



# ENVIRONMENTAL MONITORING

## Software Solution

Novatek's Environmental Monitoring (EM) software is a proven industry standard system with over 20+ years of global use in the Pharmaceutical and Biotech industries. As a true "out-of-the-box" solution, the core of our environmental monitoring solution has evolved in response to years of user specifications and continuous improvement, meeting at least 95% of your requirements while anticipating industry trends. In addition, having the core competency of a true software engineering company, our EM solution's integration into LIMS, ERP Systems and instrumentation is seamless and fast.

With global regulatory pressure increasing, pharmaceutical companies must prove that their processes are under control and that measures are in place to correct any problem that arises. Simply addressing an excursion in a reactive way is not enough, as production has continued and product is already at risk. There is a need for proactive EM programs to recognize problems before they happen. This has resulted in a shift in thinking toward a Risk-Based approach to monitoring critical manufacturing processes such as aseptic filling of sterile product.

### WHERE'S THE RISK? ...IN YOUR DATA.

Risk-Based Environmental Monitoring involves first assessing high risk areas in production and then building a sampling program around them. In order to do this you must first be able to score the level of risk in predetermined areas of production with tools like FMEA (Failure Mode & Effects Analysis). Your data is more than just a number. That's why traditional EM software needs to go beyond current capabilities and provide the tools necessary to support the risk assessment process.



Novatek's Environmental Monitoring software is a powerful, process-based solution that maps your process and enforces compliance. Our solution goes beyond traditional EM systems and provides the following features necessary to automate your Risk-Based approach:

**REAL-TIME  
TRENDING**

**VISUAL PATTERN  
RECOGNITION**

**AUTOMATED  
INVESTIGATION  
MANAGEMENT**

**ROOT-CAUSE  
ANALYSIS**



## NOVATEK'S BENEFITS WITH RISK MITIGATION

Take advantage of the features and functions of an industry-recognized standard.

### + EFFICIENCY & AUTOMATION

- △ A truly paperless system with centralized data
  - Connectivity to instruments, ERP and LIMS
  - Automatic visual and electronic notifications
  - Rapid data entry and sample tracking via barcoding

### + PROCESS-ENFORCED COMPLIANCE

- △ Procedural controls enforcing best practices
  - USP <1116> reporting
  - 21 CFR Part 11 compliant
  - EU Annex 11 compliant

### + BUILT-IN PROCEDURES

- △ Sample scheduling, acquisition and tracking
  - Automated incubation transfer and end notification
  - Alert and action level excursion management
  - Mandatory approval procedures

### + COMPREHENSIVE REPORTING

- △ Real-Time data trending (viable/non-viable)
  - Batch-specific reporting
  - Visualization of facility control (Maps)
  - Alert/action counts, recovery rate reporting
  - Excursion reporting

### + INSIGHTFUL DATA MANAGEMENT TOOLS

- △ Visual pattern recognition features
  - Root cause analysis capabilities
  - Reverse traceability search tools
  - Automated investigation management reporting

These powerful tools will help identify high risk areas in production and to understand why they are at risk, helping you with the risk scoring process. Once your Risk-Based program is in place, Novatek's real-time trending feature will monitor data for patterns, allowing you to correct a problem before it occurs while protecting the integrity of your products.

## NOVATEK ENVIRONMENTAL MONITORING MOBILE



The integrity of your sampling process is important to producing meaningful data for your EM process. The added benefit of collecting data and managing the sampling process from inside the cleanroom ensures compliance with your GMP process.

### EM MOBILE FEATURES:

- Real-time cleanroom data capture to secure your sampling process
- Sample tracking from acquisition to identification
- Wide array of cleanroom-compatible hardware for all classifications

By combining Novatek's Environmental Monitoring with our EM Mobile add-on, you get a powerful solution that lets you record real-time electronic data to manage your pharmaceutical manufacturing process more efficiently than ever.

**Novatek's Environmental Monitoring Management software not only delivers optimum automated monitoring solutions for an organization's production environment, it also leverages the efficiency and effectiveness of a Total Quality Management System, eliminating paper-based processes and reducing overall production costs.**

**NOVATEK**  
INTERNATIONAL

ADDITIONAL PRODUCTS: NOVA-LIMS / NOVA-STABILITY / NOVA-QMS / NOVA-CPM

Contact us for more information on  
Automated Risk-Based Environmental Monitoring.

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