

We all knew that when we passed an AIB audit, we would easily pass an FDA audit. We also knew that if we failed an AIB audit more than once, we were quickly looking for another job! I can tell you from personal experience that our preparation for an AIB audit was intense and ongoing. It was a pleasure to work for a company like Frito-Lay that took consumer safety so seriously and with such a professional organization as AIB International. Right now, compounding pharmacies are at an inflection point on what do to be prepared for upcoming audits with so many unknown variables. The following is one recommendation on how good compounding pharmacies can tackle this dilemma.

The Best Defense Is a Good Offense

Several state boards of pharmacy are also scrambling to figure out how and who will do the audits for compound manufacturing facilities that are truly manufacturers (should be the FDA) and all other compounding pharmacies (should be the state boards of pharmacy). The complications arise when these facilities reside in one state (such as NECC in Massachusetts) and the compounding pharmacies are in another state. There is a lot of hallway chatter in the state boards of pharmacy to work with their state legislators to pass legislation authorizing the use of out-of-state companies to perform the required audits. Some states have already done this, as we noted in Chapter 1. There are several firms—both industry firms and private equity groups—participating in these conversations to perform the out-of-state audits.

There is an opportunity for an existing firm such as PCCA (with potentially a nonprofit hospital group) to initiate an audit program similar to AIB's for all compounding pharmacies. These audits could be designed around the current and still emerging guidelines from the FDA and the guidelines set forth by the state boards of pharmacy. The key success factor is to audit to the highest standards of the FDA and the state boards of pharmacy. There are also additional governing agencies that need to be included, such as the Drug Enforcement Administration (DEA), but this will be covered in Chapter 8. These audits would be done on a subscription basis, and be available to regulators if and when their auditors request the audit findings.

There is also an opportunity for compounding pharmacies to use these audits with their “for office use” customers. Two large top 10 hospital systems I spoke with said they have extensive quality control reviews