

Turnkey Environmental Monitoring Solutions

FROM DESIGN TO CALIBRATION







PHARMAGRAPH
Pharmaceutical Monitoring Systems





At Pharmagraph, we take pride in developing world-leading clean room facility and environmental monitoring solutions that have been trusted by contractors and end-users for over 30 years.

We are highly experienced in collaborating with contractors and assisting you in providing a fully managed EMS project life cycle for your end-users.

Our turnkey, in-house developed EMS solutions provide unrivalled operational assurance and compliance, whilst also providing the flexibility and expertise needed during complicated build projects.

Our software suite, enVigil, boasts a range of compatible hardware so that we can have full overview of the project at hand. This enables us to deliver innovative and creative solutions to address the most daunting challenges faced by your end-users. From small startups to full-scale manufacturing projects, our team excel in crafting bespoke solutions tailored to your clients' unique needs.

Solutions for your Clients Challenges in Clean Room Monitoring

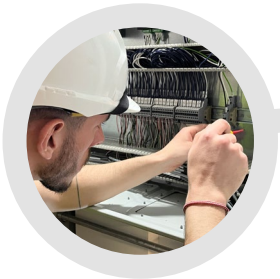
Be One Step Ahead

In the fast-paced world of client service, being one step ahead can make all the difference. Taking a proactive approach to addressing your client's FAQs can enhance their experience, build stronger relationships, and set your company apart as a trusted partner.

We understand that taking the time to understand your client's concerns and objectives is crucial in this process. Therefore, to help you prepare thoughtful questions in advance, we have created a repository of key questions you should ask your clients, as well as their FAQs and answers regarding our EMS solution.

Save time and effort in the long run by fully understanding your client's needs and finding the best EMS solution.









End-Users FAQs

Key Questions You Should Ask Your Client

To provide the best EMS solution for your client, you need to gather critical information that will enable you to meet all their requirements. See below the ten key questions you should be asking.

01. What are your specific environmental monitoring needs and objectives?

This first question will give you an overview of your client's objectives and requirements. However, be aware that they might still miss important points as they tend to overlook technical aspects.

02. Do you have a completed or draft User Requirement Specification (URS)?

The URS is a critical step in the early stages of project planning, as it provides a foundation for design, development, and testing. This formal document should be as comprehensive as possible, capturing and defining what users expect from the EMS solution.

03. What industry regulations or standards must the EMS solution comply with?

It is paramount that your client complies with the EU-GMP Annex 1, cGMP, GAMP, 21 CFR Part 11 and the UK's MHRA Orange Guide.

04. How many facilities or locations require environmental monitoring?

Learning the number of facilities/locations - ideally by the client providing a floorplan - will help with tailoring the solution. As experienced partners, Pharmagraph can provide a transparent assessment and advise what is or isn't needed.

05. What are the critical parameters that need to be monitored in your facility?

This key question will help you identify whether the solution of choice is the best fit for your client and what features you should look for. Typically, these are pressure, temperature, relative humidity, viable and non viable particle counts.

06. Are there any existing environmental monitoring systems in place? If so, what are the pain points or limitations?

If your client is searching for a new EMS solution, it is critical to understand their motivations and their current system's limitations. At Pharmagraph, we also take on partially installed systems and other manufacturers' hardware and find solutions for the end-user's pain points.

07. Do you have any preferences or requirements regarding the scalability and flexibility of the EMS solution?

Although some clients may not have specific requirements regarding how scalable and flexible the EMS solution should be, it is something that you should consider in order to future-proof for expansions.

08. Are there any integration requirements with existing systems or hardware?

This question demands more technical information and should be answered by your client's IT team to ensure that the new EMS solution provides seamless integration and will not affect the client's activities and productivity. In particular it is useful to know if data will be exported to other systems such as data historians or electronic batch reporting systems.

09. Is there a set timescale and budget for this project?

Knowing of any budget and time limitations from the outset will help us to tailor our solution to fit with your client's needs. The range of options and associated costs for an EMS can vary greatly, from monitoring a small hospital pharmacy to an entire manufacturing site.

10. How do you want the information to be displayed?

Every client has preferences regarding how the information should be displayed on screen, which can optimise their daily activities.

How We Can Help You With Your Client's Queries

01. Can Pharmagraph supply a monitoring system for my cleanroom facility?

Yes. We are experts in environmental monitoring systems for cleanroom facilities. Our in-house developed enVigil software suite is a powerful, robust solution with a pedigree that has been derived from thirty years' experience in providing EU-GMP compliant monitoring solutions.

02. Can Pharmagraph provide all the required compliance documentation?

Pharmagraph are committed to ensuring their clients compliance to relevant regulatory requirements and support Quality Assurance, both during the project and the system life cycle.

03. Can Pharmagraph supply hardware as well as software?

Yes. The enVigil software suite is an open platform, being compatible with a wide range of 3rd party hardware. However, if your client requires hardware, we also provide in-house developed hardware solutions and industry standard instrumentation that interface with our software, including particle counters, viable air samplers and a range of environmental sensors.

04. Can Pharmagraph come in person to meetings and pitches to consult?

Yes. Our services extend beyond being a software developer and provider. We work as true partners, attending meetings when requested and acting as consultants, offering invaluable insights and strategic guidance. You can entrust Pharmagraph as your confidential, discreet partner in navigating your client's complex challenges and achieving success.

05. What level of customisation is available for enVigil?

Our enVigil suite is configurable from a solid platform and highly customisable. Since we are the developers of our own solution, that gives us flexibility to adapt our software to unique client requirements whilst keeping its best features: reliability and safety.

06. Are there any ongoing maintenance or subscription fees for enVigil?

Our EMS solution, enVigil-V, is available with license sizes of 25, 50, 100, 200, 500 and 10,000 Input/ Output (I/O) point database with a single lifetime license fee. After the initial warranty period Pharmagraph offer optional support and maintenance contracts that cover ongoing technical support for the system as well as any annual calibration required for the installed sensors.

07. Can enVigil be scaled up or down as the client's needs change?

Yes. The scalability of enVigil allows seamless adjustments to match the evolving needs of your client, ensuring adaptability and flexibility as their requirements change.

08. Are there any additional services or support included?

Yes. Our highly skilled Service and Support teams can assist your client far beyond the initial deployment of their system. We work with customers to establish a routine calibration programme to meet their GMP requirements whilst fitting around their scheduled shutdown teams. Return to base calibrations with a 48-hour turnaround are also available where required. Moreover, a key part of any system handover is operator training. Training sessions are conducted by our expert Project Engineers.

09. How long does it typically take to implement enVigil?

The deployment process for enVigil can take only a few weeks for small systems and up to a few months for larger projects. Much of the configuration and setup for the enVigil system is performed at Pharmagraph's offices before delivery to site, minimising the disruption to your operations.

10. Can you provide references or case studies of clients who have implemented enVigil?

Yes. You can find case studies on our website.

11. Is there a trial or demo available before making a commitment?

Yes. Contact our sales team to book a demo for your client.

Other Aspects to Consider

Other important aspects that hold significant advantages for the end-user are:

- Customer experience from the early stages to the aftersales - calibration, service, and support.
- Local support and office locations.

Our EMS Solutions

enVigil V FMS:
Environmental Monitoring System

enVigil V is a fully configurable environmental monitoring software system aimed at GMP manufacturing environments. From high throughput biopharmaceuticals to patient specific ATMPs, each enVigil V system is tailored to client needs and aids their regulatory compliance.

enVigil–IMS:
Isolator Monitoring System

enVigil-IMS provides integrated particle monitoring for Isolators and RABS Filling Machines. We work with isolator and filling line manufacturers to enable seamless integration of key environmental monitoring data between the two systems, accessed through a single HMI.

enVigil–PnP:
Monitoring System for Hospital Pharmacies

enVigil-PnP provides a simple to use, cost-effective solution which ensures a GMP/GLP compliant system and is ideally suited to modern day hospital pharmacy and IVF clinic operations. With a range of package sizes optimised for systems up to 20 particle counters, 20 active air samplers and 60 environmental inputs enVigil-PnP is easy to deploy, verify and validate.



Our Customer's Journey

Your journey with Pharmagraph begins when your client decides that they need a new, enhanced, or flexible EMS for their new or renovated facility.

Throughout this journey, we will be true partners, helping you meet all your client's requirements, and providing you with exceptional customer service, alongside a fully managed project life cycle.

End-to-End Project Management

From your first contact our team of experienced sales engineers will work closely with you to help identify your client's needs and specify the system options available to meet them. Along this journey, we also help you budgeting and assist you with bids, if necessary.

From there each system installation is managed by a dedicated regional project manager who will coordinate from system design all the way through to validation. This gives you a single point of contact and enables Pharmagraph activities to fit seamlessly.

We work with you along the way to ensure the system is designed and specified to the end-user's needs. This includes engaging with stakeholders across the site to build the mimics, dashboards and tools to enable efficient day-to-day usage.

Your clients will also benefit from:

- Qualification and Training
- Ongoing Support and Calibration

We are your EMS experts and are here to guide you every step of the way.

Who We Are

Your end-to-end provider of bespoke environmental monitoring systems that deliver succinct, reliable results.

At Pharmagraph, we are proud to design and deliver world leading facility and environmental monitoring solutions.

With more than 30 years of experience in the design, production, installation, service and support of high-quality monitoring systems, the Pharmagraph team can assist you through all stages of the system life cycle.

From supply of sensors, through to installation, system qualification, training and calibration, we work closely with our clients at every stage to ensure that systems are delivered on time and to specification.



Your Journey Starts Here

Contact us today to arrange an onsite visit or call to discuss your client's requirements with our EMS solutions experts.

Sales Team

Alpha Scientific

Scientific & Environmental Monitoring Technologies



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