AURENYX
PHARMATECH PVT. LTD.

(Formerly Known as Cyclone Pharmaceuticals Pvt Ltd)

Innovation |Quality | Cost | Commitment

Your Trusted GMP Partner

Who We Are

Aurenyx Pharmatech Pvt. Ltd. formerly known as **Cyclone Pharmaceuticals Pvt. Ltd.** is one of the world's leading pharmaceutical GMP, regulatory, and business consulting organizations. Over the past decades, we have supported **more than 1,000 small, medium, and large-scale pharmaceutical manufacturers** in strengthening their GMP compliance, enhancing regulatory readiness, upgrading quality systems, and accelerating business growth.

Aurenyx is powered by a team of **senior pharmaceutical professionals with over 40 years of industry experience,** who have dedicated their careers to elevating global pharmaceutical standards.

In addition to our consulting expertise across **GMP, regulatory affairs, and pharmaceutical technology**, Aurenyx has proudly launched the **world's first fully integrated, advanced, and globally compliant GMP Software designed** to meet the requirements of every major regulatory authority worldwide.

Sachin Bhalekar

Director
Aurenyx Pharmatech Pvt Ltd
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From the Desk of the Director

At Aurenyx, we have upheld strong ethical values and consistently served the pharmaceutical industry for the past **25 years.** Our deep domain expertise has enabled us to identify the practical gaps and loopholes in GMP and regulatory practices, and to **offer realistic, implementable, and quality-centric solutions to manufacturers across the globe.**

Our clients consistently experience sustainable growth while remaining fully aligned with the principles of quality, compliance, and operational excellence. **Quality remains the core operating philosophy of Aurenyx.**

Recently, we introduced the **world's first AI-powered GMP Software,** a breakthrough innovation that combines the capabilities of multiple pharmaceutical operational platforms into a single unified system. Designed on the strong foundation of **QMS, data integrity, and global regulatory frameworks,** this intelligent platform has been developed under the close guidance of seasoned quality, manufacturing, and regulatory experts from the pharmaceutical industry.

This revolutionary technology marks a major milestone in transforming how pharmaceutical organizations manage compliance, documentation, workflows, and digital quality systems—setting a new benchmark for the industry worldwide.

WHAT WE ARE OFFERING

(World-Class Consulting Digital Transformation AI-Powered Pharma Solutions)

Enterprise Digital Platforms & AI-Driven Pharma Software

- Pharma ERP – Unified, intelligent operational platform for enterprise-wide visibility
- Paperless GMP System – AI-enabled, fully compliant, end-to-end digital QMS
- Paperless HR & Workforce Automation – Attendance, competency, skill matrix, audit trails
- Training Management System (e-TMS) – LMS, assessments, digital training records
- Electronic BMR / BPR (eBMR & eBPR) – Real-time batch manufacturing & packaging execution
- Advanced Pharma QMS – Document control, deviations, CAPA, change control, risk management
- Industry 4.0 / Pharma 4.0 Solutions – IoT, AI, ML, digital twins, smart manufacturing
- Facility, Equipment & Utility Management Software – e-calibration, e-maintenance, e-logbooks
- Pharma Retail, Distribution & Supply Chain Digitalization Suite

AI, Data Integrity & Compliance Highlights

- ALCOA+ data integrity controls
- 21 CFR Part 11, EU Annex 11 compliant
- GAMP 5 & global CSV-ready frameworks
- Integrated audit trail monitoring & anomaly detection
- Predictive analytics, real-time dashboards & root-cause insights

Key Benefits of Paperless Digital Systems

- 30% manpower optimization via automation & workflow orchestration
- 90% reduction in stationery & printing costs
- Zero non-compliance with globally validated digital systems
- High productivity & faster batch release
- Ultra-secure, encrypted, validated digital data lifecycle
- Predictive analytics for better decision-making
- Maximum inspection readiness with complete traceability
- High acceptance across regulated & emerging pharma markets

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GMP, Technical, Regulatory & Turnkey Consulting Services

Aurenyx delivers integrated, next-generation consulting to help pharmaceutical companies achieve **world-class quality, regulatory compliance, cost efficiency, and operational excellence.**

Core Offerings

- GMP Upgradation & Compliance Transformation – USFDA, MHRA, EMA, WHO, PIC/S
- Regulatory Strategy & Dossier Development Right-first-time submissions
- Technical Due-Diligence & GAP Assessments
- Mock Regulatory Inspections & Risk Mitigation
- Turnkey Project Execution for facility modernization & process optimisation
- QMS Architecture & Implementation
- Data Integrity Audits & ALCOA + Remediation
- Training, Competency & Leadership Development
- Lean Pharma, OEE Improvement & Productivity Enhancement
- Computer System Validation (CSV) & System Lifecycle Compliance

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PaperLess GMP Platform

Aurenyx's flagship, cloud-based, end-to-end GMP tool (not just an ERP) that fully digitizes all pharmaceutical manufacturing operations.

Modules include: HR & Admin, Purchase, Security, Accounts & Finance, Project Management, Inventory, Material Resource Planning, plus a fully integrated QMS (Quality Control, Microbiology, QA).

Supports eBMR / eBPR, dispatch/packaging, utilities & engineering, validations & calibration, preventive maintenance, training, vendor qualification, and artwork management.

Also covers business functions such as Marketing / CRM, Business Development, R&D / New Product Development — offering a true "single pane of glass" for pharma operations.

Built with 100% Data Integrity (ALCOA+ principles), fully validated as per GAMP 5, and compliant with US FDA, EMA, and global GMP guidelines.

Deeply customizable: aligned to each client's SOPs, quality systems, and organizational structure

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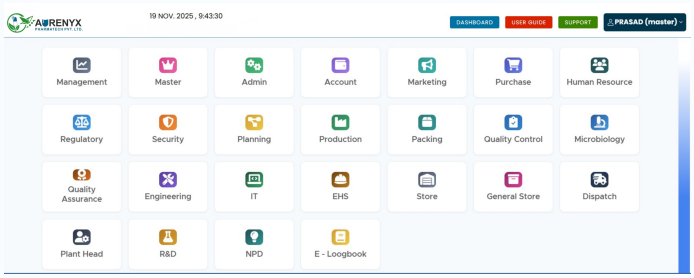
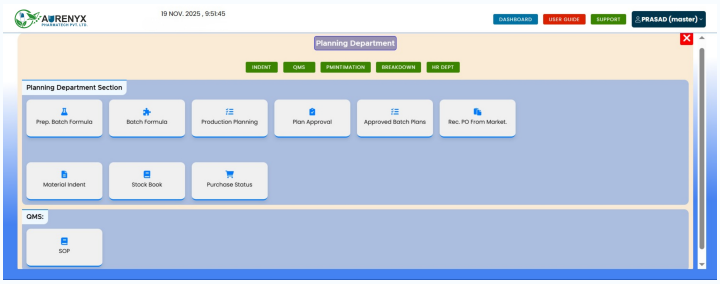
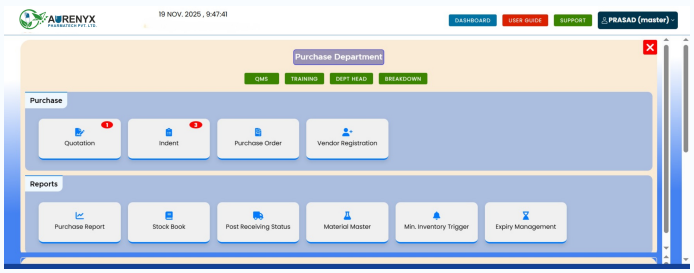
AI-backed: Advanced analytics, predictive intelligence, and insights for proactive decision-making and continuous improvement.

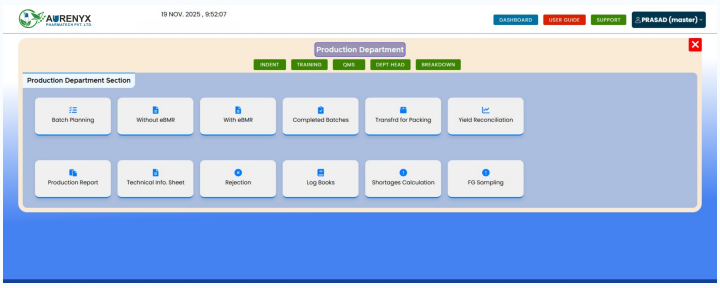
For more on the technology and compliance pedigree, see GMP Software India's Paperless GMP product.

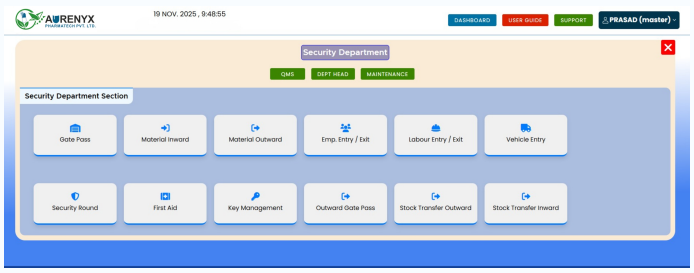
Modules Pictures :

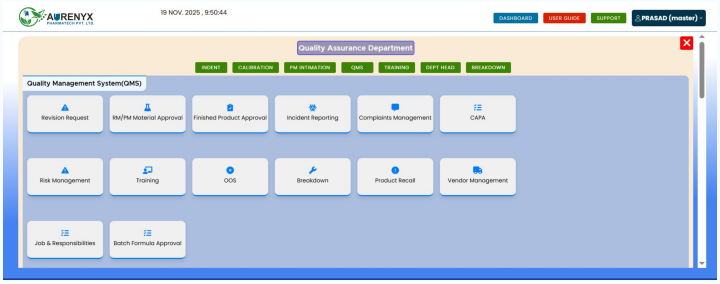


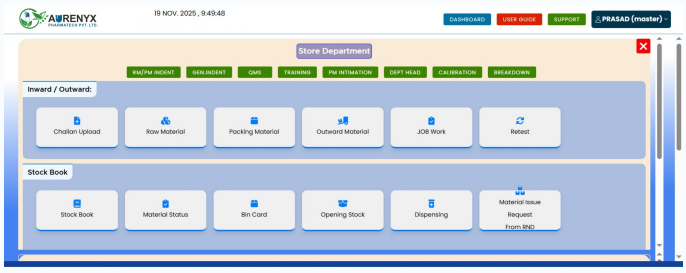


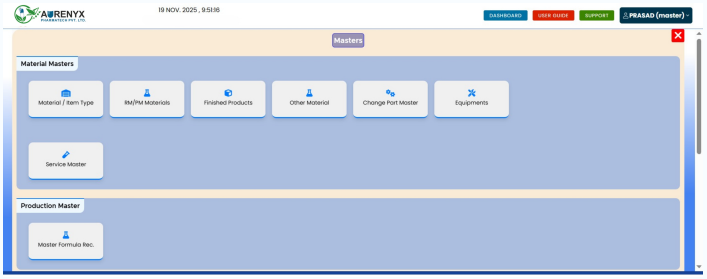


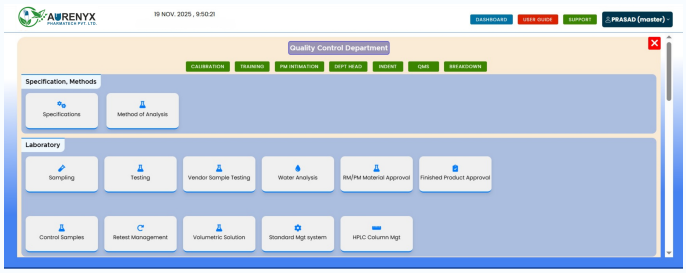


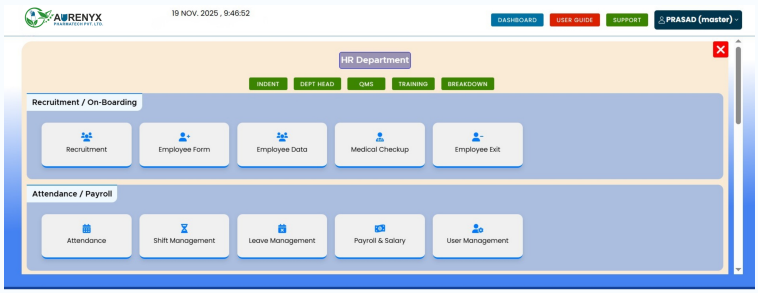












Digital QMS / Quality Software Project

A fully digitized QMS (Quality Management System) platform developed to support all core QA & QC workflows and SOPs.

Key functional areas covered: Deviation & Change Management, CAPA, Training Management, Risk Assessment, Stability Management, Testing Specifications, SOP Control, and GMP Monitoring.

Supports in-process (IPQA) / in-process QC (IPQC) sampling, release / batch approval, raw-material and packaging material sampling, raw data capture and auto-calculation for OOS (Out-of-Specification) results.

Enables complete traceability: raw-data history, audit trail, version control, document management, and report generation

Fully validated and compliant with global regulatory standards (21 CFR Part 11, WHO-GMP, ICH, etc.).

Emphasis on Data Integrity: ensures all records are tamper-evident, time-stamped, and securely stored.

Embedded AI/Analytics capabilities: predictive risk insights, trend analysis, early-warning flags, and smart dashboards to drive continuous quality improvement.

Pharmaceutical Training Software

The system is built on **ALCOA+ principles**, validated per **GAMP 5**, and fully compliant with **21 CFR Part 11 / EU Annex 11**, ensuring absolute training data integrity.

- Training Calendars (GMP, Technical, Departmental)
- Trainer Evaluation & Feedback System
- Training Workflow Automation
- Retraining Alerts & Auto-Compliance Reminders
- Trainer Registration & Competency Mapping
- Attendance Recording & Digital Acknowledgments
- Individual Training Records (ITR)
- Training Certificates & Electronic Evidence
- On-the-Job Training (OJT) Tracking
- Audit Trails & Part 11 Compliant e-Signatures
- Digital Training Manuals & SOP-Linked Learning
- Real-Time Training Compliance Dashboard
- Online Exams & Competency Evaluation
- AI-Based Analytics for Skill Gaps & Compliance Trends

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HighLights /ROI/Special Features

Aurenyx delivers a fully customizable, ready-to-implement, real-world compliant digital ecosystem engineered by senior pharmaceutical experts and technologists.
Our solutions provide measurable ROI, guaranteed regulatory confidence, and long-term operational excellence.

Key Highlights & ROI Advantages

- Accelerated ROI with realistic pricing and transparent implementation plans
- Authentic, real-world GMP digitalization—no exaggerated claims, no inflated features
- Designed by industry veterans with deep GMP, Quality, and Regulatory expertise
- 24×7 support from experienced pharma professionals & technology specialists
- Enterprise-grade, globally benchmarked security architecture
- Built on ALCOA+, Data Integrity, and global regulatory compliance by design
- Rapid deployment with minimal disruption—simple, intuitive, adoption-ready platform
- AI-powered engines with advanced data analytics for intelligent decision-making
- Most cost-effective digital transformation suite in the industry
- A complete end-to-end ecosystem covering every pharmaceutical operation

The Aurenyx Promise

Aurenyx stands for truth, trust, transparency, and technological excellence.

We don't compete—we transform.

We don't sell software—we deliver a future-ready digital revolution for the pharmaceutical world.

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