



WHITEPAPER

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A Comprehensive Regression Testing Strategy for LabVantage Implementations

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Executive Summary

In the fast-evolving world of laboratory information management systems (LIMS), change is inevitable. LabVantage implementations often unfold in phases, each bringing new capabilities to enhance efficiency and compliance. However, with every improvement comes a hidden challenge: ensuring that the existing, validated functionalities remain intact. Regression testing becomes the unsung hero in this journey - the safeguard that ensures yesterday's successes aren't broken by today's innovations. This white paper takes you inside a robust, risk-based regression testing strategy tailored for LabVantage, blending best practices, automation, and regulatory compliance into a cohesive approach.

1. Introduction – The LabVantage Journey

Imagine your LabVantage LIMS as a living organism - constantly growing, adapting, and responding to the changing needs of your laboratory. Each new phase of implementation introduces fresh features, process optimizations, and integrations. Yet, this evolution can bring unintended side effects. A change in one module may ripple through the system, subtly impacting another. Regression testing is the disciplined process of catching these ripples before they reach production. It's the final checkpoint where innovation meets stability.

2. The Strategy – Building a Safety Net

2.1 Identifying Impacted Elements

When the curtain falls on a new implementation phase, the first order of business is discovery: Which parts of the system have changed? This detective work involves combing through change logs, cross-referencing with Design Specification (DS) documents, and interviewing key project members. The goal is to create a clear, prioritized list of components potentially affected and outline the impact and risk involved.

2.2 Test Case Reusability

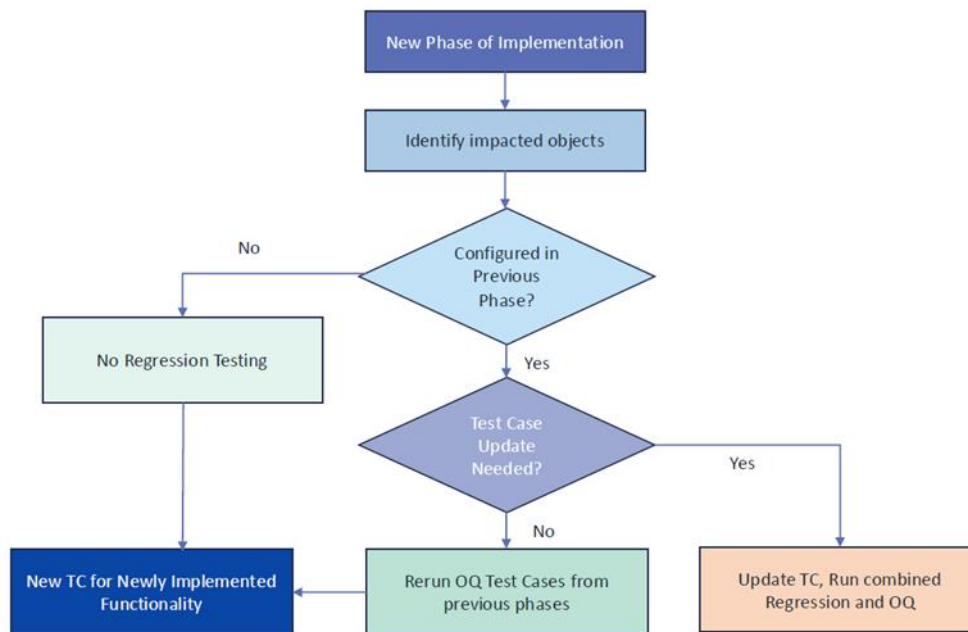
There's wisdom in reusing what's already proven effective. If an impacted element was previously configured and validated, its Operational Qualification (OQ) test cases can be rerun. This saves both time and resources, while preserving consistency and trust in results.

2.3 Updating Test Cases for Enhanced Functionality

Enhancements are double-edged swords - they bring value but alter the familiar. Updated features require updated test cases. These revised scripts become part of a combined regression and OQ execution, ensuring that both old and new work in harmony.

2.4 Risk-Based Testing

Not all changes are created equal. Some are high-risk, others barely a whisper in the system. A risk-based approach ensures that the most critical and vulnerable functionalities receive the most - or even all the - attention. This is where quality meets efficiency.



Graph1: Best practice Regression Test process

3. Automation – The Accelerator

Automation transforms regression testing from a labor-intensive chore into a streamlined, repeatable process. In LabVantage, two automation paths often stand out - Selenium and Leapwork - each with its strengths and trade-offs.

3.1 Selenium-Based Automation

Selenium offers freedom and flexibility with no licensing cost. Its customization potential is unmatched, backed by a global community. Yet, it demands programming expertise and a significant initial setup effort.

3.2 Leapwork-Based Automation

Leapwork trades code for convenience. Its drag-and-drop interface and AI-assisted recording open the door for business users to engage in automation. The trade-off? Licensing costs and a learning curve for optimal use.

3.3 Long-Term Benefits

Regardless of the tool, automation pays dividends over time - faster execution, higher accuracy, and unwavering repeatability. It becomes the silent, always ready guardian of system integrity.

4. Navigating the Regulatory Landscape

In regulated environments, automation doesn't escape oversight. While automated tools generally do not require full validation, they must undergo a documented assessment of adequacy before use. This aligns with industry guidelines.

Key Guidance Highlights:

- GAMP5 promotes a risk-based approach to tool qualification.
- ISPE GAMP RDI notes that incidental tools only need adequacy documentation.
- EU Annex 11 Section 4.7 requires documented adequacy assessments for automated testing tools.

5. Recommendations for Success

A winning regression testing strategy for LabVantage should be adaptable, risk-aware, and automation-enabled. Key actions include:

- Tailor the strategy to your organization's needs.
- Choose automation tools aligned with skills, budget, and objectives.
- Maintain a baseline regression suite for future reuse.
- Apply risk-based prioritization to optimize efforts.

6. Conclusion – Balancing Change and Stability

In the LabVantage world, change is inevitable, but instability is not. With a well-structured regression testing strategy, organizations can embrace innovation without sacrificing reliability & compliance. Automation and risk-based testing transform regression from a burden into a strategic advantage - allowing laboratories to move faster, with confidence.

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Our expertise lies in delivering specialized consulting services, primarily centered around Manufacturing Execution Systems (MES), Laboratory Information Management Systems (LIMS), seamlessly integrating these Level 3 systems with Enterprise Resource Planning (ERP) platforms and driving Manufacturing Intelligence initiatives such as Overall Equipment Effectiveness (OEE) reporting.

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Thinking about taking your next steps towards the digitalization journey? We are ready to support you! Contact us under ReachUs@frontwell-solutions.com or via +49 (6101) 595 89 85.