



BROCHURE

Octave Attune EAM for Pharmaceutical





Compliance that strengthens performance

Regulatory risks? You need reliable systems and clear results. Octave Attune EAM (formerly HxGN EAM) scales your asset strategy so that you meet regulations, keep productions steady and protect product quality.

Elevate efficiency. Cut waste. Deliver consistent products. Meet evolving regulations with confidence.

Find efficiency, unlock outcomes

Our experience becomes your advantage. Octave helps you meet strict regulatory requirements and turn operational data into actionable plans.

Attune EAM for Pharmaceutical supports Code of Federal Regulations Title 21 Part 11 (21 CFR Part 11) requirements and other industry standards while applying analytics that clarify priorities and drive measurable gains.



Connected and comprehensive

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

- **Asset reliability management:** Track and analyze physical assets. Facilitate metered usage measurement and automatic usage 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, letting the solution adjust schedules to compensate for early and late work completion.
- **Performance-based maintenance:** Notify operations of potential problems before they disrupt production by using real-time monitoring, analyzing asset performance and alerting management.
- **Call center management:** Centralize incoming maintenance requests and empower operators and customer service representatives. Provide fast access to all the information they need to handle maintenance, service and asset management requests.
- **Inspection management:** Automatically generate corrective work orders when an inspection result exceeds preset limits.
- **Materials management:** Monitor and control the inventories of storerooms with materials management tools such as economic order quantity (EOQ), class classifications and assignments. Manage parts, receipts, issues, returns and cycle counts.
- **Reports:** Select from a variety of predefined reports including assets, materials, purchasing, schedule, work, budget analysis, projects and commercial services.

Attune EAM for Pharmaceutical helps businesses create an ecosystem across equipment and facilities to support compliance, quality and business innovation.



Evolving Attune EAM for pharmaceutical

Provide industry-specific asset performance capabilities. Capture and deliver big data to power analytics and machine-learning strategies.

Business analytics

From specific equipment performance to cross-enterprise data - Attune EAM scales to fit your needs. Mine data, examine trends and establish meaningful insights. Use configuration tools to create graphs supported by ad-hoc reporting options and see data in new ways. Design ad-hoc reports to contain data specific to good manufacturing practices (GMP) equipment and streamline regulatory data.

Digital work

Mobile-first, Attune EAM for Pharmaceutical sends complete computing power to any tablet or smartphone. Record activities anytime, as it happens. Yield better service, improve accuracy and elevate efficient asset management by accessing data in real-time.

Workforce management

Reduce labor and increase wrench time with Attune EAM for Pharmaceutical's built-in optimal work allocation functionality.

Lifecycle asset management

Powerful data and insights to support the full lifecycle asset management process? Your ability to make better decisions all along the way.



Meeting 21 CFR Part 11 requirements

Provide industry-specific asset performance capabilities. Capture and deliver big data to power analytics and machine-learning strategies.

- **Print and electronically transfer records:** Print and export records in multiple formats, including Microsoft® Excel spreadsheets and Adobe® Acrobat® PDF files. Build a library of records for FDA inspectors' easy access.
- **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, changes to values, the date and time of a change.
- **Maintain document control:** Control distribution rights and the ability to revise documentation of 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. Develop routing and sequenced approval for electronic signatures on revisions of PMs, Tasks and Material Lists to ensure process execution. Maintain a clear audit trail for FDA inspectors.

Maintenance and operations regulations constantly evolve, including FDA Title 21 CFR Part 11. Attune EAM solutions update 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

You need documentation to meet federal agencies' monitoring requirements. Show how your equipment performs, company conducts traces and how it achieves consistency in products.

With easy-to-use screens and menus, you'll ensure proper calibration and documentation with functionality that includes:

- **Instrumentation & calibration:** Establish a calibration PM program for each piece of equipment - calibration instructions, approved calibration procedures, original equipment manufacturer (OEM) specifications, process control limits and standard procedures for performing the calibration. Build a calibration PM schedule based on fixed calendar days, usage and the results of previous calibrations.
- **Track calibration results:** Track results such as calibration sequences, test-point data, tolerances, process control limits, as-found results, as-left results, action taken and calibration status. Each calibration work order is linked to a specific piece of equipment. This allows you to easily roll-up costs and maintain historical tracking of all equipment information based on parent equipment, department or organization. Also track corrective action procedures and root-cause analysis related to out-of-tolerance work orders.
- **Traceability:** 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 a selected piece of equipment. byView equipment class, department or date range. Choose from several standard calibration reports, including the frequency and date of last calibration and the next scheduled date of calibration. Directly export calibration data to Excel and other programs for ongoing analysis and reporting.
- **Mobile entry of calibration data for digital work:** Use mobile devices for digital work 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 consumption of energy and other natural resources. Combine energy efficiency with overall asset management strategies. Monitor and control greenhouse gas emissions, other fugitive emissions, water discharge and material byproducts from your operations. 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

Sharper performance. Elevated efficiency. Teamwork that doesn't miss a beat. Attune EAM for Pharmaceutical helps you move fast, solve problems, and deliver results.



Connected

Integrate Octave and non-Octave solutions. Set digital swim lanes between key systems to support advanced reliability and maintenance excellence. Attune EAM facilitates the execution of all reliability and maintenance activities like interactions with ERP, capital planning and quality management. It also monitors predictive and prescriptive data from sensors and building management systems.



Organized

Role-based dashboards. Powerful personalization tools. One screen for all the information you need to make better decisions, faster. Save inbox configurations and individual preferences so that you can go directly to data for your specific objectives.



Reliable

Scattered systems across your business? Attune EAM for Pharmaceutical provides a single, reliable source for all your reports. Our 30+ years of experience in the life sciences industry? Your data-driven edge.



Confident

Proactive and alert. Pre-defined workflows deliver critical, role-based information automatically to your desktop and smartphone. Act faster with early notification of late deliveries, missed shipments and quality failures.



Social

With our social collaboration capabilities, you can transform the way your company works. Imagine being able to work together on the same project or document in real time. Everyone in your organization will be able to work in communities of shared interests, collaborate more effectively, improve processes, act faster, be more productive and get better results.



See results now

Managing assets to optimize operational efficiency and decision making is just the beginning. Turn compliance into a competitive advantage with Attune EAM for Pharmaceutical, which helps you:

- Establish repeatable business processes and work execution methodologies
- Ensure the traceability of GMP assets through configured workflows to ensure electronic records and change control approval features
- Create separate workflows and processes for non-GMP assets for segregation and simplification of work based on asset classifications
- Optimize the reliability and maintenance program to achieve a risk-based, cost-effective asset care model
- Optimize resource and skill availability
- Uncover hidden profit potential to enhance your bottom-line performance
- Manage energy efficiency and scale ESG performance
- Avoid FDA 483 observations and warning letters resulting in costly fines and plant closings associated with compliance issues

Cloud deployment for efficiency and excellence

Octave's two decades of cloud solutions experience? Your validated and tested SaaS solution, before implementation.

Refocus time. Reduce inventory costs. Migrate to the cloud to improve asset management.

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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