August 10, 2020

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COMPLIANCE LETTER

Nicol,

Today I completed a remote audit of the Cole-Parmer's TraceableLIVE v6.1.0 software application for compliance with Food and Drug Administration (FDA) regulation 21 CFR Part 11; Electronic Records and Signatures.

"Since 1955, Cole-Parmer has been a leading global source of laboratory and industrial fluid handling products, instrumentation, equipment, and supplies. We are proven experts in the fields of temperature measurement and control, electrochemistry, and fluid handling. Our products are sold throughout the world through company-owned customer channel outlets and a strong network of international dealers.

TraceableLIVE® Cloud Service allows you to stay connected to your critical environments. Remotely monitor temperature, humidity, barometric pressure and CO_2 and receive alerts in real-time. With secure cloud data storage, access data and reports on PC or mobile devices anytime, from anywhere." – (Provided by Cole-Parmer).

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 change control, and software validation. All SOPs show mature processes and commitment to quality standards.

10001 v1 Document Management and Identification
10002 v1 Competency, Training & Awareness

10003 v1 Facilities Security
10004 v1 Control of Records
10005 v1 Internal Audits
10006 v1 Software Development and Validation
10007 v1 Source Code Control
10008 v1 C# Coding Standards
10009 v1 JavaScript Coding Standards
10010 v1 Issue Tracking
10011 v1 Network Backup
10012 v1 Network Security
10013 v1 Hardware and Software Installation Qualification
10014 v1 IT Disaster Preparation
10017 v1 How to Release to Customer Facing Environments
10018 v1 Software Inventory
10019 v1 Software Development Change Control
10020 v1 Host an Audit

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

Product Features: The Cole-Parmer TraceableLIVE v6.1.0 software application demonstrated compliance with the current Part 11 industry standards feature set for security, data transfer, and audit trails. No deficiencies were found. The application is provided as web, iOS, and Android applications.

Validation: I reviewed the following validation documents for the Cole-Parmer TraceableLIVE v6.1.0 software application. The validation package shows a mature software development life cycle and commitment to quality software development practices.

20019 v1 TraceableLIVE v6.1.0 Product Requirements
20020 v1 TraceableLIVE v6.1.0 Project Plan
20021 v1 TraceableLIVE v6.1.0 Design Specifications
20022 v1 TraceableLIVE v6.1.0 Technical Specifications
20023 v1 TraceableLIVE v6.1.0 Code Review Report
20024 v1 TraceableLIVE v6.1.0 Build Notes
20025 v1 TraceableLIVE v6.1.0 Testing Protocol
20026 v1 TraceableLIVE v6.1.0 Testing Report
20027 v1 TraceableLIVE v6.1.0 Release Notes

Summary: Cole-Parmer's SOPs, product features, and validation documentation for the TraceableLIVE v6.1.0 software application meet the current industry standards required for FDA 21 CFR Part 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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