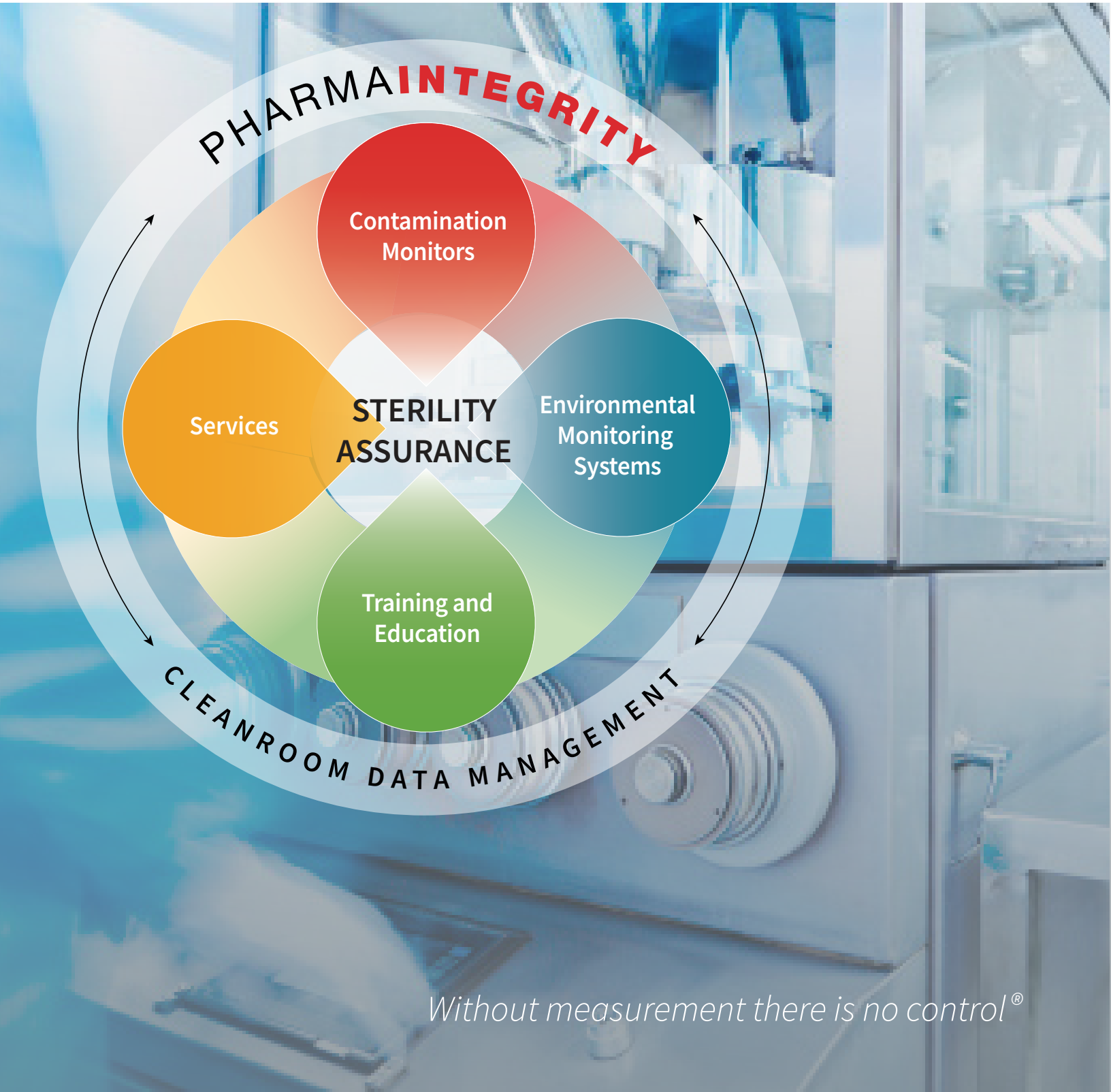
PARTICLE MEASURING SYSTEMS®
a spectris company

PharmaIntegrity™

CLEANROOM DATA MANAGEMENT SYSTEM

Paperless Solution To Meet Data Integrity Requirements



Without measurement there is no control®

PharmaIntegrity™ Data Management Solution

*PharmaIntegrity™ is the **definitive solution for managing the collection, analysis, and trending of environmental monitoring data**, ensuring timely detection of problems in production, facilitating product release and reducing risks and costs associated with product loss and recalls.*

PharmaIntegrity brings the overall environmental monitoring process into a modern, compliant and easy-to-learn paperless data management solution.

Quality Assurance Resolution

Microbial Analysis
- Collect and store pictures of microbial identification
- Trend and report contamination flora by room, department, genus, species, strain, etc.
- View the distribution by room, department, etc.
- Correlate microbial test results with any other environmental data

MiniCapt® Mobile
- Automated recipe transfer
- Automated upload of results to PharmaIntegrity
- Enhanced microbial analysis management

Lasair® III
- Automated recipe transfer
- Automated upload of results to PharmaIntegrity
- Enhanced data trending

FacilityPro®
- Realtime data transfer
- Long term data trending
- Timely problem detection

PharmaIntegrity Mobile
- Easily navigate your digitized facility map
- Intuitively manage your workflow and ensure samples completion
- Label samples in real time

Features and Benefits

Data Generation & Workflow Management

Workflow Management

Manage your sample plan and workflow

- Control and maintain your environmental monitoring process
- Define protocols for each sampling plan or production campaign
- Automatically create your schedule and track results
- Eliminate missed samples or sampling procedure errors
- System sampling with a click of a button!

Inventory Management

Keep your inventory updated and under control, in realtime

- Manage the list of media that you use
- Get a notification when inventory is low or expiring
- Prevent the use of unqualified or expired media

Sample Management

Automatically configure your devices, minimizing error

- Plug n Play: Fast and easy connectivity to Lasair® Particle Counters, MiniCapt® Air Samplers, and FacilityPro® Systems
- Reduce training requirements and operator errors
- Prevent the use of non-calibrated instruments
- Avoid missing or duplicating samples
- Collect and manage data from instruments and media

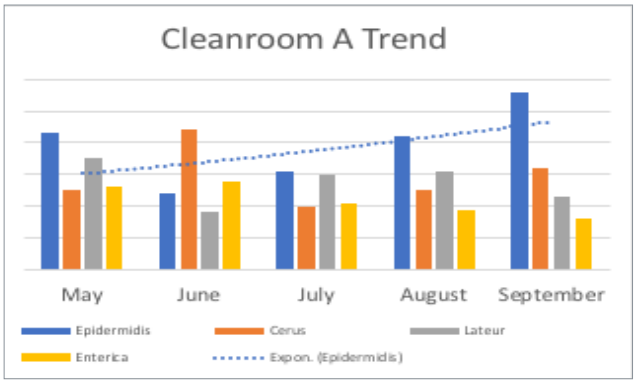
Store Data

Automatically transfer data to the data management system with one click.

- Stored and managed from central cloud location
- Consistent entry organization and naming with helpful drop-down menus
- Compatible with Microsoft SQL, Oracle database and AWS and Azure Cloud

Data Reporting & Analysis

Identify issues before problems occur



- Graphically analyze your data with a single click
- Correlate possible problems with who/what/where
- Real-time trending and correlation
- Detect and trend any contamination related to the environmental system
- PharmaIntegrity recognizes and alerts you of trend patterns

Investigate Possible Issues

Reliably achieve actionable data

- Evaluate alert and action limits
- Identify the root cause so that you can take the right action and effectively release product
- Store the investigation information in the software for easy access during inspections
- Manage excursions quickly and effectively to minimize risks
- Know who did what and when, anywhere in the world

Advisory and Project Support

Process Mapping

We facilitate your migration from paper-based systems to paperless data management.

Collect the information needed to correctly configure PharmaIntegrity and prepare a fast and easy migration from your legacy system, reducing the commissioning cost.

Process Evaluation & Improvement

The analysis of your unique historical data helps you improve your processes at every step.

- Evaluate historical data and ensure compliance with the latest regulations, by deeply analyzing your process, SOP, Environment monitoring plan, and alert and action levels.
- Revise the End User Quality Management documents to provide risk evaluation and recommendation for improvement.

SOP, IQ/OQ/PQ Document Creation, including:

- PharmaIntegrity use and operation
- Report and trend creation process
- Audit trail retrieval and review
- User management SOP

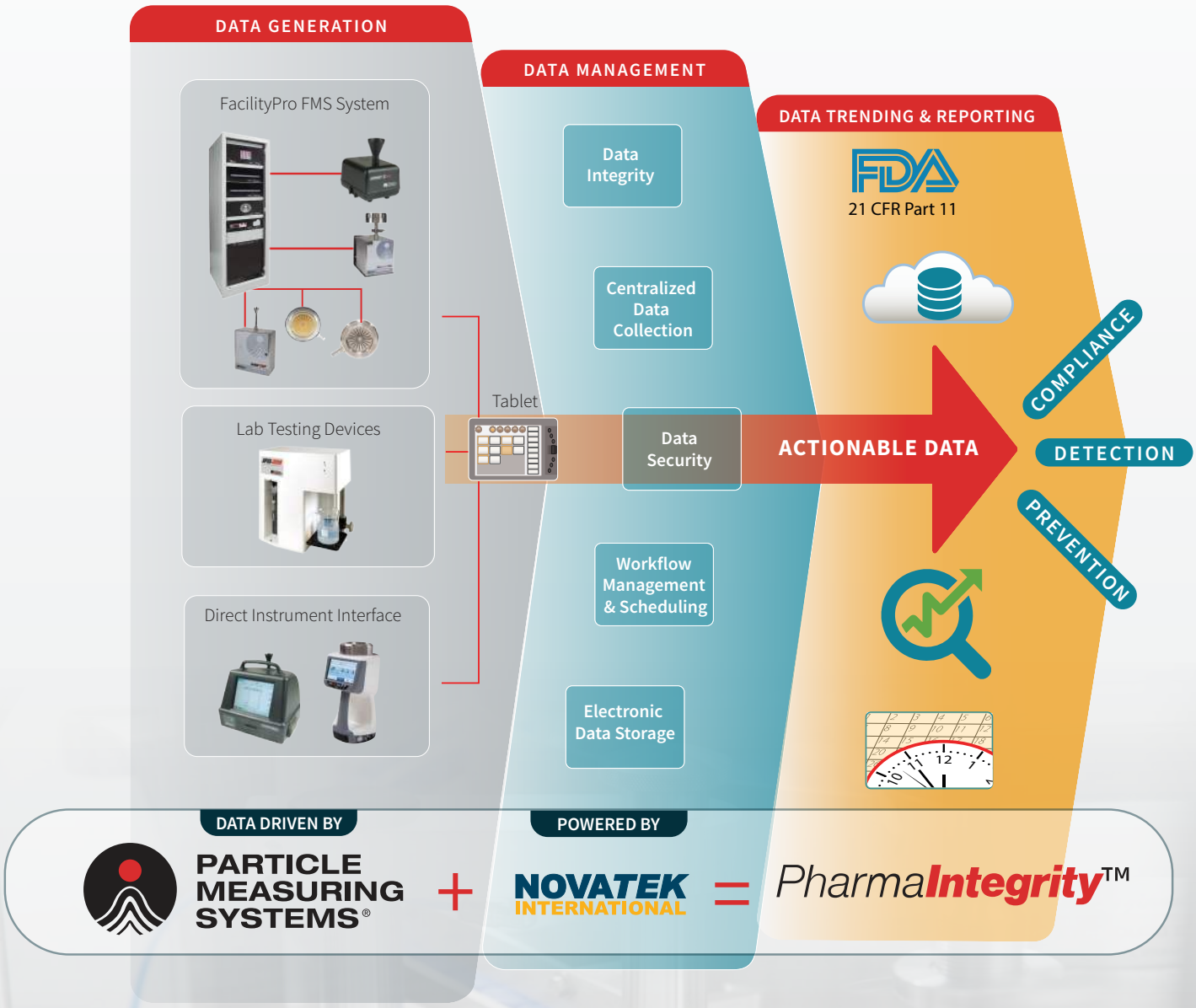
Project Support

PharmaIntegrity projects are made possible by your local Particle Measuring Systems team in collaboration with the global data management team to ensure high level expertise.

PharmaIntegrity Mobile

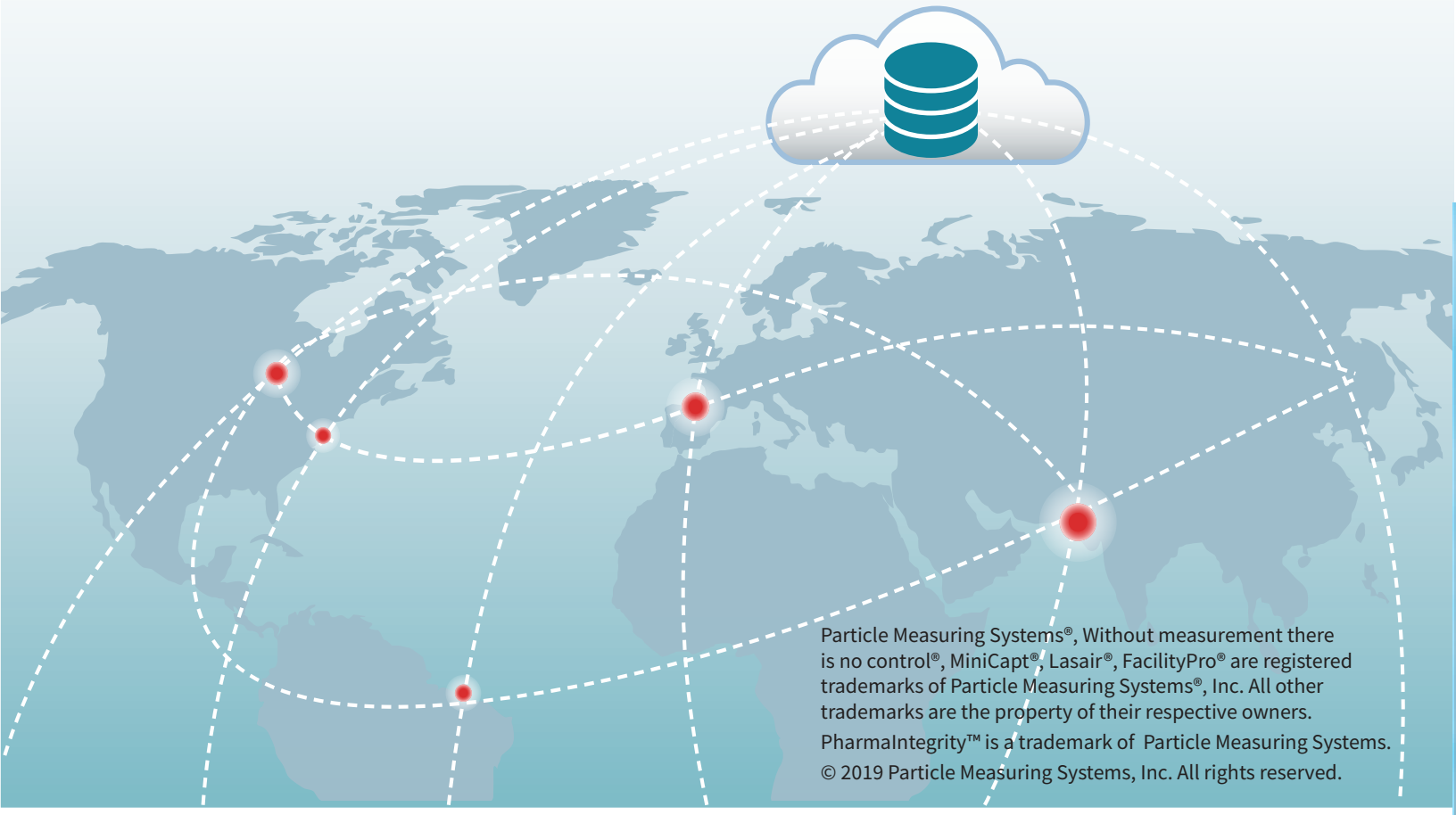
- Paperless throughout the cleanroom
- Cleanroom-designed tablet and peripheral printer and bar code reader
- Reduce error and increase productivity
- Easy use with double gloved hand (no pen)

Release your product, forecast potential adverse deviation and gain complete environmental contamination control



Local Access to Global Data

Access to and management of global information from anywhere in the world.



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- Multi-language and Global support
- Tailored package for your needs
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