

Why BLine Suite is built like *enterprise infrastructure* — not a Local application.

A framework-level view of how BLine aligns with proven Enterprise Architecture principles — strategy, application core, workflow, runtime maturity, and extensibility — for evaluation by your technical and procurement teams.

“Why should we trust BLine?”

Trust in enterprise software is not a feeling — it is engineered, layer by layer. Every claim on this page is backed by a mechanism inside the platform, not a marketing line.



Data Integrity

Every record follows ALCOA+ — attributable, accurate, and tamper-evident by design.



Access Control

Role-based permissions, MFA, and session control decide who can see or touch what.



Audit Trails

Every read, write, and delete is logged with who, what, and when — immutably.



Validation

GAMP 5 risk-based CSV with IQ/OQ/PQ documentation, ready for inspection.



Resilience

Automated backups, RTO under 4 hours, RPO under 1 hour — proven, not promised.



Architecture

Five-layer enterprise architecture, not isolated tools stitched together.



PILLAR 01

Data Integrity by Design

BLine's core engine enforces the ALCOA+ principles at the database layer — not as a policy document, but as code: validation rules, locked timestamps, and constraint checks that make non-compliant records impossible to save.



Attributable

Every action traceable to a specific logged-in user



Legible

Structured forms eliminate corrupt or unreadable entries



Contemporaneous

Timestamps are real-time and locked — no backdating



Original

First capture or verified true copy, never a re-creation



Accurate

Front and back-end validation blocks bad inputs



Complete

Partial logs or skipped steps cannot be submitted



Consistent

Sequence-enforced entries — no time-travelling edits



Enduring

Retained, backed up, and protected from silent loss

Security & Access Control

Who can get in, and what they can touch once they're inside — controlled at every layer.



Multi-Factor Authentication

TOTP-based MFA (e.g. Google Authenticator) on every login



Encrypted Credentials

Passwords hashed with bcrypt — never stored in plain text



Role-Based Permissions

Granular control over read, write, create, and delete by role



Session Governance

Auto logout, forced revoke, and full login/logout history



Brute-Force Protection

Login attempts monitored and throttled automatically



Device & IP Control

Static IP locking and device monitoring on regulated networks



Approval-Level Passwords

Critical actions require a second password authentication

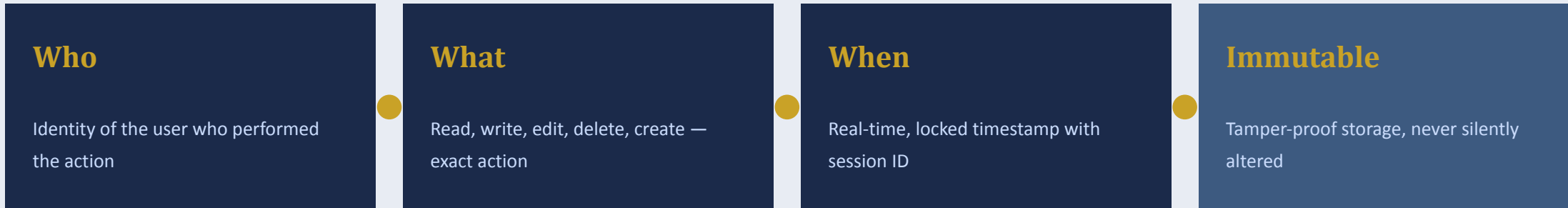


SSL-Encrypted Transit

All data in motion is encrypted, cloud or on-premise

Audit Trails & Electronic Signatures

A continuous, tamper-proof record of who did what, when — and a legally accountable signature on every approval.



Electronic Signatures with Accountability

Prepared → Reviewed → Approved → Cancel — each state change requires a password prompt and displays “I take full responsibility for this action.” The username, timestamp, and approval state are recorded read-only.



Approval increments version automatically



Edits after approval move the doc back to Draft



Every change logged in the audit trail

Validation & Regulatory Compliance

Built against named global frameworks — and validated with documented evidence, not assumptions.

GAMP 5 Risk-Based CSV

- VMP — Validation Master Plan
- URS — User Requirement Spec
- FS — Functional Specification
- IQ — Installation Qualification
- OQ — Operational Qualification
- PQ — Performance Qualification

Delivered as hardcopy documentation with server log screenshots — inspection-ready from day one.

Aligned with Global Regulatory Bodies

USFDA 21 CFR Part 11

EU GMP Annex 11

WHO TRS 996

EMA

MHRA (UK)

TGA (Australia)

ICH Q7

GDPR

HIPAA

Also covers GxP (GMP, GCP, GLP, GDP, GAP, GSP) and PIC/S conventions.

Resilience: Backup & Disaster Recovery

Continuity isn't hoped for — it's scheduled, tested, and measured against hard targets.

< 4 hrs

Recovery Time Objective (RTO)

< 1 hr

Recovery Point Objective (RPO)

Daily

Full backup, plus weekly / monthly /
half-yearly

Quarterly

Backup restore validation, tested — not
assumed

What gets backed up — and how

- ✓ Database backups
- ✓ File store backups
- ✓ Encrypted backup copies
- ✓ Offsite storage



Verified, Not Just Stored

A dedicated Backup Verification Server checks every backup for integrity and usability. Only authorized IT users can access backup keys, and access control governs every recovery step.

Enterprise Architecture: the blueprint behind a reliable system

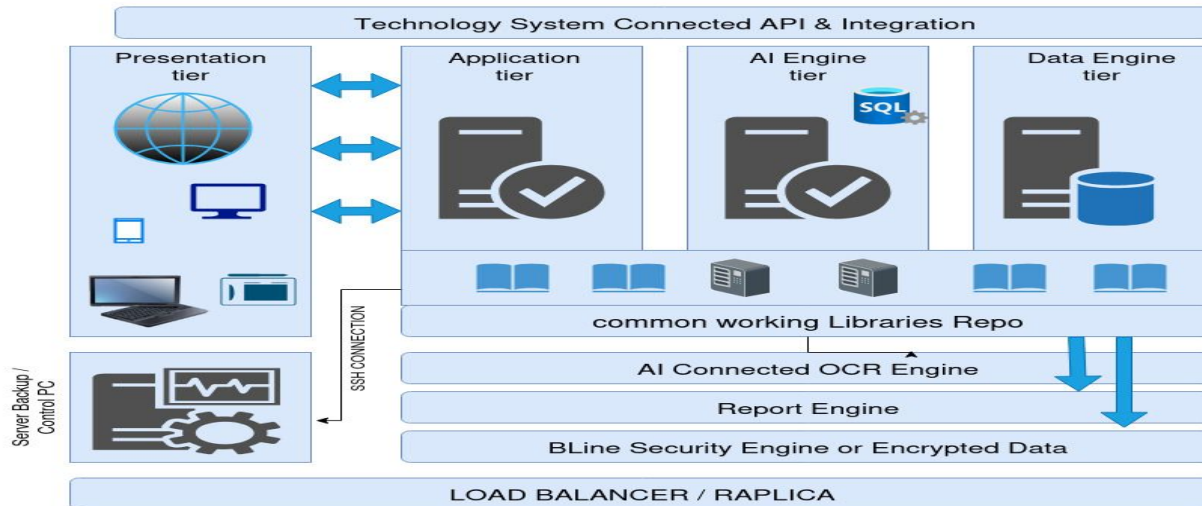
Enterprise Architecture (EA) is the strategic layer that ensures an entire IT landscape stays aligned with business objectives. It acts as the blueprint guiding a platform's evolution — and the reason serious organizations avoid costly misalignment when choosing core systems.



Why this lens matters

Most pharma software vendors are judged only on features. EA evaluation asks a deeper question: will this platform still make sense in 5 years, across 5 plants, under regulatory change?

This document walks through the five pillars used to evaluate any serious enterprise framework — and where BLine stands on each.



Strategic Alignment

Application Core

Workflow Engine

Runtime Maturity

Extensibility

Five layers. One aligned system.

ENTERPRISE ARCHITECTURE

Strategic alignment with business objectives

BUSINESS APPLICATION CORE

Integrated modules across every business function

WORKFLOW MANAGEMENT

End-to-end process modeling & automation

MATURE RUNTIME FUNCTIONALITY

Proven, stable, ready-to-use business objects

EXTENSIBILITY & DEPLOYMENT

Hooks for customization · Cloud or on-prem

Top = strategy. Bottom = foundation. BLine is engineered with all five layers present and connected — not bolted together from disconnected tools.

Business Application Core Suite

The functional layer: integrated modules that manage every area of the business — not a single point tool wearing an ERP label.



API - Application Programming Interface

Electronic batch manufacturing, real-time



Automation Flow

Lab execution & sample management



Master Technical Admin - Enterprise Grade Control

CAPA, deviations, change control



Inbuilt Native Library

FEFO/FIFO, GRN, expiry tracking



IT/OT - PLANT AUTOMATION Protocols

Training records & certification



AI API Server connect Chatgpt and Claude AI

Autonomous material handling

Differentiator: BLine is the only platform in its category combining ERP + MES + LIMS + QMS + OT integration + AI + Robotics under one vendor, one data model.

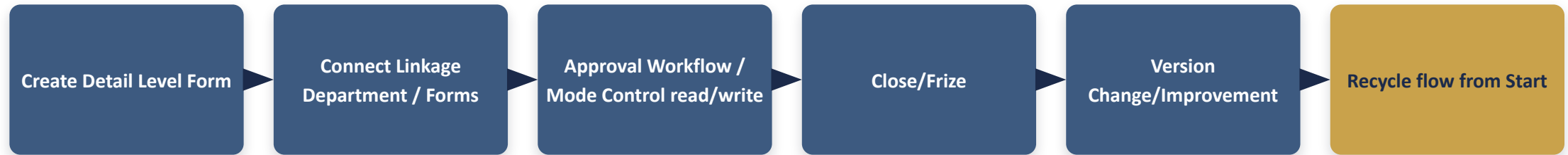
Workflow Management

A mature framework provides a metaphor for modeling and automating end-to-end business processes — not isolated screens stitched together by manual handoffs.



Why this matters for trust

Delays often come from manual handoffs between tools. A native workflow engine removes that risk by design.



One continuous, auditable chain — end to end, with no gaps between departments.

PILLAR 04

Mature Runtime Functionality

A framework must be proven and stable — a catalog of ready-to-use business objects that reflects a deep understanding of enduring business themes, not a system still finding its footing.

Consultancy

Digital Maturity Assessment, ROI modeling, FDA / Schedule-M readiness planning.

Validation

GAMP 5 risk-based CSV — VMP, URS, FS, IQ, OQ, PQ, fully documented.

20 + GMP

Countries guidelines follow

98%

Core success rate

Governed by ALCOA+ data integrity principles:

Attributable

Legible

Contemporaneous

Original

Accurate

Complete

Consistent

Enduring

Available

Proven stability isn't a claim — it's documented, auditable, and inspection-ready from day one.

Extensibility & Customization

A good framework is built to be tailored. It provides hotspots — defined extension points — where custom code can be added without breaking the core system underneath it.



Each connection point is a defined "hook" — your customizations live safely outside the validated core, so upgrades and audits stay clean.

Cloud-native, with the choice still yours

Industry trend is clearly moving toward cloud-native solutions — but enterprise maturity means supporting both, without compromise on validation or control.



Google Cloud Platform (GCP)

- ✓ World-class global infrastructure
- ✓ Automatic failover & redundancy
- ✓ ISO 27001 certified
- ✓ Instant scalability on demand



BLine Private Cloud / On-Prem

- ✓ Dedicated, isolated servers
- ✓ Full data sovereignty control
- ✓ Custom configuration available
- ✓ Fits regulated on-site mandates

Both options ship with the same validated core, same IQ/OQ/PQ documentation, same compliance coverage.

MARKET POSITION

The only unified platform in its category

Most vendors specialize in one function — eBMR, LIMS, or MES — and require multiple vendors to cover a full plant. BLine is engineered as one connected system.

Capability	BLine Solution	eBMR/MES Specialists (Pas-X)	LIMS/Quality Specialists (Calibarr/Spectra)	Global ERP Giants (SAP/ORACLE)	MES Specialists (Rockwell/Siemens)
Pharma-Specific ERP	✓	—	—	✓	—
eBMR / MES	✓	✓	✓	●	✓
LIMS (Lab Mgmt)	✓	●	✓	●	—
QMS (CAPA/Deviations)	✓	✓	✓	●	●
OT Integration (PLC/SCADA)	✓	●	—	—	✓
AI / Omnimind AI	✓	●	●	●	●
Robotics / AGV	✓	—	—	—	—
Single-Vendor Ownership	✓	●	●	—	●

✓ Full native capability ● Partial / third-party required — Not available

Source: comparative capability mapping across major pharma-software categories.

THE TAKEAWAY

BLine isn't a feature list. It's an enterprise architecture.

- ✓ Strategic alignment built into the product roadmap, not bolted on after
- ✓ One integrated application core — ERP, MES, LIMS, QMS, OT, AI, Robotics
- ✓ A real workflow engine connecting every department end-to-end
- ✓ Proven runtime: 99.9%+ uptime, 25+ deployments, 98% success rate
- ✓ Validated extensibility — your customizations, without touching the core
- ✓ Deployment flexibility: Google Cloud or your own private infrastructure