Issue 20

Welcome to the Instron® Materials Testing Accessories Newsletter

In This Issue: FDA 21 CFR § 11 Regulations Software Solution – Bluehill® ComplianceBuilder™

ComplianceBuilder for Bluehill Software

ComplianceBuilder is an add-on compliance solution that is specifically integrated with Instron Bluehill software to provide features necessary to meet the latest FDA 21 CFR § 11 regulations.

What is 21 CFR § 11?

21 CFR § 11 is a set of compliance requirements for electronic records and electronic signature procedures that apply to industries regulated by the US Food and Drug Administration (FDA).

As the world transitions to more electronic based forms of information storage, sharing and communications, the FDA has developed regulatory guidelines found in 21 CFR § 11 that applies to electronic records created and stored by pharmaceutical, biomaterials and medical device companies, as well as other industries that need to conform to the requirements. This regulation is intended to ensure that electronic records are trustworthy, reliable, and equivalent to paper documentation.

Why is 21 CFR § 11 important?

Test methods and results are the cornerstone to any testing laboratory within a pharmaceutical, biomaterial or medical device company, especially in quality control or production. Historically, these methods and results have been stored in files or on paper, signed and submitted accordingly when required, to the FDA. During audits from the FDA, these physical records were pulled from a storage file cabinet for examination.

In recent years many organizations have been moving toward a more electronic approach to recording, sharing and storing of these important product quality and reliability parameters and results generated by their testing systems.

Contact Us

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Online Request

For More Information

- Download our PDF "ComplianceBuilder for Bluehill Software – 21 CFR § 11 Compliant Solution"
- Download the whitepaper "21 CFR § 11 Overview for Materials Testing and Electronic Records"
- Contact Us Online

Related Links

- Fourth Edition of the Accessories Catalog for Materials Testing is now available!

- Missed previous issues of the Accessories Newsletter? Catch up at the Instron Library. Follow the link and select "Newsletter" as the Document Type.

File Audit Trail Report

System: **Bluehill**
Folder:
File Name Contains:
Sign-off Workstation Contains:
Event Time From: **06/01/2008 00:00**
Event Time To: **06/03/2008 23**

File Name	Revision	Action	Size (KB)	Event Time	Modified At	Modified By	Sign-Off Timestamp	Sign-Off User	Sig Work
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			

What are the risks of not complying with 21 CFR § 11 completely?

- Delays in delivering your product to market
- Company fines
- Inaccurate representation of your device's true quality, clinical behavior or efficacy
- Lost time spent preparing for FDA audits
- Lost time and money spent troubleshooting errors in electronic records

How does Bluehill ComplianceBuilder allow you to comply with 21 CFR § 11?

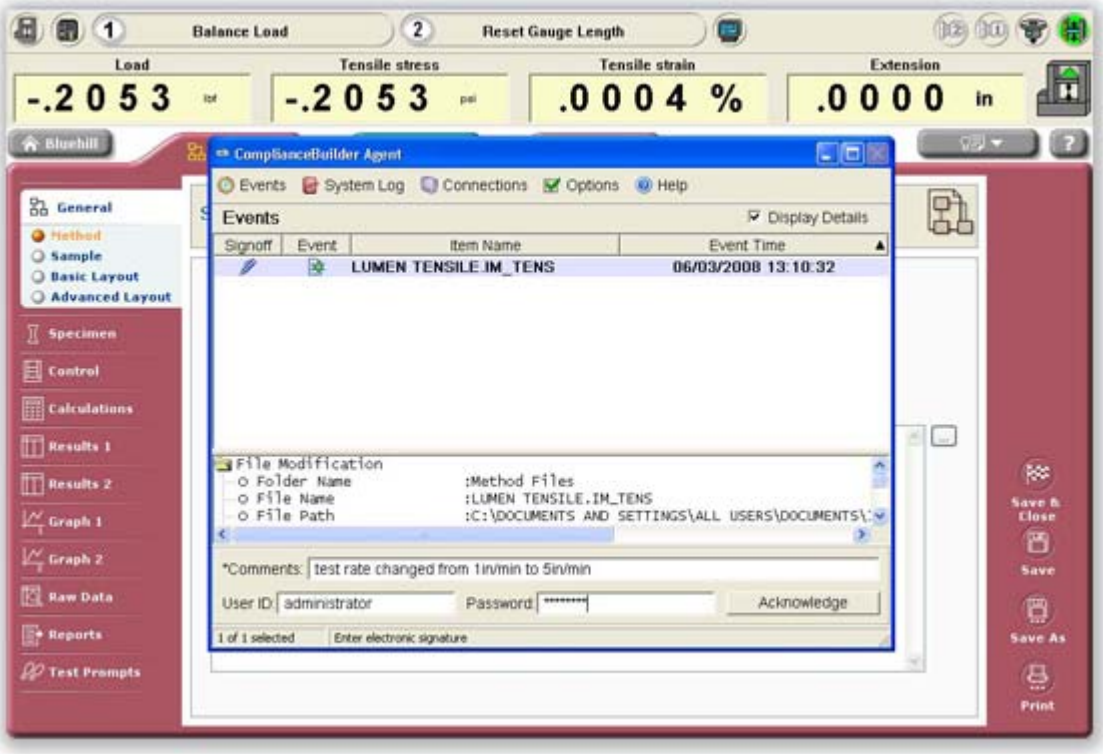
- Security that limits access to only authorized individuals for all Bluehill software test methods, data files and reports
- Ability to generate copies of electronic records at anytime, including any version of that record, such as the original and most current
- Secure, computer-generated and time-stamped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

How do you make your lab compliant?

The Instron Bluehill ComplianceBuilder solution includes installation, one-year warranty and support, as well as the IQ/OQ documentation that is also required by the FDA. Bluehill ComplianceBuilder can be installed on a single frame and it has the benefit of being scalable over time using a corporate network to allow for a clear upgrade path as the needs of your lab change.

Future Events

- For a list of upcoming shows that Instron will be attending, please visit the Events page of our website.



For further information, please contact your local Instron office or follow the links on this page.

For more information on Accessories, visit us on the web,submit an online request, or call us at +1 800 473 7838 (US only) or +44 1494 456815 (Europe only)

Are you testing something a little different? Do you think more people should know about it? Would you like to submit an article for possible publication in the Instron accessories newsletter? If so, please submit your story.

What do you think? Tell us!

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