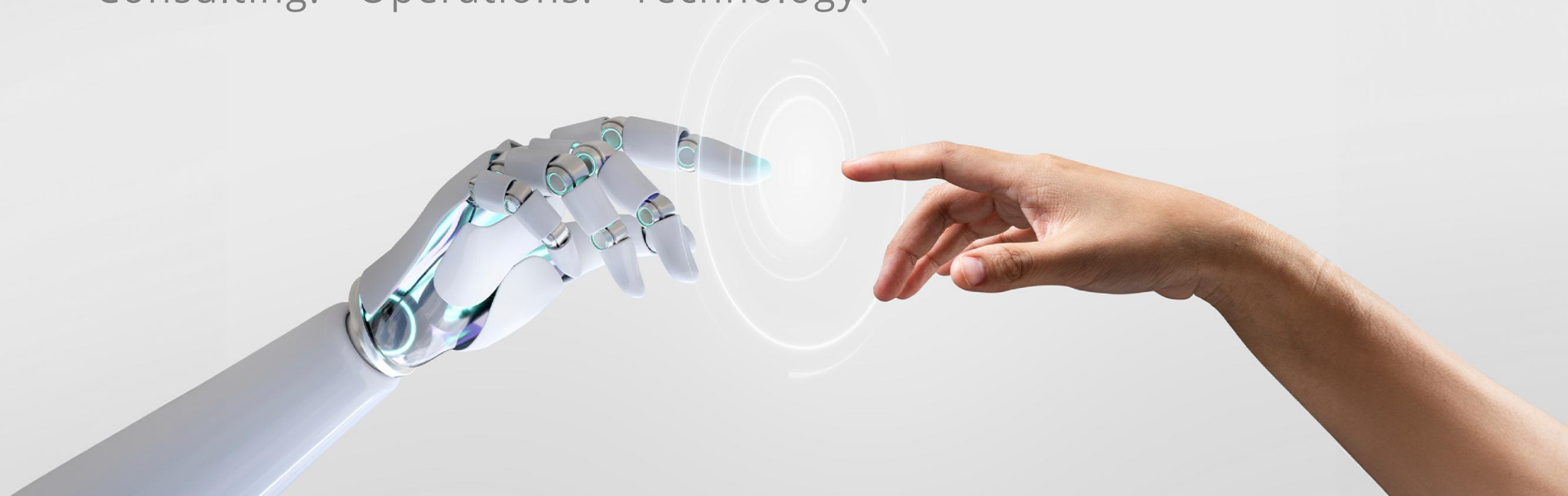


The GxP Operations & Technology Company

Consulting. Operations. Technology.



OUR TECHNOLOGY AND PRODUCTS

PivotOS[®] GXP-READY CLOUD FOUNDATION THAT RUNS EVERY PLATFORM

Foundationally secure and compliant architecture

The operating foundation that powers every platform. Engineered for the strict security, operational, governance, and scale for the Life Sciences sector.

Continuous Audit Readiness

-  Region specific deployment
-  Role based access control
-  Automated backup & DR
-  Continuous monitoring & logging
-  High availability & easy scalability



PivotAI[®]

Model agnostic, logically isolated AI Platform

Every AI feature is assistive, grounded in your approved content, fully audit-trailed and human-reviewed.

-  Your data stays yours
-  Human always decides

Pivot Sight[®]

Turning Big Data into KPIs and Actions

Centralizes structured and un-structured data across the entire organization. Logically connecting every source of data into one data store.

-  Medallion architecture
-  Self-service enablement

21 CFR Part 11

EU Annex 11

GAMP 5

CSV/CSA

ALCOA++

PRODUCTS POWERED BY PivotOS^{AI}



AI⁺

Literature and case review in patient safety.

63% faster reviews · 50% lower FTE overhead



AI⁺

Anomaly detection across manufacturing and quality data.

85% faster detection · 70% less manual effort



AI⁺

Root-cause and CAPA investigations grounded in your records.

60% shorter investigation cycles



AI⁺

Document, training, validation & regulatory intelligence in one platform.

Content authored, reviewed and routed with AI assistance



End-to-end commercialization readiness for launches.

45% more time on strategic activities



Manufacturing execution grounded in GxP compliance.

Shop-floor execution digitized, from batch to release

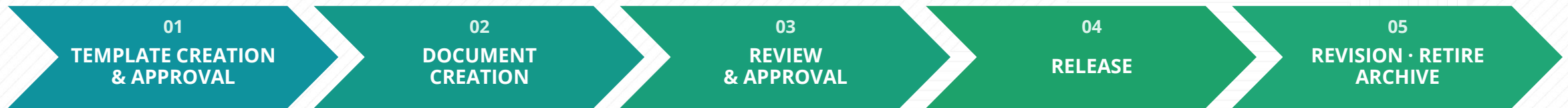


Procurement automation platform.

Requests, approvals and vendor data unified.

AI-powered, audit-ready document management for regulated enterprises

END-TO-END DOCUMENT LIFECYCLE



BUSINESS NEED

- Reduce compliance risk
- Inspection readiness
- Improve productivity
- Single source of truth

Inspection-ready by default.

CORE CAPABILITIES

- Lifecycle management
- Workflow & governance
- Template standardisation
- Integration & review
- Virtual Data Room

AI CAPABILITIES

- Authoring
- Proofreading
- Summarisation

BUSINESS IMPACT

- Audit-ready records
- Faster document creation
- Controlled execution
- Higher user adoption

Faster, configurable deployment.

✓ **ALCOA++ · 21 CFR PART 11 READY**

✓ **TRAINING & PRINT-LOG CONTROL**

✓ **SECURE EXTERNAL COLLABORATION**

Compliance-driven training management with intelligent automation and workforce readiness

TRAINING LIFECYCLE



BUSINESS NEED

- Real-time compliance
- Document-to-training linkage
- Reduced audit effort
- Higher team productivity

CORE CAPABILITIES

- Lifecycle management
- Curriculum management
- Training delivery & scheduling
- Competency management
- Compliance dashboards

AUTOMATION

- AI question generation
- Auto-assignment & alerts
- Role/event-based training
- Annual training calendar

Runs without manual chasing.

BUSINESS IMPACT

- Continuous compliance
- Audit readiness
- Skill readiness
- Minimal manual effort

Inspection-ready, continuously.

✓ UNIFIED COMPLIANCE VISIBILITY

✓ VERSION-CONTROLLED CONTENT

✓ CERTIFICATIONS & AUDIT TRAILS

AI-powered regulatory intelligence from monitoring to compliance action

Automated Workflow



BUSINESS NEED

- Stay ahead of regulatory changes
- Improve regulatory visibility
- Centralize regulatory intelligence
- Scale compliance operations

CORE CAPABILITIES

- Auto-ingestion from 5 leading regulatory authorities
- Smart filtering & routing
- Full Audit Trail
- Task Management & reports
- Structured review workflows

AI CAPABILITIES

- Intelligent tagging
- AI summarization
- Impact assessment

BUSINESS IMPACT

- Faster awareness
- Better compliance visibility
- Reduced manual effort
- Audit readiness

✓ 21 CFR PART 11 COMPLIANT

✓ DIRECT INTEGRATION WITH QMS

✓ AUTO-INGESTION FROM
REGULATORY AUTHORITIES



AI-powered CAPA & RCA platform for consistent, compliant investigations

InvestigationIQ Workflow



BUSINESS NEED

- Standardize investigations
- Improve RCA quality
- Strengthen CAPAs
- Accelerate resolution



SOLUTION

- AI-assisted investigations
- Structured planning
- Intelligent RCA guidance
- Recurrence insights



KEY PROCESS

- Supports 5-Why, Fishbone, Interview & FMEA
- Guided RCA generation
- Knowledge-driven investigations



BUSINESS IMPACT

- 30-50% cycle-time reduction
- 4-7 hrs saved/investigation
- Higher-quality investigations
- Better CAPAs & decisions
- Harmonized reporting

✓ AI GUIDED ROOT CAUSE ANALYSIS

✓ STANDARDIZED CAPA INVESTIGATIONS

✓ ORGANIZATIONAL KNOWLEDGE REUSE



From reactive compliance monitoring to proactive anomaly intelligence

How It Works



BUSINESS NEED

- Real-time quality visibility
- Proactive anomaly detection
- Reduced manual monitoring
- Stronger compliance oversight



CORE CAPABILITIES

- Human error & delayed CAPA closure
- Higher investigation / remediation costs
- Data integrity and regulatory risk



AnomIQ SOLUTION

- Real-time anomaly detection
- Automated routing & workflow management
- Centralized dashboards with unified visibility



BUSINESS VALUE

- 60–70% reduction in manual effort
- 85% faster detection
- Risk reduction, ROI & scalable compliance



REAL TIME ANOMALY DETECTION



AUTOMATED WORKFLOW ORCHESTRATION



UNIFIED COMPLIANCE VISIBILITY

ENTERPRISE-GRADE MES, RIGHT-SIZED FOR PHARMA

Pivot-MES is a lite, modular Manufacturing Execution System purpose-built for growing pharma and life sciences manufacturers enterprise compliance rigour without the cost, complexity or IT footprint.



WHAT IT DELIVERS



eLogbooks

AVAILABLE NOW

Digital equipment, room and activity logbooks replacing paper logs across the entire shop floor — running continuously through every production stage.



eBMR + eBPR

COMING SOON

Electronic Batch Manufacturing and Batch Processing Records for controlled, traceable manufacturing, processing and packaging execution.

BUILT-IN COMPLIANCE CONTROLS

Guided task execution

Process interlocks

Audit trail & e-signatures

Exception reports

Escalation alerts & CAPA

Equipment integration

PLUGS INTO WHAT YOU ALREADY RUN

ERP · PLC & SCADA · Shop-floor instruments · Historian & data lake

WHY PIVOT-MES



Live in weeks

Modular rollout, starting with paper-on-glass.



Compliant from day one

Validated architecture aligned to GxP, 21 CFR Part 11 and EU Annex 11.



No IT burden

Runs without a dedicated IT/OT team, unlike heavy enterprise MES.



Truly connected

Real-time integration with ERP, instruments and shop-floor equipment.



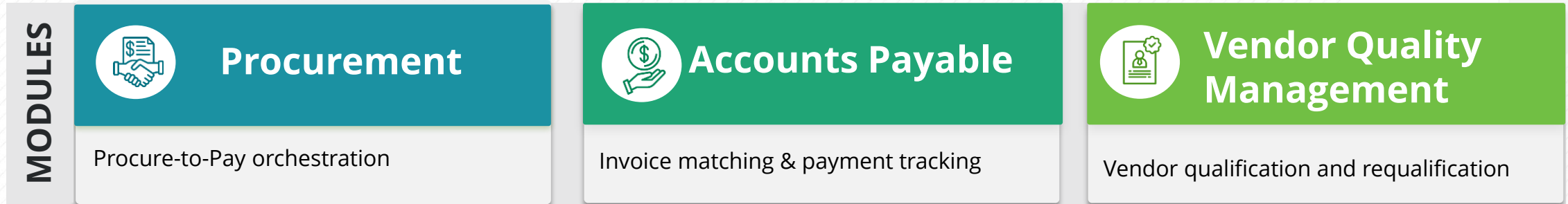
Lower TCO

Right-sized licensing and infrastructure for growing manufacturers.

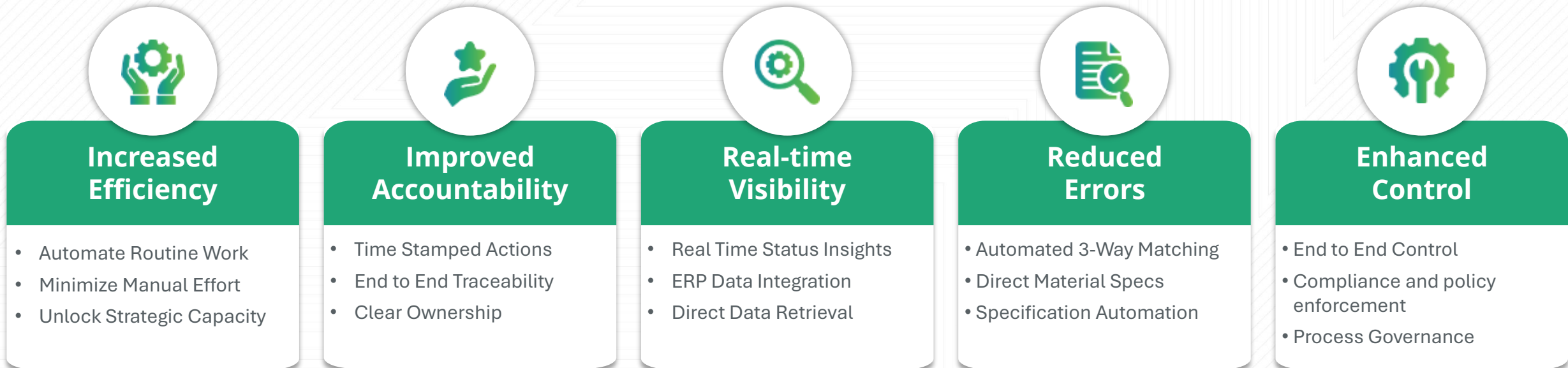
VALIDATED & DEPLOYED YOUR WAY

GxP · 21 CFR Part 11 · EU Annex 11 · Your private cloud or ours

ONE PLATFORM FOR THE PROCUREMENT LIFECYCLE



A unified platform simplifying procurement and connecting stakeholders with vendors



PRACTICE IN VR. PERFORM IN AR.

One SOP library, delivered on every surface: Headset, glasses, tablet and phone, built on digital twins of your exact machines.



LEARN → PRACTICE → PERFORM → REFRESH



HintVR

LEARN · PRACTICE

SOP-level simulation on digital twins of your exact equipment — 90+ validated modules across injectables and OSDs, from dismantling to line clearance.

HTC Vive headset · mobile run-throughs · shop-floor display

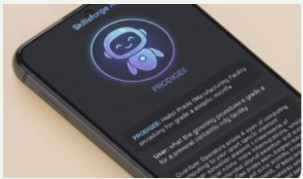


HintAR

PERFORM

Video and text work instructions at the machine, plus hands-free remote assist so an expert can guide any operator, anywhere.

AR glasses, tablet or desktop · optional evidence capture



SkillsForge

PERFORM · REFRESH

Pocket trainer for every shift — five-minute refreshers, case-based podcasts and mock inspections that keep readiness a habit.

Multi-language · voice-first · adaptive assessments

90+ validated modules

21 CFR Part 11 ready

~20% faster changeovers

3x faster training

ONE PLATFORM. EVERY STAKEHOLDER ALIGNED.



Owner & Control

- Drives end-to-end launch execution
- Assigns tasks, timelines & ownership
- Tracks progress in real time
- Ensures on-time delivery



Users

- Provide updates directly into GolanZar
- Own milestone delivery with full accountability



Viewers

- Real-time portfolio view of all launches
- Track on-time vs delayed launches
- Identify risks early with alerts
- Data-driven decision-making

Every Cross-Functional Team



Portfolio



Regulatory



Business Finance



Procurement



Packaging



Planning



Business Development



BD Operations



Manufacturing

From silos to synchronization : GolanZar unites every stakeholder across the launch journey

Pivot Path Private Limited

Demerged Entity of Arcolab

✉ info@pivotpath.com

📍 19/2, SKR Towers, 15th Cross Road, Dollars Layout,
JP Nagar 4th Phase Bangalore – 560078, India



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