

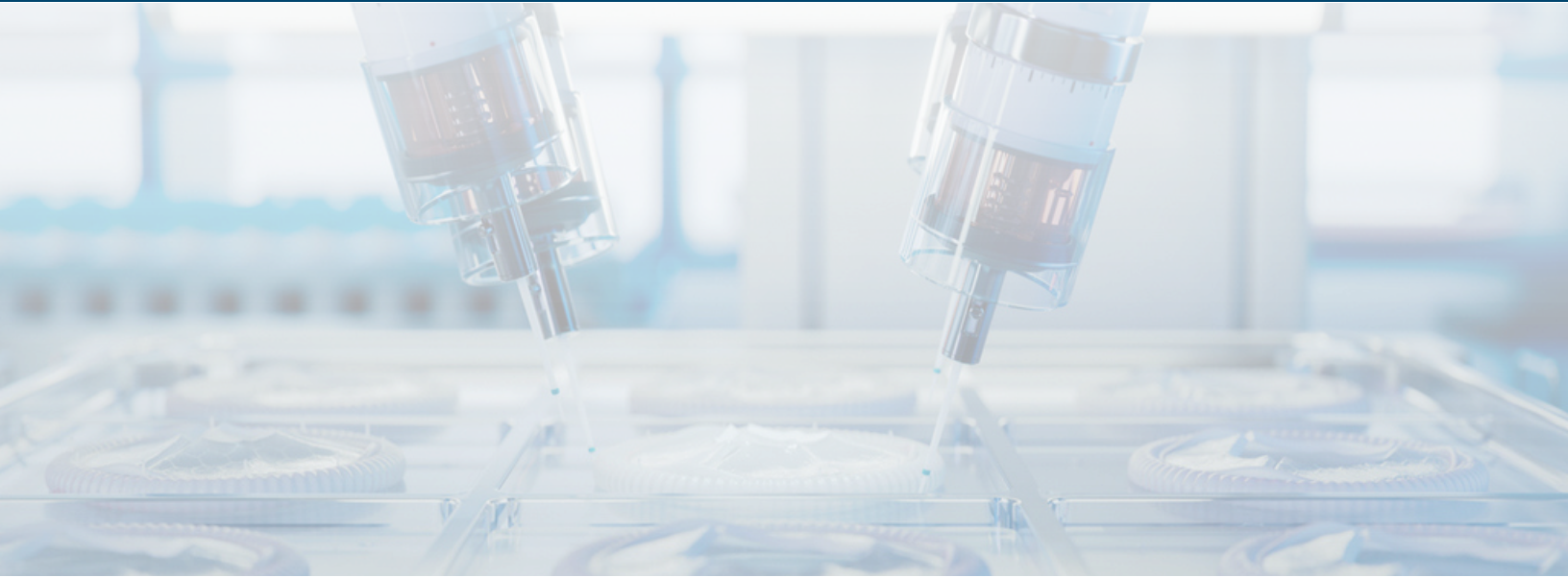
AI & Operational Excellence in Life Sciences Manufacturing

Leadership Briefing



AI Is Already Being Deployed Across Life Sciences

IX® in Action



The Gap Is No Longer Strategy. It's Execution.

Across pharma and medical device organizations, AI adoption has moved past experimentation.

Most companies have:

- Rolled out copilots
- Established AI governance
- Identified use cases

But only a small group has moved into:

AI embedded directly into core workflows tied to measurable outcomes

At the same time, leading organizations are already deploying:

- Agentic AI across regulatory, quality, and manufacturing
- AI-driven execution in supply chain and operations
- Digital systems replacing manual processes in regulated environments
- Structured operating systems to sustain performance

This is not conceptual.

This is already being implemented.

Where These Apply in Medical Device Manufacturing

Area	Example Use
1 Device Assembly	eDHR automation to eliminate manual documentation
2 Quality Inspection	AI vision for real-time defect detection
3 Equipment Reliability	Predictive maintenance to reduce downtime
4 Regulatory Documentation	Structured workflows for faster, compliant submissions
5 Supply Chain & Planning	AI-driven scheduling and inventory optimization
6 Operations Leadership	Management Operating System (MOS) deployment

What This Drives

- Higher throughput and yield
- Reduced manual work and cost
- Faster release and submission cycles
- Improved reliability and uptime
- Scalable, consistent execution

Eliminating Manual Quality Processes to Unlock \$12M+

IX® in Action

25%

of manual
DHR entries
automated

\$12.4M

annual cost
savings

Implementing eDHR in Medical Device Manufacturing

Client Context

A leading medical device manufacturer producing trauma plates in a highly regulated environment where documentation accuracy directly impacts quality, compliance, and cost.

The Problem

- Paper-based DHRs required 50–60 pages per unit with 400–500 manual entries
- Documentation reviewed up to 13 times per build
- Errors triggered rework orders and production delays
- Significant labor tied up in data entry, review, and archiving

What Changed

We implemented a fully integrated **electronic Device History Record (eDHR)** system embedded directly into production workflows.

- Replaced manual documentation with **digital, process-driven data capture**
- Integrated **connected devices** for automatic measurement recording
- Built process-aligned applications across each step of production
- Eliminated redundant reviews through **error-proofed workflows**
- Embedded the system into **operator routines and quality execution**

Impact

\$12.4M annual cost savings

25% reduction in manual data entry

Reduced documentation errors and rework

Labor shifted from admin work to production

Eliminated paper storage and printing costs

Stabilizing Operations with AI-Driven Predictive Maintenance

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99%

defect detection
accuracy

<3%

false rejects

Turning Maintenance into a Proactive Execution System

Client Context

A sterile sampling solutions manufacturing operation where uptime, consistency, and compliance directly impact output and cost.

The Problem

- Maintenance was reactive and schedule-driven
- Failures discovered only after performance dropped
- Sensor data existed but was not used in execution
- Downtime drove scrap, instability, and overtime

What Changed

We embedded **predictive intelligence directly into maintenance and production execution.**

- Connected real-time sensor data across equipment
- Implemented models to detect early-stage failure conditions
- Installed failure risk prioritization into daily planning
- Triggered maintenance actions before breakdowns occur
- Integrated alerts into **operator and maintenance workflows**

This shifted maintenance from reacting to failures → **controlling performance.**

Impact

- Reduced unplanned downtime
- Increased line stability and throughput consistency
- Lower maintenance cost from fewer emergency repairs
- Improved labor productivity through planned work

Eliminating Manual Inspection with AI Vision

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99%+
Inspection
consistency
across shifts

60–80%
Reduction in
Manual
Inspection Time

<1
Second
Defect Detection
Per Part

Improving Quality While Increasing Throughput

Client Context

A medical device manufacturer producing precision components in a highly regulated environment.

The Problem

- Manual inspection was inconsistent and labor-intensive
- Defects were small and difficult to detect
- Operator fatigue created variability
- Inspection constrained throughput

What Changed

We embedded **AI-driven inspection directly into production lines**.

- Installed automated vision systems for defect detection
- Identified and classified defects in real time
- Eliminated variability across operators and shifts
- Integrated inspection into production flow

This transformed inspection from manual activity → **automated quality control system**.

Impact

- **60–80% reduction in manual inspection time**
- **<1 second detection per part**
- **99%+ consistency across shifts**
- Increased throughput and reduced defect risk

Stabilizing a High-Volume Operation to Unlock \$16M

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\$3M

bottom line
impact

Installing a Management Operating System (MOS)

Client Context

A global biotech manufacturing site with high output variability and a reactive operating culture.

The Problem

- Supervisors spent the majority of time on admin vs. the floor
- KPIs existed but did not drive action
- Output fluctuated due to downtime and poor coordination
- Maintenance lacked structure and discipline

What Changed

We installed a **Management Operating System (MOS)** to run the operation.

- Implemented **tiered daily management routines (Tier 1–3)**
- Installed visual management and short interval control
- Defined KPIs tied to performance and accountability
- Shifted supervisors to active floor leadership through standard work
- Created closed-loop execution across shifts and functions

This created a system to **run the business daily**, not react to problems.

Impact

- **\$3M realized bottom-line impact (phase 1)**
- **\$16M total identified value**
- Increased throughput and reduced variability
- Improved accountability and execution discipline
- Shift from reactive to performance-driven culture

Increasing Throughput 15% and Delivering \$16M

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\$16M

annual
financial
benefit

15%

throughput
improvement

Operations, Maintenance, and Execution Transformation

Client Context

A diagnostics manufacturer unable to meet demand due to downtime, scrap, and inconsistent execution.

The Problem

- High downtime and unstable production lines
- Inefficient changeovers and high scrap
- Reactive maintenance
- Lack of coordination between operations and maintenance

What Changed

We implemented a full **operations and maintenance execution system**.

- Installed MOS with clear performance ownership
- Reduced downtime through structured problem solving
- Optimized changeovers to improve responsiveness
- Implemented root cause and reliability processes
- Aligned operations and maintenance around throughput

This created a stable system to **consistently produce at target performance**.

Impact

- **15% throughput increase**
- **\$16M annual financial benefit**
- Reduced downtime and scrap
- Improved yield and reliability
- Increased ability to meet demand

Why AI Stalls in Large Life Sciences Organizations

1 **Council-Level AI**
Ideas discussed
→ **Nothing deployed in operations**

2 **Pilot Overload**
Use cases launched
→ **Never scaled**

3 **Disconnected Systems**
SAP / MES / QMS not integrated
→ **AI can't execute**

4 **No Execution Ownership**
No one accountable
→ **No measurable impact**

What Happens Instead

- Manual work continues (DHRs, submissions, inspections)
- Downtime, scrap, and delays persist
- AI sits outside the operation

What We See Working

- AI embedded in workflows (maintenance, manufacturing, quality)
- Digital systems replacing manual execution
- Clear ownership tied to results (\$, throughput, cycle time)

Let's Turn Your Vision Into Results

At Implementation Engineers, we don't just execute projects - we transform your vision into operational reality. Our proven 3-phase approach - **Align, Design, Execute** - delivers lasting value, from aligning your team on strategic goals to optimizing operations and driving measurable outcomes. Whether you're aiming to lead your market, boost efficiency, or maximize shareholder value, we're here to make it happen, step-by-step, side-by-side.

Ready to Get Started?

Let's explore how we can bring your vision to life. Contact us today to schedule a conversation. Together, we'll chart the path to your success.

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