Insanitary Conditions at Compounding Facilities Guidance Document
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In November 2020, the FDA released a revision of their "Insanitary Conditions at Compounding Facilities" Document. The last time this was updated was in 2016. It's intended to describe examples of insanitary conditions that FDA has observed ~~shed light on what the FDA is seeing when it inspects facilities,~~ and ~~some of~~ what FDA~~it feels is~~considers important in regards to cleanliness of facilities, and processes to reduce contamination of compounded products. As stated, these guidance documents do not establish legally enforceable responsibilities but instead describe the agency's current thinking on the topic. Unless specific regulations or statutory requirements are cited the agency believes these should be viewed as recommendations.

The FDA focuses on regulating compounding facilities that are directly registered with them (503B Outsourcing Facilities). They typically only get involved in 503A pharmacies (Class A or B Licenses for our state), when they get reports of adverse events or quality issues. It will be a rare occasion that a 503A pharmacy receives an inspection by the FDA. It will be even rarer if there isn't a precipitating event.

Some of the items mentioned in this document are ~~above and beyond~~different from what USP and the State of Utah require~~. and may not make sense for a pharmacy operation. If we were to give a recommendation, we would instruct pharmacies that engage in compounding to put all your efforts into complying with USP first, and to use the FDA's guidance documents as a stretch goal if you feel the need to go farther.~~ The state of Utah has adopted currently approved USP <795> and USP <797> into rule. Each pharmacy should ensure they are following these regulations. The inspections sheets for each of these can be found on the DOPL website for your reference. Each pharmacy will need to decide what to do with the conflicts between FDA and USP. ~~Being able to pass an inspection on USP's standards will prevent almost all the issues the FDA considers problematic.~~

~~-rephrase to make statements of fact regarding the FDA document and statement about DOPL Rule/Law. Reference the inspection sheet from DOPL to comply with Utah State Law and meet inspection requirements.~~

~~-Each site will need to decide what to do with the conflict between FDA and USP.~~