

No	Company	Product(s)	URL	Claim
1.	ABB	Advant	<a href="http://www.abb.com">www.abb.com</a>	Layered on to and designed to be integrated into the hardware packages is the expertise of ABB's Knowledge solutions. Continually evolving to meet the current and emerging standards important to the Pharmaceutical business, such as Electronic Batch Records based on 21 CFR part 11, or Batch Control Systems compatible with ISA S88.01 standards, ABB prides itself in providing the customer the optimized package solution for his current and future needs.
2.	Agile Software Corporation	Agile Anywhere™	<a href="http://www.agilesoft.com">www.agilesoft.com</a>	Agile Software Corporation provides collaborative manufacturing commerce solutions for the e-supply chain. The Agile Anywhere™ product suite allows supply chain partners to leverage the Internet and form virtual manufacturing networks for design control, product introduction, manufacture, and change. Agile Buyer™ enables Internet-based demand aggregation, RFQ processes, and online procurement of direct (production) materials. Agile Anywhere is 21 CFR Part 11 compliant for electronic records and electronic signatures with a proven validation methodology.
3.	AssurX	CATSWeb	<a href="http://www.assurx.com">www.assurx.com</a>	Are you concerned about Title 21 CFR Part 11 FDA regulations governing electronic records and electronic signatures? Don't be. The FDA edition of CATSWeb is fully compliant.
4.	Automsoft International LTD	Rapid-Pharma	<a href="http://www.automsoft.com">www.automsoft.com</a>	Automsoft's RAPID-Pharma is the first Plant Information Management System to offer out of the box compliance with the specification, which will enable companies to keep complete audit trails of their electronic records in a highly secure system.
5.	AVATAR Consulting	LABTrack	<a href="http://www.labtrack.com">www.labtrack.com</a>	LABTrack incorporates a function called Electronic Signature that was defined by the United States Food & Drug Administration (21 CFR Part 11). Electronic Signature is a mechanism to accurately identify the user of the software at the time data is saved. It can do so using either controlled passwords or biometric devices like fingerprint readers. LABTrack supports both.
6.	Beckman Coulter	Pinnacle	<a href="http://www.beckmancoulter.com/pinnaclep11">www.beckmancoulter.com/pinnaclep11</a>	Pinnacle is the first CDS to be designed from the ground up to meet Part 11 requirements. Its Oracle* relational database and built-in security system ensure that no data can be deleted and that modifications are only performed by authorized personnel. Not only do Pinnacle's electronic records meet Part 11 requirements, system administrators can also minimize the compliance burden by determining when electronic signatures and modification reasons are required.

No	Company	Product(s)	URL	Claim
7.	Blue Mountain Software	Calibration Manager®	<a href="http://www.coolblue.com">www.coolblue.com</a>	Our flagship product, Calibration Manager® software, is among the world's leading calibration management database programs. Calibration Manager automatically calculates due dates, tracks histories and prints reports of calibration schedules. It also tracks preventive maintenance. Flexible data retrieval and reporting capabilities permit customization according to your exact needs. Password protection, audit trail and electronic signature features facilitate your validation process and ensure effective FDA record-keeping compliance. The electronic signature functionality was specifically designed to meet FDA 21CFR Part 11 requirements.
8.	Brendan Scientific	StatLIA	<a href="http://www.brendan.com/">http://www.brendan.com/</a>	Brendan develops laboratory software to provide one complete standardized program for all immunoassay testing technologies. For automating workflow, the software is designed for easy interfacing and networking to any LIM system, instrument and PC. And all raw, computed and statistically analyzed data are organized, secured, and easily accessible. We believe that the less time spent processing, computing, validating, organizing, and troubleshooting data, the more time laboratories can spend using the data generated. 21 CFR Part 11 Compliant.
9.	ChemScope	eGMP	<a href="http://www.egmp.com">www.egmp.com</a>	eGMP is compliant with FDA regulations, including 21 CFR Part 11. And all through a single web browser!
10.	Clinsoft	Clintrial Connect™ Clintrial™ Clintrace™ Integrated Review™ Jreview™	<a href="http://www.clinsoft.com">www.clinsoft.com</a>	Clinsoft Corporation is the world's largest provider of clinical research systems. Market leadership and innovative technology position Clintrial™ as the industry-standard information platform for biopharmaceutical and related industries. Clinsoft's information platform enables companies to focus development resources on product "winners" sooner and has brought more pharmaceutical products to market than any other software platform.
11.	Communication Intelligence Corporation (CIC)	Sign IT	<a href="http://www.penop.com">http://www.penop.com</a>	Provide electronic signature software. Communication Intelligence Corporation (CIC), provides input, security and electronic signature offerings to Enterprises, OEMs, integrators, Asps, Strategic Partners and End Users. And by making possible the legally secure electronic signing of documents anywhere at any time, CIC leadership is a prime mover of businesses toward a paperless world.

No	Company	Product(s)	URL	Claim
12.	Computer Compliance, Inc.	EFLEXION	<a href="http://www.e-flexion.com">http://www.e-flexion.com</a>	<p>A revolutionary, powerful monitoring tool, EFLEXION fully automates the tasks of process data management. E-Flexion automates every step, every task, in quality information management. Manual data handling is eliminated, saving considerable time and freeing people for higher level, strategic use. Human time can be spent interpreting results and taking action.</p> <p>Comprehensive in operation, analytical abilities, and features, E-Flexion gathers, analyzes, and delivers all the information you need. Data is collected and analyzed around the clock from any piece of equipment, for any desired analysis. Everything from production data to run comments is stored in a complete record.</p> <p>Built for compliance from the ground up, E-Flexion meets strict federal regulations for electronic record keeping, including requirements of FDA 21CFR Part 11. An internal audit log -- with assigned access privileges -- tracks any changes made to any records in the database repository. Repository data cannot be deleted. Data transfer from collection to repository is error-free and fault-tolerant.</p>
13.	Creon	Q-DIS/R	<a href="http://www.creon.com">www.creon.com</a>	<p>The extended use of computer technology and the increasing automation in the field of modern chemical analytic, produces large quantities of analytical data.</p> <p>In consideration of:</p> <ul style="list-style-type: none"> <li>• the diversity of data sources</li> <li>• GLP and GMP guidelines</li> <li>• governmental requirements (FDA 21, CFR Part 11)</li> <li>• company objectives</li> </ul>
14.	Cyber-SIGN Inc.	Cyber-SIGN	<a href="http://www.cybersign.com">www.cybersign.com</a>	<p>Cyber-SIGN and Biometric Dynamic Signature Verification Cyber-SIGN®, we are a leader in the area of on-line enterprise user authentication utilizing biometric dynamic signature verification technology. With Cyber-SIGN, using handwritten signatures, on-line identity is securely authenticated and a trusted electronic signature is created. Our technology is a simple and natural biometric system that increases data security and enables trusted document authorization. We analyze the shape, speed, stroke order, off-tablet motion, pen pressure and timing information captured during the act of signing. The captured values are unique to an individual and virtually impossible to duplicate.</p>
15.	Dionex Corporation	Chromeleon	<a href="http://www.dionex.com">www.dionex.com</a>	<p>New Electronic Signature and Signoff feature provides electronic signatures in conformance to FDA's 21 CFR Part 11 rules. Unique signoff levels allow users to submit, review, and approve electronic records from CHROMELEON efficiently and completely.</p>

Compiled by Serentec, Inc.

[www.serentec.com](http://www.serentec.com)

(919) 831-1166

No	Company	Product(s)	URL	Claim
16.	Document Control Systems, Inc.	MASTERControl	<a href="http://www.mastercontrol.com/">http://www.mastercontrol.com/</a>	MASTERControl regulates secure access to documents and other electronic files created in any software application. MASTERControl FDA Edition was written to address stringent security requirements for FDA companies. This includes both the enhanced features needed to comply with these standards and assistance with the on-site validation process.
17.	Doxis	SCCM	<a href="http://www.doxis.com">www.doxis.com</a>	Doxis and 21 CFR Part 11 Compliance Allows you to keep process records (required by GMPs) securely and in strict compliance with 21 CFR Part 11 Has been designed to ensure record authenticity and integrity - features are carefully crafted to provide: Strict control of user access, and of permitted user actions by role Accurate and easy date retrieval for authorized users Automatic audit trailing of data entries and user actions Provides options for biometric (handwritten) and non-biometric electronic signatures Automatically stamps all data entries and signatures with date, time, and user identification Binds all e-signatures to their records, so they cannot be excised or copied
18.	Enmed	Acceliant™	<a href="http://www.enmed.com/">http://www.enmed.com/</a>	Enmed's Acceliant™ Clinical Trial Solution is a comprehensive, flexible, and integrated solution designed to improve the speed and efficiency of clinical development. The Acceliant Clinical Trial Solution has been designed to exceed current industry regulations for clinical trial software, including the FDA's 21 CFR Part 11.
19.	Entrust Technologies	Entrust/PKI™	<a href="http://www.entrust.com">http://www.entrust.com</a>	Digital Certificate technology can be used to ensure access control, authentication and non-repudiation of digital transmissions, providing a secure and reliable means of communicating and affecting transactions over public and private networks. The Entrust family of products offers a complete security infrastructure that is supported across multiple platforms and applications. Entrust provides a complete digital certificate-based solution for digital signature and encryption, that will meet the requirements of the FDA for organizations that want to use electronic records and electronic signatures.
20.	eOriginal Inc.	eOriginal™	<a href="http://www.eoriginal.com">www.eoriginal.com</a>	The eOriginal™ system meets or exceeds all of the FDA requirements for electronic filings

No	Company	Product(s)	URL	Claim
21.	Fisher-Rosemont	DeltaV	<a href="http://www.frco.com/">http://www.frco.com/</a>	Significant batch enhancements in the Version 5 release include support for both running batches in campaigns and enhancements focused to support FDA regulations in 21 CFR Part 11. New patented Configuration Audit Trail software controls, manages and tracks all changes to the DeltaV configuration database saving time, effort and improving accuracy of configuration management. This software supports electronic record keeping per 21 CFR Part 11.
22.	Foss NIRSystems, Inc.	Vision	<a href="http://www.foss-nirsystems.com">www.foss-nirsystems.com</a>	Foss NIRSystems, Inc., a unit of Foss A/S of Denmark, is the world's leading supplier of scanning Near Infrared products and services for the pharmaceutical and chemical markets. Our extensive application knowledge, global distribution, and support network ensures efficient method development and routine implementation for years to come. Our software is fully compliant to 21 CFR, Part 11 for the benefit of our pharmaceutical customers.
23.	Hewlett Packard	Cerity	<a href="http://www.agilent.com">www.agilent.com</a>	Agilent Cerity Networked Data System for Pharmaceutical QA/QC data system, based on Microsoft Windows NT® 32-bit architecture, is part of the Agilent Cerity networked data system family of chromatography software. (Formerly Chemstation.)
24.	Honeywell-POMS	POMS	<a href="http://www.poms.com/">http://www.poms.com/</a>	Honeywell-POMS Corporation is the global leader in providing Manufacturing Execution Systems (MES) for the healthcare products and consumer packaged goods industries. The company's solutions are an essential component to successful E-Business supply chains, providing manufacturers with agility in their product development and manufacturing operations. Honeywell-POMS provides integrated solutions that help you control, track, and view every aspect of your product development life cycle. Our solutions are in use within Clinical and Commercial Pharmaceuticals, Biotechnology Products, Medical Devices, Primary Pharmaceutical Chemicals, and Nutritional Products organizations. POMS products deliver value and help you:

No	Company	Product(s)	URL	Claim
25.	InnaPhase	Watson™ LIMS	<a href="http://www.innaphase.com">http://www.innaphase.com</a>	Watson™ uses a central Oracle™ database and offers a simple, point-and-click graphical interface that is quick to learn and easy to use. Watson™ has been expressly built to promote compliance with GLP regulations and the 21 CFR Part 11 guidance. The system security and audit trail are designed to provide maximum flexibility and configurability to our clients while preserving data integrity. Watson™ is capable of handling standard and complex study protocols, providing audit trails to track deviations and amendments to each study. Watson™ has full bi-directional interface capability to analytical instruments, tracks shipments and samples through user-designed barcode labels, supports a wide range of PK/TK analyses, and organizes study results in a unique document management system. Watson™ also fully supports unit management, allowing true data consolidation across studies and projects.
26.	Intellution, Inc.	iFix iBatch	<a href="http://www.intellution.com/">http://www.intellution.com/</a>	Intellution, Inc., the world's leading developer of industrial automation software, has been developing and delivering the industry's most advanced HMI/SCADA, batch, softlogic, and internet solutions to top manufacturers for more than 20 years. In an effort to help businesses from across the FDA-regulated spectrum comply with 21 CFR Part 11, Intellution has taken a leadership role in developing software-level solutions to meet the demands of this critical regulation. Working in unison with key biotech and pharmaceutical representatives, FDA regulatory personnel, original equipment manufacturers and systems integrators, Intellution is developing the tools that will empower all FDA-regulated companies to come into compliance.
27.	J.D. Edwards	J.D. Edwards OneWorld	<a href="http://www.jdedwards.com">www.jdedwards.com</a>	Designed to meet the needs of regulated companies, J.D. Edwards OneWorld solutions not only ensure the integrity of authorized signatures executed within the OneWorld environment, they also enable companies to feel secure that the transactions being executed are meeting the approval, audit trail, and time stamping functions required in 21 CFR Part 11.
28.	Kaye Instruments	Validator 2000 LabWatch	<a href="http://www.kayeinc.com/">http://www.kayeinc.com/</a>	The <b>Validator 2000</b> meets all the new FDA regulations for thermal validation, including 21 CFR Part 11 on electronic signatures and records. It provides many time-saving benefits such as automating sensor calibration and report generation. The <b>LabWatch</b> System operates in compliance with the FDA regulation on 21 CFR Part 11 Electronic Signatures and Records

No	Company	Product(s)	URL	Claim
29.	LabLogic Systems Ltd.	Debra Laura	<a href="http://www.lablogic.com">http://www.lablogic.com</a>	Debra, by Lablogic Systems, Ltd., is a Protocol-Driven GLP-Compliant Laboratory Information System (LIMS) designed to meet the unique needs of an ADME Laboratory environment Laura 3 is the latest evolution of the widely used Laura chromatography acquisition and analysis system from LabLogic. Produced to accommodate the latest networks platforms Laura 3 offers the researcher the facility to create and edit methods, set up sample runs and view data collection in real time across the network without being confined to the bench-top PC.
30.	Labtronics, Inc.	LimsLink™ LimsLink <sup>CDS</sup>	<a href="http://www.labtronics.com">www.labtronics.com</a>	For over 14 years Labtronics has been recognized as a world leader in innovative instrument interfacing technology. LimsLink is the complete instrument to LIMS interfacing solution, designed to collect data from a broad range of instruments, reformat that data and report it to any LIMS or database application. With 100 levels of password protection and a full audit trail implementation, LimsLink <sup>CDS</sup> provides the level of security and accountability required to make it a necessary and valuable component for 21 CFR Part 11 compliance.
31.	Matrix One	eMatrix 9	<a href="http://www.matrixone.com">www.matrixone.com</a>	The eMatrix 9 platform combines an open, flexible Internet platform with extensive collaboration services, an array of adaptable development tools. The growing collection of software offerings provides proven product lifecycle capabilities - from concept and design through manufacture and ongoing service.
32.	Micromass	CyberLAB™	<a href="http://www.micromass.co.uk">www.micromass.co.uk</a>	CyberLAB™, is carefully designed to help you achieve 21 CFR Part 11 compliance, protecting your critical information to the fullest extent possible with features like CyberLAB's Electronic Signature plug-in. Utilizing Adobe Acrobat, an industry-standard technology, CyberLAB lets you electronically sign documents, placing an encrypted signature within the document and an unalterable "watermark" on the page indicating the signatures validity.
33.	Nicolet Industrial	RESULT™	<a href="http://www.nicoletindustrial.com/NISmain.html">http://www.nicoletindustrial.com/NISmain.html</a>	RESULT™ Software Provides tools to comply with 21 CFR Part 11 Regulations The operation of Nicolet Industrial Solutions' analyzers is simplified with its software. RESULT was designed for the specific requirements of process instrumentation. With digital signatures, an audit trail and Logon/Passwords, RESULT helps you meet the requirement of 21 CFR Part 11.

No	Company	Product(s)	URL	Claim
34.	NuGenesis Technologies Corporation.	ARCHIVE® UNIFY® VISION®	<a href="http://www.nugensis.com/">http://www.nugensis.com/</a>	NuGenesis can be a key part of your 21 CFR Part 11 compliance strategy. FDA requirements governing the archiving and retrieval of raw data make it essential that companies be able to provide the original source data for all electronic records and reports. NuGenesis provides an application-independent method for storing and cataloging raw laboratory instrument data as well as human readable information from common business applications (such as word processing and spreadsheet files). When your analytical reports are online in the NuGenesis database, you can provide auditors with documented evidence back to the original source, quickly and easily. NuGenesis Technologies family of products work as an application independent Scientific Data Management System (SDMS) which automatically aggregates data from disparate sources providing greater access and insight into critical knowledge generated in the laboratory. These products provide scientists, from the lab to the enterprise, unique capabilities to enhance the value of information.
35.	Perkin Elmer	Connect Turbochrom	<a href="http://instruments.perkinelmer.com/">http://instruments.perkinelmer.com/</a>	Use CONNECT to transfer data between SQL*LIMS and Turbochrom. "Unsurpassed GLP/GMP Features Perkin Elmer's broad range of experience includes providing GLP/GMP data systems since 1980. With Turbochrom Client/Server, the embedded GLP/GMP features provide the most secure and documented data handling system ever. Turbochrom Client/Server provides controls for user and instrument access, user configuration of software menus and screens, file access, controlled modification of active methods and sequences and more."
36.	Pharsight	WinNonlin WinNonMix	<a href="http://www.pharsight.com/">http://www.pharsight.com/</a>	Pharsight is also working with our customers to help them achieve compliance with 21 CFR Part 11 (Electronic Records; Electronic Signatures; Final Rule) regulations. The Enterprise Editions of WinNonlin and WinNonMix are initial steps toward achieving this compliance which can be implemented today, allowing users to read PK/PD data and save analysis results directly to/from a secure centralized database protected by user login procedures. Pharsight is also developing a secure repository for PK/PD data and analysis results from WinNonlin, WinNonMix, and other analysis tools called the Pharsight Workbench Repository.
37.	Phase Forward Incorporated	InForm InFusion	<a href="http://www.phaseforward.com">www.phaseforward.com</a>	Phase Forward's InForm solution is designed to allow sponsors to meet with FDA's 21 CFR Part 11 and can be used in accordance with the FDA's "Guidance: Computerized Systems Used in Clinical Trials." Phase Forward's product development team works to meet rigorous GCP quality control standards and conducts regular independent audits using an industry leader in external regulatory quality assurance.

Compiled by Serentec, Inc.

[www.serentec.com](http://www.serentec.com)

(919) 831-1166

No	Company	Product(s)	URL	Claim
38.	Pilgrim	Q&MIS®	<a href="http://www.pilgrimusa.com">www.pilgrimusa.com</a>	The 21 CFR Part 11 Electronic Signature requirement defines the electronic signature as the binding signature and is equivalent to that of handwritten signatures, and Pilgrim's Electronic Signature component provides the necessary controls for each electronic signature to be unique to each individual.
39.	Pricewaterhouse Coopers Documentum	GMPharma	<a href="http://www.GMPharma.com">www.GMPharma.com</a>	GMPharma is the first e business solution jointly developed by PricewaterhouseCoopers and Documentum for enterprise wide management of pharmaceutical GMP regulated content.
40.	Process Analysis & Automation		<a href="http://www.paa.co.uk">http://www.paa.co.uk</a>	Process Analysis & Automation Ltd provides state-of-the-art automation and measurement technology to the pharmaceutical and chemical industries. Custom software and application services. Many products listed as 21 CFR Part 11 compliant.
41.	ProIRB Plus, Inc.	PRO_IRB™	<a href="http://www.proirb.com">www.proirb.com</a>	PRO_IRB™ is a Microsoft Access-based Institutional Review Board Software Application providing productivity and compliance assurance tools for managing the Institutional Review Board process. Agenda preparation, records SAE, manage continuing review. Complies and exceeds 21CFRpart11 requirements where applicable.
42.	Propack Data	PMX MES CTM RDM MQS	<a href="http://www.propack-data.com">http://www.propack-data.com</a>	Propack Data was first established as a company in 1984. As a pioneer and visionary in the Manufacturing Execution System (MES) sector, Propack Data has risen to become the leading supplier for the pharmaceuticals industry. Focusing on FDA/GxP-regulated industries such as pharmaceuticals, food-stuffs and cosmetics, Propack Data provides validatable standard software for the entire manufacturing and packaging processes in the field of supply chain execution under an ERP system. Propack Data's current release, PMX 3.1, satisfies the requirements of 21 CFR 11 by tracking the changes within your production documents via audit trails. Additionally, strike the right balance between the amount of data stored and the essential traces by trailing only the required attributes of the records.
43.	QAD	MFG/Pro	<a href="http://www.qad.com">www.qad.com</a>	QAD understands patient device tracking (PDT), serial traceability, and validation, and what these conditions mean up and down the business chain, from procurement to distribution and all points between.
44.	Qumas	DocCompliance ®	<a href="http://www.qumas.com/">http://www.qumas.com/</a>	QUMAS DocCompliance® for Oracle® is a complete enterprise compliance application designed exclusively to manage the full lifecycle of regulatory controlled documentation. Organizations are assured of compliance with regulatory bodies' guidelines and directives (including the FDA's Final Ruling on Electronic Signature CFR 21 Part 11). The risk of non-conformance is avoided through complete auditing and traceability on document history including event logs, audit trails and comprehensive reports.

No	Company	Product(s)	URL	Claim
45.	Rockwell Automation	RSView32™	<a href="http://support.software.rockwell.com/consulting">http://support.software.rockwell.com/consulting</a>	Rockwell Automation has announced that its flagship HMI products, RSView32™ and RSView32 Active Display System™, fully support the development of projects and systems that comply with FDA (Food and Drug Administration) Title 21 - Code of Federal Regulations - Part 11 (21 CFR Part 11) regulations.
46.	SAP	cGMP Regulated Manufacturing Module	<a href="http://www.sap.com">www.sap.com</a>	Create of EBR after final completion of Production order, using documentation of process as well as of results of the process, including staged and identified Materials and reconciled material consumptions, EBR approval can be made mandatory for usage decision. EBR will be saved with version number as non-editable ( PDF) file. Future updates of the EBR will require a new version number. Stored EBR can be retrieved, viewed and printed as necessary. Full support for 21 CFR Part 11 signature and record requirements.
47.	Scientific Software, Inc.	EZ Chrom Elite	<a href="http://www.scisw.com/">http://www.scisw.com/</a>	Manufacturer of EZ Chrom Elite v2.7 chromatography data system. EZChrom Elite fully complies with 21 CFR Part 11 Electronic Signature requirements. In addition to the display of electronic signatures on the report, the signature information (Who, When, and Why) is stored within the data file with a CRC checksum to prevent tampering with the signature record. This information is also logged in the data file audit trail.
48.	Shimadzu	Class VP	<a href="http://www.shimadzu.com">www.shimadzu.com</a>	Supplier of Chromatography and analytical equipment, 21 CFR Part 11 is not specifically identified, but their sales brochures make it sound like the raw data files can be archived by VP Archive software if acquired on either Lab Solutions (GC) software or Class VP (HPLC) software interfaced with Shimadzu equipment
49.	Silanis Technology	ApproveIT	<a href="http://www.silanis.com">http://www.silanis.com</a>	Meets FDA 21 CFR Part 11 right out of the box ApproveIt from Silanis moves signature approvals on-line without additional hardware, software or programming. Its native support for the most widely used document creation tools leverages your organization's existing communications infrastructure so you can continue doing business as usual, with little or no additional training
50.	Sotax AG	WinSOTAX	<a href="http://www.sotax.com/">http://www.sotax.com/</a>	SOTAX is the technology leader in the development and manufacture of Instruments for tablet Dissolution Testing for over 25 Years. WinSOTAX is a modular and configurable software package to collect data from various laboratory instruments, to store this data in a database, to retrieve it for analysis, monitoring and report generation. From the beginning the package has been developed following the rules of GLP, GALP and the GAMP guidelines. It therefore matches the requirements of 21 CFR Part 11 with few exceptions by design. The next upgrades will address the remaining 3 issues.

No	Company	Product(s)	URL	Claim
51.	Sparta Systems, Inc.	TrackWise	<a href="http://www.sparta-systems.com">www.sparta-systems.com</a>	<p>Sparta Systems' TrackWise is a powerful system for tracking and managing:</p> <ul style="list-style-type: none"> <li>• Problem Reports</li> <li>• Bugs/Defects</li> <li>• Change Requests</li> <li>• Customer Complaints</li> <li>• Corrective Action Items</li> <li>• Investigation Reports</li> <li>• Audit Observations/Findings</li> </ul> <p>TrackWise software is fully equipped with electronic signature to comply with CFR 21 Part 11.</p>
52.	Taratec	TeC	<a href="http://www.taratec.com">www.taratec.com</a>	<p>TeC, Taratec's e-Compliance Solution, will help ensure compliance for computer systems used in all phases of the product development cycle.</p>
53.	Thermo LabSystems	Nautilus Atlas	<a href="http://www.labsystems.com/">http://www.labsystems.com/</a>	<p>Thermo LabSystems has been successfully developing and supporting Chromatography Data Systems (CDS) since the early 1980's. Atlas™ is our latest generation solution. The recent ruling by the US Food &amp; Drug Administration on electronic records and signatures (21 CFR Part 11) has impacted upon chromatographers. <b>Atlas</b> facilitates full compliance with this ruling and is relieving much of the burden faced by our regulated customers and, therefore, assisting in achieving a validated CDS solution. <b>Nautilus</b> sets the standard in delivering LIMS functionality into the laboratory. Nautilus includes assisting customers in complying with the FDA ruling on electronic records and signatures (21 CFR part 11). Nautilus can also play a compliance role in organizations certified to ISO9001 standards.</p>
54.	Waters Corp.	Millennium 32	<a href="http://www.waters.com">www.waters.com</a>	<p>Millennium 32 Chromatography data system. The first major version of the company's chromatography software adds complete 21 CFR Part 11 compliance, dual-tower control, and data acquisition support for Agilent 5890 and 6890 gas chromatographs and the Waters Alliance dissolution system, pattern recognition algorithms for chromatogram comparisons, and full support of Microsoft Windows web standards; an Open Access option builds in routine operating features for technicians who are not experts in the company's software.</p>
55.	Werum	PAS-X MES	<a href="http://www.werum.com/">http://www.werum.com/</a>	<p>Werum supplies perfect technical MES (Manufacturing Execution Systems) solutions and services for the GxP/FDA related pharmaceutical industry in compliance with 21 CFR 11. The standard PAS-X MES product range provides easy qualification and validation. PAS-X supports a rich set of features that help to streamline the whole pharmaceutical production process e.g. Electronic Batch Recording/EBR.</p>

Compiled by Serentec, Inc.

[www.serentec.com](http://www.serentec.com)

(919) 831-1166

No	Company	Product(s)	URL	Claim
56.	Wimmer Systems, LLC	Data Compliance System™	<a href="http://www.wimmersystems.com/">http://www.wimmersystems.com/</a>	Wimmer Systems has developed the Data Compliance System™ for Microsoft Excel®. Many organizations working towards full compliance with the requirements of 21 CFR Part 11 still rely on Excel for their data processing needs. DaCS provides a simple, cost-effective solution that allows for continued use of Excel in such an environment.
57.	Xcert	Sentry CA Sentry RA	<a href="http://www.xcert.com/">http://www.xcert.com/</a>	Sentry CA provides a certificate issuance and management solution that enables global Public Key Infrastructure (PKI). The US Food and Drug Administration (FDA) has outlined requirements for the pharmaceutical industry regarding the use of electronic records and electronic signatures through their 21 CFR Part 11 regulations. Xcert Sentry allows pharmaceutical companies to meet these regulations and take advantage of the cost savings and conveniences that e-business brings.
58.	Zymark	TPW II	<a href="http://www.zymark.com">www.zymark.com</a>	Engineered specifically for time-squeezed labs in a regulated environment, the TPW completely automates content uniformity and composite assay testing, from preparation through sample introduction and provides an audit trail consistent with 21 CFR Part 11.