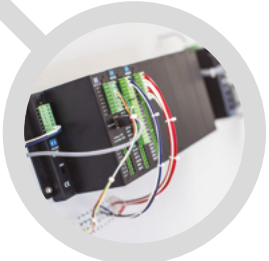
Pharmaceutical Monitoring Systems



PHARMAGRAPH

Pharmaceutical monitoring systems that deliver succinct, secure results

At Pharmagraph we are proud to design and deliver world leading facility and environmental monitoring solutions. Offering exceptional customer service, alongside a fully managed project life cycle, our turn-key solutions provide unrivalled operational assurance and compliance.

By providing our own in-house software suite enVigil, with a range of compatible hardware, we can have full overview of the project at hand. This allows us to bring innovative and creative solutions to our customers challenging problems. We collaborate with our customers every step of the way, extending our offering beyond project delivery with a comprehensive service and support infrastructure. This agility and flexibility allows Pharmagraph to meet the constantly changing business needs of our customers. In short, we make it happen for you!

Our Software

At the core of our Monitoring Solutions is our enVigil software suite. Developed in house by Pharmagraph for more than 30 years, the enVigil software range offers a market leading, EU-GMP/GLP compliant monitoring system for a variety of end uses. From pharmaceutical cleanrooms to satellite manufacturing facilities, Pharmagraph's enVigil systems are deployed worldwide to measure various environmental parameters. These systems may also be expanded to include equipment monitoring of fridges, freezers, and incubators.

The enVigil software suite ensures our clients can meet the requirements of the EU-GMP Annex 1, cGMP, GAMP and 21 CFR Part 11 by offering:

- An easy-to-use graphical interface
- High level facility mimics and alarm displays
- Trending of real-time and historical data
- Batch reporting with electronic signatures
- Compliance prediction tools
- Reconciled alarm reports with Trend Metrics
- Powerful reporting and data analytics
- The ability to integrate with other data systems via OPC, Modbus and more
- Drivers for multiple particle counters, air samplers and environmental sensors

The enVigil suite of software is provided in three variants:

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 V can be configured to run on a single PC running on the Windows operating system to a full Windows Server based application running on virtual machines with optional Hot Standby functionality, ensuring no loss of data. It features the most powerful reporting tools and electronic signatures to ensure full GMP 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.

enVigil™

Scan here to download our brochures

Our Hardware

Alongside our enVigil software suite, we supply a range of hardware to support and enhance our monitoring systems.

Viable Air Samplers – iVAS

Our own range of intelligent air samplers offering:

- Unrivalled efficiency and consistency in microbial monitoring.
- Integrated HPV tolerant controller measuring actual flow and sample volume.
- Compatibility with 90mm media plates.
- Regulatory compliance to EU-GMP Annex 1 and USP 797 requirements.

Distributed or Rack-based I/O Modules

Pharmagraph designed and manufactured Series 2000 and MX5000 I/O modules can be deployed flexibly in central instrumentation panels or conveniently distributed on larger sites and provide:

- Local logging of key data enabling total business continuity in the event of unscheduled server or network downtime.
- Optimised use with enVigil FMS or PnP systems.
- Direct connection to transducers with no additional wiring or external energisation required.

Visit our website for more information

Particle Counters

Our enVigil monitoring software is compatible with a wide range of particle counter manufacturers allowing for easy integration with new or existing sensors, these include:

- Beckman Coulter
- PMS
- Lighthouse
- Climet

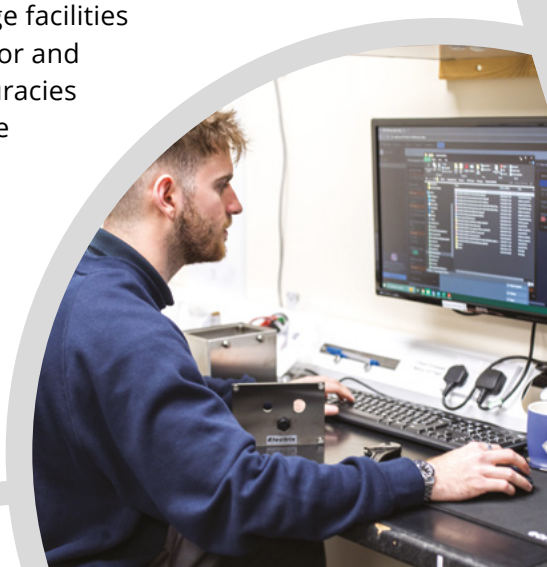
In the UK Pharmagraph is a distributor for Beckman Coulter Met One particle counters and manufacture our own enclosures to ensure they are cleanroom compliant.

Environmental Sensors

The Pharmagraph Series 2000 and MX5000 I/O systems connect to a broad range of industry standard sensors to accurately measure key environmental conditions including:

- Differential pressure
- Humidity
- Temperature
- Airflow

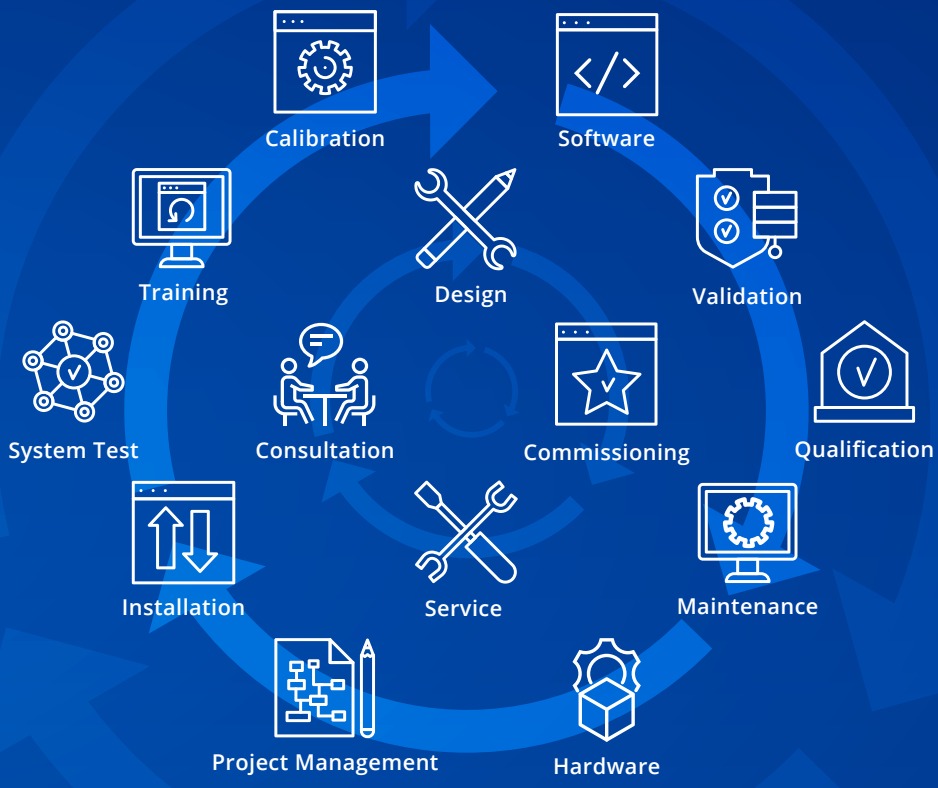
Equipment storage facilities are also catered for and temperature accuracies of +/- 0.1°C can be achieved for the monitoring of fridges, freezers and incubators.



Project Management

Here at Pharmagraph we understand that seeking trustworthy, compliant systems for your facility and environmental monitoring requirements can be a daunting task. That's why we focus on working with our customers every step of the way.

We offer a fully managed turnkey environmental monitoring solution from system design all the way through to project completion and ongoing support and calibration. Our experienced sales and project teams will be on hand throughout the project lifecycle to answer any queries and use their expertise to find the best solution for the job at hand.



Service and Support

At Pharmagraph our commitment to the customer doesn't stop at project completion; our services extend to helpline support, routine calibration, and maintenance, decommissioning and data migration.

Offering tailored contracts that ensure these requirements are met, whilst maximising system uptime, we have a wealth of experience in supplying application specific solutions for a wide range of varied end clients.

We are an ISO9001:2015 certified company who employ highly experienced, GMP trained staff. We work with industry standard suppliers and partners employing industry proven and accepted robust measurement techniques.

We can also offer ISO17025 compliant calibrations, enhancing the high level of trust and confidence that our customers have in our validated processes.

We can provide on-site end to end loop calibrations for most measurements, tailored to meet specific equipment ranges.*

**exceptions apply*

Quality and Compliance at Pharmagraph

Pharmagraph aims to deliver products and services that meet or exceed our customers' expectations, and that comply with all statutory and regulatory requirements for the industry. Our aim is to provide the customer with goods and services to the agreed requirement in accordance with the scope and price.

Pharmagraph are committed to achieving and maintaining Quality and Compliance.

Our Quality Management System is certified as meeting the requirements of ISO 9001:2015 and we can offer ISO 17025:2017 accredited calibrations. Giving our customers confidence in the high quality of products and services we provide.

bsi ISO 9001 Quality Management Systems CERTIFIED

FS 621150

bsi UKAS MANAGEMENT SYSTEMS 0003

FS 621150

CYBER ESSENTIALS CERTIFIED

SafeContractor APPROVED

JOSCAR REGISTERED

UKAS CALIBRATION

24752

Constructionline Silver Member

Accreditation

Our attainment of the following accreditation demonstrates our commitment to work to the highest industry standards, as well as our dedication to continuous improvement.

- ISO 9001:2015
- ISO 17025:2017
- Cyber Essentials
- Safe Contractor
- Constructionline
- JOSCAR Registered

Tel: +44 (0) 1252 861700 sales@pharmagraph.co.uk www.pharmagraph.co.uk

Pharmagraph

Glossop House, Hogwood Lane,
Finchampstead, RG40 4QW, UK

Pharmagraph is a division of Acquisition Systems Ltd

Finchampstead | Runcorn | Stirling | Lisburn

TRI 6PP 06/26