Reliable.
Compliant.
Future-ready.

enVigil™ FMS
Environmental Facility Monitoring Software

Compliance Delivered.

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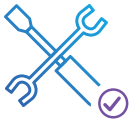
Trusted by pharmaceutical and healthcare leaders worldwide.



The flagship monitoring solution for the pharmaceutical industry

Pharmagraph has been empowering pharmaceutical and healthcare leaders to protect product quality and meet the strictest regulations for over 25 years. enVigil FMS is our flagship monitoring software, engineered for resilience, built for compliance, and designed to evolve with your facility.

Why environmental facility monitoring matters

Pharmaceutical manufacturing leaves no room for error. A single lapse in monitoring can mean compromised products, failed audits, reputational damage or lost production impacting revenue. enVigil FMS goes beyond the basics of monitoring, it provides complete confidence that your cleanrooms and controlled spaces are protected around the clock.

Regulatory alignment

Environmental monitoring sits at the heart of every effective Contamination Control Strategy (CCS). EU GMP Annex 1 (Manufacture of Sterile Medicinal Products) makes it clear that facilities must have a documented, proactive approach to controlling contamination, from cleanroom design and utilities through to processes, personnel, and monitoring. Without robust monitoring, even the best CCS cannot prove it is working.

That's where enVigil FMS plays a vital role. It provides the secure, continuous data trail regulators expect, while giving your teams the insight to strengthen contamination control day by day. It supports continuous improvement across your entire operation.

Global Compliance, Built In. Our enVigil FMS software is designed to meet the world's most recognised regulatory frameworks, including EU GMP Annex 1 and FDA 21 CFR Part 11 requirements for electronic records and signatures. It provides the validated, traceable data needed to demonstrate full compliance across global operations.

The system also aligns with **Good Automated Manufacturing Practice (GAMP 5)** and Current **Good Manufacturing Practice (CGMP)** guidance, ensuring robust software validation and data integrity at every stage.

*Virtual Machine deployments can cut server energy use by up to **80%** compared to continuously running hardware.*

Stay operational, no matter what happens

In GMP (Good Manufacturing Practice) environments, downtime isn't just inconvenient, it can be dangerous. When monitoring systems fail, production can grind to a halt, data gaps appear and audit trails weaken. Even a short interruption risks product quality and can leave compliance exposed.

enVigil FMS is built to make sure that never happens. Its Hot Standby servers provide immediate redundancy, while Buffered Data keeps logging locally, so no information is ever lost during network outages.

Virtual Machine compatibility makes recovery faster and IT management simpler, ensuring systems are always future-ready. Maintenance and calibration can be carried out without shutdowns, keeping facilities live and productive.

The result is continuous monitoring, complete data integrity, and total confidence that your audits will stand up to the toughest scrutiny, and your system never stops, even when the unexpected happens.

Hot Standby:
Redundant servers take over immediately if the primary fails.

Buffered Data:
Instruments locally log readings, ensuring no data loss during network interruptions.

100% Data Integrity:
Every data point captured, reconciled, and verified, providing regulators with full confidence.

Virtual Machine Compatibility:
Deploy on VMs for faster recovery, simplified IT management, and future-proof scalability.

Maintenance & Downtime Management:
Instruments can be swapped out in minutes, planned maintenance performed without disruption, and predictive service indicators keep calibration schedules on track.

Downtime isn't an option, we make sure it never happens.

Benefits in action

- Zero data loss, zero audit gaps.
- Resilient IT deployment with reduced overheads.
- Maintenance that doesn't halt production.

Intelligent system features can support a significant reduction in annual energy costs.

Smarter monitoring, lower costs and less disruption.

Compliance doesn't have to mean compromise. Too often, pharmaceutical teams face a trade-off. Maintain compliance but accept higher costs, wasted energy, and constant interruptions, or risk efficiency by cutting corners. Alarm fatigue, unnecessary shutdowns, and excessive energy use drain time and resources that should be focused on production.

Our enVigil FMS software changes that equation. It's designed to build efficiency into compliance. Features like Night Setback Mode reduce energy consumption automatically during non-production hours, while Targeted Alarms ensure only the right people are notified at the right time. Instrument tracking and swap-ability streamline maintenance and calibration, avoiding costly downtime.

The result is a smart monitoring system that reduces waste, lowers costs, and frees teams from firefighting, so they can focus on what matters most protecting product quality and delivering life-saving medicines.

Night Setback Mode: Lower energy consumption automatically during non-production hours.

Targeted Alarms: Notify only the right people, reducing alarm fatigue and sharpening responses.

Instrument Tracking & Swap-ability: Replace devices instantly without pre-programming. Traceability and calibration are built-in, ensuring full compliance.

Efficiency in Practice: By reducing nuisance alarms, avoiding shutdowns, and cutting energy use, enVigil FMS helps lower operational costs while protecting compliance.

Benefits in action

- Reduced energy costs and environmental impact.
- Faster responses to critical alarms.
- Simple, reliable maintenance and calibration.

Always audit-ready, every record, every signature, every time.

Be audit-ready, every day.

We know regulatory audits demand proof, and that proof must be instant, complete, and trustworthy.

With enVigil FMS, you're always ready. Every record is automatically secured, time-stamped, and traceable, so the full audit trail is available at the click of a button. Batch reporting with electronic signatures ensures compliance with global regulations, from FDA 21 CFR Part 11 to EU GMP Annex 11.

And it goes further, enVigil FMS doesn't just log what's already happened, it gives you the insight to spot issues before they develop. Trend and compliance metrics help you identify risks early, protecting production and ensuring your facility remains audit-ready, every day.

Benefits in action

- Always "audit-ready" rather than "audit-preparing."
- Clear reporting that speeds regulatory reviews.
- Early warning of risks before production is impacted.

Batch Reporting: Generate clear, time-defined reports with built-in electronic signatures.

Full Audit Trail: Every action recorded, who, what, when, simplifying CAPA investigations and training needs.

ALCOA+ Compliance: Data that is attributable, legible, contemporaneous, original, accurate, plus secure, complete, and consistent.

Regulatory Alignment: Fully supports EU GMP Annex 1 Contamination Control Strategy (CCS) requirements by providing continuous, validated environmental data.

Ringfenced Data: Records are securely stored in modular, validated structures. Data is integrity-checked and cannot be altered or corrupted, even as systems expand.

Trend & Compliance Metrics: Identify emerging risks and process improvements before they trigger alarms, strengthening contamination control and demonstrating proactive compliance.

In a high-speed filling line (~500 vials/min), a single m^3 particle count alarm could put up to 19,000 vials at risk. Using enVigil FMS Compliance Predictor, early warning alerts can reduce potential product impact by up to 85%, saving thousands of vials and potentially millions in lost revenue.

A system that grows with you, without costly overhauls.

A system that grows with you.

Every pharmaceutical site evolves. What works today won't always be enough tomorrow. New cleanrooms come online, equipment is upgraded, regulations tighten, and digital systems must keep pace. The challenge is making these changes without disruption, keeping your facility running, compliant, and efficient.

That's why enVigil FMS is built to evolve with you. Its modular architecture means you can expand or adapt your monitoring system without interrupting live operations. As your facility grows, enVigil FMS scales seamlessly, connecting isolators, incubators, LIMS, and IT backup systems into one coherent ecosystem.

The result is a system that protects product quality, strengthens compliance, and grows in step with your business, from local sites to global networks, without costly system overhauls.

- **Modular Architecture:** Expand systems without disrupting live operations.
- **Containment of Issues:** Problems are ring-fenced to one area, protecting the rest of your facility.
- **Full Facility View:** Even with modular deployment, you always see the complete picture.
- **Seamless Integration:** Connect to LIMS, isolators, incubators, and IT backup systems with ease.
- **LAN to Global WAN:** Secure gateways for access at site; enterprise, or global scale.
- **User Flexibility:** Alerts and reports delivered your way, via SMS, email, dashboards, or APIs.

Benefits in action

- Scale without costly overhauls.
- Integrate with existing infrastructure for unified control.
- Provide oversight from the cleanroom to global management.

More than a system, a partnership.

Choosing enVigil FMS means choosing more than a system, it means choosing a partner. Pharmaceutical monitoring isn't just about software, it's about trust. Environmental monitoring facilities need a partner who understands the challenges of regulated environments, who can deliver systems that meet the strictest compliance standards, and who will be there long after installation is complete.

That's where Pharmagraph stands apart. We have decades of experience in the pharmaceutical sector, our team doesn't just install the enVigil FMS environmental monitoring system, we guide you through the entire lifecycle. From design and validation to training, calibration, and ongoing support, we ensure your monitoring evolves in step with your operations.

The result is confidence that your investment is protected, your systems remain compliant, and you always have expert support at your side, wherever your facility grows.

Turnkey delivery, from design to validation

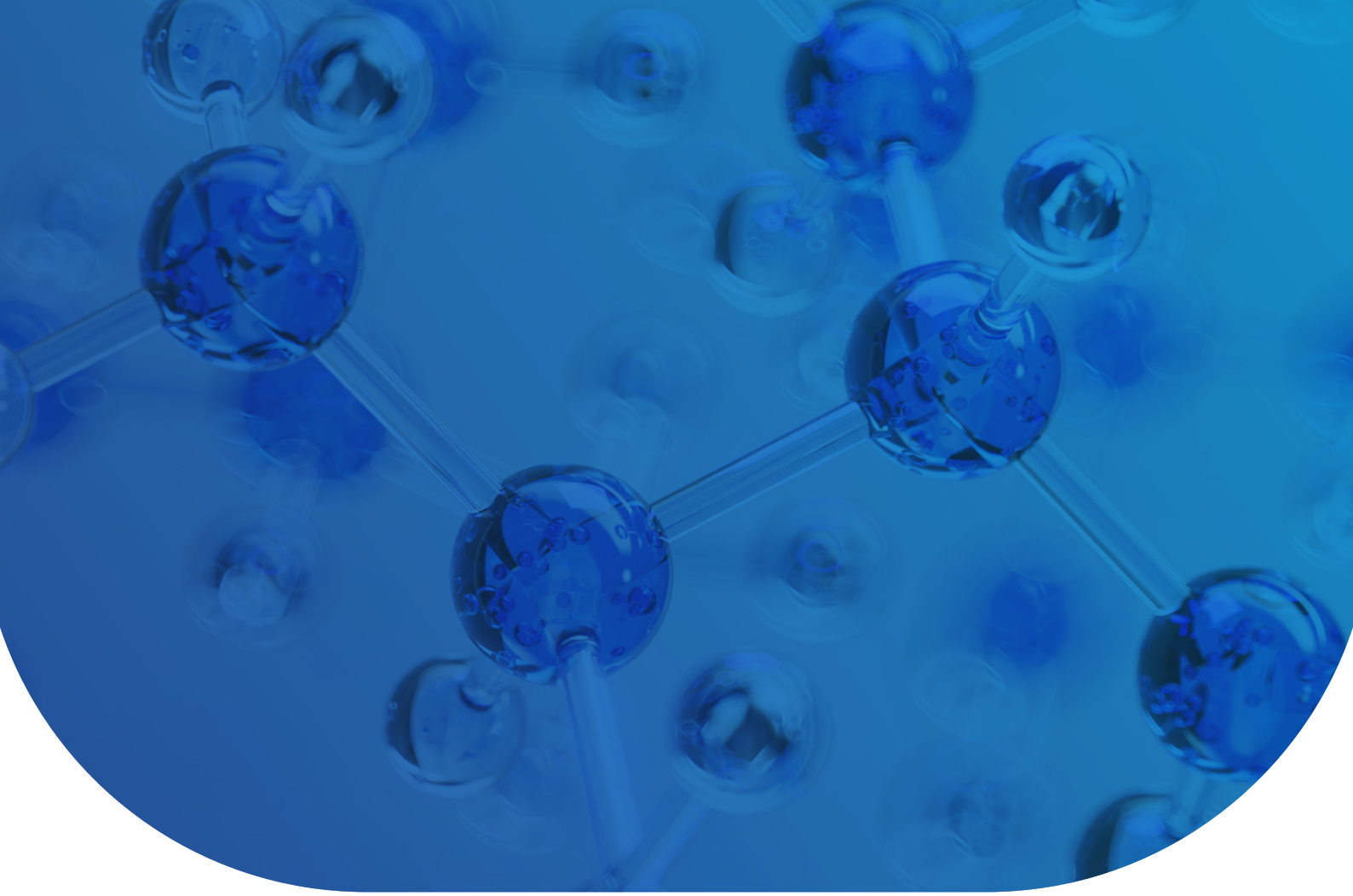
Lifecycle support, calibration, training, service, and updates

30+ years' experience in regulated pharma

Trusted by leading manufacturers worldwide

Compare our Environmental Monitoring Software Solutions

Feature / Benefit	enVigil FMS Flagship Facility Monitoring	enVigil PnP Pharmacy Monitoring
System Resilience	Hot standby, buffered data, VM support	Single-server configuration
Data Integrity	Full recovery, ALCOA+ compliant audit trails, 21 CFR Part 11 compliance	Standard logging, 21 CFR Part 11 compliance but basic
Operational Efficiency	Night setback, targeted alarms, swap-ability	Core monitoring only
Predictive Insights	Trend & Compliance Metrics	Not available
Scalability	Modular, expandable architecture	Fixed, compact design, upgradable to FMS
Integration	Seamless links to LIMS, isolators, IT backup	Limited connectivity
Access & Flexibility	Remote troubleshooting, WAN gateway, SMS/email/API alerts	Local and remote access, basic alerts
Best Fit For	Pharmaceutical manufacturing & GMP facilities	Hospital pharmacies, smaller cleanrooms, start-ups



enVigil™ FMS

Facility Monitoring with Confidence.

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