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## COMPLIANCE LETTER

Andrew,

Today I completed a remote audit of the Weever Apps' Process Manager v1.0 software application for compliance with Food and Drug Administration (FDA) regulation 21 CFR Part 11; Electronic Records and Signatures, and European Union (EU) Annex 11; Computerized Systems.

"Weever Apps Inc. is a software firm located in Hamilton, ON. Weever Apps products help enterprise manufacturing clients take their production, maintenance, and safety processes digital. Customers use Weever Apps to create and fill out digital forms, record machine inspection results, and review maintenance tasks and reports.

Process Manager is Weever Apps' flagship product. Process Manager is a manufacturing 'Electronic Batch Records' software solution designed for 21 CFR Part 11 compliant manufacturing process execution, data capture, and reporting.

Production line operators use Process Manager to:

- Review and complete a sequence of production tasks;
- Capture digital form records of manufacturing line activities;
- Record electronic signatures indicating review and approval of form records.

Quality Assurance (QA) staff and supervisors use Process Manager to:

- Review overall process execution status (tasks, form records) in real-time;
- Capture digital form records of QA activities, safety tests, and "paperwork" reviews;
- Review specialized alerts indicating possible quality irregularities and/or product issues (exceptions);
- Record electronic signatures indicating review and approval of form records and product quality data." – (Provided by Weever Apps).

Part 11/Annex 11 have 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 change control, and software validation. All SOPs show mature processes and commitment to quality standards.

- 10001 v2 SOP Management and Document Identification for Weever Apps Process Manager
- 10002 v2 Training for Weever Apps Process Manager
- 10004 v2 Source Code Control for Weever Apps Process Manager
- 10005 v2 Issue Tracking for Weever Apps Process Manager
- 10007 v2 Information Security for Weever Apps Process Manager
- 10008 v2 Internal Audits for Weever Apps Process Manager
- 10009 v2 Hosting an Audit for Weever Apps Process Manager
- 10010 v2 Information Classification and Handling for Weever Apps Process Manager
- 10012 v2 Business Continuity and Disaster Recovery Plan for Weever Apps Process Manager
- 10013 v2 Data Backup for Weever Apps Process Manager
- 10021 v3 Software Development and Validation (Nine Step) for Weever Apps Process Manager
- 10022 v2 Two Step Change Control For Software Development and Validation for Weever Apps Process Manager
- 10023 v2 Coding Standards – Ruby for Weever Apps Process Manager
- 10024 v2 Coding Standards – Javascript for Weever Apps Process Manager
- 10026 v2 Data Privacy Statement for Weever Apps Process manager
- 10027 v3 Hardware and Software Installation Qualification for Weever Apps Process Manager

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

Product Features: The Weever Apps' Process Manager v1.0 software application demonstrated compliance with the current Part 11/Annex 11 industry standards feature set for security, data transfer, audit trails, and electronic signatures. No deficiencies were found.

The software deserves special recognition for not only meeting, but also exceeding and improving upon industry best practices:

- Registration security: Process Manager avoids security risks associated with a temporary password system. Users who register are provided with a "disabled" account, which must be reviewed and approved by an administrator for activation.

- Real-time alerts: When Process Manager detects that the same user account is logged-in by more than one device at a different location, an alert immediately displays on all devices in question (no refresh or manual user action is required).

Validation: I reviewed the following validation documents for the Weever Apps' Process Manager v1.0 software application. The validation package shows a mature software development life cycle and commitment to quality software development practices.

- 20001 v1 Product Requirements for Weever Apps Process Manager v1.0
- 20002 v1 Software Development and Validation Project Plan for Weever Apps Process Manager v1.0
- 20003 v1 Design Specifications for Weever Apps Process Manager v1.0
- 20004 v1 Technical Specifications for Weever Apps Process Manager v1.0
- 20005 v1 Code Review Report for Weever Apps Process Manager v1.0
- 20006 v1 Build Notes for Weever Apps Process Manager v1.0
- 20007 v1 Testing Protocol for Weever Apps Process Manager v1.0
- 20008 v1 Testing Report for Weever Apps Process Manager v1.0
- 20009 v1 Release Notes for Weever Apps Process Manager v1.0

Summary: Weever Apps' SOPs, product features, and validation documentation for the Process Manager v1.0 software application meet the current industry standards required for FDA 21 CFR Part 11/EU Annex 11 compliance.

The application is provided to clients using the Software as a Service (SaaS) hosting model that involves a third party provider. That third party hosting model was not included in this audit.

Regards,



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