



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

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.)

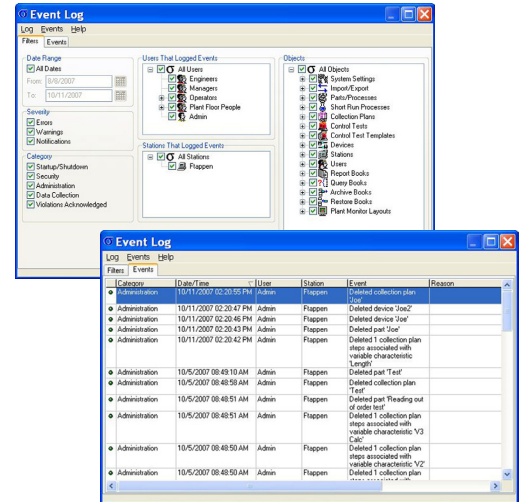
Save time, lower costs & improve productivity with DataNet's Software Validation Services

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

“It’s been a great process improvement tool for us. Since implementing WinSPC we’ve been able to stabilize our process, increase throughput, 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.



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