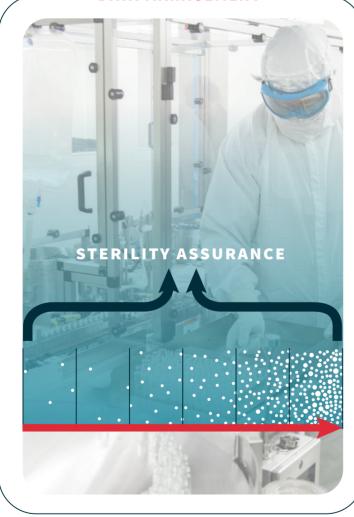
PharmaIntegrity[™]

Data Management System, Powered by Novatek International

PharmaIntegrity 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*.



→ DATA MANAGEMENT

BENEFITS

- Real-time trending and correlation of criteria
- Process control by data trending
- Effective setup of limits and tools to monitor excursions for successful CAPA implementation
- Compliance with FDA Aseptic Processing, EU
 Annex 1 and USP 1116
- Audit trail with e-signatures and data validation
- Effective tracking and mapping of sample sites coupled with trending methods
- Regular monitoring, tracking and scheduling of samples
- Paperless, rapid data entry system
- Significant assistance in root-cause analysis

FEATURES

- Scheduling and tracking of samples, including chain of custody
- Allows for routine, non-routine, batch, process, at rest, dynamic monitoring
- Storage of microorganism identification data and analysis
- Recording of alert/action specs (with frequency analysis for limit setup), media, incubation, lot, equipment, etc
- Site mapping and setup analysis
- Barcoding/RFID technology
- Investigation initiation and tracking
- Trending and reporting
 - For any number of sites in your cleanroom(s) and department(s)
 - Number and location of microorganisms and particles with environmental correlation
 - By lot, equipment, batch

APPLICATIONS

- Aseptic process monitoring (sterile fill, injectables, pre-filtration bioburden, etc)
- Utility monitoring (water, clean steam, compressed gas, etc)
- Personnel monitoring



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PharmaIntegrity is designed to work with Particle Measuring Systems products:

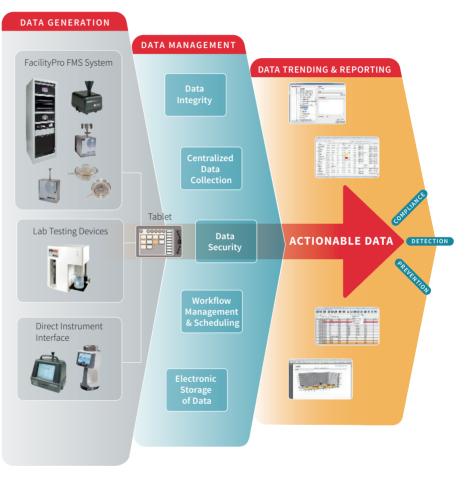
- FacilityPro®
- Airnet[®] II
- Lasair® III
- MiniCapt[®] Mobile and Remote

• BioCapt[®] Single-Use

and Stainless Steel

- IsoAir[®] 310P
- APSS-2000

Pharma**Integrity** from Particle Measuring Systems **automates and refines** your process to mitigate risk and reduce operator error.



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PARTICLE MEASURING SYSTEMS®

a **spectris** company

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