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COMPLIANCE LETTER

Ted,

Today I completed a remote audit of the Online Computing's MasterTools Administration Module v12.0 software application for compliance with Food and Drug Administration (FDA) regulation 21 CFR Part 11; Electronic Records and Signatures.

"Since 1969, Online Computing has helped small to mid-sized businesses across the U.S. utilize the MasterTools software suite to manage work flow, solve problems, and report results. They provide a complete ERP solution that includes accounting, inventory control, distribution and manufacturing. It contains 21 CFR Part 11 functionality related to security, audit trails, and electronic signatures. Online Computing offers not only a robust software solution, but a partnership that provides implementation experience, in-depth training, and responsive support, enabling clients to compete in today's environment. MasterTools users testify that dealing directly with the developers of the software, instead of a reseller or integrator, makes a real difference in their organization's go-live and ongoing experience.

MasterTools is a complete ERP solution that includes core components of accounting, inventory control, distribution and manufacturing. These can be configured to meet the unique needs of different clients. Whether their concern is lot or serial number traceability, predicting material requirements, tracking quality issues, taking physical inventory, or analyzing financial data, clients depend on MasterTools to increase efficiency and productivity. In addition to the core components, supplemental components consist of e-commerce, a rules-based product configurator, job control, Electronic Data Interchange (EDI), and credit card processing. Additional integrated solutions include portable wireless scanners, UPS Worldship, FedEx Ship Manager, USPS Shipping, time & attendance clocks, and CCH Sales Tax Database.

The MasterTools Administration module contains 21 CFR Part 11 functionality related to security, user access privileges, audit trails, and electronic signatures. Within this module users can determine password requirements, set security parameters, configure user access, and monitor user activity. Electronic signatures can be

established with multiple statements of meaning, and the number of required signatures can be determined. An audit trail can be configured which will show adds, changes, and deletions of data within a table, whether that activity is done within the software or by an SQL statement. The Administration module is at the core of determining how users operate securely within MasterTools." – (Provided by Online Computing)

Part 11 has three primary areas for compliance: infrastructure Standard Operating Procedures (SOPs), product features, and validation documentation.

SOPs: I reviewed the following infrastructure SOPs that are related to the quality system, security, information technology, software development, software validation, and software change control. All SOPs show mature processes and commitment to quality standards.

1001 v1 SOP Management and Document Identification
1002 v1 Training
1003 v1 Coding Standards for FourJs Genero BDL
1004 v1 Coding Standards for IBM Informix SPL
1005 v1 Coding Standards for Erlang
1006 v1 Coding Standards for JavaScript and HTML
1007 v1 Office Security
1008 v1 Data Backup
1009 v1 Computer Security
1010 v1 Disaster Preparation
1011 v1 Internal Audits
1012 v1 How to Host a Client Audit
1013 v1 Source Code Control
1014 v1 Software Development and Validation
1015 v1 Change Control for Software Development and Validation
1016 v1 Issue Tracking

Training records related to these SOPs were reviewed for two staff members and showed training appropriate for their job duties.

Product Features: Online Computing's MasterTools Administration Module v12.0 software application demonstrated compliance with the current 21 CFR Part 11 industry standards feature set for security, data transfer, audit trails, and electronic signatures. No deficiencies were found.

Validation: I reviewed the following validation documents for the Online Computing's MasterTools Administration Module v12.0 software application. The validation package

shows a mature software development life cycle and commitment to quality software development practices.

2001 v1 Product Requirements for MasterTools Administration Module v12.0
2002 v1 Project Plan for MasterTools Administration Module v12.0
2003 v1 Design Specifications for MasterTools Administration Module v12.0
2004 v1 Technical Specifications for MasterTools Administration Module v12.0
2005 v1 Code Review Report for MasterTools Administration Module v12.0
2006 v1 Build Notes for MasterTools Administration Module v12.0
2007 v1 Testing Protocol for MasterTools Administration Module v12.0
2008 v1 Testing Report for MasterTools Administration Module v12.0
2009 v1 Release Notes for MasterTools Administration Module v12.0

Summary: Online Computing's SOPs, product features, and validation documentation for the MasterTools Administration Module v12.0 software application meet the current industry standards required for FDA 21 CFR Part 11 compliance.

Regards,

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