No	Company	Product(s)	URL	Claim
1.	ABB	Advant	www.abb.com	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™	www.agilesoft.com	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.	Agilent Technologies, Inc.	ChemStation Plus	www.chem.agilent.com	The system enables users to comply with audit and approval requirements such as 21 CFR Part 11.
4.	Aitken Scientific Ltd.	A-S Login	http://www.aitken-sci.co.uk/	A-S Login for Electronic Signature Compliance is a software product which provides complete 21 CFR Part 11 compliant user login functions, and a comprehensive administrator console
5.	Alchemedia Technologies, Inc.	Mirage	http://www.alchemedia.com	DALLAS, TEXAS — January 9, 2002 — Alchemedia Technologies, Inc., a leading provider of Enterprise Digital Rights Management (EDRM) software, today announced the availability of Mirage Enterprise for pharmaceuticals, providing critical data currency and confidentiality functions for companies governed by FDA regulation 21 CFR Part 11. Electronic documents, the subject of Part 11, are easy to copy and distribute, but copies are difficult to manage. The resulting rogue documents cannot be audited or updated, and therefore are violations to the FDA regulation. By controlling the saving, copying, forwarding and printing of documents, Mirage enables pharmaceutical companies, for the first time, to cut off rogue documents at the source, greatly reducing the scope of their exposure under Part 11.

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6.	American MSI Corp.	CelltrackPro™	www.americanmsi.com	Celltrack PRO™ is an enterprise solution for manufacturers of medical devices that need to record, maintain, archive, retrieve, and transmit relevant manufacturing data, in compliance with the FDA's 21 CFR Part 11 regulation.... With Celltrack PRO™ you can record, maintain, archive, retrieve, and transmit relevant manufacturing data, including batch detail and downstream processing, equipment settings and measurements, as well as who changed what, when, where and even why. A closed data chain with high-level access control, record validity checks and data encryption guarantee tamper-free data integrity from the point of data collection through reporting and archiving. Celltrack PRO™ can generate accurate and complete copies of records in both print and electronic form (PDF) for inspection and review.
7.	Amersham Biosciences	UNICORN Control System, version 4.0	http://bioprocess.apbiotech.com/	UNICORN Control System, version 4.0, is fully compliant with 21 CFR Part 11. It is currently in use in many biopharmaceutical production processes approved by the FDA.
8.	Analex	ESign™	http://www.analex.com/html/med_erecords_esignatures.html	Aside from merely understanding the 21 CFR Part 11 regulation, Analex has successfully developed Electronic Records and Electronic Signatures components, known as ESign™, for its own in-house software. Analex has also been invited to give presentations regarding Part 11 at medical device and pharmaceutical conferences. Using our experience and expertise, Analex can help your company become compliant as well.
9.	Ankersmid	TOC Talk, Version 3.5	http://www.ankersmid.com/Holland/index holland.htm	TOC Talk, Version 3.5 is designed to handle and manage TOC data and metadata within the TOC Talk application in compliance with 21 CFR Part 11 protocols
10.	Applied Biosystems	Analyst™ SQL LIMS	www.appliedbiosystems.com	Analyst™ software unites power and ease to set a new standard in Windows NT® platform-based data processing. Automated software routines rapidly and completely optimize the instrument for quantitative analysis. After data acquisition, the Quantitation Wizard quickly guides the creation of new quantitation methods. Queries, metric plots, configurable results table, and slide show mode provide fast and thorough data review. For regulated laboratories, you can easily achieve GLP compliance including the recommendations of 21 CFR Part 11 with comprehensive Security and centralized Audit Trail Manager. Analyst software provides flexible data acquisition, fast and easy data. SQL*LIMS® software is a complete laboratory information management system (LIMS) that gives you control over sample tracking, laboratory processes and workflow, data access and storage, and regulatory compliance. Supports your laboratory's compliance with the FDA's 21 CFR 11 Rule with dynamic security and regulatory compliance features

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11.	Applied Statistics Inc.	Applied Stats v4.4 SPC	www.appliedstatistics.com/press/21CFR.htm	ASI offers the most comprehensive tools available today to address the security and data collection requirements posed by 21 CFR Part 11. Applied Stats v4.4 SPC software package incorporates a robust set of security options and policies that allow our customers to comply with these rigorous requirements and collect data with confidence.
12.	ARC Systems, Inc.	TrendReader Standard Data Logger	http://www.acrsystems.com/	ACR Systems Inc. has introduced a new update version of the TrendReader Standard Data Logger Software, version 1.2 beta, which includes data validation that permits our software and hardware to conform to the FDA's 21 CFR Part 11 regulations. This assures users that the data viewed on either the PC or printed form is authentic by providing a data file sign-off mechanism, a CRC check (Cyclic Redundancy Check) for data integrity, and an overall data validation pass/fail statement with sign-off right on the graph.
13.	Aspen Tech	InfoPlus.21® and Batch.21™; Aspen Alarm and Event™;Aspen eBRS™	http://www.aspentech.com/	Aspen Technology Inc. announced new software solutions that provide pharmaceutical and other regulated process manufacturers with a broad range of solutions to comply with Title 21 of the Code of Federal Regulations.
14.	AssurX	CATSWeb	www.assurx.com	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.
15.	Automsoft International LTD	Rapid-Pharma	www.automsoft.com	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.
16.	AVATAR Consulting	LABTrack	www.labtrack.com	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.
17.	Beamex	QM6, Quality Manager Calibration Software	http://www.beamex.com/products/qm6_004.htm	The Log Book option now also includes an Electronic Signature feature. If the Electronic Signature is enabled, QM6 prompts for user id and password when a calibration is saved or approved.

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18.	Beckman Coulter	Pinnacle	www.beckmancoulter.com/pinnaclepart11	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.
19.	BioLog	MicroLog and OmniLog Systems	http://www.biolog.com	The MicroLog and OmniLog systems are designed to exist within a 21CFR Part 11 environment and provide the basic functionality to support our customer's compliance efforts. Biolog provides all of the necessary software features, validation packages, and optional assistance to support full (including 21 CFR Part 11) compliance.
20.	BioMedion	INDexxis™	http://www.biomedion.com/en/indexxis.html	INDexxis™ is designed to manage data in accordance with predicate rules (GxP) and the new regulations on electronic records and electronic signatures, especially FDA 21CFRpart11.
21.	Blaze Systems Corp.	BlazeLIMS Enterprise Plus	www.blazesystems.com	BlazeLIMS Enterprise Plus provides flexible sample registration functions, including ad hoc logs, batch/requests, QC batch, and stability studies, with manual or automated results entry in a 21 CFR Part 11-compliant environment.
22.	Blue Mountain Software	Calibration Manager®	www.coolblue.com	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.
23.	Brendan Scientific	StatLIA	http://www.brendan.com/	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.

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24.	Cayenta	Mainsaver EAM	http://www.cayenta.com/manufacturing/description.html - fda	Cayenta's state-of-the-art, award-winning, Computerized Maintenance Management Software is used by companies both small and large to minimize operation costs and maximize productivity. Mainsaver is a total solution for Enterprise Asset Management (EAM). Mainsaver offers a robust Enterprise Asset Management (EAM) solution, professional consulting services, implementation and training services and now compliance to FDA's 21 CFR. 11 so you can maintain your competitive edge.
25.	Charles River Laboratories	EndoScan-V version 1.0.13	http://www.criver.com/faq/endotoxin/	Our EndoScan-V version 1.0.13 is the first endotoxin-specific software that addresses the 21 CFR Part 11 requirement for validation.
26.	Chemera Inc.		http://www.chemera.com/chemera/encryption.asp	**Chemera, inc.** has developed proprietary software utilizing 128-bit encryption technology that fully complies with 21 CFR part 11 (FDA regulation).
27.	ChemScope	eGMP	www.egmp.com	eGMP is compliant with FDA regulations, including 21 CFR Part 11. And all through a single web browser!
28.	ChemSW	CIS Chemical Inventory System®	www.chemsw.com	ChemSW announced a new option for its CIS Chemical Inventory System® that provides audit trail and electronic signature, for 21 CFR Part 11 compliance. The system incorporates multiple levels of security, transaction logging and signature verification. Ideal for use in pharmaceutical laboratory applications, the new security and audit trail option allows the system administrator to determine which users are authorized to make various kinds of changes, and enables accurate tracking of all change sources.
29.	Cimage Novasoft	NovaGMP	http://www.cimagenovasoft.com/news/newsreleases/prgmp0601.htm	Cimage NovaSoft, a global provider of eBusiness application solutions to industry, today announced the release of NovaGMP. This product helps FDA regulated companies, such as pharmaceutical and medical device manufacturers, to comply with the FDA regulation 21 CFR Part 11 for electronic records and signatures. NovaGMP is part of the Cimage NovaSoft GMP suite, which is based upon Cimage NovaSoft's extensive pharmaceutical manufacturing and medical device industry experience. It enables FDA regulated companies to manage laboratory and processing information throughout its lifecycle, helping them to achieve the documentation, safety and quality standards required to comply with Current Good Manufacturing Practices (cGMP).
30.	Cimcon Software, Inc.	eInfoTree ™	www.part11solutions.com	Designed specifically to meet the regulatory requirements of the life science industries, the eInfotreeTM Digital Compliance solution replaces traditional paper-based regulatory data and processes and is fully compliant with 21 CFR Part 11 requirements for Electronic Records and Electronic Signatures. eInfotree's patent-pending Digital ComplianceTM Architecture seamlessly integrates disparate "islands of information" without affecting existing business processes into a regulated, controlled and compliant digital nervous system with single point access throughout the workgroup, department or enterprise.

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31.	CIMTechniques, Inc.	CIMScan®	http://www.cimtechniques.com/	The FDA has now started aggressive enforcement of 21 CFR Part 11, which is the regulation regarding electronic records and electronic signatures. CIMScan now contains all the necessary functions and capabilities to insure compliance.
32.	Client Solutions	Silverstream V2.5	http://www.clients.ie/casestudies/janssen.shtml	Conclusion: The system was implemented within spec, within budget and on-time. Change requests are now being processed more efficiently and with greater speed. Users know where their request is, what is its status and who is holding it Janssen have successfully removed the paperwork from the change control process The system is compliant with FDA regulation 21 part 11 The system is currently being used by fifty staff members and can be deployed further at zero cost Because the system is intranet based, changes or ammendments can be made at server level and deployed immediately
33.	Clinsoft	Clintrial Connect ™ Clintrial ™ Clintrace ™ Integrated Review ™ Jreview ™	www.clinsoft.com	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.
34.	ClinSource	TrialXS / EDC	http://www.clinsource.com/	TrialXS / EDC complies with FDA 21 CFR Part 11 regulation and conforms to GCP guidelines.
35.	Cognex	In-Sight ™	http://www.cognex.com/corporate/n_news-compliance.asp	Cognex Corporation (NASDAQ - CGNX), the world's leading supplier of machine vision systems, announced that its In-Sight ™ family of networkable vision sensors are compliant with the U.S. Food and Drug Administration's 21 CFR Part 11 regulations. Cognex Corporation designs, develops, manufactures, and markets machine vision systems, or computers that can "see." As part of its compliance initiative, the company has authored and published detailed Application Guidelines that provide recommendations for developing 21 CFR Part 11-compliant automation projects, which incorporate machine vision technology.

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36.	Communication Intelligence Corporation (CIC)	Sign IT	http://www.penop.com	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.
37.	Compliance Software Solutions Corp.	EMSS©	www.csoftsol.com	Compliance Software Solutions Corporation (CSSC) has developed the Environmental Monitoring Software System (EMSS©) to comply with the requirements defined in the FDA's 21 CFR Part 11 for Electronic Documents
38.	Computer Compliance, Inc.	EFLEXION	http://www.e-flexion.com	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. 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. 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.
39.	ConsenSys Software Corporation	ConsenSys MedDev	http://www.415.com/demos/consensys/02ourprod/02c.cmdds.html	ConsenSys MedDev has been specifically designed to meet the requirements of the Part 11 rule, which dictates the accepted use of electronic signatures and electronic records. ConsenSys MedDev ensures that every release or revision of a part or document has associated with it one or more reviews or change orders. These work records in turn contain the signatures, comments, and justification records for the release or revision. This web of related records forms a cohesive audit trail that completely addresses FDA/ISO requirements.
40.	Creon	Q-DIS/R	www.creon.com	The extended use of computer technology and the increasing automation in the field of modern chemical analytic, produces large quantities of analytical data. In consideration of: • the diversity of data sources • GLP and GMP guidelines • governmental requirements (FDA 21, CFR Part 11) • company objectives

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41.	CRF Box	CRF Box Wireless™	http://www.crfbox.com/3.html	THE KEY FEATURES OF CRF BOX WIRELESS™ INCLUDE: Patient-generated data entry via a wireless or handheld device Edit checks to diary data before entry into trial database 2-way communication between clinical R&D stakeholders Diary page amendments during the trial conduct Multiple languages and technology platforms in the same trial Flexible generation of reminders and alerts to patients, based on the cumulative history in the trial Interface to the major clinical data management systems with industry-standard XML High level of security based on PKI (Public Key Infrastructure) digital signature technology 21 CFR Part 11 compliance
42.	CSEngineering AG	CIWOS	http://www.ciwos.com/	CSEngineering AG has software called CIWOS that is 21 CFR Part 11 compliant.
43.	Cyber-SIGN Inc.	Cyber-SIGN	www.cybersign.com	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.
44.	Daon	DaonSign	www.daon.com	Biometrically secured electronic signing capabilities for the Pharmaceutical Industry. Daon's e-signature solution adheres to Worldwide Regulations & Legislation around the use of electronic signatures.
45.	DataMirror	LiveAudit	http://www.datamirror.com/resourcecenter	DataMirror provides real-time data integration software that helps companies ensure cost-effective compliance with FDA Regulation 21-CFR Part 11. LiveAudit™ for DataMirror Transformation Server enables FDA-regulated companies to create real-time audit trails that preserve historical information

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46.	DataSweep	DataSweep	http://www.datasweep.com/	Datasweep, Inc. provides collaborative solutions for the medical industry to establish a paperless GMP environment that is compliant with 21 CFR Part 11. Datasweep's solutions leverage the Internet to give medical OEMs and their partners the Web visibility into and control of real-time manufacturing and quality information to drive improvements in planning, manufacturing, record archiving and product lifecycle management, while driving down the total cost of compliancy.
47.	DataTrak International	Datatrak EDC	http://www.datatraknet.com	**CFR21;Part 11 Compliant -** Contact us for a document with details. **Audit Trail:** When you compare EDC product you'll find DATATRAK's Audit Trail to be the best of breed. DATATRAK EDC gives you an audit trail down to the data field unlike many systems that give you a snapshot at each page turn (roughly equivalent to filling out a CRF with a pencil). This also means that if the Investigator loses a communications connection, they do not lose data.
48.	Datastream	Datastream 7i	http://www.datastream.net/common/21cfr11.asp	Datastream delivers security for electronic records and signatures and is able to meet the individual needs of various companies who have to deal with *21 CFR 11* concerns.
49.	DatumEBusiness Solutions	TrustedTime	http://www.datum.com/tt	Trusted Time is a solution for providing the necessary components to meet the e-business need for secure and non-repudiatable time stamps. It is comprised of two main concepts: the security of the time stamp and the auditability of the time stamp. The security aspect addresses both the transmission of the time from a National Measurement Institute to the local time stamp system and the protection of time and audit information within any of the systems that the time stamp may reside in along the way. The audit nature of Trusted Time is the storing of time source and cryptographic information within each time component and the PKIX-compliant time stamp itself.
50.	Deadline Solutions Inc. (DSI)	EDS (Electronic Documentation System)	http://www.deadlinesolutions.com/dsiEDS.htm	In 1999, DSI envisioned a system that would allow companies to easily define a "process" with a tool that was easy and quick to use. By using this tool, an entire process could be defined and then an "electronic batch record" could then be readily extracted. All of this was done with the goal of helping companies who are committed to meeting the 21 CFR Part 11 Specification do exactly that.
51.	Decision Management International	ProcessPro	http://www.processpromfg.com/	Decision Management International, Inc. develops leading-edge software for FDA regulated industries. The integrated solution set includes a robust document-authoring and control suite, resource-tracking suite, and an RF-enabled Weigh Dispense application. Products are engineered specifically for 21 CFR Part 11 compliant environments, and support electronic signatures, real-time data exchange with legacy systems, and handheld barcode scanning technology

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52.	Dionex Corporation	Chromeleon	www.dionex.com	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.
53.	Docent	Docent Enterprise	http://www.docent.com/solutions/br_21CFR11.html	Docent explicitly designed Docent Enterprise to enable pharmaceutical companies to meet the United States Code of Federal Regulations, Section 21, Part 11 requirements of managing Electronic Records and Electronic Signatures. Docent's specific features supporting 21 CFR Part 11 include: • Secure role-based system access control • Guaranteed unique non-reusable user accounts • Comprehensive data management and retrieval including encrypted storage and network access • Electronic signatures consist of unique user ids and an encrypted password • Biometric hardware/software authentication support
54.	Document Control Systems, Inc.	MASTERControl	http://www.mastercontrol.com/	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.
55.	Documentum/PricewaterhouseCoopers	GMPharma	http://www.gmpharma.com	GMPharma is the first enterprise-wide solution that offers an out-of-the box e-business platform for global content management of GMP regulated documentation. Conforming to 21 CFR Part 11 requirements, GMPharma cuts operational costs, accelerates transfer times from development to manufacturing and improves GMP compliance. Standard functionality includes electronic signatures, audit trails, controlled printing with overlays and watermarks, automatic version control, preconfigured life-cycles and role based viewing models. Additionally, GMPharma includes deployment packages that accelerate implementation, streamline validation and manage document migration.
56.	DocWave	QualWave ™	www.docwave.com	DocWave provides Life & Health companies with high level consulting services and business solutions. Compliant with pharmaceutical good practices, FDA and International regulations, QualWave™ is a complete solution for managing Quality Documents, (integrating 21CFR part 11 rules). QualWave™ is a part of our " Wave " business solutions suite for the R&D, QA, Manufacturing, Distribution and Marketing Departments of Pharmaceutical, Cosmetic and Food Companies

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57.	Doxis	SCCM	www.doxis.com	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
58.	DSI	dsiEDS SCADAeds	www.deadlinesolutions.com	Deadline Solutions, Inc. delivers high quality Client/Server and Internet enabled applications that will provide 21 CFR Part 11 Compliance for the Food and Drug Industries. DSI's Electronic Documentation System (dsiEDS) is a Rapid Application Development tool that is used by our staff to quickly create a 'Manufacturing/Production Process' or map functionality to a given piece of process equipment. Any given piece of data can then be selected as passive or required to have an electronic signature to ensure compliance. DSI's SCADA Electronic Documentation System (SCADAeds) takes the best features of dsiEDS and ties it to the pharmaceutical industry's most popular packaging line hardware. SCADAeds currently works with Ramsey AC4000/AC9000 checkweighers, Lakso Fillers, Omega Unscramblers, and Fowler Cappers.
59.	DUII	LIMS	www.duii.com	DUII develops and markets its products and services of laboratory information management system (LIMS), 21CFR11-aware computational infrastructure, and Standard Operating Procedure (SOP)-driven networks. These satisfy the requirements of 21CRF11 by authority check, operational system check, device check, SOP, electronic signature and closed systems. DUII creates tools to enhance communication and to enforce compliance.

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60.	EMedia-IT	MCS *Now*	http://www.emediait.com/products/index.html	eMedia-IT's web-based infrastructure allows your company to meeting key FDA compliancy requirements while managing the secure sharing of files within your organization as well as with other organizations, and implementing features such as: • User authentication upon login • Dynamic file viewing • Group and user management • File and folder access permissions • Version control and file history • Read-only audit trail
61.	Emerson Process Management	DeltaV™	http://easydeltav.com	The DeltaV™ digital automation system delivers integrated batch automation that's easy to engineer, easy to use, and easy to validate. It's built to S88 standards and fully addresses the FDA's 21 CFR Part 11 requirements with integrated recipe and campaign management, batch history, automatic version control, and change management.
62.	Enmed	Acceliant™	http://www.enmed.com/	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.
63.	EnsureLink	DocuStore Repository eNow™	http://www.ensurelink.com/resources.html	Biotechnology research, discoveries and applications ultimately find their way to public use. Under the auspices of the Health Care Insurance Portability and Accountability Act (HIPAA) and FDA regulation 21CFRPART 11, any entity that accepts, maintains or transmits electronic data must comply with a standardized Electronic Data Interchange (EDI) format. The FDA, in particular, has indicated it is committed to a set of regulations that apply to all areas of electronic technology that are compatible with the FDA's mandate to promote and protect public health. It is reasonable to expect the FDA regulations to be even more broad-based than those of other agencies, and for the other agencies to broaden their rules to meet expanded FDA requirements. Any firm that produces information or products that eventually reach the public will fall under the auspices of the new, emerging "alphabet-soup" regulatory environment. Those who begin with security protocol in place are laying the groundwork for successful long term industry and market leadership.

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64.	Entrust Technologies	Entrust/PKI™	http://www.entrust.com	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.
65.	eOriginal Inc.	***e***Original™	www.eoriginal.com	The ***e***Original™ system meets or exceeds all of the FDA requirements for electronic filings
66.	Etrials	iSuite	http://www.etrials.com/edc_deploy.htm	etrials offers iSuite, an innovative and powerful data entry system that allows investigators and site administrators to make immediate decisions based on having cleaner data -- faster. Our eCRF form is 21 CFR Part 11 compliant.
67.	EtQ Solutions®	A Browser Based Suite	http://www.knowledgearc.com/	EtQ Solutions® is a complete ISO/QS 9000 solution, now **21 CFR Part 11** compliant. The workflow engine under girds solutions for ISO 9000, QS 9000, ISO 14000, including Document Control, Corrective Action, Audits, APQP, Training, etc.
68.	First Consulting Group	FirstDocs™	www.fcg.com	First Consulting Group (FCG) has combined the industry's best practices, state-of-the-art technology, and consulting services to produce FirstDocs™ for GMP, a comprehensive prepackaged electronic document management solution in support of pharmaceutical manufacturing and quality processes. It's a part of our FirstDocs™ solution suite, which offers a set of services and software for research and development, case report form management, and regulatory submissions.
69.	Fisher-Rosemont	DeltaV	http://www.frco.com/	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.
70.	Flexware Integration	21 CFR Part 11 Remediation Toolkit	http://www.flexint.com/21cfrpart11.asp	Flexware Integration's 21 CFR Part 11 Remediation Toolkit was designed to help simplify the remediation process for client/server systems. It can drastically reduce your cost of remediation by providing "common solutions to common problems."

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71.	Foss NIRSystems, Inc.	Vision	www.foss-nirsystems.com	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.
72.	Gould Instrument Systems	Gould Life Science Suite	http://www.gouldis.com/ponemah_Iss.html	Data Security -An optional Data Security feature provides compliance to FDA 21 CFR Part 11.
73.	H&A Scientific, Inc.	SLIM	http://hascientific.com/slim.htm	"21 CFR Part 11 Compliant"; "All changes are event logged. Audit trail includes references to the date and time of the change, the user making the change, the event type that caused the event to be logged, and description. When data results are changed a change code and comments are logged. Multiple levels of security. "
74.	Hertzler Systems, Inc.	GainSeeker Suite	http://www.hertzler.com/html/news_pr_v7.asp	In response to the growing need to find more powerful software to help manufacturers and businesses collect, manage, analyze and report quality information, Hertzler Systems is introducing their newest product, QA/S GainSeeker® 7 Suite. Among the dozens of new features in the new release, noted highlights include: • Additional security features such as enhanced 21 CFR Part 11 compliance.
75.	Hewlett Packard	Cerity	www.agilent.com	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.)
76.	Honeywell-POMS	POMS	http://www.poms.com/	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
77.	Icalis Data Systems	2.0 Dissolution Data Management Software	www.labocat.nl/Icalis/LaboCAT_Icalis_Page_2a.htm	The new Version 2.0 Dissolution Data Management software from Icalis Data Systems employ an extensive range of restrictive access rights to aid compliance to 21 CFR Part 11 and Online Sample processing with Autosamplers including sample dilution. Icalis FDA 21 CFR part 11 allows the company to comply with this requirement of record keeping and authentication, by having the possibility to specify records or Groups of records that must be signed. The company can also specify which Users can sign records, which records and how many users are required for signature. Records specified for signing clearly show this requirement if printed and the status of the singing. An audit trail is kept of all activity in the system which is also user queryable to help keep information in an orderly manner.
78.	Iconics	Genesis32	www.iconics.com	ICONICS, a leader in the development of Web-enabled OPC-based industrial automation software for Microsoft® Windows® operating systems, announced that Version 6.1 of GENESIS32™ offers a wide variety of tools for complying with the FDA 21 CFR 11 regulations. It enables proper handling and recording of FDA-regulated electronic information, and applies "electronic signatures" such that the FDA considers them to be "equivalent" to that of handwritten signatures and documents.
79.	Industry Dynamics Associates, Inc.	Xtrials	www.mymatrixml.com/xTrials.pdf	We offer a breakthrough, workgroup management technology that is native XML-based, fully 21 CFR Part 11 compliant, and able to be customized for individual company implementations in a fraction of the time of competitive offerings. The XTrials ™ Application Architecture is a fully-scalable clinical data management environment that harnesses the power XML for EDC, Clinical Data Review, CSR Analysis/Verification/Peer review, and electronic Regulatory Submissions production.
80.	Infotehna	ePharma	http://www.infotehna.com/	Infotehna is committed to providing integrated solutions for pharmaceutical industries, covering regulatory affairs, QA/QC are a procedures management, and change control. It combines experience and technology to produce ePharma, a comprehensive suite of applications, designed specifically for pharmaceutical and process industries. ePharma is ready for the efficient and effective implementations featuring two major components, GLORYA and eProcess Manager. Both applications are completely internet/intranet based, utilize full life cycle support of Documentum D4i, and XML

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81.	InnaPhase	Watson™ LIMS	http://www.innaphase.com	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.
82.	Innovatum	DataThread™	www.innovatum.com	DataThread ™;Total solution to FDA's Part 11 requirements; AS/400 based and using the available functionality of the operating system, DataThread ™does not require any modification to existing applications; Highly configurable, able to identify at the file and field level, auditing and signature requirements; Captures data changes into a secure auditable database; Capture the user id, user name, local time and date, before and after image of the data change; Allows user to electronically sign for changes; Signature can be captured at time of change or grouped for signing at a later time; Multiple signatures can be required for the same change, allowing for work flow management and oversight.; Signature can be captured through biometric devices or passwords independent of the AS/400 password; Provides user-friendly audit capabilities through electronic files, hard copy reports, and on-screen reports.Auditable data from several AS/400 can be combined into network based data repositories for reporting and archiving; Specifically developed for part 11, DataThread™has a very small footprint with efficiency as its cornerstone; Infinitely scalable to the largest AS/400 environments
83.	Intellution, Inc.	iFix iBatch	http://www.intellution.com/	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.

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84.	Interpharm Press	Training Tracker III	http://www.ihshealthgroup.com/pressreleases/press9.htm	The Food and Drug Administration (FDA) mandates strict regulations regarding electronic signatures and audit trailing on electronic data collection methods under 21 CFR Part 11. Healthcare manufacturers using electronic record-keeping systems must comply with stringent regulations regarding the training of their employees, including the methods of recording and reporting such training for audits. Training Tracker III helps companies stay in compliance with these regulations by tracking employee training records and cross-referencing employees with their job titles / grades, courses required for those jobs, instructors and course scheduling. Once an employee's training has been completed, the information is recorded with the electronic signature, and all changes to that record are also date- and time-stamped for auditing purposes.
85.	Invensys	Foxboro I/A Systems; Wonderware; Avantis; Eurotherm	http://www.foxboro.com/iaseries/automation_systems/hottopics/21_cfr.htm	Invensys Pharmaceutical Solutions, a division of Invensys Production Management is a leading supplier of manufacturing control (Foxboro I/A Series System, Wonderware), manufacturing execution (Avantis) and environmental systems (Eurotherm) that meet and exceed the guidelines of 21 CFR part 11. Invensys Pharmaceutical Solutions has a dedicated group of pharmaceutical engineers and specialists focused on this industry, regulations, and new technology tools. Our unique solution includes a full range of products, automated tools, validation services (VTI), and procedures to help comply to 21 CFR part 11. We leverage our expertise to provide systems, tools, policies, and procedures for compliance.
86.	Ionics Instrument Business Group	DataPro/DataGuard	http://www.ionicsinstruments.com/	Ionics Instrument Business Group (formerly Sievers Instruments) makes the world's most sensitive and selective scientific instruments to measure total organic carbon (TOC) for the pharmaceutical, semiconductor and power industries. A 21 CFR 11 compliant Sievers brand TOC system is available with a new DataPro/DataGuard software package that includes audit trails, electronic signatures and user-level security.
87.	Isotrain	Isotrain Training Management Solution	http://www.isotrain.com/	ISOtrain Training Management Solution is a powerful compliance driven, quality based training tracking system. ISOtrain allows you to manage employee training records on your global network. With a click of a button, you can notify employees of scheduled training, e-mail a report to management, review employee qualifications, or retrieve a course outline. ISOtrain runs on multiple desktop platforms, network operating systems and databases. Validation is made easy with a comprehensive validation package.

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88.	J.D. Edwards	J.D. Edwards OneWorld	www.jdedwards.com	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.
89.	Kaye Instruments	Validator 2000 LabWatch	http://www.kayeinc.com/	The **Validator 2000** 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 **LabWatch** System operates in compliance with the FDA regulation on 21 CFR Part 11 Electronic Signatures and Records
90.	LabLogic Systems Ltd.	Debra Laura	http://www.lablogic.com	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.
91.	Labtronics, Inc.	LimsLink™ LimsLink^{CDS} Nexxis Information Integration System	www.labtronics.com	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^{CDS} provides the level of security and accountability required to make it a necessary and valuable component for 21 CFR Part 11 compliance. The Nexxis Information Integration System from Labtronics Inc., allows laboratories to use new and existing Excel spreadsheets within a framework that meets with the requirements of FDA Rule 21 CFR Part 11. This benefits laboratories, working in a regulated environment, who currently utilize Excel to perform calculations on data generated in the laboratory. By incorporating their Excel spreadsheets into a Nexxis method, they are able to implement electronic signature, password protection and audit trail controls over the use of the Excel application.

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92.	Labware Inc.	LabWare LIMS	www.labware.com	LabWare Inc. has been an established leader in supplying Laboratory Information Management Systems and instrument integration software to companies in diverse industries worldwide since 1988. LabWare's successful validation record and compliance to 21 CRF Part 11 guidelines are some of the reasons why many of the world's pharmaceutical companies have standardized on LabWare LIMS.
93.	Linton Instrumentation	Gould-PoNeMah P3-Plus	www.lintoninst.co.uk/P3PDSO.htm	The P3-Plus Data Security Option utilizes a 'Smart Card' for each user. These smart cards are initialized with unique encryption Public/Private Key set for digital signatures. P3-Plus Data Security Option uses PKI (Public Key Infrastructure), a legally binding equivalent to a handwritten signature – PKI is the standard adopted by Verisign and other leading security/verification organizations. Files can be electronically signed using the operator's electronic signature.
94.	Liquent	CoreDossierX	www.liquent.com	CoreDossierX Features • Can be used alone or in conjunction with your document management system • Supports over 135 native file formats • Select from a wide range of output channels: HTML, PDF, TIFF, CD-ROM, kPortal, paper, standard PostScript, Docutech PostScript, CDER and CBER • Audit trail capabilities support 21 CFR Part II compliance on a per publication basis • Enables the assembly of smaller publications that feed into larger submissions • Automatic finishing options: table of contents generation, cross-references, headers, footers, watermarks and pagination schemes
95.	Malvern Instruments	Self-sign	www.malvern.co.uk/images/tb1155%20-%20Electronic%20signatures%20using%20adobe%20acrobat.pdf	The digital signature solution that is provided with the full acrobat package is called "self-sign". This solution is 21 CFR Part 11 compliant and will provide an immediate solution to using electronic signatures with minimum investment and minimal impact on legacy systems. Simply install the adobe acrobat package and use the "PDF Writer" device as your default printer. Whenever a report is printed a file is created containing the report in PDF format. This file can then be viewed and signed using the Acrobat package.
96.	Master Control Systems™	MASTERControl FDA Edition	http://www.mastercontrol.com/fda1.htm	The MASTERControl FDA Edition was developed in 1998 to address electronic signature and document security requirements for 21 CFR part 11 of the FDA GMP. This includes both the enhanced features needed to comply with these standards and assistance with the on-site validation process.

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97.	Matrix One	eMatrix 9	www.matrixone.com	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.
98.	Micromass	CyberLAB™	www.micromass.co.uk	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.
99.	MIDI	Sherlock 4.0	www.midi-inc.com/pages/21cfrII.html	The MIDI Sherlock Microbial Identification System (MIS) is 21 CFR Part 11 compliant. This software package is called Sherlock Electronic Records and Signatures (ERS). To help you conform with FDA regulations, the Electronic Records and Signatures package incorporates the following features: Preserves ChemStation raw data, Sherlock Sequences, and Sherlock Methods associated with a set of analytical runs. Data is stored in a single, secure file that cannot be altered by ordinary means. Files are stored in a location determined by the system administrator. Maintains data integrity such that data can be utilized to regenerate the original results. Electronic signature at operational points by means of a logon consisting of an operator name and password. Permits review and verification of electronic records through a windows based interface. Provides designated personnel with capability to review, approve and electronically sign records. Creates an audit trail of all entries and actions that create, modify or delete an electronic record.
100.	MiGG Systems	Qstream iCompliance 4	http://www.migg.com/	Qstream iCompliance 4 is a leading edge development platform for the rapid assembly of 21 CFR Part 11 compliant web enabled applications providing companies within regulated markets a rapid approach to application development that is simple to validate.
101.	NetRegulus	PQIntelligence	http://www.netregulus.com/	NetRegulus offers product quality intelligence software and services for FDA regulated medical products organizations. Our user-friendly, 21 CFR Part 11 compliant, PQIntelligence™ Software System keeps everyone involved in a product's life cycle on the same page. PQIntelligence allows firms of all sizes to collect, analyze, report, share, and act on critical regulated data within one streamlined package. Use PQIntelligence for clinical studies management, complaint handling, CAPA management, audit management, and other regulatory needs.

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102.	Nicolet Industrial	RESULT™	http://www.nicoletindustrial.com/NISmain.html	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.
103.	NoteBookMaker	NoteBookMaker ™	www.NoteBookMaker.com	NoteBookMaker™ is a totally secure, completely electronic Laboratory Notebook. The first electronic notebook that looks and prints like a real notebook. This system is easily modified and can be custom designed to fit any organization. In fact, NotebookMakerTM meets the requirements of 21 CFR Part 11
104.	NuGenesis Technologies Corporation.	ARCHIVE® UNIFY® VISION®	http://www.nugenesis.com/	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.
105.	Numoda	DataStream™	www.numoda.com/pages/productmed.htm	Numoda DataStream wireless solution provides clients with better control over market evaluations and enables the collection and redistribution of error free study data in significantly less time than existing methods. We have delivered this leading technology to some of the world's largest medical device companies. They realize the power, efficiency and simplicity of Numoda DataStrea. Eliminates time of testing and data entry Greatly reduces paperwork and overall costs Creates a virtually Error-Free Study environment, With point of service data collection and instant distribution Provides tailored access to custom reports and workflow logistics Instant, remote updates Works with any handheld device Secure and validated 21 CFR Part 11 compliant

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106.	OnGAutomation, Ltd		http://www.ongautomation.com/	O.N.G. Automation are the official Rockwell Automation (Allen Bradley) and Foxboro I/A DCS Authorised integrator in Ireland, providing us direct access to the vast range of services and support which is available from both Companies. O.N.G. Automation has proven experience in the implementation of Control Systems from design stage through to final commissioning, In the Pharmaceutical, Biochemical, Food, Water and Electricity generation industries. We specialise in GAMP3 and 21 CFR part 11 compliant systems.
107.	OpenText Corp.	LiveLink	www.opentext.com	Open Text's mandate is to deploy high-value specific implementations of Livelink for all areas across the enterprise of pharmaceutical companies. Livelink is a collaborative commerce application used for document management, project management and workflow. Livelink is 21-CFR Part 11 compliant and integrates with scientific applications and databases.
108.	OSI Software, Inc.	PI System™	http://www.osisoft.com/osinews/pressreleases/cfr-pt11.htm	OSI Software, Inc. announced new features for its PI System™ software that allow pharmaceutical customers to meet FDA 21 CFR Part 11 compliance requirements for storing electronic records. OSI Software is the leading provider of real-time information systems for the process industries. Nine of the top 10 global pharmaceutical companies currently use the PI System to record and monitor real-time information in their manufacturing and research facilities.
109.	Particle Measuring Systems, Inc.	APSS-200 Automated Parenteral Sampling System	http://www.pmeasuring.com/html/lauto.htm	21 CFR Part 11 Compliant; Secure System Audit Trails; Encrypted Data; Ease of Validation; Unique User Names And Passwords; Software Validation Notebook
110.	PENSA Technology Solution Inc.	TVM (The Validation Manager)	www.gmps.com/extnews.html	We are on the verge of launching version 2.0 of TVM that is our own Windows-based software package offering an expert knowledgebase of compliance and regulatory information to assist with every kind of validation project. Using The Validation Manager can greatly reduce the cost and complexity of managing validation projects thanks to the unique use of a Tractability Matrix and OneClick preparation of validation documents. TVM is also designed to be fully compliant with 21 CFR Part 11.
111.	Perceptive Instruments		www.perceptive.co.uk/Sorcerer_UDS.HTM	In addition to the standard Sorcerer system, we supply a fully validated suite of software for UDS which is also compliant with international GLP's and FDA 21 Part 11.

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112.	Perkin Elmer	Products include: Connect Turbochrom UV WinlabES Spectrum™ ES Spectrum Assure ID Pyris™ ES TotalChrome Labworks ES Lims	http://instruments.perkinelmer.com/	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." Technical compliance, ncluding comprehensive audit trails and electronic signature points, is designed into the heart of the system, providing strict security (Fig. 1) and ensuring no compromise to laboratory throughput. All methods and results are stored in a secure, tamper-evident encrypted database that allows authorized users to manage and interpret results more efficiently. Spectrum™ ES incorporates rigorous access control to ensure that valuable data cannot be deleted, overwritten or edited. To meet the requirement in 21 CFR Part 11 for authority checks, password-protection is linked to configurable user permissions to tailor the software to the training levels and responsibilities of individual users. Permissions and access groups are set by an administrator who can also configure the screen layout and menu structure to simplify analyses, reducing operator training and avoiding errors. Login history is fully audit trailed, including dates and times of successful and unsuccessful login attempts. Data is stored in secure databases (Fig. 5). Full audit trails for administrative activities, method development history, instrument validation and results generation are easily accessible. Electronic signatures are supported when generating results as well as when approving methods and results. Pyris™ ES ensures strict compliance with 21 CFR Part 11 for users of thermal analysis instrumentation in QA/QC and research functions. Rigorous user level management defines user groups and grants permission levels reflecting the laboratory workflow and the differing responsibilities of each user. Stringent password control ensures that only authorized individuals can access system functions, modify electronic records and sign off methods and results. Fully configurable electronic signatures can be defined throughout each analysis. Fully compliant password protection. Highly configurable access control with controlled group permissions; Timestamped audit trails; Electronic Signatures with configurable "reasons" lists; Tamper-proof data integrity with tamper-evidence tracking The new LIMS incorporates tools for managing electronic records and ensures traceability of data from time of entry through all subsequent business processes, establishing both a comprehensive event log and an audit history. Data is protected from accidental or intentional intervention by limiting access to authorized persons via a single, centralized point of authentication, which also allows implementation of electronic signatures

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113.	Pharsight	WinNonlin WinNonMix	http://www.pharsight.com/	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.
114.	Phase Forward Incorporated	InForm InFusion	www.phaseforward.com	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.
115.	PHT Corp	Esendant Clinical Network	http://www.phtcorp.com/company/corpsummary.html	PHT's Esendant Clinical Network fully conforms to CDISC standards (www.cdisc.org) and is compliant with FDA 21 CFR Part 11.
116.	Pilgrim	Q&MIS®	www.pilgrimusa.com	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.
117.	Prelude Computer Solutions, Inc.	DocuKnowledg™ Compliance Layer on Domino.doc	www.preludeinc.com	Domino.Doc provides a robust platform for document management that already incorporates most of the requirements specified in the FDA 21 CFR Part 11 document. The DocuKnowledgeTM Compliance Layer adds the additional functions that are required to create FDA Part 11 Domino.Doc based applications.
118.	Pricewaterhouse Coopers Documentum	GMPharma	www.GMPharma.com	GMPharma is the first e business solution jointly developed by PricewaterhouseCoopers and Documentum for enterprise wide management of pharmaceutical GMP regulated content.
119.	Princeton Softech	Active Archive Solutions™	http://www.princetonsoftech.com/products/21cfr11.htm	Princeton Softech's Active Archive Solutions™ can assist with 21 CFR Part 11 compliance, and go well beyond the traditional definition of archiving to provide additional benefits. "Active archiving" is unique because it stores research data with 100% accuracy and full relational integrity. This capability makes it easy to browse or research archived data — even generate reports — without restoring a single row. By safely removing historical research data from production databases, active archiving improves application performance and availability without expensive hardware or software upgrades.

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120.	Prisym	MAP 80 Prisymedica	www.map80.co.uk/medica.htm	Prisymedica is the only label design and production software that exceeds FDA standars for compliance, as demanded by the Pharmaceutical, Clinical Trials and medical device industries. Prisymedica, the latest product from MAP80, has been specifically introduced to meet the requirements of the FDA 21 CFR Part 11 rules regarding Electronic Records and Electronic Signatures.
121.	Process Analysis & Automation		http://www.paa.co.uk	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.
122.	ProIRB Plus, Inc.	PRO_IRB™	www.proirb.com	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.
123.	ProofSpace	ProofMark	www.proofspace.com	ProofSpace, Inc. has designed ProofMark to perfect the electronic documentation process, withstanding audit and minimizing risk. Complementary to current identity-based models that supplied the who of a transaction, record or data, ProofMark encapsulates what occurred, when it happened based on provable time, and includes who participated in the activity... In the Pharmaceutical industry, proofmark aids companies to comply with 21CFR part 11 regulations.
124.	Propack Data	PMX MES CTM RDM MQS	http://www.propack-data.com	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.
125.	PureEdge	E-forms	www.pureedge.com	We offer compliance with FDA 21-CFR-11
126.	QAD	MFG/Pro	www.qad.com	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.

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127.	Q-mation	Wonderare Intouch Active X Controls	http://www.qmation.com/	Q-mation has developed a set of Active X controls and script functions that significantly ease the development of 21 CFR Part 11 compliant applications using Wonderware's InTouch 7.x software. These tools help address the regulation's requirements around security management, electronic signatures and authority checks (i.e. - UserID/Password maintenance, use of Full Printed Name, "Done by/Checked by" authority checks etc.). In addition, we've developed Audit Trail technology that can be applied to any Microsoft SQL Server database table.
128.	Quality Systems International	QSI System For Document Control	www.qualitysys.com	Features include multi-level access security, FDA compliant electronic signatures, revision control and automated document status updates. Activities associated with every document are automatically recorded in the history section. Document archiving of approved documents is automatic and an optional Draft Documents database automatically provides an audit trail that documents time-sequenced development and modification of documents.
129.	Qumas	DocCompliance®	http://www.qumas.com/	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.
130.	Relsys	Argus Safety ™ EasyTrak ™	http://www.relsys-inc.com/	Argus Safety ™ Features: 21 CFR Part 11 Compliant ICH E2B - Electronic Submission ICH E2C - PSUR Compliant with current MedDRA™ versions CIOMS V EasyTrak ™ Features: 21 CFR Part 11 Compliant Meets FDA complaint handling requirements Integrated adverse-event reporting for FDA and EU Device Vigilance Reporting Return Goods Authorization Alternate Summary Report

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131.	Revelink	Revelink's Enterprise Executive	http://www.revelink.com/	Revelink has developed a validated enterprise application development platform that enables developers serving regulated industries to build enterprise applications in 10% of the time currently required to design and develop using typical application development methodologies. Building with Revelink's Enterprise Executive results in Enterprise Applications that are robust & scalable; are based on open software standards; use common enterprise repositories; and are 21CFR11 compliant.
132.	Rockwell Automation	RSView32™	http://support.software.rockwell.com/consulting	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.
133.	SAI	Sample Guardian	www.sai.com	Software Associates International,® LLC (SAI), is a leading provider of innovative and practical information-processing solutions that meet the specific sales and marketing needs of the Life Sciences industry. SAI has demonstrated the existence of adequate procedures and controls within Sample Guardian™, which are designed to ensure the authenticity and integrity of electronic records utilized to meet requirements of the PDMA. In addition, SAI implements extensive documentation outlining their processes and procedures. It is PDMA, Inc.'s regulatory opinion that Sample Guardian complies with the requirements 21 CFR Part 11 pertaining to closed systems.
134.	SAP	cGMP Regulated Manufacturing Module	www.sap.com	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.
135.	Scientific Software, Inc.	EZ Chrom Elite	http://www.scisw.com/	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.

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136.	Shimadzu	Class VP	www.shimadzu.com	Firm claims that compliance with 21 CFR Part 11 is achieved through the integrated data management system for all common laboratory instruments. Instruments included are LC, GC, GC-MS, LC-MS, UV, FTIR, AA, and balances. CLASS-Agent version 2 provides electronic record and electronic signature with the secure database archiving required for compliance. Also provided is a network based browser for review and authorization of data packages including raw data, all processed results files, meta files and notes.
137.	Siemens	ERB	www.sea.siemens.com/chemphar/newsprod/cpelerec.html	Siemens began laying the foundation for FDA 21 CFR part 11 compliant control systems early in 1995 before the FDA made its final ruling. Based on the 1994 proposed ruling and user input from major pharmaceutical customers all the major groundwork had already been completed by August of 1997 when the FDA ruled on electronic records and electronic signatures with 21 CFR Part 11. Only minor modifications were needed to meet the final ruling. Since that time Siemens has continued to lead the competition in 21 CFR Part 11 with numerous installations in the pharmaceutical industries. Those installations include the creation of one of the first paperless pharmaceutical manufacturing facilities specifically designed to meet the requirements of 21 CFR Part 11.
138.	Silanis Technology	ApproveIT	http://www.silanis.com	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
139.	SmarTeam	SmarTeam for the FDA kit	http://www.smarteam.com/main.asp?fLang=2&fLevelOneIdSubject=151&fLevelTwoIdSubject=445&fLevelThreeIdSubject=5346&fLevelFourthIdSubject=&fId=5346&fLangName=eng&fCurrentLevel=3&fItemDocType=1&fActionMain=&fDocId=&ParentId=445&fDocIdTraining=&resolus	SmarTeam Corporation's SmarTeam for the FDA solution provides your company with a much-needed competitive advantage: instant compliance with the technical requirements of FDA Regulation Rule 21 CFR Part 11 and facilitating compliance with the procedural control requirments.
140.	Softeck, Inc.	ISOTrain	www.isotrain.com	ISOtrain is a compliance driven training management software that meets government regulations, ISO 9000 standards and comprehensive validation protocols for a total quality based training. It has been developed based on industry reactions to government inspection observations (FDA, OSHA, EPA, etc.), 483's citations, and current or future client's requirements. Yes, ISOtrain is 21 CFR Part 11 compliant!

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141.	Software House Enterprise Solutions		http://www.shes.com/web/SHESWeb.nsf/LUvwAllPages/Software+Solutions?OpenDocument&Topic=7&SubTopic=0	Software House Enterprise Solutions has years of experience building software solutions for the pharmaceutical industry. Some of our systems have been validated, and all of our work is done according to the high standards maintained in this demanding, regulated environment. Based on our own internal SOP's, our systems are built to comply with 21CFR11 (when required), with full implementation of electronic signatures.
142.	Sotax AG	WinSOTAX	http://www.sotax.com/	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.
143.	Sparta Systems, Inc.	TrackWise	www.sparta-systems.com	Sparta Systems' TrackWise is a powerful system for tracking and managing: • Problem Reports • Bugs/Defects • Change Requests • Customer Complaints • Corrective Action Items • Investigation Reports • Audit Observations/Findings TrackWise software is fully equipped with electronic signature to comply with CFR 21 Part 11.
144.	Stelex, Inc.	Compliance Builder	http://www.stelex.com	We have developed ComplianceBuilder: The Turnkey Part 11 Compliance Solution, which has been designed for FDA Regulated environments to bring their existing or legacy data collection systems into 21 CFR § 11 compliance. This turnkey solution integrates seamlessly and quickly into existing topology and is delivered with all required software, validation documents and services.
145.	Sycamore Group, The	Mobil Data Acquisition	www.thesycamoregroup.com	The Sycamore Group is helping companies comply with 21 CFR Part 11 through Mobil Data Acquisition. Mobile wireless data capture technology provides Environmental Monitoring departments the capability to improve quality and productivity issues. Mobile wireless devices provide laboratory technicians immediate and real-time access to environmental data systems while meeting regulatory compliance standards. The real-time communication eliminates redundant data entry time, reduces the need for redundant testing, ensures data integrity and ultimately increases productivity

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146.	Symfo	Sympho V3/V4	www.symfo.com	The Symfo is a portable, one-hand operable, electronic patient diary capable of recording patient data in REAL TIME. This secure data transmission will provide a better follow-up of the patient without making a contact between the patient and the investigator necessary. At the end of the trial, the patient will return the Symfo to the investigator/CRO who will download the recorded parameters onto a computer (xls, sas or any other file). The system has been developed and is produced according to the strict ISO 9001 procedures. The system is FDA Part 11 Compliant.
147.	Taratec	TeC	www.taratec.com	TeC, Taratec's e-Compliance Solution, will help ensure compliance for computer systems used in all phases of the product development cycle.
148.	Tekmar Dohrmann	TOCTalk Version 3.5 For Phoenix 8000	www.tekmar.com	TOCTalk Version 3.5 combined with the reliable, high-throughput Phoenix 8000 TOC Analyzer is the ideal solution for today's Pharmaceutical water for injection (WFI) and clean in place (CIP) applications.
149.	Tenrox	Projeca™	http://www.tenrox.com/en/industry_solutions/pharma_bio.htm	Provides compliance with government and regulatory regulations such as FDA 21 CFR Part 11
150.	ThermoGalactic	GRAMS/ AI version 7	http://www.galactic.com/products/pdfs/GRAMSAI7.pdf	Thermo Galactic's latest version of its popular spectroscopy data processing software, GRAMS/AI provides tools to help laboratories handle data in a way that is compliant with 21 CFR Part 11.
151.	Thermo LabSystems	Nautilus Atlas	http://www.labsystems.com/	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 & Drug Administration on electronic records and signatures (21 CFR Part 11) has impacted upon chromatographers. **Atlas** 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. **Nautilus** 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.
152.	Thermo Nicolet	OMNIC	http://www.thermonicolet.com/labsys/	Document at http://www.nicolet.com/labsys/pdf/21cfr1.pdf explains how OMNIC 6.0 and higher is part 11 compliant.
153.	Tiscor	Inspection Manager	http:/www.TISCOR.com	TISCOR designs software for hand-held computers for technicians performing site and equipment inspections. Technicians use small, hand-held computers to scan barcodes placed at various checkpoints requiring inspections by regulatory agencies. TISCOR solutions prove compliance and prevent the falsifying of records. Among TISCOR's many products is Inspection Manager, which effectively addresses 21CFR Part 11

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154.	Varian	ICPExpert	www.varianinc.com	Varian, Inc. understands the importance of providing software tools for its customers that facilitate their compliance with US FDA regulations. Varian's instrument control software provides its customers with a robust, reliable platform that continues to evolve to meet their changing requirements. In continuing with this commitment, it is Varian's intention to provide software for selected Optical Spectroscopy Instruments to help its customers meet the requirements of the FDA Electronic Records and Electronic Signatures Rule (21 CFR Part 11).
155.	Vector Corporation	InfoWizard	www.vectorcorporation.com	Vector Corporation provides a full range of control systems for the operation of the Fluid Bed, Hi-Coaters, Roller Compactors, High Shear mixer granulators, and the Rotary Presses. Vector's InfoWizard is now fully FDA 21 CFR Part 11 Compliant! Vector InfoWizard is a tool to allow the operator to perform various functions pertaining to the batch information. There is no need to search all over the system to get the necessary information.
156.	VelQuest Corp	ePMC	http://www.velquest.com/	VelQuest's ePMC solution acquires data electronically at its source, links the data to analytical test procedures, secures the data and provides a platform for a wide range of IT applications. Furthermore, the VelQuest ePMC solution provides a means to meet recent FDA regulations, specifically 21 CFR Part 11, governing the use of electronic records and signatures in regulated laboratories.
157.	Veriteq	VLog Software	http://www.veriteq.com/html/vrtq2800.htm	Completely tamper-proof, password-protected and secure, VL-series data loggers and vLog Software produce traceable high-accuracy documentation that meets the electronic record requirements of 21 CFR Part 11.
158.	Visual Automation	Secure Desktop 5	http://www.visualautomation.com/comprod/	21 CFR Part 11 (FDA) - Secure Desktop has several features to aid the pharmaceutical, biotechnology, food, and beverage industries. Using Secure Desktop, program and data access can be controlled, user activity can be logged to disk, and users can be automatically logged off from Windows NT 4.0 or 2000 due to inactivity.
159.	Waters Corp.	Millennium 32	www.waters.com	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.

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160.	Werum	PAS-X MES	http://www.werum.com/	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.
161.	Wimmer Systems, LLC	Data Compliance System™	http://www.wimmersystems.com/	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.
162.	Winchester Business Systems	ComPac	http://www.wbsnet.com/wbsweb.nsf?opendatabase	All of Winchester Business Systems' products and services comply with the requirements of the FDA's 21 CFR Part 11 for electronic signatures and electronic records using the ComPac software module.
163.	Wonderware	InBatch	www.wonderware.com	InBatch has been designed to meet the requirements of even the most regulated industries. InBatch is100% compliant with the United States Food and Drug Administration (FDA) final ruling on Electronic Records and Electronic Signatures referred to as 21CFR Part 11.
164.	Xcert	Sentry CA Sentry RA	http://www.xcert.com/	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.
165.	Zolera Systems	Tamarin Integrity Server	www.zolera.com	The Zolera Tamarin Integrity Server protects critical information assets and essential online business processes with digital signatures and encryption. This product uses a unique server-based software architecture that eliminates the need for client key and configuration management and enables corporate visibility and control over critical business processes. It is designed to conform to regulations and best practices associated with information integrity, such as the 21CFR11 FDA regulations
166.	Zymark	TPW II	www.zymark.com	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.