Bluehill Universal's Traceability Module enables users to meet the audit requirements associated with FDA 21 CFR Part 11, ISO 17025, NADCAP, A2LA, and other accrediting bodies. Through seamless integration of electronic signatures and approvals, file revision history, and an automated, secure audit trail, this powerful add-on provides unmatched data traceability.

STANDARD FEATURES

BLUEHILL SECURITY

Bluehill Security allows lab managers to configure permissions in the software, granting access to trained personnel and limiting access where needed. Bluehill users can choose one of three different security options offering various levels of integration with your organization's existing security network.

REVISION HISTORY

Revision history allows users to view the full revision history of Bluehill methods, tested samples, and report templates. Each revision contains the details of the affected item, including a time stamp, both the previous and the new value, and the name of the users involved with initiating and, if required, approving the change.

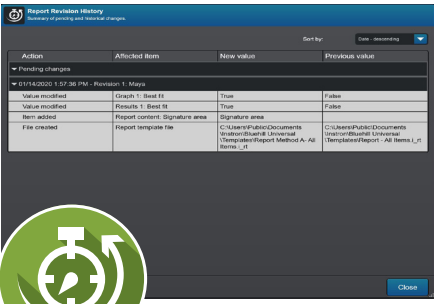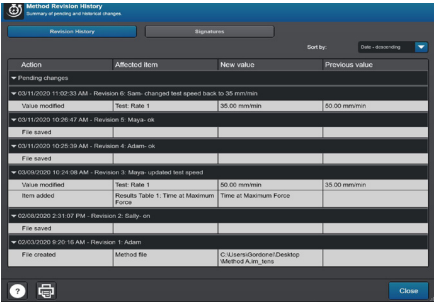## OPTIONALLY INCLUDED WITH TRACEABILITY

ELECTRONIC SIGNATURES

Electronic signatures serve as electronic approvals and replace the need for manual, hard copy signatures. Electronic signatures can be configured for primary, secondary, and tertiary electronic sign off to ensure that method revisions and test data are reviewed before a change is implemented or data is publicized.
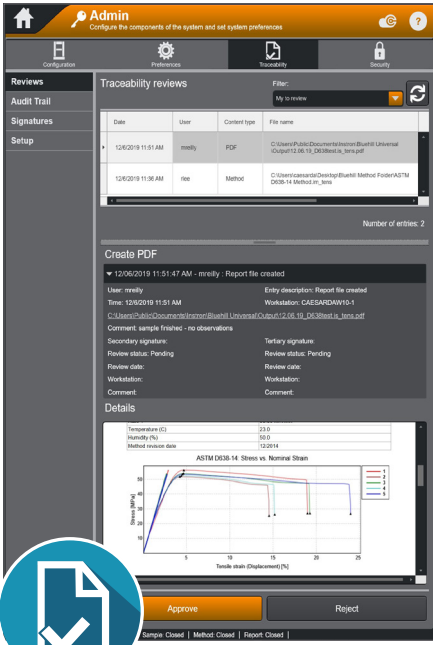
AUDIT TRAIL

Bluehill Universal's built-in secure and searchable audit trail tracks system level usage such as log-ins and log-outs, as well as additions, modifications, and deletions to all Bluehill files. The audit trail also captures usernames, dates, and timestamps for all activities. This allows full visibility into all system activities during an audit.
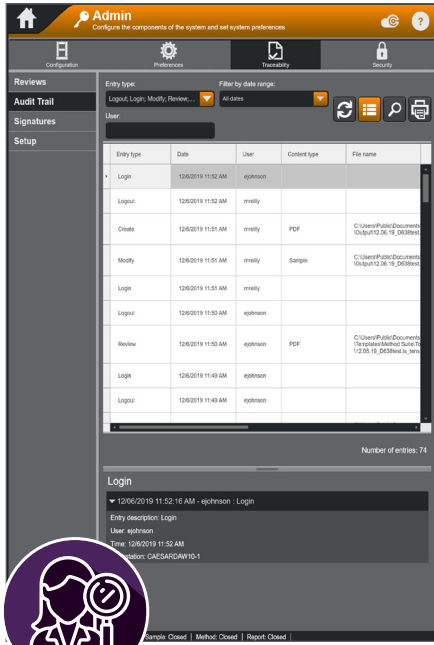
REVISION HISTORY

Revision history is stored with each of the three Bluehill files types: Method files, Sample files, and Report templates. If an addition, modification, or deletion occurs, it will be recorded in the file revision history. Files saved to local and network locations retain file revision history.

*Revision history is available without the Traceability Module add-on

ELECTRONIC SIGNATURES

Electronic signatures allow users to sign off on their work when saving files. Secondary and Tertiary electronic signatures can be used to approve files. For example, if Method A requires secondary approval, an operator cannot run tests with Method A until the file is electronically signed by a secondary approver. Files saved to local and network locations retain electronic signatures and approval history.

AUDIT TRAIL

The audit trail is a secure and searchable repository of all system-level interactions. A lab manager can utilize the audit trail to know who, did what, when, and why on their Instron® system. The audit trail is stored on a SQL Server Express database local to the Instron system. For network version, see Bluehill Central.

BLUEHILL CENTRAL

Bluehill Central is a lab management application that allows lab managers to remotely manage all Bluehill Universal users, test templates, results, file revision approvals, and audit trail data from multiple Instron systems. The network version of Traceability supported by Bluehill Central eliminates the burden locally managing file approval and audit trail data on each system.

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