Leading2Lean™

November 5th, 2018

To: Leading2Lean Customers and Partners,
Subject: U.S. FDA CFR 21 Part 11 Compliance

The U.S. FDA monitors the manufacture, import, transport, storage, and sale of products including:

- Food for human and animal consumption
- Pharmaceuticals consisting of ethical, generic, and over-the-counter drugs for human use as well as medicines for animals
- Biological and related products including blood, vaccines and biological therapeutics
- Medical devices
- Radiation-emitting devices such as microwaves
- Cosmetics

Compliance with FDA regulations is a market requirement. In addition, products require FDA approval before they can be marketed or sold in the United States. Noncompliance with any of the laws enforced by the FDA can be very costly in the form of recalls and legal sanctions, such as import detentions. When warranted, FDA seeks criminal penalties, including prison sentences, against manufacturers and distributors. Due to the critical nature to consumers of products controlled by FDA regulations, manufacturers of these products require both comprehensive record keeping of certain activities and a quality production system to assure consistent quality and safety of these products. Electronic record systems, while authorized as a method of maintaining the records required by each part of the FDA regulations, must also meet requirements to assure proper record retention and access is available when needed. Clarification to electronic records and electronic signatures is now contained in Part 11 of CFR 21 to provide clear guidance to medical manufacturers and to allow for innovation and modernization.

Based on the interpretation of FDA Title 21 CFR Part 11 rule of the U.S. Food and Drug Administration and the functions and features discussed within this document, Leading2Lean believes the cloudDispatch SaaS solution version currently being deployed in November 2018 as a managed service technically complies with the intent and requirements of the Part 11 rule.

For more detailed information, please read our whitepaper titled "U.S. FDA CFR 21 Part 11 Compliance Assessment, Leading2Lean cloudDispatch SaaS Solution" dated November 5th, 2018.

Sincerely,

Tyler Whitaker,
CTO/COO
Leading2Lean, LLC