



WHITEPAPER

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Introduction

The pharmaceutical industry is evolving through a rapid digital transformation driven by increasing regulatory expectations, growing product complexity, and the need for greater transparency across manufacturing operations. Manufacturing Execution Systems have become a central pillar of this transformation, enabling real time process control, electronic batch recording, and robust data integrity across the product lifecycle. As a result, upgrades of established MES platforms are critical and compliance relevant transformations.

Within this context, upgrading from PAS X V2 to PAS X V3.3.2 represents far more than a cosmetic or technical system update. The new version introduces new system capabilities, different functional patterns, and tighter expectations on data integrity and electronic batch execution. At the same time, manufacturers cannot afford long verification cycles, duplicated effort, or uncertainty about whether migrated Master Batch Records (MBRs) are truly fit for use in the new environment.

Regulators and industry guidance consistently point toward risk based, proportionate approaches for computerized systems, emphasizing that compliance must be achieved efficiently, not through document inflation.

This project demonstrates how a structured, template driven verification approach for 64 MBRs and 2 GMBRs transformed a complex PAS-X migration into a controlled, scalable and economically sound process employed at a large, multinational science and technology company headquartered in Germany.

The Challenge: One Upgrade, Many Risks

The client used existing PAS-X V2 MBRs as the functional reference for PAS-X V3.3.2. On paper this migration sounds simple. In practice, the gaps were clear:

- System level differences between V2 and V3.3.2 changed how functions, checks, parameters and user interactions were implemented.
- Each migrated MBR risked silent deviations: missing checks, misaligned limits, or misunderstood platform capabilities.
- Traditional one-off verification per recipe would have led to:
 - Repeated interpretation work for every MBR.
 - Long review and approval cycles.
 - High QA workload with limited transparency.
 - Increased probability of late rework before go-live.

The risk was not only non-compliance, but slow time to effectiveness, high internal cost, and a fragile foundation for future changes.

Our Approach: Industrializing MBR Verification

Instead of treating each MBR as a standalone verification problem, the team implemented a standardized verification model built directly on the client's QMS and SOP framework.

One verification template, two purposes

A single structured verification document was designed in tabular form, combining a predefined set of generic checks that apply to all MBRs and GMBRs (core PAS-X V3 behaviour, data integrity, standard functions) and dedicated sections reserved for system driven functional differences between V2 and V3.3.2 as well as concrete change requests and process specific adjustments.

This template was split logically into a plan part and a report part, within the same structure making it easier to see what was intended to be verified and how the verification was performed, side by side.

Plan-Driven workflow

Before any testing started:

- The plan sections were populated using the PAS-X V2 MBR as the reference.
- All relevant changes and checks were clearly documented, including where V3 features replaced or enhanced V2 behaviour.
- The plan entered a formal approval workflow (technical review, author review and QA review).

Only once the plan was approved did the review and test execution start. This approach prevented ad hoc testing, avoided misaligned expectations, and stopped rework before it started which aligns with risk-based life cycle thinking promoted in GAMP, where clarity and proportionality up front reduce downstream testing and documentation waste.

Focused verification for clear outcomes

Execution followed the approved checkpoints exactly:

- Each item was verified against the migrated MBR.
- Deviations or mismatches were documented directly in context, with rationale.
- If required, the MBR was corrected and the relevant checkpoints reverified.

The report section then went through the same streamlined approval route. Once approved, the MBR was demonstrably fit for intended use in PAS-X V3.3.2 and ready to be set effective.

Across all 64 MBRs and 2 GMBRs, this standardized strategy created a repeatable engine rather than 66 separate verification stories.

How This Reduced Time, Cost and Operational Risk

Less reinvention, more reuse

Using one common template with fixed generic checkpoints meant that test concepts no longer had to be redesigned for each individual MBR. Project members were onboarded more quickly because expectations and structure were clearly visible within a single, consistent framework. QA and management reviewers always encountered the same document layout, which significantly shortened review times and reduced clarification loops.

This approach mirrors broader MES practice where standardized electronic MBR management shortens approval cycles and reduces documentation effort by increasing consistency and transparency across large MBR portfolios.

Value translation:

- Fewer hours spent on planning per recipe.
- Less time per review cycle.
- Lower risk of missing critical checks across the portfolio.

Targeted effort on real changes

By separating generic checks from specific system and process changes, verification effort concentrated on what differed between V2 and V3.3.2 or what was newly requested.

This is directly aligned with modern risk-based verification and Computer Software Assurance logic: focus depth where there is change and risk, not where behavior is unchanged and already proven.

Value translation:

- Testing volume stayed proportionate.
- Avoided bloated scripts for low-risk areas.
- Freed senior resources to focus on critical functions and edge cases.

Fewer approval bottlenecks

Because both the plan and the report followed the same transparent structure, approvers knew exactly where to find the scope, the delta to PAS-X V2, and the evidence and rationale for any deviations. This clarity reduced email back and forth, parallel document versions, and late questions during review. For a large MBR package, this cumulative reduction in delays becomes highly significant.

Value translation:

- Shorter lead time from modelling to effective status.
- Smoother alignment between production, QA, and IT.
- Earlier productive use of PAS-X V3.3.2 functions, which means earlier realization of MES benefits such as reduced errors.

Lower cost of future change

The standardized verification model does not end with this migration, as it can be reused for new MBRs, future enhancements, and rollouts to other sites. It establishes a documented and defensible pattern that is robust during audits and inspections. As a result, every subsequent change benefits from existing checklists, well-defined approval pathways, and clear traceability from requirements through the recipe to the supporting evidence.

Value translation:

- Reduced marginal cost per additional MBR or site.
- More predictable verification timelines.
- Less dependency on individual heroics and tacit knowledge.

Conclusion

MES upgrades are often seen as unavoidable cost. This project turned the verification of 64 MBRs and 2 GMBRs into a structured asset.

By combining:

- A single, robust template,
- Risk based focus on deltas,
- Early alignment through formalized plan approvals,
- And disciplined execution and reporting,

the client reduced nonvalue adding activity, accelerated readiness of recipes in PAS-X V3.3.2, and laid down a reusable framework for ongoing digitalization.

In an environment where regulatory expectations, data integrity scrutiny, and competitive pressure continue to rise, structured verification like this is not only good practice. It is a direct lever for faster time to market, leaner operations, and more reliable manufacturing performance, fully in line with leading guidance and MES vendor capabilities.

Our Company

FrontWell Solutions is an expert in the digital transformation of the pharmaceutical manufacturing process. Our team of experts is engaged in providing digital solutions to 12 of the 20 leading pharmaceutical, biotechnology, chemical, and medical device companies and suppliers spanning Europe, the United States, and Asia. Our expertise lies in delivering specialized consulting services, primarily centred 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.

Next Steps

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