

Frequently Asked Questions

LifeNet Health of Florida FDA Registration

Is LifeNet Health of Florida registered with FDA?

Yes. LifeNet Health of Florida is considered to be registered with FDA through LifeNet Health's corporate FDA registration (attached).

Why were the individual Florida facility registrations for Pensacola and Jacksonville discontinued? They were discontinued, because FDA informed us that facilities used to store recovery supplies are exempt from registering unless tissue is stored there as well. Recovered tissues are sent immediately to our registered locations for storage and processing.

What regulation describes this registration exemption?

21 C.F.R. § 1271.15(f): You are not required to register or list your HCT/P's independently, but you must comply with all other applicable requirements in this part, if you are an individual under contract, agreement, or other arrangement with a registered establishment and engaged solely in recovering cells or tissues and sending the recovered cells or tissues to the registered establishment.