Pharmabilities™

EXCELLENCE IN ENVIRONMENTAL MONITORING SINCE 1972

KNOWLEDGE EXPERIENCE SERVICES QUALITY

PARTICLE MEASURING SYSTEMS

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Excellence in Environmental Monitoring

Knowledge and Experience

Since 1972 Particle Measuring Systems has worked closely with the standards commissions and regulatory agencies to ensure the right technology is used to prove control over critical environments. We are closely tied to global industry forums, such as the PDA and ISPE, which support the training and development of Life Sciences professionals. With thousands of validated systems installed worldwide, this knowledge and experience ensures our products and services will meet the needs of your organization, now and in the future.

Services

Particle Measuring Systems offers solutions for all environmental monitoring requirements including management of services through project completion.

Quality

Quality is designed into everything we do. Our quality systems are rigorously maintained and audited by clients regularly. One of our company philosophies states "Without measurement there is no control." This is a principle by which we live every day in all aspects of our worldwide organization.

Complete Solutions

As a turn-key supplier of integrated viable/non-viable environmental monitoring systems, we deliver total solutions. We set the standard for high-quality instrumentation and couple this technological leadership with services and experience to design, install, and validate systems to meet the rigorous requirements of the Life Sciences industry.

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PARTICLE MEASURING SYSTEMS

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Leaders in Microcontamination Monitoring

Founded in 1972, Particle Measuring Systems is the global leader in microcontamination monitoring systems and services. Our technology leadership began with the invention of the laser-based particle counter and continues today, as evidenced by our advanced detection capabilities and innovative new products and services in areas such as microbial air monitoring. Our comprehensive portfolio of products and services enables process-driven companies to monitor their environmental quality and make fact-based decisions to improve yield and meet regulatory requirements.

ISO 9001:2008 Quality Management System

Located in Boulder, Colorado USA, our manufacturing facility has been ISO 9001 registered since 1998. Our mission to be the leader in our markets, to provide better solutions, high quality products, technology and services, requires consistent improvement throughout our worldwide organization. Our commitment to quality can be found in every aspect of manufacturing, product development and service organizations located in the US, or our international subsidiaries and affiliates throughout the world.

Knowledge and Experience in Environmental Monitoring

The Life Sciences Division has in-depth knowledge and experience to reduce the complexity of GMP compliance. Recognized for our expertise in life sciences regulations and applications, we contribute to leading global technology forums and associations. Our renowned Particle College™ educates industry professionals worldwide.

Integrated Solutions to Simplify Compliance

We have engineered thousands of monitoring systems worldwide in a varied range of GMP manufacturing applications. We deliver value from planning and design through execution, validation, and ongoing operation support. Particle and microbial monitoring, as separate activities, increase the cost and complexity of environmental monitoring. Our products and services integrate these processes into a single, validated system. This approach is consistent with Quality by Design (QbD) initiatives and results in streamlined operation, cost reduction and improved performance.

GMP Regulations for Environmental Monitoring

Pharmaceutical manufacturers must comply with numerous GMP regulations from multiple regulatory agencies around the world. However, the major global regulatory agencies require all environmental monitoring programs to include two major functions: Classification and Monitoring of Cleanrooms and Clean Air Devices.

Cleanroom Classification

The requirements for cleanroom classification are determined by the ISO 14644-1 standard, with testing typically performed once every six to 12 months. The test results indicate whether the cleanroom meets the conditions required and is suitable for the intended activities. The approach to classification is formulaic, with the number of sample points driven by the area of the cleanroom, not the nature of manufacturing activities.

Cleanroom Monitoring

Monitoring is an ongoing program to demonstrate control and detect excursions in the cleanroom environment. Each regulatory agency has different requirements. All of them require the choice of locations and frequency to be risk-based decisions, driven by the nature of cleanroom activities, equipment, and process workflow. There are three major types of cleanroom monitoring activities:

- Continuous monitoring of critical aseptic areas (Grade A/B)
- Routine monitoring in background cleanroom areas (Grade C/D)
- Routine monitoring of compressed gas lines

Environmental Monitoring Applications

Critical areas and varying types of process equipment require a customized approach to ensure the collection method and sampling location are optimized. Point-of-use particle and microbial monitors have small footprints, enabling close proximity installation and control from a central processing and monitoring system. Experts from Particle Measuring Systems have the knowledge and experience to design the best monitoring program for any pharmaceutical application.

- FILLING LINES
- ISOLATORS AND RABS
- POWDER FILLING
- BLOW-FILL-SEAL MACHINES
- LYOPHILIZER PROCESSES
- BIOSAFETY CABINETS
- BACKGROUND MONITORING

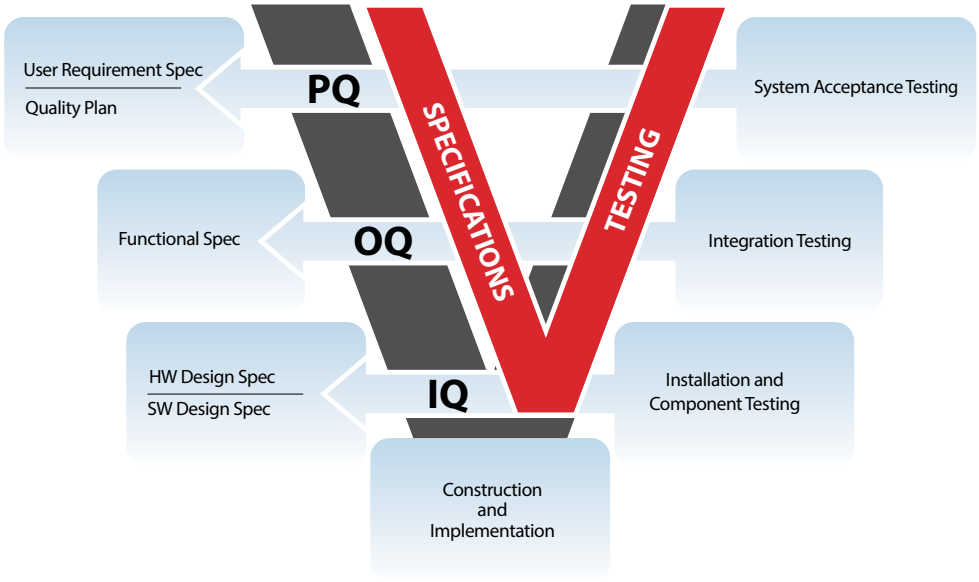
Full Suite of Services

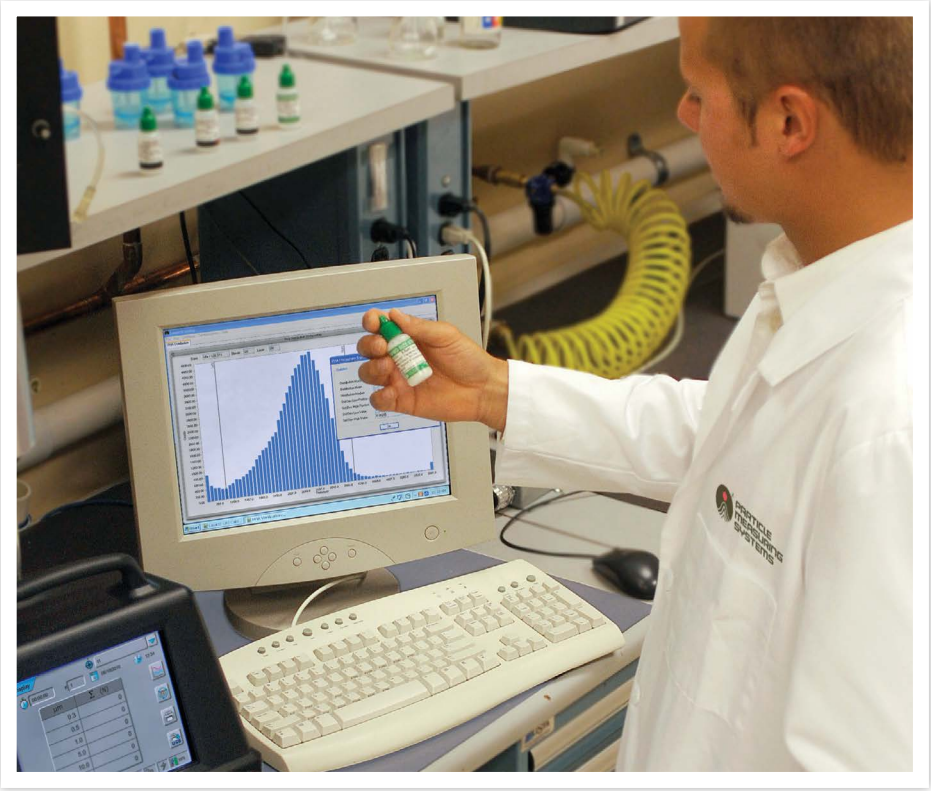
Particle Measuring Systems offers a complete range of services from initial risk assessment to validation. Full turn-key solutions or projects tailored to suit specific needs – we'll get it done for you, on-time and on-budget.

- Risk Assessment
- System Design
- User Requirements Specifications
- Functional Specifications
- Design Specifications
- Standard Operating Procedures
- Project Management
- Installation, Commissioning, Validation
- Training and Education
- Data Interpretation and Alarm Limits
- QbD/PAT Consulting
- Rentals and Lease Financing

THE GAMP 'V' MODEL

Specify, Build, Test





Quality Calibration and Service

ISO 21501-4:2007 Calibration

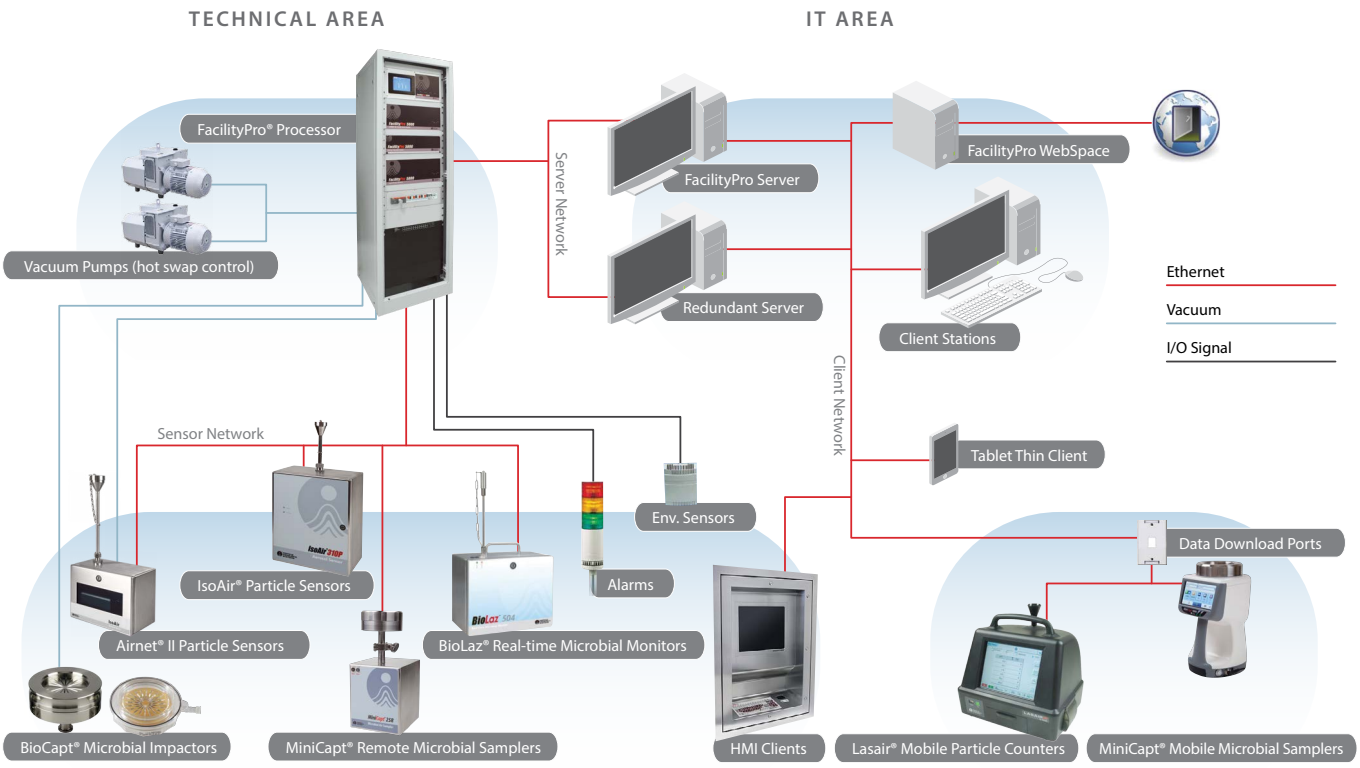
Calibrations for all particle counters used in pharmaceutical applications meet this exacting standard. The process involves measurements to verify and set flow rate, counting efficiency, particle sizing, resolution, signal ratios, and zero count.

Engineered Consistency

Critical steps are automated using software that drives consistency in each calibration, giving you confidence in the data you rely upon. This software-controlled approach ensures the same calibration result and performance, consistent with the factory calibration, regardless of where the calibration is performed – *anywhere in the world.*

Monitoring System Architecture

FacilityPro® monitoring systems integrate viable (microbial), nonviable (particle), and environmental sensors with multiple I/O and networking capabilities. The industrial automation architecture provides high reliability, data integrity, and flexible options for system design. Paperless management of data from mobile instruments further improves operating efficiency.



The FacilityPro® Advantage

Designed Specifically for Pharmaceutical Environmental Monitoring

Data Integrity

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 Error

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

- Viable / Nonviable / Environmental integrated data
- 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, with easier upgrade and expansion capability.

- Modular and expandable design
- Prebuilt vacuum and power infrastructure (5000 series)
- GAMP 5 Category 4 software
- Standard configurable components

Flexible Integration

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

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

FacilityPro Processors

The FacilityPro Processor is the central hub for an environmental monitoring system. The Processor controls sensors and other I/O, buffers data, and checks tolerances. FacilityPro Processors are available in three versions to support a range of applications.

	FacilityPro 1000	FacilityPro 3000	FacilityPro 5000
Particle & microbial points per Processor	8, 16, 32 (groups of 8)	16 (8 particle, 8 microbial)	32 (groups of 8)
Digital outputs (selectable relay or 24VDC)	0	16	64 (groups of 16)
Digital inputs	0	8	32 (groups of 8)
Analog inputs (optional)	0	8	96 (groups of 24)
ENODE support	X		
Cubic meter algorithms	X	X	X
Tolerance checking	X	X	X
Recipe-driven sampling	X	X	X
Data buffer	X	X	X
Real-time microbial monitoring			X
Vacuum and air flow control			X
Microbial monitoring with central vacuum			X

FacilityPro 5000

FacilityPro 1000

FacilityPro 3000

FacilityPro Software

FacilityPro software provides the interface, data management, and reporting for an environmental monitoring system.

	FacilityPro SMART Server	FacilityPro SCADA Server
Viable / nonviable / environmental integration	X	X
21 CFR Part 11 compliant	X	X
Facility map for data and status visualization	X	X
Configurable display	X	X
Alarm notification and e-signatures	X	X
Configurable reports including audit, statistics, and trend reports	X	X
Batch identifiers and data filters	X	X
Automated sample collection, recipe-driven	X	X
Cubic meter algorithms for nonviable data	X	X
Volume-based or time-based viable sampling	X	X
Client software for remote viewing and reports	X (2 max)	X
Maximum number of FacilityPro Processors	1	5
Built on GE Proficy iFIX SCADA and Historian DB		X
Redundant servers		X
Third-party PLC support		X
Email software support		X
FacilityPro Webspace support		X
iOS (iPad®) and Android™ app (works in conjunction with Webspace)		X
Language support	English, Spanish, German, French, Italian, Portuguese, Swedish, Russian, Chinese (simplified and traditional), Korean, Japanese	

Remote Location Particle Counting

Remote particle sensors operate unattended in critical areas (Grades A/B) and are designed to provide accurate and reliable data to your monitoring system. Models are available with 2 or 4 particle size channels and a variety of choices for communication, I/O, power, enclosure, and vacuum.

	Airnet II®	IsoAir® 310P
ISO 21501-4 Compliant	X	X
Vacuum source	External	Internal (HEPA-filtered)
Auto-laser shutoff	X	X
Ethernet protocols	Modbus TCP, OPC	Modbus TCP, OPC
Wi-Fi option[1]	X	X
Data buffer	1,440 samples	3,000 samples
Power	DC	AC
Power over Ethernet (PoE)	X	
VHP-resistant version	X	
4-20mA output option	X	X
Digital output / analog input option[2]		X

[1] External to Airnet II; Internal to IsoAir 310P (approved in EU, USA, Canada)
[2] The digital output / analog input option is only available without the 4-20mA output option

Airnet II
in stainless steel enclosure

Airnet II

IsoAir 310P

Remote Location Microbial Sampling

Remote microbial samplers are installed in fixed locations in critical areas (Grades A/B) and execute automated sampling recipes from a central system. Multiple instrument types are available with different use models, vacuum source, and technology.

BioCapt® and BioCapt Single-Use Microbial Impactors

- Remote vacuum source
- Multiple types of vacuum connectors
- Radial-slit inlet pattern helps identify false positives
- Stainless steel and single-use versions

MiniCapt® Remote Microbial Air Sampler

- Internal vacuum (HEPA-filtered exhaust)
- Ethernet communication to software
- 25, 50, or 100 LPM flow rate
- Accessory kits for isolators or compressed gas

BioLaz® Real-Time Microbial Monitor

- Laser-induced fluorescence optical technology
- Internal vacuum (HEPA-filtered exhaust)
- Ethernet communication to software
- Validated to USP <1223> and EP 5.1.6

BioLaz

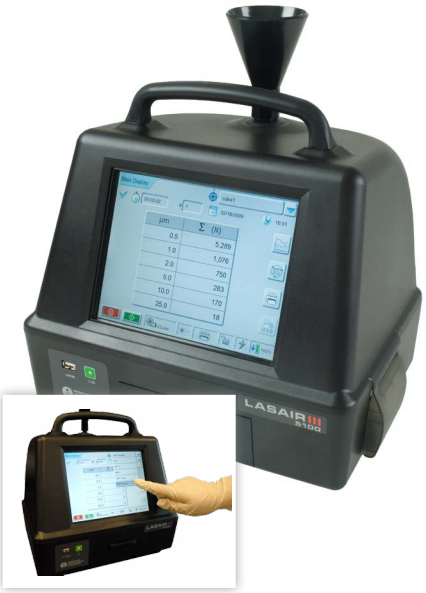
MiniCapt Remote

BioCapt

The stainless-steel version uses traditional media plates and has multiple vacuum connector types.

BioCapt Single-Use

The single-use version eliminates false positives by protecting the internal media plate from direct operator contact. It also eliminates sterilization costs and risks.



Lasair III

Compressed Gas Accessory

Mobile Particle Counting

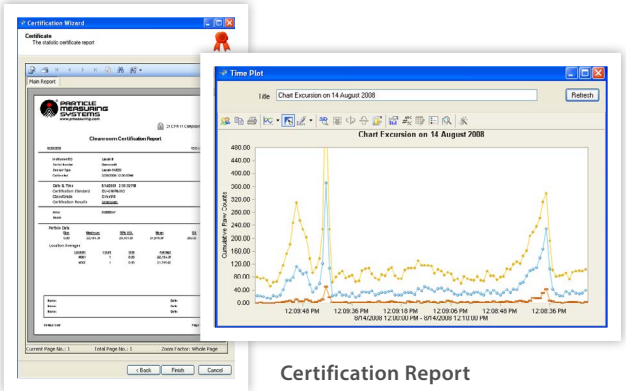
Lasair® III Mobile Particle Counter

This all-purpose instrument is the foundation of any environmental monitoring program. Onboard batteries allow for mobile monitoring and cleanroom classification.

- ISO 21501-4:2007 compliant
- 28.3, 50, or 100 LPM flow rate (HEPA-filtered exhaust)
- IR touchscreen works with gloves – no stylus needed
- 6 particle size channels (or pharma mode: 0.5 and 5.0 µm)
- Supports 2 lithium-ion batteries, with hot-swap capability
- Cleanroom classification to ISO 14644, EU GMP, China GMP, or FS 209E
- Samples compressed gases with HPD III accessory
- Ethernet, RS232, USB outputs and thermal printer
- Wi-Fi (with external hardware)
- 4 4-20mA inputs
- Supports control through a web browser
- 12 interface languages supported

DataAnalyst software

- Paperless storage and reporting of Lasair III data
- 21 CFR 11 compliant
- Single-click data transfer via Ethernet or encrypted USB key
- Classification reports for ISO 14644, EU GMP, or FS 209E
- Tabular reports and interactive charts for data analysis
- SQL Server® database provides data access across a network

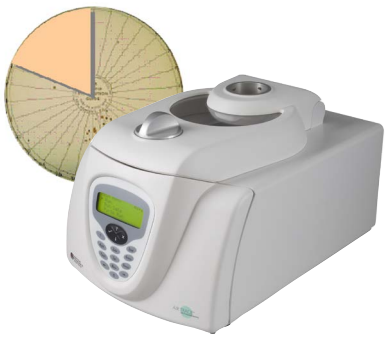


Certification Report

Interactive Chart

Mobile Microbial Sampling

Mobile microbial samplers provide versatile use for routine monitoring and troubleshooting of cleanrooms, critical equipment, and compressed gas lines. Two instrument models are available with different particle collection techniques.



AirTrace

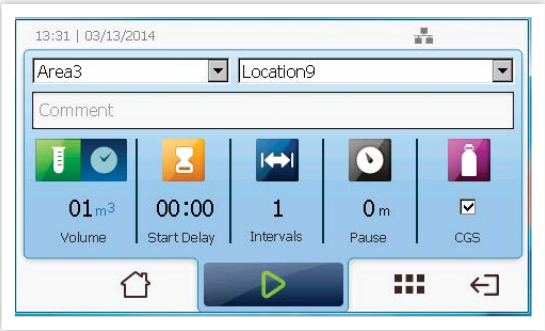
Air Trace® Slit-to-Agar Sampler

- Slit-to-agar impaction technique with single-slit inlet
- 28.3 LPM flow rate (HEPA-filtered exhaust)
- Time-based readings with agar plate rotation
- Programmable rotation speed and auto-height adjustment
- Designed for 150 mm agar plates
- Compressed gas version
- 6 interface languages supported

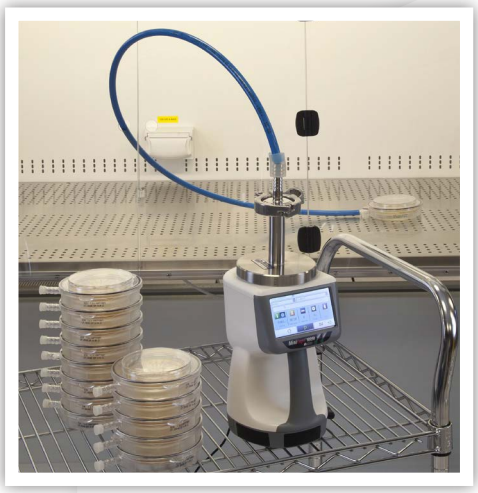
MiniCapt Mobile

MiniCapt® Mobile Microbial Air Sampler

- Sieve impaction technique with 20 precision-cut slits
- 25, 50, or 100 LPM flow rate (HEPA-filtered exhaust)
- Intuitive touchscreen works with gloves – no stylus needed
- Area/location storage simplifies data management
- Radial-slit inlet pattern helps identify false positives
- Lithium-ion batteries
- Ethernet and USB for printing and data transfer
- Compressed gas sampling kit
- Remote sampling kit with BioCapt or BioCapt Single-Use
- 11 interface languages supported



MiniCapt Main Display



MiniCapt Mobile with BioCapt Single Use

Liquid Particle Testing

Injectable and ophthalmic products require testing to prove compliance to USP, EP, JP, and other pharmacopeias. These standards are based on the 10 µm and 25 µm particle size thresholds that present potential risk to patient health. The APSS-2000 system consists of an SLS-1000 syringe sampler, a LiQuilaz® E20P light obscuration spectrometer, and SamplerSight-Pharma software.

APSS-2000 Automated Parenteral Sampling System

- Exceeds all current USP, EP, and JP requirements
- 21 CFR Part 11 compliant for electronic records and signatures
- Supports multiple users and security levels
- Standard and configurable sampling recipes
- Configurable reports with multiple formats including tabular data, statistics, histograms, and time plots
- Data filtering on up to three variables
- Data export in several formats including a secure PDF
- Multiple sampling accessories available, including IV bag stand, coring needles, stir bar, sonic tank, and sample tubing with Luer-Lock fittings
- Includes a validation manual and test scripts for IQ/OQ/PQ testing, as well as sample SOPs and EOPs for instrument integration into your laboratory

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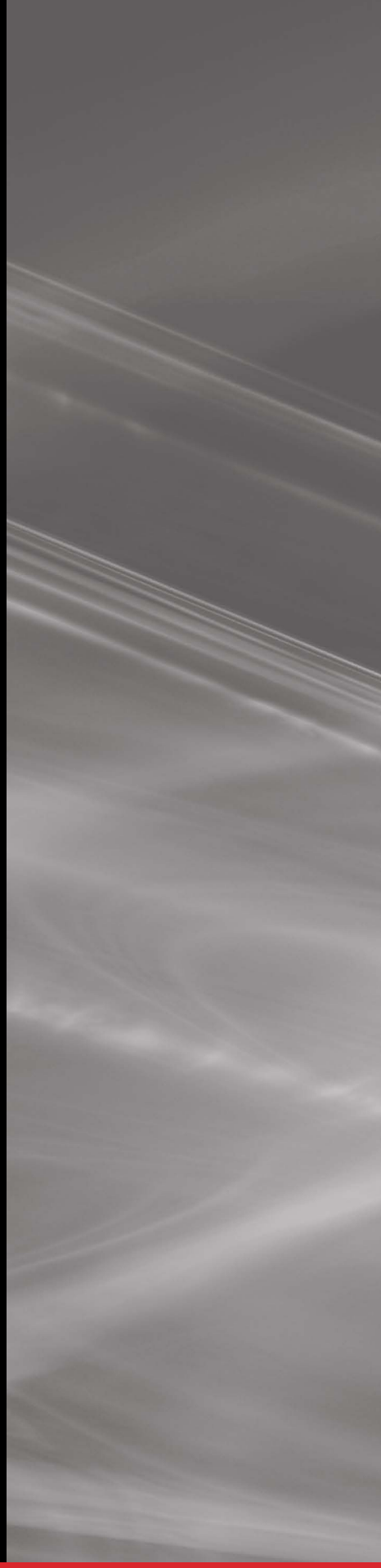

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