documents and Settings\All Users\Documents\Instron\Bluehill\Output\MDM DATA.IS_TENS	1	Create	233.430	06/03/2008 10:11:54	06/03/2008 10:11:53	INSTRON\DEMOLAB09	
DemoLab09XP\\C:\Documents and Settings\All Users\Documents\Instron\Bluehill\Output\MDM DATA_1.ID_TENS	1	Create	0.064	06/03/2008 10:22:56	06/03/2008 10:22:00	INSTRON\DEMOLAB09	
DemoLab09XP\\C:\Documents and Settings\All Users\Documents\Instron\Bluehill\Output\MDM DATA_1.ID_TENS	2	Modify	27.285	06/03/2008 12:59:20	06/03/2008 12:45:07	INSTRON\DEMOLAB09	
DemoLab09XP\\C:\Documents and Settings\All Users\Documents\Instron\Bluehill\Output\MDM DATA_1.IS_TE	2	Modify	309.186	06/03/2008 12:59:20	06/03/2008 12:59:19	INSTRON\DEMOLAB09	

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

How can You make Your Lab Compliant?

The ComplianceBuilder™ Solution includes installation, one-year warranty and support, as well as the IQ/OQ documentation to facilitate the software validation that is required by the FDA. ComplianceBuilder can be installed on a single Instron® frame today, but as the needs of your laboratory or organization change, ComplianceBuilder has the benefit of being scalable over time with a corporate network to allow for a clear upgrade path. Additionally, ComplianceBuilder may be installed on a wide variety of non-Instron laboratory equipment with the purchase of license upgrades.

What are the Risks of Non-Compliance with 21 CFR § 11?

- Delays in delivering products to market
- Fines costing your company millions of dollars
- Inaccurate representation of your device's true quality, clinical behavior, or efficacy
- Lost time spent preparing for internal FDA audits
- Lost time and money spent troubleshooting errors in paper records

Questions You can Ask about Other Compliant Solutions

Can raw data files or audit trail files be accessed, modified (using standard Microsoft® tools), or deleted by unauthorized personnel using routine means?

If yes, then the solution is not compliant. ComplianceBuilder ensures that both the software application and the data storage files are protected by requiring authentication by a User ID and password.

Can the solution be left idle for any period of time without re-authentication of the user?

If yes, then the solution may not be compliant. Data integrity and security are compromised without workstation time-out settings that require a user to re-enter their User ID and password after a specified amount of idle time. ComplianceBuilder provides these settings.

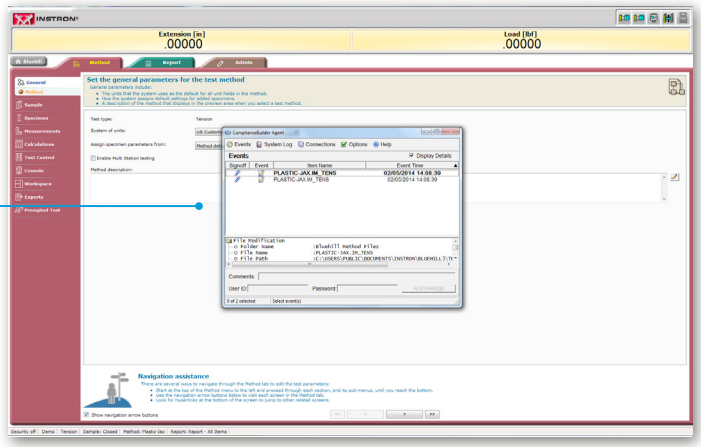
Can each testing instrument have its own unique User ID?

If yes, then that solution will not allow for e-signatures. Although e-signatures are not currently enforced by the FDA, they are documented in 21 CFR § 11, they will reduce time and effort when preparing for an internal audit, and they will allow you to submit records to the FDA electronically.

Can the standalone solution be upgraded to a centralized solution with other testing systems in the lab or throughout your company in the future?

If no, then you may be putting your lab at risk in the long term. ComplianceBuilder has a variety of solutions that can be customized to meet any of your future needs.

When a change is made to an Instron sample or method file, the user can log in with a unique ID and password, and also explain the reason for the change.



Note: ComplianceBuilder is a product of Xybion Technology Solutions, Inc.

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