LEUCINE · PHARMACEUTICAL PRODUCTION

# Manufacturing Execution System

Plan, execute, and optimise every batch. Deliver On Time In Full with AI-powered manufacturing and compliance intelligence.

FACILITIES

30

CONCURRENT USERS

2,500+

On a single platform simultaneously

BATCH REVIEW

20→1 Day

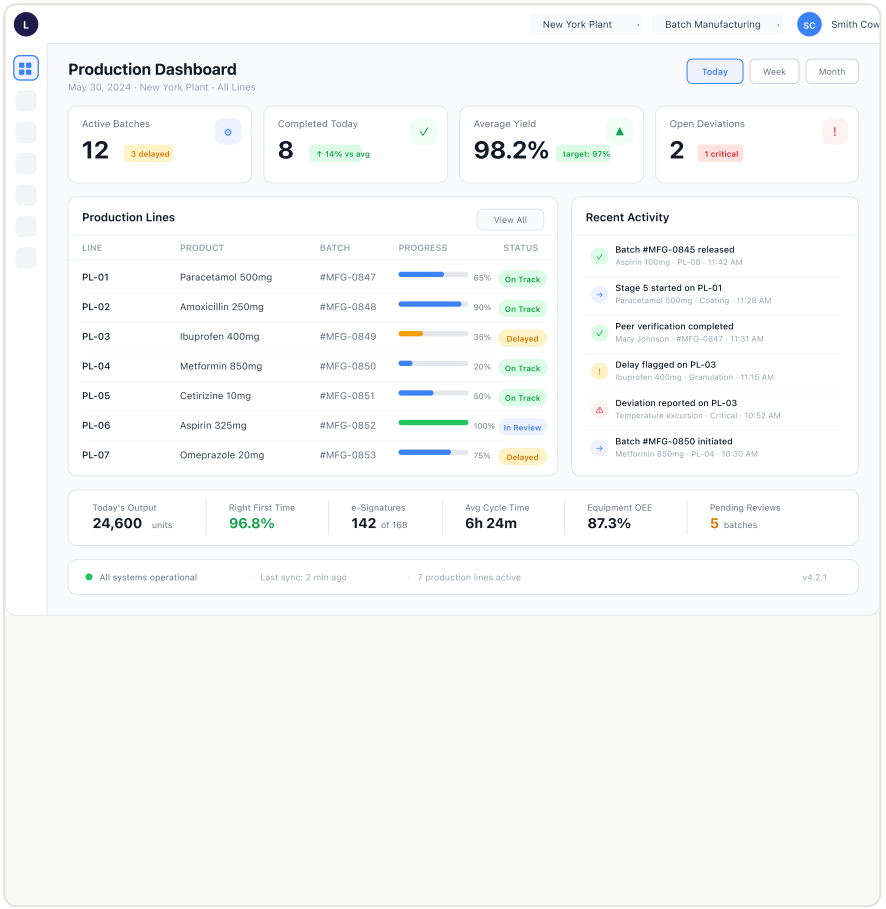
Specialty biopharma manufacturer · 2,700 hrs saved annually

REGULATORY JURISDICTIONS

3

FDA · MHRA · EMA

# Most production floors generate data continuously. None of it becomes intelligence.




THE DATA PROBLEM

**Every batch generates thousands of operational data points — process parameters, operator decisions, material states, environmental readings.**

On paper, those data points are transcribed once, reviewed weeks later, and never connected across batches. The signal disappears into filing cabinets.

THE TIMING PROBLEM

**By the time QA sees a deviation, the batch is complete. By the time a yield trend is visible, dozens of batches have run under the same faulty conditions.**

The gap between the production floor and quality oversight is measured in weeks — and in risk.

WHAT CHANGES

**Execution, compliance, and intelligence — on a single platform, in real time.**

Every step captured at the moment it happens. Every deviation surfaced before it escalates. Every batch connected to the history of every batch that came before it.

# Core Capabilities



Four capability layers covering the full batch lifecycle — from MBR authoring and shop-floor execution to material dispensing and QA release.

### 01 — DESIGN & SETUP

**No-Code MBR Builder**
Build and version-control Master Batch Records in the platform — no IT needed.

**ERP Integration**
SAP process orders auto-create executable batch records on QA release.

**Role & Training Assignment**
Only trained, role-matched operators can access and execute GxP tasks.

**Conditional Workflows**
Steps auto-skip or activate based on live process conditions — no manual N/A entries.

### 02 — EXECUTION & COMPLIANCE

**GMP Instructions & E-Signatures**
Mandatory acknowledgments timestamped and locked — 21 CFR Part 11 & Annex 11.

**Compliance Interlocks**
Expired cleaning, overdue calibration, or campaign breaches block execution automatically.

**Same-Session 4-Eye Verification**
Checker verifies in-session without logout — no credential sharing, full audit trail.

**Timed Conditions & In-Process Checks**
Countdown alerts enforce critical time windows; recurring checks flagged if missed.

### 03 — MATERIALS & DISPENSING

**BOM + FEFO Pick List**
Only QA-released, in-date lots shown — FEFO rules and expiry checks applied automatically.

**Assay-Based Calculations**
Adjusted dispensing quantities calculated live from LIMS potency — no manual math.

**Live Balance Integration**
Tare, gross, and net weights captured directly from connected balances — no transcription.

**Material Verification at Point of Use**
Barcode re-scan confirms right material, quantity, and dispensing hold-time before use.

### 04 — MONITORING & RELEASE

**Review by Exception**
QA sees only flagged CPP deviations — not every entry. FDA 2022 CGMP guidance endorsed.

**Auto-Save Audit Logs**
Every action locked instantly — retroactive edits structurally impossible. ALCOA+ by design.

**Yield Calculations & Deviations**
Out-of-range yields alert supervisors and trigger deviation workflows automatically.

**Digital eBR & PDF Reporting**
Full batch record exportable as PDF — CPP view, exceptions view, or yield summary.

# Deployment Use Cases

**Paperless Batch Execution** — Execution

- Guided step-by-step workflows with in-process checks
- Review by exception — flag only what deviates

**Material Traceability** — Materials

- Barcode verification at each dispensing step
- Full genealogy from raw material to batch release

**Electronic Logbooks & Area Management** — Compliance

- Searchable, Part 11 compliant records at every entry
- Real-time area status and structured shift handovers

**Real-Time Production Visibility** — Visibility

- Live batch progress, OEE dashboards, bottleneck alerts
- Shift performance analytics across all production lines

# Autonomous AI agents that reason over your manufacturing data — and act on it.

Cortex deploys goal-oriented AI agents directly on top of your Leucine MES data. Each agent accesses batch records, process parameters, equipment data, and quality events through standardised MCP tools — and acts on what it finds.

AGENT 01

## Compliance Agent

`Deviation Detection` `Regulatory Cross-Ref` `Audit Trail Analysis`

Monitors batch execution against GMP requirements in real time. Flags deviations before they escalate, surfaces review-by-exception candidates, and pre-populates investigation reports with batch context and historical patterns.

AGENT 02

## Yield Optimisation Agent

`Parameter Correlation` `Trend Analysis` `Predictive Modelling`

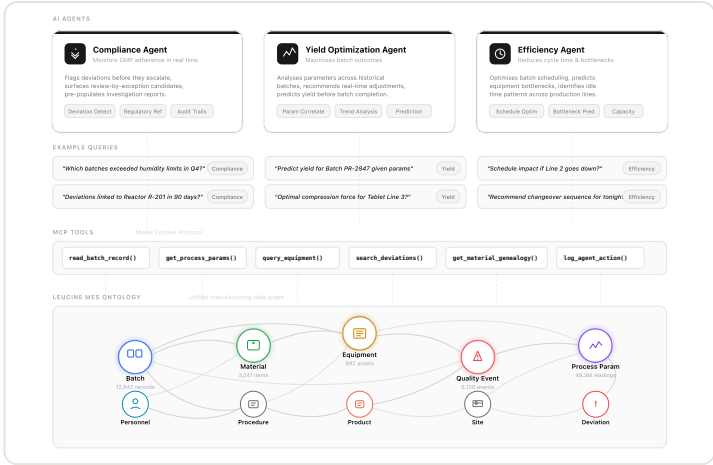
Analyses process parameters across thousands of historical batches to find what produces the best outcomes. Recommends real-time adjustments and predicts yield before batch completion.

AGENT 03

## Efficiency Agent

`Schedule Optimisation` `Bottleneck Prediction` `Capacity Planning`

Optimises batch scheduling, predicts equipment bottlenecks, and reduces cycle times. Identifies idle time patterns and forecasts throughput impact of changeovers and planned maintenance.




### Skills-Based Architecture

Modular skills assembled without code. New capabilities added by composing existing skills, not retraining models.

### MCP Tool Access

Agents query batch records, equipment status, quality events, and material genealogy through standardised, auditable tools.

### Goal-Oriented Execution

Define the objective — OEE, batch release time, right-first-time rate — and the agent plans a strategy to get there.

### Human-in-the-Loop

Every recommendation requires human approval. Agents advise; qualified operators decide. Full audit trail on every action.

# Shop floor to cloud — out of the box.

Production-grade connectivity from shop floor to cloud — every connector, gateway, and cloud pipeline ships ready to deploy.

### Edge Gateway Connectors

OPC-UA, Modbus TCP, MQTT, PI/Historian, Serial RS-232, REST/SOAP — translating data at the edge. Supports brownfield PLCs and SCADA without modification.

### Azure Cloud Pipeline

Ingestion via Azure IoT Hub, Stream Analytics, and Time Series Insights. Data enriched with batch context before entering the MES data layer.

### Configuration Portal

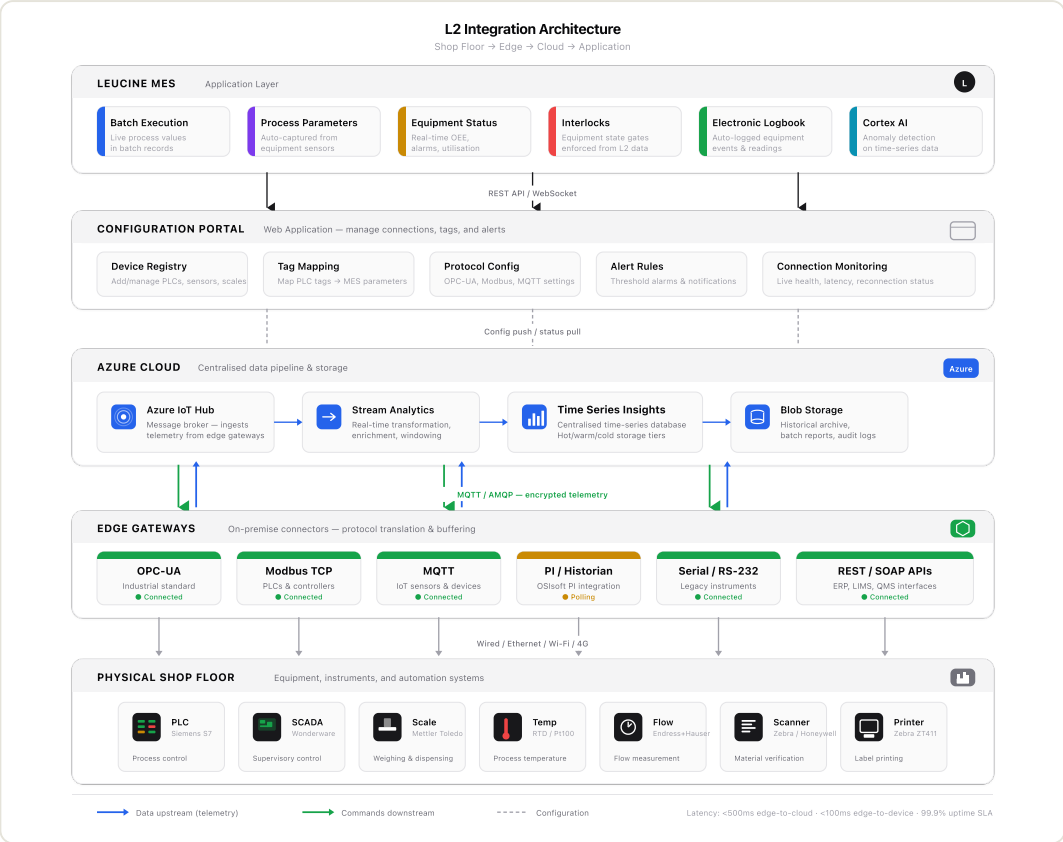
Manage device registries, tag mappings, protocol configs, and alert rules from the browser — no engineering involvement required.

### Real-Time Equipment Data

Live process values flow directly into batch records and interlocks. Set-point deviations trigger in-line alerts automatically.

SUPPORTED PROTOCOLS & PLATFORMS

OPC-UA · MODBUS TCP · MQTT · PI/HISTORIAN · SERIAL RS-232 · REST/SOAP · AZURE IOT HUB · SAP · ORACLE ERP



# Start with Logbooks. Scale to Full MES.

Leucine's implementation sequence is designed for quick wins and progressive depth — starting with production logbooks where compliance risk is highest, building toward a fully connected manufacturing execution platform.

1

PHASE 1

Weeks 1-8

### Production Logbooks

Digitise area clearance, equipment usage, cleaning logs, and room logbooks. Shift handovers become structured, searchable, and Part 11 compliant — delivering compliance value from week one.

2

PHASE 2

Months 2-4

### ERP Integration

Connect SAP or Oracle to auto-generate batch records from released process orders. Material BOMs, production schedules, and order data flow directly into the MES without re-entry.

3

PHASE 3

Months 3-6

### Batch Records

Replace paper batch execution with guided digital workflows, e-signatures, and 21 CFR Part 11 compliant records. Pre-configured templates mean most products go live in weeks, not months.

4

PHASE 4

Months 6-9

### Cortex AI

Activate AI-powered review by exception, autonomous deviation detection, and predictive CAPA. Agents reason over the accumulated logbook and batch data to surface patterns and risks.

5

PHASE 5

Month 9+

### Equipment Integrations

Connect shop-floor equipment via L2 edge gateways. OPC-UA, Modbus TCP, and MQTT connectors bring process parameters directly into batch records — eliminating transcription and enabling interlock enforcement.

**Most sites go live in 8–12 weeks.** Leucine MES ships with pre-configured templates so implementation is configuration, not custom development. **A top-5 generic pharma group deployed across 30 facilities** with 2,500+ concurrent users; **a global CDMO went live across 10+ sites** spanning FDA, MHRA, and EMA regulatory jurisdictions from a single platform.

# Frequently Asked Questions.

**How long does it take to deploy Leucine MES at a new site?**

Most sites go live in 8–12 weeks. Leucine MES ships with pre-configured templates for common pharma workflows — batch execution, material dispensing, electronic logbooks — so implementation is configuration, not custom development.

**Does Leucine MES generate electronic batch records automatically?**

Yes. As operators execute batches, the system captures every step, parameter, material usage, and signature into a complete electronic batch record. One specialty biopharma manufacturer reduced batch review from 20 days to 1 day and saved 2,700 hours annually as a direct result.

**Is Leucine MES 21 CFR Part 11 compliant?**

Fully compliant. Every action is backed by electronic signatures with identity verification, immutable audit trails, role-based access controls, and configurable approval workflows. Deployed in FDA, MHRA, and EMA inspected facilities without remediation findings.

**What makes Leucine MES different from legacy MES platforms?**

Leucine MES is AI-native — built with Cortex AI agents that reason over your manufacturing data. Legacy MES platforms capture data; Leucine acts on it. Cortex agents detect deviations, predict batch yield, and optimise scheduling autonomously.

**Does Leucine MES integrate with SAP and other ERP systems?**

Yes. Leucine MES connects with SAP, Oracle, and other ERPs to receive production orders and return batch data. The L2 layer also supports OPC-UA, Modbus TCP, MQTT, and PI/Historian through pre-built edge connectors — no bespoke middleware required.

**Can Leucine MES scale across multiple manufacturing sites?**

Yes. Master Batch Records are authored centrally and deployed across sites with locale-specific overrides — multi-language interfaces, region-aware compliance, and local units. One large-scale generics manufacturer runs across 30 facilities with 2,500+ concurrent users on a single platform instance.

**Does Leucine have implementation partners?**

Yes. Paraxis is Leucine's partner programme for consulting firms, system integrators, and validation specialists trained to deploy Leucine MES, CLEEN, and LeucineOS. Visit leucine.ai/paraxis/ to learn more about becoming a partner or finding one near you.

GET STARTED

## See how Leucine MES performs in your environment.

leucine.ai
Product & platform

leucine.ai/paraxis
Partner programme

# Talk to someone who's done this before.

Our team has deployed MES across regulated pharma manufacturers in 3 regulatory jurisdictions. Book a 30-minute call to see what a deployment looks like at your sites.

BATCH REVIEW TIME

**20→1 Day**

95% reduction · specialty biopharma

FACILITIES ON ONE PLATFORM

**30**

2,500+ concurrent users · WEF Lighthouse

REGULATORY JURISDICTIONS

**3**

FDA · MHRA · EMA · single deployment

HOURS SAVED ANNUALLY

**2,700**

Manual record assembly eliminated

## WHAT WE COVER IN THE CALL

- ✓ **Your current state** — paper vs. digital, pain points, upcoming inspections or audit cycles
- ✓ **Deployment scope** — number of sites, products, and departments in scope
- ✓ **Customer references** — connect you with manufacturers at a similar scale and regulatory footprint
- ✓ **Live product walkthrough** — batch execution, logbooks, Cortex AI, and L2 integrations in your context
- ✓ **Indicative timeline** — what a phased rollout looks like for your site count and complexity

## WHO SHOULD BE ON THE CALL

- ✓ **Head of Quality / VP Quality** — compliance requirements, audit readiness, Part 11 architecture
- ✓ **Head of Manufacturing / VP Operations** — batch cycle times, OEE, scheduling, and production floor integration
- ✓ **CIO / Digital Transformation Lead** — ERP integration, infrastructure, security, and platform architecture

BOOK A MEETING

## See Leucine MES in your environment.

30 minutes · no obligation · bring your questions

LEUCINE.AI/CONTACT-SALES