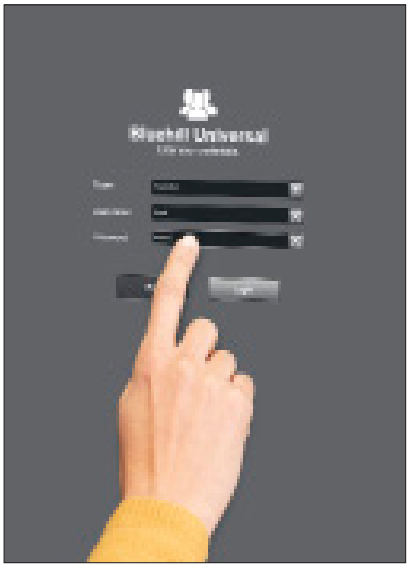
INSTRON®

The difference is measurable®

DATA INTEGRITY & BLUEHILL TRACEABILITY

Creating a More Efficient Lab

Within the biomedical industry, the concept of data integrity is foundational to the quality programs driving the product manufacturing. Globally, there are numerous regulatory frameworks aiming to define how data integrity is ensured, whether dictated by the FDA, GMP, or other international/national body. Even when solely serving a local market, internal quality requirements should promote processes designed with data integrity in mind. During required inspections, data credibility is a key component of the regulator's assessment and will determine whether the facility is deemed compliant or not. Addressing the challenges of data integrity with Bluehill Traceability can not only help maintain compliance with regulatory requirements but enable the lab to operate more efficiently and with greater confidence in their results. By utilizing Bluehill Universal with Traceability, labs can more easily navigate or bypass common data issues, and lab managers can maximize their efforts spent on value-added activities.



Does your lab struggle with keeping track of operator permissions and ensuring the appropriate access rights to testing software?

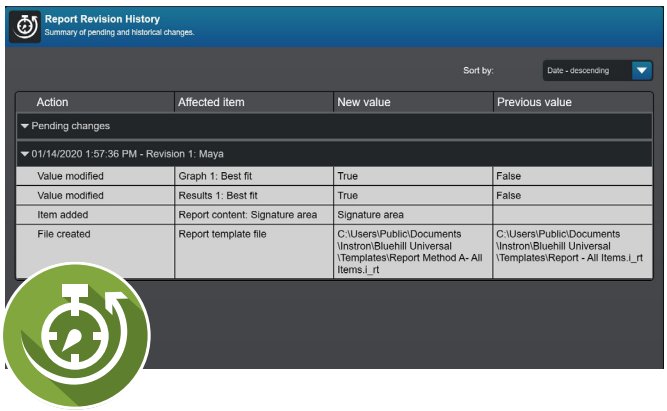
Potential Issue: Manually tracking and setting user permissions for each operator on each system is tedious, and time consuming for lab managers of a lab manager. Especially if employee turnover is frequent, or multiple groups use the same piece of test equipment, changes can be made to a validated method or test results can be altered by somebody with the wrong permission settings.

Efficiency Improvement: The built-in security of Bluehill is flexible, even allowing for use of Windows Active Directory user management. This functionality means additional passwords and logins are not required and any IT driven password management can continue to be handled by IT. Users can be structured into user groups, with shared permissions settings defining their accessibility to the software. Technicians can be limited to running samples without any edit privileges, while lab managers can have full access depending on their specific needs.

Does performing manual sign offs on test results and method changes slow down lab throughput?

Potential Issue: Most labs implement multi-check systems for results sign off to improve accountability and mitigate the chance of mistakes being made. Paper sign offs are inherently insecure and cannot be validated through password protection. They also require physical handoffs, taking additional time away from testing.

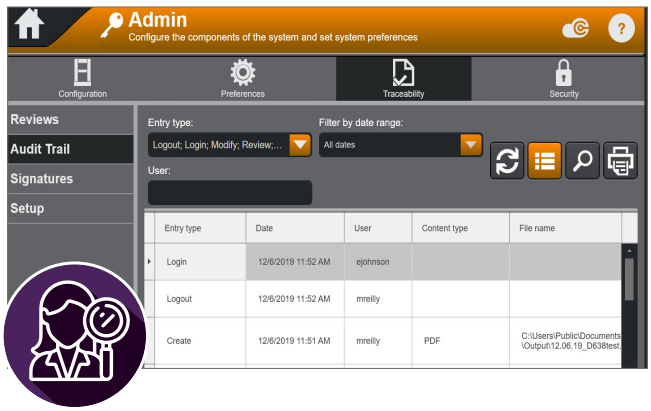
Efficiency Improvement: Electronic signatures can be required upon completion of a sample or of a method, automatically prompting the user to enter their credentials and an optional comment about the changes. User permissions also define the ability to add secondary or tertiary signatures, providing lab managers a dashboard in the software to see pending approvals. Once approved, the method changes will be validated, and the method can officially be used. Or if approving a sample's results, an electronic signature is appended to the PDF test report. This workflow reduces the time required to move documents to approved states and decreases the likelihood for unintended approvals.



Does your lab spend excessive time trying to identify the root cause of changes in results?

Potential Issue: Even the smallest accidental change made to a method, such as a test speed reduction or a calculation parameter change, can have significant downstream effects on the results. The change in results may get flagged, but until the issue can be found, product will not be able to be shipped and the company will lose money.

Efficiency Improvement: Revision history is a feature that provides detailed logs outlining any changes that were made, who made them, when they made them, and what the previous value was. These logs will track method, sample, and report files, providing an unparalleled amount of visibility into changes. This level of information means identifying issues can be done quickly, minimizing downtime.



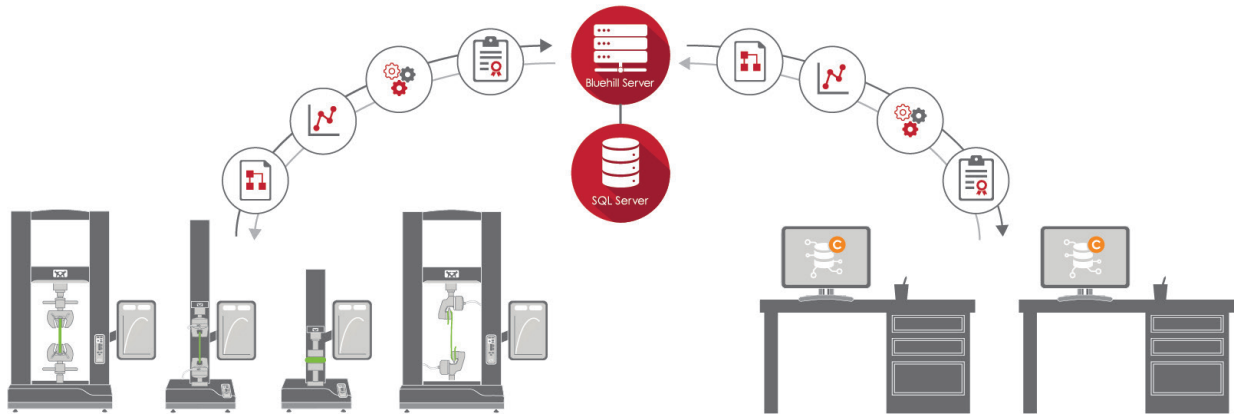
Is finding necessary data for an audit a painstaking process, requiring manual searching through paper files or a complicated third-party software solution?

Potential Issue: Audits are an inevitable part of bringing a product to market and failures can cause significant delays and additional costs. Identifying specific results related to a specific batch or the introduction of a new material will be required, and any issues or delays with obtaining this information can erode the auditor's confidence in the lab's data management system.

Efficiency Improvement: The searchable audit trail within Bluehill allows the lab manager extensive visibility over their test system, able to quickly pull results according to criteria ranging from the operator to the specific date. Additionally, the audit trail can be triggered for backups within the software to prevent any unexpected loss of data. This level of visibility also helps lab managers visualize the usage of the systems over time.

LOCAL vs NETWORKED

Depending on the size of your lab, the use of a local traceability system could become burdensome over time. With a local setup, settings need to be created and maintained on the individual system level and all necessary signoffs must be performed at the system. If using multiple frames with many operators a networked solution like Bluehill Central would provide the most tangible benefits, allowing all user settings, sign offs, and audit trails to be visible from any networked location that has the Bluehill Central application. Ultimately, this solution provides the highest level of visibility and oversight for a lab manager, allowing them to make changes and perform administrative tasks from their desks, without requiring downtime of the system.



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