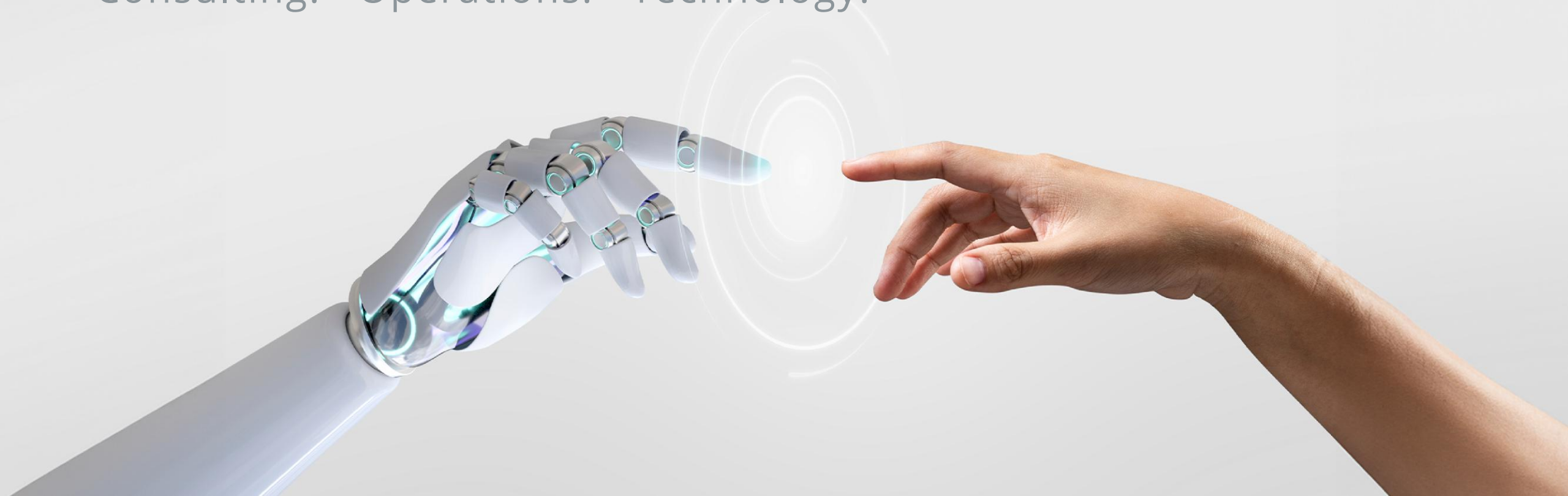


The GxP Operations & Technology Company

Consulting. Operations. Technology.



QUALITY & DIGITAL COMPLIANCE SERVICES

OUR CAPABILITIES - QUALITY & DIGITAL COMPLIANCE

Plan, Build, Run

Integrated Validation Services

Consulting · Operations · Technology

- **One validation practice**
 - What we set up, run and hold — across the estate
- **Computer Software Assurance (CSA)**
 - Migration roadmap, program implementation and automation at scale
- **Validation as a service**
 - The validated state held through upgrades and patches
- **Commissioning, qualification & validation**
 - Equipment, utilities and facilities — same practice
- **Validation management on NotelQ**
 - One record, requirements to qualification

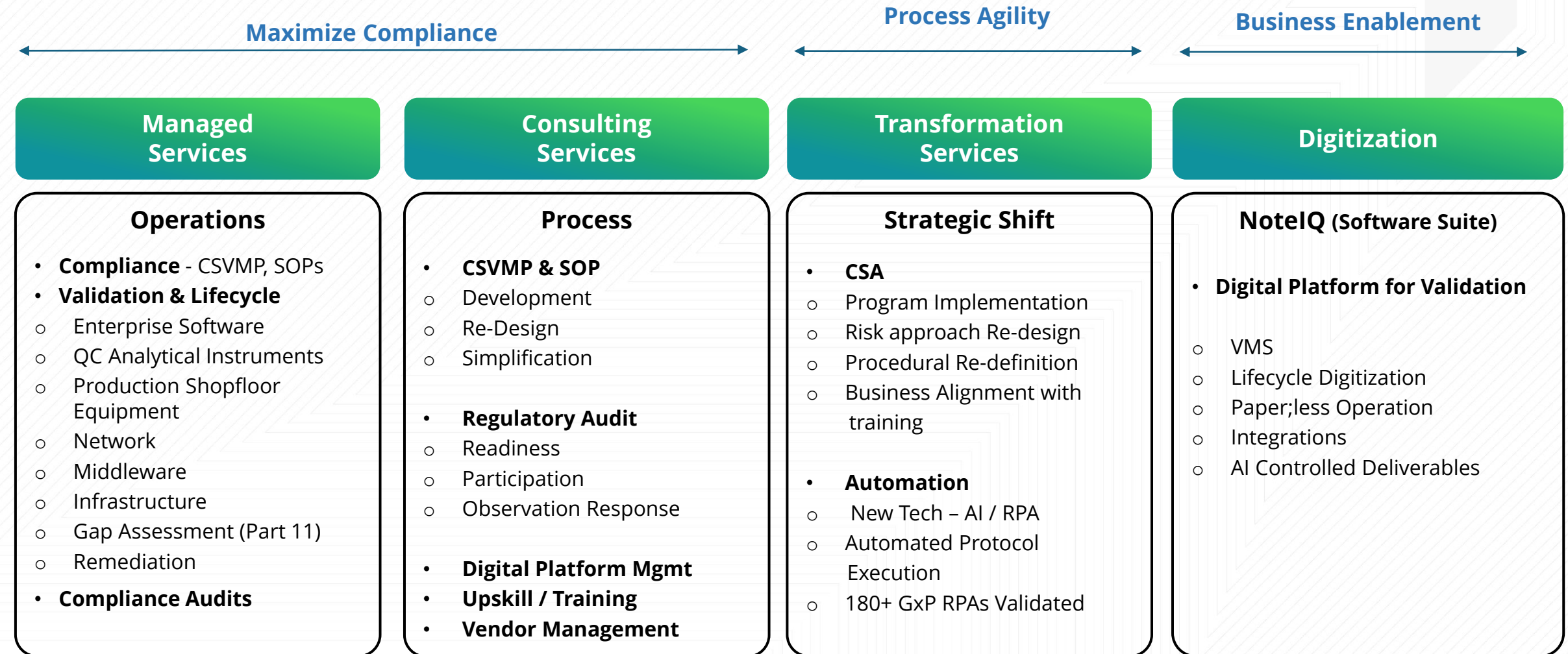
Assure & Protect

Quality Assurance

One programme, four verticals

- **One assurance programme, four verticals**
 - Corporate QA
 - IT QA
 - Medical Affairs QA
 - Pharmacovigilance QA
- **IT QA and data integrity**
 - Regulatory audit prep, ALCOA++, audit-ready evidence
- **Anomaly detection & investigation support**
 - AnomIQ and InvestigationIQ, working together

CSV SERVICES AND SOLUTIONING



CSV SERVICES AND SOLUTIONING

Managed Services



CSV Operations Management
(On-Site / Off-site)



SMEs
(For System and Exp Requirement)



Compliance
(To Effective CSVMP and Procedures)



Maintenance
(IT systems in validated state)



Validation
New Systems
Older Systems - Retrospective



Audit
(Preparedness and Management)



QMS
(Discipline)



Training
(CSV, DI Compliance , CSA)

Capability Span



Enterprise Applications (ERP, MES)



Analytical Instruments (QC N/w and Non N/w)



Production Equipment (SCADA, PLC, HMI)



Network Assessment and Qualification



Engineering Systems (BMS, EMS)



Integrated Systems (Middleware)



DC and DR (Infrastructure)



Gap Assessment (Part 11) & Remediation



Compliance Audits (Internal Audits)

Specialization



Enterprise Applications



IT Compliance



ERES Gap Assessment



Remediation



Network Qualification



Data Assessment Validation

COMMISSIONING, QUALIFICATION AND VALIDATION (CQV)

EQUIPMENT & INSTRUMENT QUALIFICATION

SYSTEM STATE - NEW

Installation & Configuration

- Verify systems for compliance in Applicable Customization, Configurations,..
 - (User Management, Audit Trails, Logs, Usage controls, Security Settings)
- Test Changes and Release Preparation.

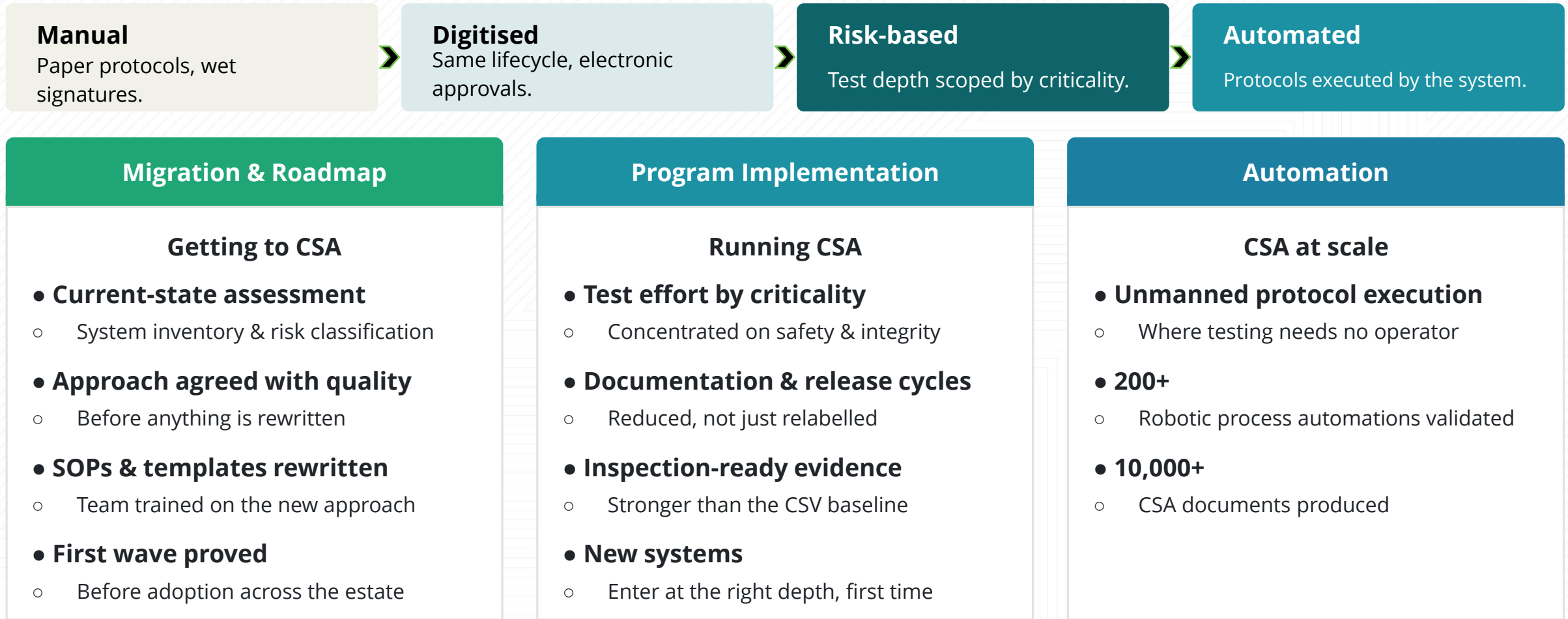
SYSTEM STATE – COMMISSIONED

System Assessment and Upgradation

- Retrospective Qualification
- ERES gap assessment
- Corrective action plan
- Remediation - System updates, corrections to address assessment gaps.

COMPUTER SOFTWARE ASSURANCE (CSA)

Everything we deliver under Computer Software Assurance, from the migration roadmap to unmanned execution at scale.



ONE ASSURANCE PROGRAMME, FOUR VERTICALS

Run as one operating programme across regulatory-exposed functions, audit-ready, with the record to prove it.

CORPORATE QA

- **ISO 27001 & 27701 attainment**
 - Delivered as a service
- **Training management**
 - Design to content
- **Vendor management**
- **SOP analysis and harmonization**
- **Root cause analysis and CAPA support**

IT QA

- **Regulatory audit preparation**
 - Readiness, gap closure by risk, inspection support
- **Data integrity assurance**
 - ALCOA++, audit trail, access, backup & restore verified
- **IT QA as a service**
 - Digital maturity assessment
 - Compliance assessment
 - Ongoing assurance work

MEDICAL AFFAIRS QA

- Vendor management
- Compliance report validation
- Clinical trial data validation

PHARMACOVIGILANCE QA

- Vendor management
- Vendor audits
- Compliance report validation

Zero

Critical inspection findings on record: FDA, TGA, EU and UK

160+

Audits fronted, regulatory and customer

DRIVING MANUFACTURING OPERATIONAL EXCELLENCE

GOLD SEEM National Energy Management Awards

We train, coach, implement and sustain lean systems on the shop floor, keeping plants audit-ready at all times. Our SMEs work to Kobayashi's 20 Keys® framework across quality, cost and lead time, building improvement that holds after we leave.

1,800+

Employees trained on lean implementation

650+

5S Zones led by 900+ trained champions

₹19.2 cr

Cost avoidance from 2,900+ shop-floor ideas

30 MW

Renewable portfolio, ₹10+ cr saved annually



LEAN FOUNDATION PROGRAMS

5S, GEMBA, Ideation and Daily Huddle run as one connected system with an in-house GEMBA app and idea capture in regional languages.



20 KEYS® IMPROVEMENT MODEL

Twenty operations focus areas spanning quality, cost and lead time, benchmarked site by site through a PPORF plant maturity assessment.



ENERGY & SUSTAINABILITY

Renewable transition managed end to end Group Captive, BOOT, CAPEX and OPEX open access against ESG and net-zero commitments.



AUDIT & INSPECTION READINESS

Plants held at all-time readiness for USFDA, TGA, WHO and customer audits, with analytical dashboards giving leadership live visibility.

HOW WE ENGAGE

01

INITIATION

Preliminary assessment and site visit · 20 days



02

PHASE 1

Stabilize lean foundation: 5S & Visual Factory · 6-9 months



03

PHASE 2

World-class lean platform via special projects · 12-15 months

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