

Why Modern Pharma Requires A Central Nervous System For Assets

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Within manufacturing environments, equipment breakdown is an expensive inconvenience. In pharma, it is a catastrophic event. When a high-speed tablet press faults or a sterile fill-finish line loses pressure, the clock doesn't just tick in terms of lost labor hours—it ticks in ruined batches, missed validation windows and potential regulatory scrutiny from bodies like the FDA and EMA.

Pharmaceutical maintenance teams can no longer afford to be firemen. They must act as core drivers of regulatory compliance and risk mitigation. This shift requires trading outdated, passive work-order software for a data-driven [computerized maintenance management system](#) (CMMS), built for the complexities of modern life sciences.

The Pharmaceutical Triad: Downtime, Yield And Compliance

Pharmaceutical manufacturing exists at the intersection of extreme capital intensity and rigid regulatory boundaries. Three distinct pressures dominate the factory floor:

- **The Validation Bottleneck:** Every critical asset—from lyophilizers (freeze-dryers) to water-for-injection (WFI) distillation systems—must be rigorously validated. Unplanned maintenance can break the validation chain, requiring hours or days of recalibration and documentation before production can resume.
- **The Perishability Of Batches:** Unlike automotive assembly, where a stopped belt simply pauses production, a stopped line in pharma can spoil an entire active batch of biologics or oral solid doses. A single prolonged outage can wipe out hundreds of thousands of dollars in raw materials.
- **The Strictures Of 21 CFR Part 11:** Compliance isn't a post-production paperwork step; it's embedded in the machinery. Every adjustment, every part replacement and every signature must create an unalterable, audit-ready electronic trail.

From Reactive Firefighting To Predictive Orchestration

If failures occur under these conditions, one metric that can make a difference is [mean time to repair](#) (MTTR). Keep in mind that within legacy environments, MTTR is routinely bloated by what I call "the dark minutes"—the hidden time spent diagnosing error codes, hunting for cleanroom-grade parts or waiting for a technician with the correct gowning clearances to find a paper binder.

An effective CMMS often solves the MTTR crisis by acting as the digital thread that connects real-time machine conditions with frontline operational execution. Rather than waiting for a machine to fail, it creates a closed-loop system driven by AI and machine-level sensors.

When an industrial pump or automated vision inspection system begins to fail, it tells you long before it breaks. By monitoring real-time variables like micro-

vibrations, thermal shifts and fluid pressure via Message Queuing Telemetry Transport (MQTT) or Open Platform Communications Unified Architecture (OPC UA) protocols, a CMMS can catch anomalies that a human operator would miss. The software doesn't just sound an alarm; it automatically logs the fault, matches it against historical repair trends and serves up the exact diagnostic solution to the technician's mobile device before they even step onto the floor.

Eliminating Diagnostic Lag

For cleanroom environments, moving back and forth to a parts stockroom isn't just inefficient; it forces technicians to constantly repeat time-consuming gowning and de-gowning protocols. However, a CMMS will dynamically link work orders to real-time inventory management. So, if a sterile liquid filler triggers a preventative alert, the system automatically verifies that the exact cleanroom-grade gaskets and seals are in stock, "kits" them for pickup and attaches the digital step-by-step SOP to the technician's tablet. They walk in once, fix it right and walk out.

Forward-thinking manufacturers build native compliance protocols as a workflow, not as an afterthought—a pitfall that many struggle with. The traditional approach of filling out work orders on paper and manually entering them into a compliance ledger days later is a massive liability. Automated systems today embed compliance directly into the repair process. The moment a technician completes a step on their mobile app, a secure, timestamped, 21 CFR Part 11-compliant electronic signature is captured. Audit trails are built in real time, reducing audit preparation time by up to 70% and removing human error from the regulatory equation.

A Roadmap For Readiness: How To Start

Transitioning a multinational pharmaceutical network or a fast-moving CDMO toward this digital reality can feel daunting. However, safeguarding your organization against compliance risk and sudden mechanical failure does not require a rip-and-replace overhaul overnight. Leaders can insulate their operations by focusing on three foundational steps.

1. Conducting A 'Criticality And Compliance' Asset Audit

Before plugging in sensors or deploying mobile apps, map your floor. Categorize assets based on their direct impact on product quality and validation parameters (e.g., direct-impact vs. indirect-impact systems). Prioritize your digital transformation around the "heartbeat" assets—like freeze-dryers,

cleanroom HVACs and primary filling lines—where an unexpected failure carries the highest risk of batch spoilage or regulatory non-compliance.

2. Standardizing Cleanroom SOPs For Digital Consumption

Take your existing, paper-bound standard operating procedures and break them down into granular, step-by-step digital workflows. Ensure that when a technician is dispatched to a high-containment area, the mandatory tool lists, cleanroom gowning instructions and lock-out/tag-out (LOTO) protocols are completely digitized and mapped to the asset profile. Removing paper from the sterile environment removes human error from the repair.

3. Building Validation Timelines Into The Software Rollout

For life sciences companies, software changes are bound by the same strict validation requirements as production machinery. When selecting or updating your asset management ecosystem, ensure that the vendor provides clear compliance paths—such as pre-engineered patches designed for 21 CFR Part 11 requirements—and bake a dedicated user-acceptance and system-validation window into your deployment timeline. Validating the system properly upfront ensures smooth, legally compliant day-to-day data capture later.

The Strategic Takeaway

As the pharmaceutical industry continues to prioritize domestic supply chain security and agile manufacturing, the companies that thrive will be those that treat asset reliability as a competitive advantage.

We must stop viewing the maintenance department as a cost center that handles broken machines. With the right digital framework, it becomes the central nervous system of the pharmaceutical facility—predicting failures before they happen, slashing MTTR, protecting product yield and ensuring that life-saving therapies move smoothly from the production line to the patients who need them.

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