GMPPros

CASE STUDY

How GMP Pros **Blueprint** Process Accelerates ROI

Fully Integrated eBR Accelerates MES Deployment, Reduces Costs, and Saves Time

EXECUTIVE OVERVIEW

A multi-area pharmaceutical manufacturing site executed Phase 2 and Phase 3 of an enterprise eBR transformation spanning manufacturing and packaging operations, including primary container filling and secondary packaging. The deployment environment included multi-process manufacturing trains, multiple production process locations, coordinated material management between areas, segmented production staff working with shared records, full equipment management (usage status, line clearance, cleaning, and campaign control), cross-area data dependencies, and multiple SKU configurations within each operational area.

Through a structured GMP Pros Blueprinting and Business Change methodology, deployment cycle times were reduced from 8–9 months to 6 weeks. Go-live issue volume was reduced by 90%, stabilization windows were shortened, and recurring oversight exposure was eliminated.

QUANTIFIED DEPLOYMENT IMPACT ON TIMELINE ACCELERATION

METRIC	BEFORE BLUEPRINTING	AFTER BLUEPRINTING
Deployment Cycle Time	8–9 months	~6 weeks
Go-Live Issue Volume	Baseline	~90% reduction
Stabilization Window	Extended Hypercare	~4 weeks reduction
Oversight Cost Exposure	$20–30k/month	Eliminated

CONSERVATIVE FINANCIAL IMPACT (BLUEPRINTING ONLY)

- ~$294,000 internal burn avoidance per deployment
- ~$10,000 (estimate) direct go-live labor avoidance per deployment
- ~$39,000 stabilization compression value per deployment
- ~$150,000 oversight cost elimination (6 months)

Across three areas, conservative, measurable impact exceeds **$1,000,000,** not including throughput acceleration and release timing impact.

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PROJECT CHALLENGE

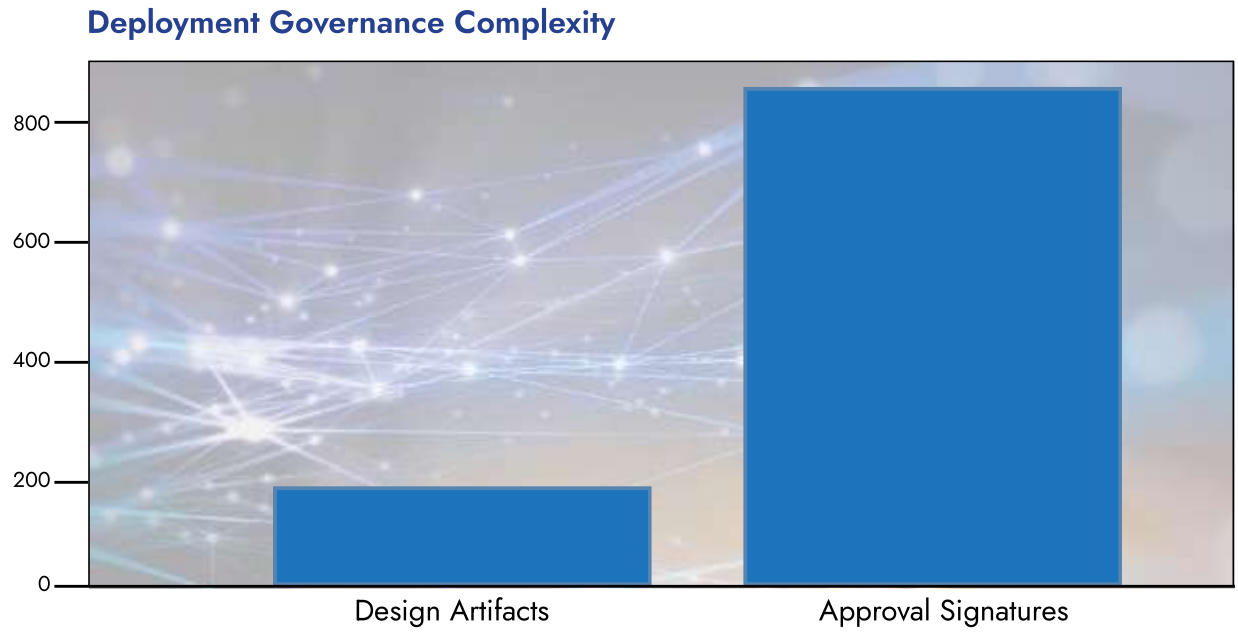
In multi-process, multi-SKU environments with upstream and downstream dependencies, Blueprinting functions as both a deployment accelerator and governance stabilizer. By aligning technical controls with business process before execution, complex eBR deployments were transformed from prolonged, reactive efforts into predictable, scalable execution cycles.

The deployment spanned multiple operational areas, including manufacturing processes and packaging operations involving primary container filling and secondary packaging activities.

Prior to Blueprinting maturity, deployments averaged 8–9 months. Cycle duration was driven not solely by configuration effort, but by iterative design rework, approval cycling, cross-area reconciliation conflicts, equipment state control challenges (clearing, cleaning, campaign transitions), segmented staffing execution, and extended stabilization periods across interconnected production locations.

PROGRAM SCOPE AND COMPLEXITY

- 192 Design Artifacts (GMBRs, PVLs, PMBRs, ESPs) [1]
- 952 Required Approval Signatures1



DEFINITION OF A DEPLOYMENT

For clarity, a 'deployment' represents the full eBR implementation of a discrete operational area — not an isolated record or single packaging configuration

[1] *Totals exclude PQ/ELS defect cycles and additional revision approvals*

MANUFACTURING DEPLOYMENTS ACROSS THREE PRODUCTION LINES

- Process steps: Weigh and dispense, granulation, blending, compression, coating
- Associated material management workflows
- Batch reconciliation logic across upstream and downstream processes
- Material flow governance and exception handling
- Coordinated material management across multiple production process locations
- Segmented production staff executing different stages on the same electronic batch record
- Equipment management including usage status control, line clearance, cleaning verification, and campaign management
- QA review and electronic signature workflows
- Deviation and exception handling configuration
- Validation (PQ/ELS) and operator training

Each manufacturing area supported multiple SKU configurations requiring variant logic, parameterization, and approval governance across product families. SKU configurations were not isolated to individual steps but required synchronized control across upstream and downstream operations to ensure batch continuity and reconciliation integrity.

Packaging Deployments Included:

- Primary filling
- In-process controls
- Secondary packaging operations
- Labeling and reconciliation workflows
- QA release configuration
- Validation and go-live support

BLUEPRINTING AND BUSINESS CHANGE INTERVENTION AND STRUCTURED CONTROLS

- Mapping technical controls directly to business processes
- Alignment of technical equipment state controls with defined business process rules before record configuration
- Standardized cross-area design templates
- SKU variant governance prior to configuration
- Cross-area dependency mapping before record generation
- Line and SKU dedication mapping
- 1:1 vs 1:many vs many:many vs many:1
- Early sponsor and approver alignment
- Embedded business change engagement with operations and quality
- Proactive risk identification prior to go-live

MEASURED RESULTS AND BUSINESS IMPACT

- Deployment Cycle Reduction by approximately 80%
- Go-Live Error Reduction: Approximately 90% reduction in issue volume
- Stabilization Window Compression: ~4-week reduction per deployment.
- Enabled repeatable deployment scaling across operational areas
- Established enduring governance standards for future implementations
- Oversight Cost Elimination: Removal of $20–30k/month exposure.

CONCLUSION: IMPROVED BUSINESS PROCESSES AND OUTCOMES

In multi-process, multi-SKU environments with upstream and downstream dependencies, GMP Pros Blueprinting functions as both a deployment accelerator and governance stabilizer. By aligning technical controls with business processes before build execution, complex eBR deployments were transformed from prolonged, reactive efforts into predictable, scalable execution cycles.

Beyond financial return, GMP Pros Blueprinting delivered durable governance architecture, reduced risk associated with equipment state misalignment (usage, cleaning, campaign transitions), improved coordination across segmented production teams operating within shared electronic records, reduced QA burden, improved operator adoption, enabled parallel deployment, and reduced executive visibility risk.