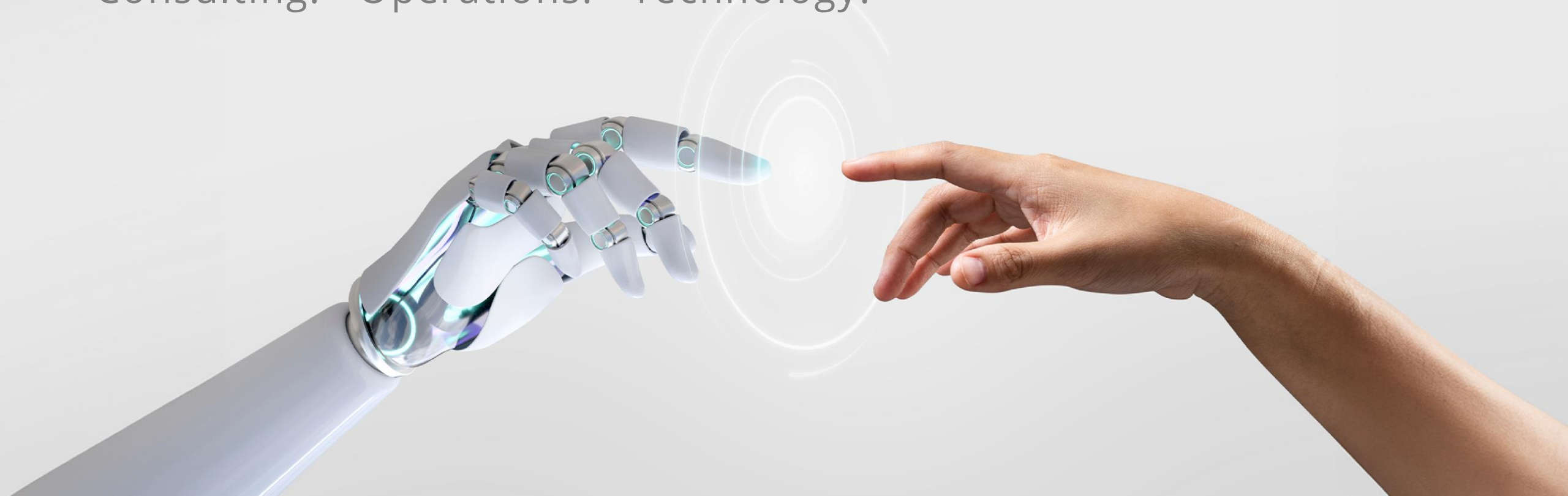


The GxP Operations & Technology Company

Consulting. Operations. Technology.



BORN IN PHARMA. BUILT TO RUN IT.



2019

Born Inside A 35-year-old Pharma Group



2022

Tech-Enabled Value Creation Centre



2026

Demerged As Pivot Path

We combine deep domain expertise with technology across core GxP pillars.

QUALITY & DIGITAL COMPLIANCE

DIGITAL TRANSFORMATION

CLINICAL OPERATIONS

PATIENT SAFETY

550+

PHARMA-NATIVE OPERATORS

40+

GLOBAL CLIENTS

1000+

PROJECTS DELIVERED

160+

AUDITS FRONTED

ISO

27001 & 27701 CERTIFIED

DELIVERING ACROSS



API



Injectables



Biopharma



Oral Dosage



Chemicals



Topicals



OTC Products

EXECUTION ACROSS CORE GXP PILLARS.

Supported by Upstream Advisory & Enabled by Human Capital Practice

Intellectual Property

Product Identification | Patent Landscape & White Space |
Protection & Enforcement | Litigation Support

UPSTREAM ADVISORY

Clinical Operations

Preclinical & BE Studies | Trial Management |
Toxicology & Medical Writing | Ambulatory Services

Quality & Digital Compliance

Prepared For Inspection At All Times

- Computer System Validation
- Equipment Validation
- Quality Assurance
- Compliance Audits
- ISO Certification Consulting
- Standardization Of SOP Landscape
- Shop Floor Excellence Programs

Digital Transformation

One Backbone For The Digital Enterprise

- Data & Digital Strategy
- Digital Manufacturing
- Supply Chain Automation & EDI
- Track And Trace
- RPA, AI, ML, IoT
- Quality Applications
- Enterprise Applications
- AR & VR – Immersive Digital Platform

Patient Safety

End-to-end PV You Can Hand Over

- Global Pharmacovigilance
- ICSR Processing
- Signal Management
- Aggregate Reporting
- Risk Management
- Toxicology Writing
- Medical Information Call Center

Supported by our Technology Platforms



Enabled by human capital practice for Consulting, Digitization & Talent Acquisition

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}



AI¹

Literature and case review in patient safety.

63% faster reviews · 50% lower FTE overhead

AnomIQ

AI¹

Anomaly detection across manufacturing and quality data.

85% faster detection · 70% less manual effort

InvestigationIQ

AI¹

Root-cause and CAPA investigations grounded in your records.

60% shorter investigation cycles

NoteIQ

AI¹

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

Content authored, reviewed and routed with AI assistance

Golanzar

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.

DELIVERING VALUE AT SCALE

OUTCOMES WE HAVE DELIVERED FOR OUR CLIENTS

US-FOCUSED GENERIC PHARMA



50,000+

ICSRs MIGRATED

Legacy Safety Data Migration

Completed in 8 weeks during a 150-ANDA portfolio integration, securing Day-1 continuity.

EUROPEAN INJECTABLE FACILITY



60

DAY POST-M&A DEADLINE

IT Infrastructure Rescue & Rollout

Full IT, SAP and quality infrastructure stood up inside the acquisition window.

INDIAN BIOSIMILAR MANUFACTURER



200

DAY LAUNCH WINDOW

Greenfield IT & Systems Validation

Enterprise IT built, systems validated, 200+ personnel hired against the clock.

GLOBAL MID-SIZED PHARMA



8.5

YEARS EARLY ENTRY

Strategic Market Acceleration

Post-grant opposition filed against a competitor's formulation patent.

CHINESE PHARMA GROUP, SINGAPORE



ZERO

COMPLIANCE ERRORS

Manual Validation Digitized

Workflows digitized for an 8-member team against tight go-to-market deadlines.

LEADING INDIAN CDMO



50+

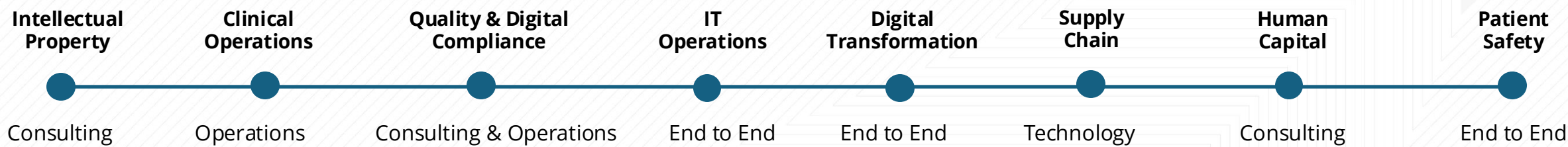
IT PROCESSES AUTOMATED

IT Operations Automation

2× growth absorbed across 4 sites with no additional headcount.

END-TO-END GxP OPERATIONS FOR A FLAGSHIP CLIENT

USD 550M Listed Indian Oral Dosage Pharmaceutical Manufacturer



SCALE

7+	220+	30,000+	2,480+	800+
Global Locations	Cloud & DC servers	ICSR Processing	QMS records / yr	eBMR executions

VALUE DELIVERED

90%	100%	30%	42%	₹30 Mn
Data records digitized through eRDS & eLog	CSV to CSA Migration	Savings through Zero Touch IT Provisioning	Cost reduction through cloud migration	IT cost savings annually

Exclusive Technology Partner for the Client's Global Lighthouse Network Initiative
Designing the world's most advanced factories, which are leading the way in the adoption of Pharma 4.0

POST M&A OPERATIONS STABILIZATION

3 CONTINENTS
SITE TRANSITIONS



SINGAPORE

Manufacturing site • post-acquisition

Managed the post-acquisition transition of a pharmaceutical manufacturing site, streamlining manufacturing processes and standing up digital platforms with complete validation.

CAPABILITIES DEPLOYED

- IT Operations
- Serialization
- Quality Applications
- CSV



EUROPE

Injectable plant • delivered through Covid

Managed the post-acquisition transition of a European injectable plant: end-to-end IT infrastructure, SAP HANA and its integrations, TrackWise, ComplianceWire, Serialization, QC Lab, Darwinbox and Practice League rollout.

CAPABILITIES DEPLOYED

- IT Operations
- CSV
- Quality Applications
- Patient Safety
- HR Consulting & Digitization



AFRICA

Full facility • pre & post-acquisition

Led the pre- and post-acquisition transition of a manufacturing facility - end-to-end handover of critical support and pharma-specific functions, streamlined processes and new digital platforms.

CAPABILITIES DEPLOYED

- IT Operations
- Serialization
- Quality Applications
- HR Consulting & Digitization

OUTCOMES
DELIVERED



Business
Continuity



Scalable & Future-
Ready Systems



Regulatory
Excellence



Cost & Resource
Optimization

DELIVERY APPROACHES



ONE ACCOUNTABLE PARTNER.

You decide how much of the work you own. The accountability sits with us either way.

Pivot Path-run

WE OPERATE

PIVOT PATH

Immediate execution

We run the process end to end and carry the regulatory and audit burden with it.

IDEAL WHEN

You need capacity now, not a hiring plan.

Co-run

WE BUILD CAPACITY

Transitional growth

We deliver alongside your team, handing over knowledge and ownership as it builds.

IDEAL WHEN

You are standing up a team and cannot afford downtime.

Client-run

WE ADVISE

YOUR TEAM

Strategic autonomy

Your team owns delivery. We are the specialist reserve, called in on request.

IDEAL WHEN

Your operation is mature and needs depth, not headcount.

THE MIX CHANGES. THE ACCOUNTABILITY DOES NOT.

Pivot Path Private Limited

Demerged Entity of Arcolab

✉ info@pivotpath.com

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