

# Pharmabilities

*Complete Contamination Monitoring Solutions*







## Why Choose Particle Measuring Systems?

### Superior Knowledge

Our experts are recognized as thought leaders, evidenced through our speaking requests, webinars, authored papers, and high education levels.

Our technology experts actively participate with customers and industry standard committees to understand the evolving needs and challenges faced by our broad customer base. Our renowned Particle College® program includes a two-day series of lectures and hands-on labs covering basic contamination measuring concepts and advanced applications of contamination monitoring and control.

### Superior Technology

A core investment in research, engineering and product manufacturing has resulted in more than 60 patents related to our products and applications. We create the technology that enables you to make fact-based decisions, improve yield process, and comply with changing regulatory requirements. We are also leaders in microbial detection, developing traditional techniques that reduce false positives and rapid techniques to improve speed and accuracy of detection.

### Superior Quality

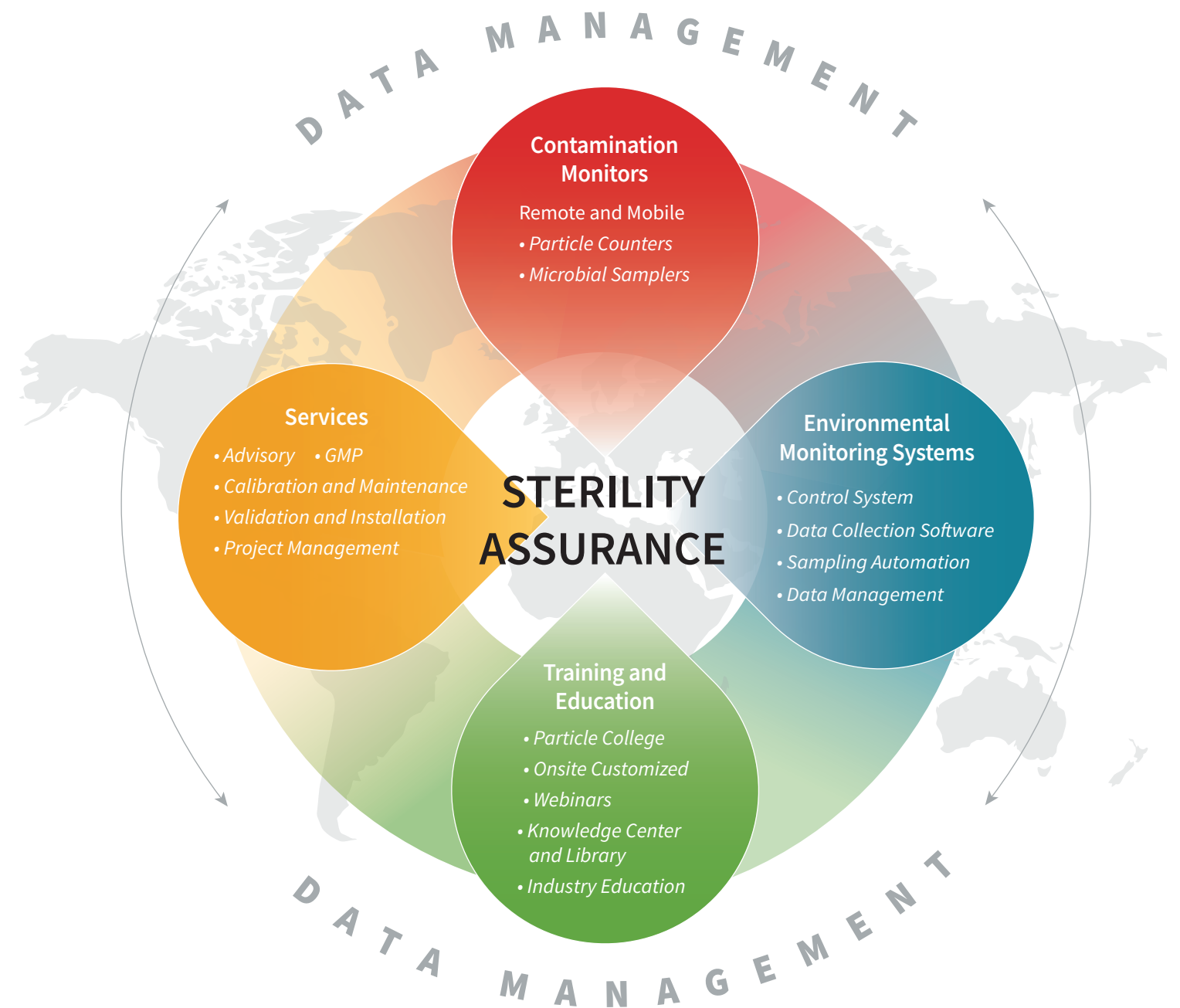
Particle Measuring Systems sets the standard for contamination monitoring by first designing reliability into our products and advisory services. We support this with an unmatched Quality Management System.

### Superior Service

Our focus on customer relationships and providing the highest quality service means that we succeed when our customers succeed.

## COMPLETE SOLUTIONS PROVIDER

Particle Measuring Systems provides you with the tools and industry experts to **detect, analyze, and manage** cleanroom contamination.



*Without measurement there is no control*



MONITORING SOLUTIONS

Control System for:  
Sampling, Detection, and  
Data Storage



FacilityPro® 5010, 3000, 1000  
Environmental Monitoring System



FacilityPro® 3000



FacilityPro® 1000

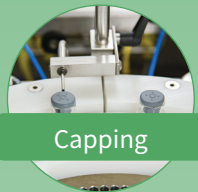
ISO 5 / Grade A



Loading



Filling



Capping



Lyophilization



Sealing

VIABLE



MiniCapt® Mobile  
Microbial Air Sampler



BioCapt® Single-Use  
Microbial Impactor



BioCapt® Microbial  
Impactor



BioLaz® Real-Time  
Microbial Monitor



SurCapt™ Microbial  
Surface Detection



MiniCapt® Remote  
Microbial Air Sampler

NON - VIABLE



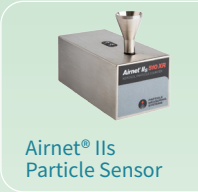
Lasair® III Aerosol  
Particle Counter



Airnet® II  
Particle Sensor



IsoAir® 310P Aerosol  
Particle Sensor



Airnet® IIs  
Particle Sensor



APSS-2000 Automated  
Parenteral Sampling  
System

ISO 5-6 / Grade B



Operator Functions



Product Transferring



Grade A Background



Materials Transferring



Sealing

VIABLE



MiniCapt® Mobile  
Microbial Air Sampler



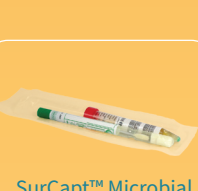
BioCapt® Single-Use  
Microbial Impactor



BioCapt® Microbial  
Impactor



BioLaz® Real-Time  
Microbial Monitor



SurCapt™ Microbial  
Surface Detection



MiniCapt® Remote  
Microbial Air Sampler

NON - VIABLE



Lasair® III Aerosol  
Particle Counter



Airnet® II  
Particle Sensor



IsoAir® 310P Aerosol  
Particle Sensor



Airnet® IIs  
Particle Sensor

ISO 7-8 / Grade C-D



Gowning



Compounding



Packaging

VIABLE



MiniCapt® Mobile  
Microbial Air Sampler



SurCapt™ Microbial  
Surface Detection



BioLaz® Real-Time  
Microbial Monitor

NON - VIABLE



Lasair® III Aerosol  
Particle Counter



IsoAir® 310P Aerosol  
Particle Sensor



Airnet® II  
Particle Sensor



HandiLaz® Mini  
Particle Counter



Airnet® IIs  
Particle Sensor

PROVIDING:

Data Management

Calibration

GMP Services

Advisory Services

Education and Training

Validation

Project Services

CONTAMINATION MONITORING SOLUTIONS

REMOTE

MICROBIAL SAMPLING



BioCapt® Single-Use Impactor

- Secures the process, product, and ultimately the patient by avoiding contamination risks
- Ready to use, triple wrapped and VHP impermeable
- Continuous monitoring of the process through increased sampling time



BioCapt® Microbial Impactor

- Meets regulatory requirements - remote sampling and ISO 14698-1/2 compliance
- Versatile petri dish compatibility through adjustable height
- 316L stainless steel sampling head ensures optimal sampling through radial slit design



MiniCapt® Remote Air Sampler

- Environment protected by HEPA filtered exhaust air
- Modern, easy to use data and sample configuration management by integration with a FacilityPro® system
- Remote sampling automation eliminates operator errors



BioLaz® Real-Time Monitor

- Full process control via real time continuous viable air monitoring
- Meets regulatory requirements for process control under PAT/QbD and USP <1223>/EP 5.1.6 compliance
- Cleanroom mapping

PARTICLE COUNTING



Airnet® II Particle Sensor

- Part of an automated monitoring system reducing manpower
- Consistent location monitoring
- Used for particle trend analysis
- Compact size for flexible mounting
- Polycarbonate or stainless steel enclosures resist cleaning chemicals
- Particle channels of 0.5 and 5.0 µm
- ISO 21501-4 compliant



IsoAir® 310P Aerosol Particle Sensor

- Simple integration into monitoring systems
- Built-in pump reduces infrastructure
- Local status LEDs for visual indication
- 4-20 mA input and digital output options
- Integration of environmental input sensors
- Automatic shutoff mode for capped probes
- 0.5 and 5.0 µm particle channels
- ISO 21501-4 compliant

MOBILE

MICROBIAL SAMPLING



MiniCapt® Mobile Air Sampler

- Unparalleled flexibility with multiple handheld, remote and compressed gas monitoring applications
- Unique safety and precision - HEPA filtered exhaust air and radial slit design
- Meets current requirements of data management



DataAnalyst Software

- Long term data archiving for Lasair III and MiniCapt Mobile
- Compliant with 21 CFR Part 11 for data security and integrity
- Simple instrument data download
- Cleanroom certification and contamination trend analysis

PARTICLE COUNTING



Lasair® III Aerosol Particle Counter

- Minimize operator errors with intuitive recipe configuration
- Meet ISO 14644-1/2:2015, ISO 21501-4, EU-GMP
- Multiple users/group access control
- Resistant against a wide range of chemical disinfectants
- Environment protected by HEPA filtered exhaust air
- 21 CFR Part 11 compliant
- Compressed gas monitoring



HandiLaz® Mini Particle Counter

- Cost effective solution
- Easy to use
- Small, handled design
- Battery allows for portable use

PROCESS TESTING

MICROBIAL SURFACE DETECTION KIT

SurCapt™ Microbial Surface Detection Kit

- Improved productivity - results within 24 hrs
- Automated readout of results
- Validated according to EP/USP guidelines



LIQUID PARTICLE COUNTING



APSS-2000 Automated Parenteral Sampling System

- Meets all US, Japanese and European Pharmacopeias.
- Particle sizing from 1.5 µm to 125 µm
- Sample volumes from 0.2 mL to 1 L per USP <787>
- 21 CFR Part 11 compliant software.
- Intuitive recipe and auto-report creation minimizes operator errors



ENVIRONMENTAL MONITORING SYSTEMS

The FacilityPro® Advantage  
Designed specifically for  
pharmaceutical environmental  
monitoring.

Sampling, Detection, Data Storage

Data Integrity Assured

A robust system architecture ensures critical data are always available and protected when needed for batch release and reporting.

- Industrial system architecture
- Built on GE Proficy® iFix and Historian platform (SCADA version)
- Redundancy and data buffering throughout the system
- Sensor-based time stamping
- 21 CFR Part 11 compliant

Ultimate Efficiency and Reduced Errors

Intelligent software features make the job of collecting and reporting data efficient, with reduced human error.

- Viable / Nonviable / Environmental data integrated
- Sampling automation and recipes
- Batch identifiers and other data filters
- Configurable reports and data management

Simple Implementation

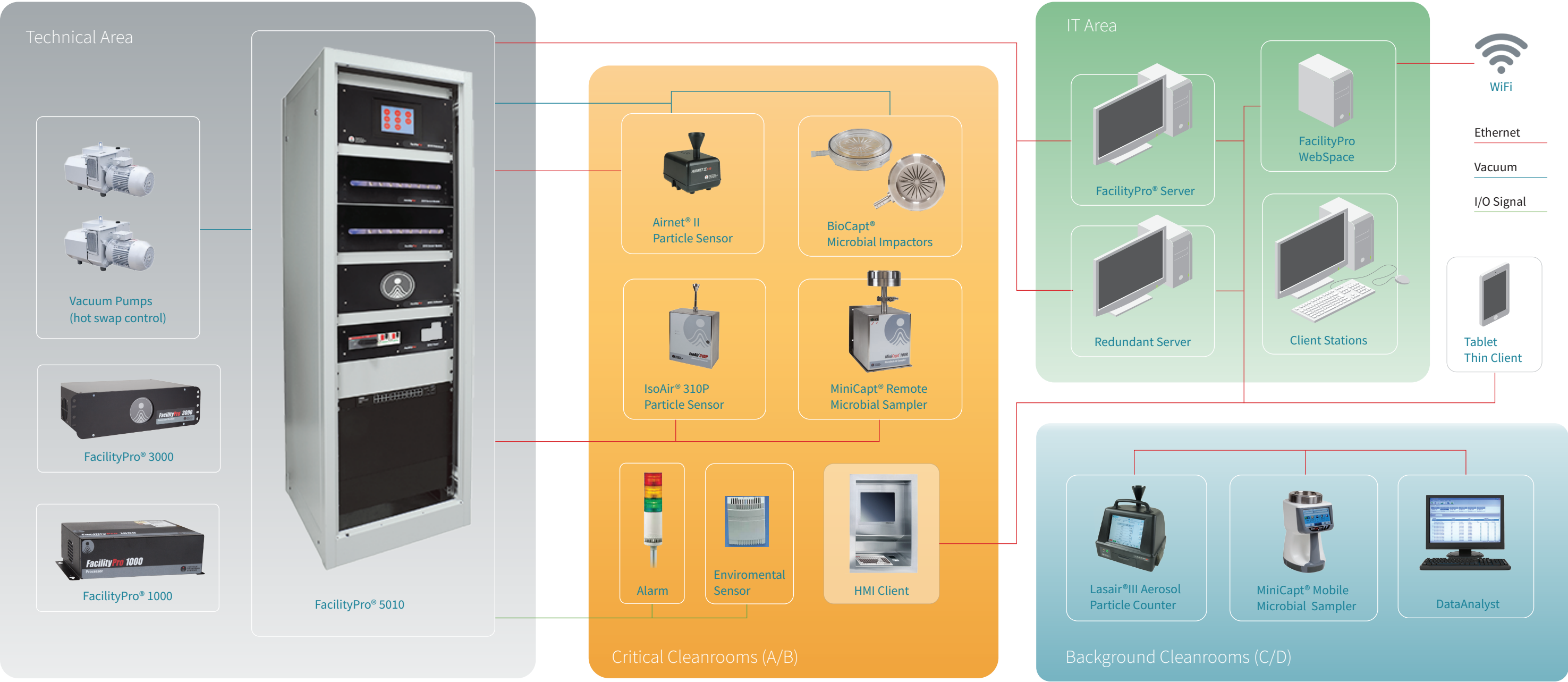
Hardware and software modules are designed to speed installation and validation. The modular design makes upgrading or expanding simple and quick.

- Prebuilt vacuum and power infrastructure (5010 series)
- GAMP 5 Category 4 compliant software
- Standard configurable components

Flexible Integration

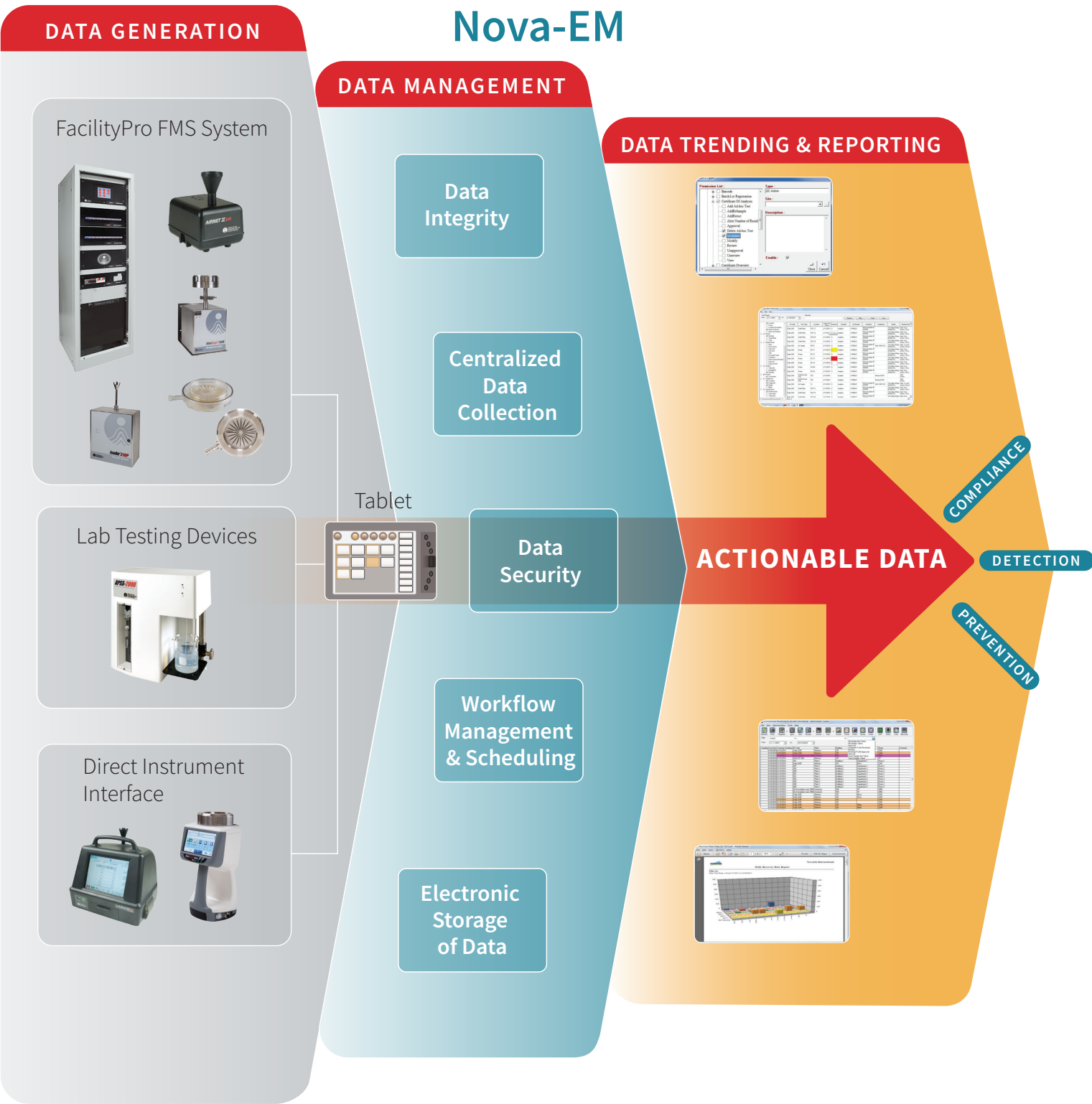
Easy to integrate with existing third-party software and hardware systems.

- Remote access through client stations, web browsers and tablets
- Industry-standard protocols



DATA MANAGEMENT

Nova-EM is integrated with PMS systems and other sources of information, helping companies manage the collection, analysis, and trending of data. Timely detection of problems in production allows issues to be addressed before they become a concern. Risks and costs associated with product loss and recalls are reduced.



ADVISORY SERVICES

Providing you with experts to support you at every step of your process. Whether it's from non-compliance issues, setting up a new process, our team has the background and education to support you.

Our team's ongoing interaction with regulatory agencies ensures continuous knowledge of new industry requirements, providing expert knowledge and background to support all stages of production.

**Advisory Services**

- Crisis management
- QbD/PAT
- Pharma microbiology
- Alternative microbial methods
- Production support
- QA support
- Risk assessment

EDUCATION AND TRAINING

Companies have relied on our accredited Particle College® to educate thousands of individuals on the fundamentals of contamination monitoring and control. In addition we offer a wide variety of pre-set and customized training services to meet the exact needs of each customer.



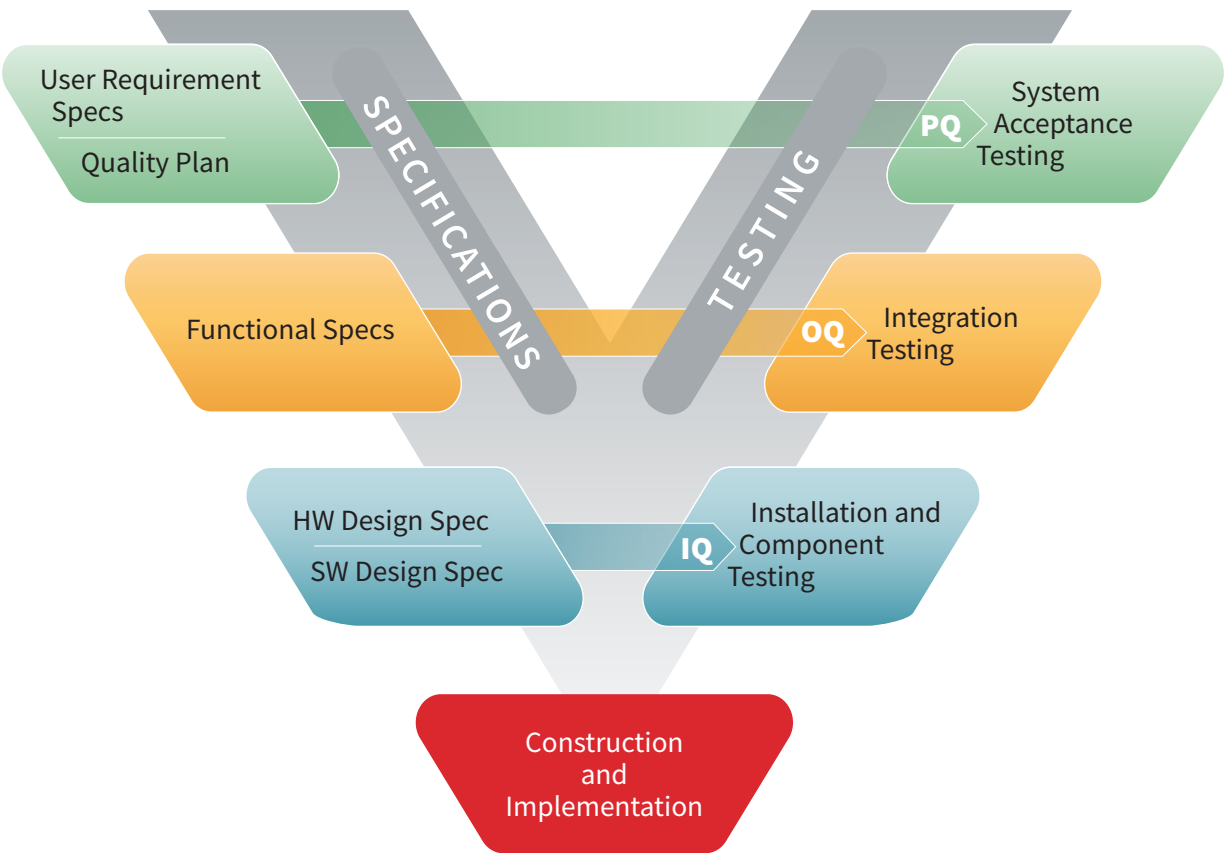


PROJECT SERVICES

From system design to installation, commissioning and validation, we can guide you through a project from conception to completion.

Subject-matter experts provide you with design and analytical consulting services, including:

- Risk assessment
- Facility monitoring system design
- Design specifications
- Validation
- Project management
- User training
- Application support



QUALITY CALIBRATION & SERVICE

Service technicians specially trained to calibrate your instruments to the highest standards, and our software-controlled approach automates critical steps that drive consistency in each calibration.

This ensures the same result and performance, consistent with factory calibration, regardless of where the calibration is performed—anywhere in the world.

Services

**Calibration Services**

- Calibration and adjustment back to factory standards – As Found/As Left data available
- Preventative maintenance
- Technical support
- NIST traceable
- ISO 9001:2008
- ISO 21501-4:2007
- ISO/IEC 17025\*

**Additional Services**

- Dedicated Particle Measuring Systems technician available year-round at your facility
- Service contracts for on-site calibration and repair at your facility or return to factory service
- Extended warranty for calibration and unexpected repairs
- Rentals and spare instruments while your particle counter is in factory for service

\*available at specific service centers

GMP SERVICES

Many years of experience and well trained technicians make PMS/CAS your partner for cleanroom certification and thermal validation.



The Swiss Accreditation Service (SAS) grants to PMS the accreditation as a testing laboratory for testing cleanroom systems and thermal processes in accordance with ISO/IEC 17025. The scope of the STS0566 accreditation is defined in the Official Directory of the Accredited Testing Laboratories.

ACCREDITATIONS

ISO 9001:2008 Certified



Limited to specific locations

ISO 14644-1:2015  
COMPLIANT

ISO 17025  
CALIBRATION  
for select parameters

Limited to specific products  
see our scope and certificate(s) at  
<http://www.pmeasuring.com/en/about-us/credibility-registrations>

Cleanroom Qualification

ISO 14644, EU GMP Annex 1, VDI 2083

- Performance data: air measurements, temperature and relative humidity, room differential pressure, etc.
- Installed filter system leakage test
- Cleanroom classification
- Recovery test
- Smoke studies

ISO 8573

- Compressed air parameters: particles, aerosol oil content, dew point, microbiological measurements

ISO 14698

- Microbiological sampling (airborne and surface)

Standard Operating Procedure

- On-site calibration
- Sound levels and luminosity
- Maintenance of filters including changes and installations

Thermal Validation

- Steam sterilization
- Process simulation
- Dry heat sterilization
- Temperature and climatic mappings





## Particle Measuring Systems

Particle Measuring Systems Inc. (PMS) is the technology leader in contamination monitoring around the globe and the inventor of laser particle counting. PMS has expanded into most forms of contamination monitoring, including microbial detection, airborne molecular contamination, as well as traditional particle counting, and is a leading supplier of advisory services related to contamination control.

## History

How did we get to be the largest particle counter manufacturer in the world? It's simple. Since 1972, we have reaffirmed our technology leadership position by continually pursuing advanced detection technologies, and regularly releasing new products that focus on current challenges and future needs of the industries we serve. Acquired by Spectris in 1996, PMS is one of 12 operating companies focused on providing productivity enhancing instrumentation and controls.

## Values

Our culture is just as important as the technology we create. We are committed to doing things the right way, whether that is interacting with our customers, employees, or technology. Our values of restless innovation, empowerment, absolute integrity, customer focus, and high performance drives our pursuit of excellence. We are proud to produce and reward a culture of ethical behavior at all levels and in all circumstances.

## Mission Statement

To be the differentiated leader for contamination monitoring by improving the performance of clean manufacturers through the application of superior technology, quality, and services.

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