DataNet
QUALITY SYSTEMS

Because your profit is on the line™

Real-time Statistical Process Control & Analysis for the Life Sciences Industry

- Prevent Product Defects
- Improve Product Release Cycles
- Maximize Productivity and Profitability
- Reduce Waste
- Meet FDA Regulatory Requirements

DataNet Quality Systems provides Life Sciences manufacturers with a real-time Statistical Process Control (SPC) solution to automate, monitor, control, and improve product and process quality, resulting in better products, faster release cycles, and increased profitability.

Through a combination of real-time SPC software, implementation and configuration services, software validation, and a variety of extended support and service programs, DataNet offers a comprehensive solution designed to support your team throughout the entire quality control program lifecycle.

- Real-time SPC software
- IQ, OQ, PQ Validation Services
- Web-based Manufacturing Intelligence
- FDA 21 CFR 11 Compliance
- Installation and Training Services
- Extended Service and Support

WINSPC®
STATISTICAL PROCESS CONTROL

Improve Product & Process Quality, Time-to-Release, and Manufacturing Profitability with Real-time Statistical Process Control
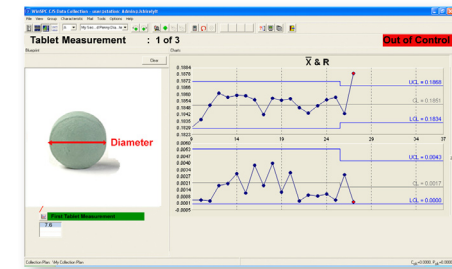
Collect

Collect data from nearly any device, machine or datasource

WinSPC collects data from a wide variety of manufacturing devices and accepts data from other software and LIMS systems. WinSPC also has a simple data entry mode for operators to enter data through a keyboard, device, or other test equipment.

Easily collect data from:

Micrometers	SCADA/HMI
Hardness testers	OPC servers
Dissolution testers	CMMs
Text files and other data sources via ODBC	Vision systems
	LIMS sytems
Lab instruments	

Operators embrace WinSPC's easy data collection interface. Product administrators are impressed by how simple it is to set-up collection plans and capture data from most test equipment.
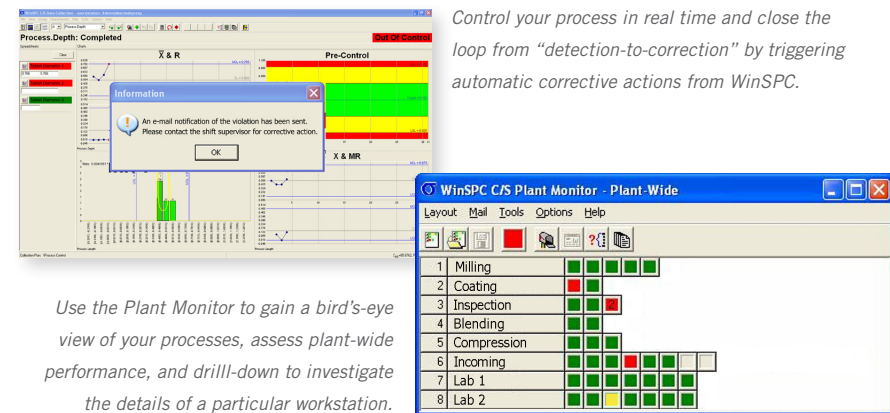
Monitor & Control

Control product & process quality in real-time

WinSPC provides real-time control charting and event feedback to deliver immediate non-conformance information throughout your organization, enabling quality teams to prevent unwanted process variation and product defects.

Monitor processes using multiple SPC charts and standard or user-defined control tests

Trigger alarms, emails, or corrective actions to trends or out-of-control situations

Collaborate and exchange data with other systems using over 500 methods and properties of OLE automation

Control your process in real time and close the loop from "detection-to-correction" by triggering automatic corrective actions from WinSPC.

Use the Plant Monitor to gain a bird's-eye view of your processes, assess plant-wide performance, and drilll-down to investigate the details of a particular workstation.

Analyze

Perform advanced statistical analysis

WinSPC offers hundreds of statistics and charting tools to examine, interpret, and improve your manufacturing processes.

Support Six Sigma programs and the DMAIC process using several built-in reports and tools

Optimize processes and asset utilization

Conduct "what-if" analysis on product and process data

Perform capability studies using normal and non-normal data

Analyze and compare business metrics and manufacturing processes using realtime data

Use Customer Web Reporter (CWR) for advanced statistical calculations and web-based reporting

Report

Quickly create quality reports for management, customers & auditors

WinSPC offers report templates that allow your team to quickly generate a variety of quality reports for managment or auditors.

Certificates of analysis (COA)
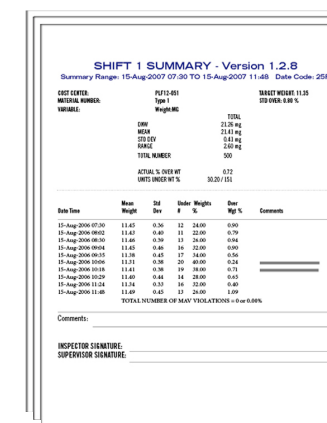
Process status reports for Cpk

Continuous improvement reports

Pareto charts for defect frequency

Capability reports with Cpk, Cpl, Ppk, Ppl, Pr, percent over/under, upper and lower Z values, sigma, mean, skew, kurtosis, #-sigma limits, chi square goodness of fit

Histograms

Customer Web Reporter™ module allows users to generate custom reports and publish via HTML

Service & Support

Quickly deploy, customize, and manage your quality control solution DataNet's Solution Delivery services provide a variety of professional software services designed to get WinSPC implemented efficiently throughout your facility. The Solution Delivery team is comprised of Six Sigma professionals, SPC experts and application engineers with years of experience implementing SPC software. Additionally, DataNet offers various levels of extended service programs to assure that your team has access to the support they need, when they need it most. Services include:

- Consulting
- Implementation and system configuration
- Software validation
- Customization
- Integration
- Training
- 24x7 support option

QUALTREND®
MANUFACTURING INTELLIGENCE

Transform Shop-floor Data into Manufacturing Intelligence

- Mine and synthesize data from a variety of real-time and historical databases
- Monitor worldwide enterprise operations from a single web page
- Conduct statistical analysis and create enterprise-level scorecards via the web
- Generate enterprise-level quality reports for customers, suppliers, and corporate management

Superior support & capabilities for FDA-regulated industries

Ensure compliance with 21 CFR Part 11

WinSPC supports the FDA 21 CFR Part 11 requirement for electronic signatures, making it easier for manufacturers to ensure compliance while focusing on product and process quality. WinSPC offers the following functionality designed specifically to enable you to comply with FDA 21 CFR Part 11:

- Complete audit trail documentation
- Lot traceability
- Electronic signatures
- Electronic records
- Advanced security controls and password protection
- Event log: Store and retrieve nearly any type of system-wide activity, such as edits to data or specification limits, failed log-ins, and more
- All system data and application data are stored centrally in a single SQL database (passwords, configurations, audit trail documentation, etc.)
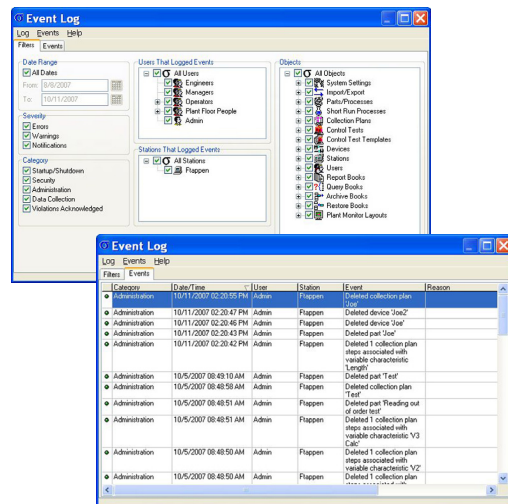
Save time, lower costs & improve productivity with DataNet's Software Validation Services

21 CFR Part 11, the FDA regulation pertaining to electronic records and electronic signatures requires that your company validate electronic record-keeping systems to ensure the accuracy, reliability, and consistent performance of your system, as well as the software's ability to detect invalid or altered records.

For many customers, the process of validating the electronic record-keeping system is complex and costly. DataNet's Software Validation services ease your burden of compliance through:

Software Validation – Our Solution Delivery professional services team offers years of experience in assisting Life Science customers with Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ).

Validation Toolkit – If you prefer to validate WinSPC on your own, our Validation ToolKit will save you thousands. It includes detailed, pre-written IQ and OQ validation test protocols and scripts specifically for validating WinSPC within a federally regulated environment.

Log, store, secure, search, trace & audit your process quality data using WinSPC's event log

WinSPC's system event log allows you to store virtually any vital process information, such as electronic signatures, corrective actions, systems edits and more. The enhanced filtering and search functions make it easy to produce reports for company audits and comply to regulatory requirements. Of course, all the event log data is stored in a central, secure database for compliance with FDA 21 CFR Part 11.

- Search, store, sort, report, print, archive or export logged events
- Capture audit trail documentation
- Enable complete traceability
- Capture electronic signatures
- Perform fast queries

Software Validation

DataNet's WinSPC Software Validation services allow you to quickly and cost-effectively validate your SPC software.

- Installation Qualification
- Operational Qualification
- Performance Qualification
- Validation Toolkits

DataNet
QUALITY SYSTEMS

"It's been a great process improvement tool for us. Since implementing WinSPC we've been able to stabilize our process, increase through-put, and reduce scrap"

-Doug McKinley
Paragon Medical

Successes Include:

Abbott Laboratories

Advance Turning & Manufacturing, Inc.

Allergan

APEX International

Astellas Pharma, Inc.

Beckman Coulter

Becton Dickinson

Bristol-Myers

Carelton Life Support

Centerpulse

Cholestech

Conor Medsystems, Inc.

Edwards Lifesciences

GAMBRO

Genpharm, Inc.

Guidant

Instrumentation Laboratory

Invitrogen

Johnson & Johnson

Lake Region manufacturing

Medtronic

Millipore Corporation

OSG Pharmaceuticals

Paragon Medical

Pall

Porex

Pulmonetic Systems, Inc.

QuadraSpec, Inc.

Schering-Plough

Superior Tube

Terumo Medical Corporation

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About DataNet

DataNet Quality Systems delivers quality control software and services that empower manufacturers to improve product and process quality through real-time Statistical Process Control. WinSPC® and QualTrend® software, in combination with DataNet's solution delivery services, enable manufacturers to:

• Assure product and process quality
• Close the quality loop from "detection to correction"
• Gain executive-level visibility into shop floor operations

With over 2500 installed facilities worldwide and distributors throughout the world, DataNet is dedicated to delivering a high level of customer service and support, shop-floor expertise, and professional continuous improvement, Six Sigma, and lean Six Sigma services.

DataNet ◯
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