BROCHURE

Octave Attune EAM for Pharmaceutical

Compliance that strengthens performance

Pharmaceutical manufacturers don't get to choose between compliance and performance. They need both. Regulatory demands keep tightening. ESG expectations keep growing. And through it all, you still need to deliver safe, consistent products without missing a beat.

That takes more than a maintenance system. It takes asset management built for pharma, one that keeps you audit-ready while sharpening the performance of every critical asset.

Cut through complexity. Stay ahead of compliance.

Octave Attune EAM (formerly HxGN EAM) helps pharmaceutical companies meet 21 CFR Part 11 guidelines and evolving compliance standards without sacrificing the operational intelligence you need to run smarter. Collect and consolidate operational data in real time. Apply advanced analytics to plan strategically, not reactively. Maximize asset value while keeping risk in check.

With decades of experience across regulated industries, we understand what's at stake. Bring us your toughest compliance challenges — we'll help you turn them into a competitive edge.

Connected and comprehensive

Attune EAM for Pharmaceutical combines proven asset management practices with advanced analytics, mobile functionality, and cloud deployment so that teams act on the right data, at the right time.

- **Asset reliability management:** Identify, track, locate, and analyze physical assets. Measure metered usage with automatic value transmission to sub-components. Define time, material and labor costs in cost-charging arrangements. Track asset costs and movements using an easily configured family tree that forms relationships between equipment, systems and locations.
- **Preventive maintenance (PM):** Base PM tasks, inspections and checklists on fixed dates, flexible time periods or metered usage. Adjust schedules to compensate for early and late work completion.
- **Performance-based maintenance:** Monitor and analyze asset performance data in real time and trigger alerts to notify operations of potential problems before they disrupt production.
- **Call center management:** Centralize incoming maintenance requests and give operators and customer service representatives fast access to all the information they need to handle maintenance, service and asset management requests.
- **Inspection management:** Automatically generate corrective work orders when inspection results exceed preset limits.
- **Materials management:** Monitor and control storeroom inventories with tools such as economic order quantity (EOQ), class classifications and assignments. Manage parts, receipts, issues, returns and cycle counts.
- **Reports:** Choose from predefined reports covering assets, materials, purchasing, schedules, work, budget analysis, projects and commercial services.

Attune EAM for Pharmaceutical connects your equipment and facilities into a unified system that supports compliance, quality and smarter operations.

Smarter asset management for pharma

Attune EAM for Pharmaceutical delivers industry-specific asset performance management practices and captures operational data to power analytics and machine-learning strategies.

Business analytics

See your data in new ways. From individual equipment performance to cross-enterprise data, Attune EAM helps you mine data, examine trends and surface actionable insights. Create flexible graphs and ad-hoc reports tailored to your needs, including GMP-specific reports that streamline regulatory data for audits and reviews.

Mobile

Better accuracy, faster service, smarter asset management. Attune EAM is mobile-first, so field workers and technicians can assign, perform, and record activities from anywhere, on any device. Work gets captured as it happens through real-time data access.

Workforce management

Get the right work done by the right people. Attune EAM uses built-in tools to optimize work allocation, reduce labor costs, and increase wrench time.

Lifecycle asset management

Make better decisions at every stage of the asset lifecycle. With properly captured safety, reliability, and maintenance data, you can effectively maintain assets, optimize maintenance practices, identify vulnerabilities, and plan replacements based on cost analysis.

Meeting 21 CFR Part 11 requirements

- **Print and electronically transfer records:** Print and export records in multiple formats, including Microsoft® Excel spreadsheets and Adobe® Acrobat® PDF files. Compile a record library that tracks progressive changes, giving FDA inspectors a clear view of every alteration to repair logs, inspection results, and preventive maintenance accounts.

- **Manage system access:** Meet or exceed 21 CFR Part 11 provisions with authority check controls. Set parameters to ensure password and ID integrity. Use an extensive network of overlapping security controls to prevent unauthorized users from electronically signing records, accessing functions outside their jobs and altering records.

- **Support audit trails:** Record selected database entries, changes and deletions with extensive auditing tools. Track user IDs, altered fields, value changes, timestamps, and whether a change was an insertion, update, or deletion.

- **Maintain document control:** Control distribution rights and revision access for protocols and procedures. Administrators can specify multiple staff members who must approve changes to procedures, such as calibrations and inspection tasks.

- **Support electronic signatures:** Ensure that each electronic signature is authentic. Set up routing and sequenced approvals for revisions of PMs, tasks, and material lists. Maintain a clear audit trail for FDA inspectors.

Maintenance and operations regulations constantly evolve, including FDA Title 21 CFR Part 11. Attune EAM is updated on a monthly or quarterly basis, so you can access compliant systems virtually as soon as changes occur.

Meeting current good manufacturing practice (cGMP) guidelines

Precise calibration is only half the job. Your documentation must also meet the monitoring requirements of federal agencies. That means clear records showing how your equipment performs, how your company conducts traces, and how you achieve product consistency.

With straightforward screens and menus, you can ensure proper calibration and documentation through:

- **Instrumentation and calibration:** Establish a calibration PM program for each piece of equipment with calibration instructions, approved procedures, original equipment manufacturer (OEM) specifications, process control limits and standard procedures. Set calibration PM schedules based on fixed calendar days or previous calibration results.

- **Track calibration results:** Track calibration sequences, test-point data, tolerances, process control limits, as-found and as-left results, actions taken, and calibration status. Each calibration work order links to a specific piece of equipment, so you can roll up costs and maintain historical tracking by parent equipment, department or organization. Also track corrective action procedures and root-cause analysis for out-of-tolerance work orders.

- **Traceability:** Quickly determine when and where a calibration has been erroneous and separate potentially affected products. Instrument calibration history supports reverse traceability if needed for investigations and analysis.

- **Calibration history and reports:** Search and view all calibration results for selected equipment by class, department, or date range. Choose from standard calibration reports covering frequency, last calibration date, and next scheduled date. Export calibration data directly to Excel and other programs for ongoing analysis.

- **Mobile entry of calibration data:** Use mobile devices to record, view, edit and transfer calibration information to and from a central database. Optimize workflows with mobile support for electronic signature standards.

- **Single source of truth for equipment and instrumentation management:** Attune EAM provides all the necessary functionality to manage both traditional assets and instrumentation within one platform. Instrumentation assets are integrated into the overall asset hierarchy and interact with the assets they support for maintenance, traceability, controls and performance.

Promote sustainability

Attune EAM for Pharmaceutical transforms energy consumption metrics and performance data into decisions and action.

Comply with environmental regulations. Reduce your company's overall energy and other natural resource consumption. Monitor and control greenhouse gas emissions, other fugitive emissions, water discharge and material byproducts. Use this information to reduce your carbon footprint. Reduce costs by making design and configuration changes in your asset infrastructure. Identify, optimize and automate proactive maintenance, as well as determine whether a piece of equipment should be repaired or replaced.

Work smarter

Stop searching for information. Start acting on it. Attune EAM is built on technologies that deliver better usability, connectivity, automation, and insight, so your employees can be productive from anywhere.

Connected

Unify your systems. Integrate Octave and non-Octave solutions, from ERP and capital planning to quality management, sensors, and building management, directly with Attune EAM to drive all reliability and maintenance activities.

Organized

Everything you need, one screen. Role-based dashboards and personalization tools put your key metrics, alerts, and inquiries in one place. Save configurations and preferences so users go directly to their tasks and data.

Reliable

One source of truth for all your reports. Attune EAM consolidates data from multiple systems across your business. Out of the box, you get powerful role-based reports and industry-specific measures built on 30+ years in the life sciences industry.

Confident

Act faster when it counts. Alerts and predefined workflows automatically deliver critical, role-based information to your desktop and smartphone. Get early notification of late deliveries, missed shipments. and quality failures.

Social

Transform how your teams work together. With social collaboration tools, everyone in your organization can collaborate in real time on projects and documents, share knowledge across communities of interest, and move faster to get better results.

See results now

In life sciences, managing assets for operational efficiency is critical. But it's not enough on its own. With Attune EAM for Pharmaceutical, you can turn compliance into a competitive advantage:

- Establish repeatable business processes and work execution methods
- Protect GMP asset traceability through configured workflows with electronic records and change control approvals
- Create separate workflows for non-GMP assets to separate and simplify work based on asset classifications
- Optimize resource and skill availability
- Uncover hidden profit potential to strengthen your bottom-line
- Manage energy efficiency and scale ESG performance
- Avoid FDA 483 observations and warning letters that lead to costly fines and plant closings

Cloud deployment for efficiency and excellence

Attune EAM has been a multi-tenant SaaS solution for nearly two decades. Your cloud deployment includes the same trusted capabilities as on-premises, with the assurance that your SaaS environment is maintained in a validated state. Patches and updates are tested specifically for pharma before implementation.

Migrating to the cloud lets you focus on improving asset management, not managing IT infrastructure, at a predictable cost. Redirect time and resources toward reducing inventory costs, deploying workers more efficiently, and driving better outcomes across your operations.

Unleash intelligence at scale.

About Octave

Octave is a leader in enterprise software, turning data into decisive action and intelligence into your edge. Our software solves for and simplifies complexity, from the design and build to operations and protection of people, property and assets – for any scope, at any scale. For decades, we've partnered with customers to sharpen performance, elevate efficiency and amplify results. From factory floors to entire cities, our solutions are tuned to scale up what's possible from day one onward.

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