Advanced
Validation Solutions

Validation Guru
Ensuring quality through knowledge and intelligence

Blood Bank Validation Solution for Cerner Millennium™

Quality assurance for **your blood bank system**

Quality assurance for your blood bank system

Frequent testing of your blood bank transfusion systems is critical to patient safety. But it can take a heavy toll on your organization's resources—especially given the growing complexity of blood bank applications.

Validation Guru's solution for validating blood bank transfusion is designed for unparalleled ease, coverage and speed of validation testing. The benefits: vastly improved cost-efficiency and truly comprehensive assurance of patient safety.

Featuring a revolutionary Scenario Definitions solution and a library of client-specific workflow scenarios developed by specialists highly experienced in FDA, AABB and CAP procedures, Validation Guru frees you from having to wait on consultants for validation or pay exorbitant recurring fees. Validation Guru's intelligent technology adapts automatically to updates and enhancements to your system, so there's no need for ongoing programming or scripting.

Our Blood Bank Validation conforms with the validation testing elements required under FDA, ISBT, AABB, EU and Australian guidelines, and is packed with useful features.

Our features include:

✔ **Full digital signature capabilities**

✔ **Test-case cross reference for Pass and Fail reports**

✔ **Error causal analysis and remediation guidance**

✔ **Comparison of database build and test result data**

✔ **Build content comparison through migration between Environments**

✔ **Enterprise-wide result set access, management and defect tracking**

✔ **Patient-safety assessment of your system**

Patient/Unit Compatibility
Validation

The Challenge

Managing the risk that comes with giving blood products to patients requires setting up patient/unit compatibility rules, a process that's complex and labor-intensive. A single setup error along the way can corrupt the accuracy of the rule processing—and compromise patient safety.

How We Help

Validation Guru can help your organization make sure that only appropriate blood products are dispensed. It can quickly, automatically test thousands of patient/product rules, identifying every combination of blood product type and patient type. After each rule has been reviewed and accepted, Validation Guru compares the application response for every combination of each blood product against all patient ABO/Rh types, including the emergency dispense.

Validation Guru automatically processes the product receive, unit confirmation testing and, if necessary, the ordering and resulting of the appropriate crossmatch procedure. At the end, you get a Pass and Fail report showing which combinations matched the expected response and which didn't.

Blood Bank Interpretations
Validation

The Challenge

Resulting tests within the blood bank system is done using interpretations through the blood bank result entry application. Testing the accuracy and reliability of these interpretations is a laborious and complicated process, but one that's essential to patient safety—and mandated by regulatory agencies accordingly. But due to the size and complexity of the interpretations setup, performing ample testing manually is next to impossible.

How We Help

Validation Guru can easily test thousands of interpretation combinations in the blood bank system. It can compare the system response for every combination of all individual reaction results against the expected interpretation, verifying the application warnings as necessary. Due to the sheer magnitude of combinations available, Validation Guru allows individual procedures, groups of procedures or combinations of procedures to be processed.
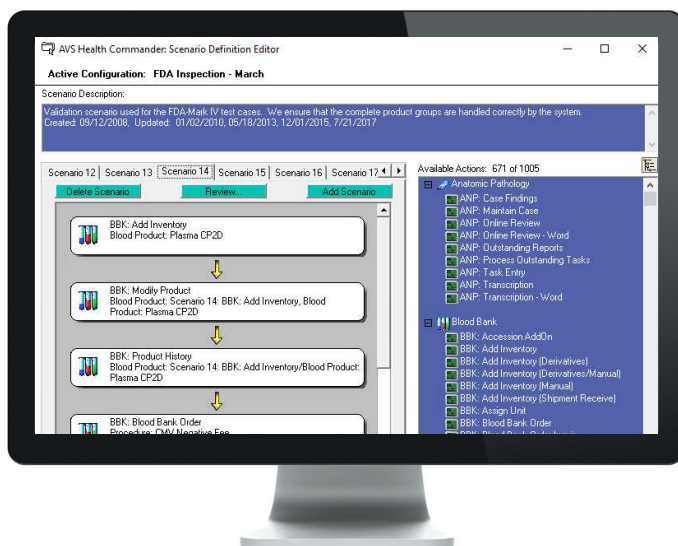
As Validation Guru reviews the system, it will determine the valid responses and then determine what types of mistakes are possible when reaction results are entered. From this it determines the expected response in every case. Validation Guru then processes each interpretation combination through the blood bank result entry application, entering the appropriate response for each part of the results reaction, and continually evaluates the application's response to see if it's correctly matching valid interpretations. Any unexpected outcomes are reported.

Features That Go Beyond Regulatory **Requirements**

Validation Guru's flexible Scenario Definition System and robust Defect Tracking and Risk Management features are designed to help you improve the quality and safety of your systems over time.
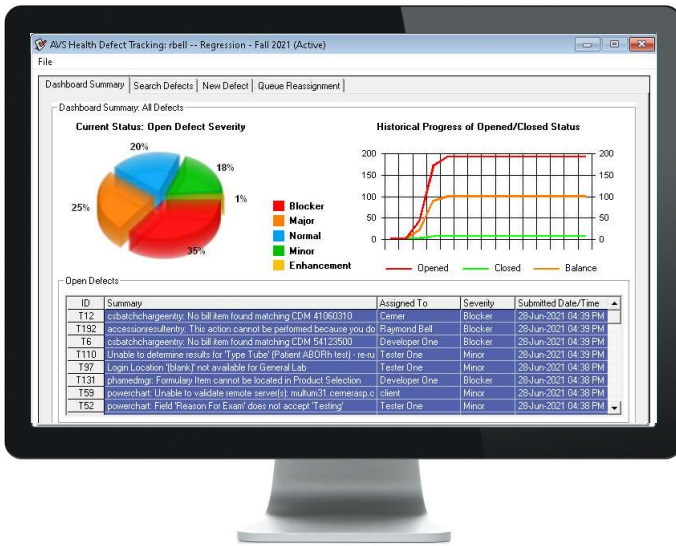
Scenario Definitions System

The Validation Guru Scenario Definitions system can build flexible process flows that replicate actual processes in the Cerner Millennium system. For example, a process flow could include pre-admitting a patient, registering the patient, placing an order, canceling the order and discharging the patient. Many areas outside of blood bank, such as the (Patient Administration System) PAS can be tested in this manner, since these areas do not follow rigid workflow rules. All areas within the Cerner Millennium system can be tested in this manner to perform any type of workflow.

Scenario Definition System
Validation Guru allows virtually any process flow to be defined, replicating actual processes in the test system.

Included Defect Tracking

The AVS Health Defect Tracking system ensures that any issues encountered can be tracked from testing right through to resolution—and never get lost along the way. The Defect Tracking system is integrated with the Validation Guru test results sets, so any issues in any test can be easily added to the defect system. Manual testing results can also be submitted, so all testing can be recorded and tracked in one place.
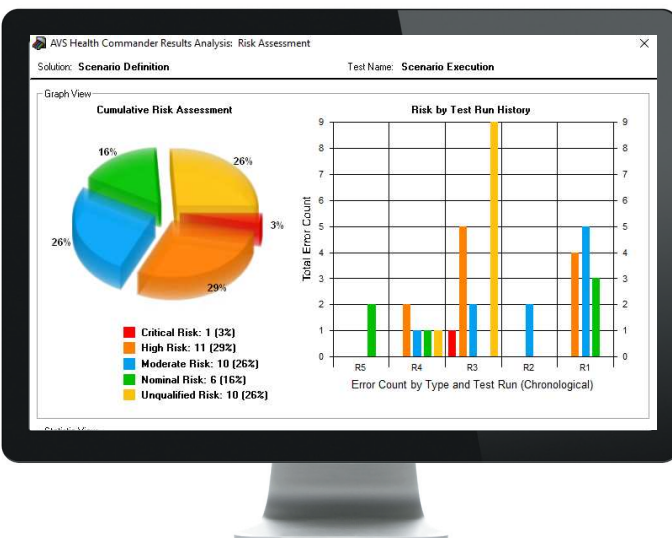

Seamless Defect Tracking
Both manual and Validation Guru results can be easily tracked through all test cycles.

Risk-Based Quality Management

Validation Guru's Risk-based Quality Management module, included with every Validation Guru installation, provides a straightforward and comprehensive way to prioritize testing and error remediation according to the level of safety risk. Each error encountered during testing is thoroughly analyzed and assigned a specific risk level, ranging from critical patient safety down to nominal. Testing cycle activity can then be prioritized based on level of risk, and protocols established for re-testing to verify that errors have been remediated.

Comprehensive Risk Management
Validation Guru analyzes and classifies the patient safety risk of each error, so you can prioritize error remediation.
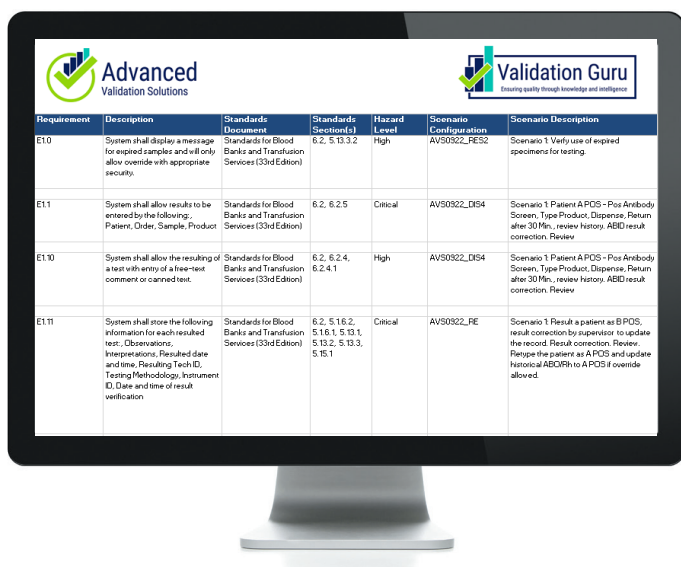
Comprehensive, Efficient Blood Bank
Validation Services

If you don't have the internal resources to run regular system validations with Validation Guru, our expert team can help. Our Blood Bank Validation service extensively covers all areas of the blood bank system—doing more than just "checking the box"—and conforms with the validation testing elements required under FDA, ISBT, AABB, EU and Australian guidelines. We provide comprehensive documentation with each test.

Our features include:

✓ **Screen image captures** for every validation workflow action.

✓ **Digital signature support** for test results review.

✓ **Large scale validation and verification of the scenario patient workflows,** Patient/Unit Compatibility rules and Interpretations (result reactions), covering thousands of combinations.

✓ **The operational qualification validation scenario workflows** are mapped directly to compliance requirements, so a regulatory inspector can identify exactly where and when specific functionality was validated.

Results Mapped to AABB Requirements
The spreadsheets provided after each test show exactly where each and every AABB requirement has been tested.

Put Validation Guru to work **for your organization**

We look forward to helping you ensure that your Blood Bank systems are at their best, so you can deliver care with confidence.

To learn more about us:

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AVS Health Health: Your true partner in improving patient care
Testing and validation technology is what we do at AVS Health.
But what's at the heart of our mission—and always has been—is
a passion for helping healthcare organizations save and improve
their patients' lives.

For more than three decades, For more than three decades, AVS Health has provided quality
assurance solutions for organizations around the world. We're a close-knit team, with deep and
extensive experience in the testing technology and healthcare worlds. We look forward to talking
with you about your quality assurance needs, and how we can help.

Ensuring quality through knowledge and intelligence.

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