

As such, pharmacy manufacturing and pharmacy compounding companies must comply with cGMP.¹⁰

Are We There Yet?

As a dad and a new grandpa, this is a frequently heard phrase on family trips. It is a very appropriate phrase for the journey to the Drug Quality and Security Act. Pharmacy compounding manufacturers and pharmacy compounding facilities are currently at a loss on what agency will audit them and what specific audit guidelines will be used. One owner of a compounding pharmacy that has three locations (two sterile compounding facilities and one nonsterile compounding facility) commented: “We just need to know the guidelines and the rules so we can be compliant. I wish I could use the money I am spending in legal fees toward helping get the compounded drugs to patients in need.”

One Best Practice to Model

For several years I worked for Frito-Lay, which is owned by PepsiCo. When I was responsible for supply chain facilities, we utilized the services of the American Institute of Baking (AIB), or AIB International. AIB provides food safety inspections, audits, and certifications, food safety education, and research and technical services.¹¹ Frito-Lay at the time contracted for quarterly audits of all manufacturing and warehouse facilities. These audits were both scheduled and unscheduled. The AIB auditors used FDA guidelines as a basis to develop their audit templates. They were very professional, knowledgeable, and engaging in transferring knowledge on both the whats and whys behind every audit point. However, Frito-Lay executives demanded guidelines above and beyond the FDA guidelines for these audits. The AIB audits reflected these stricter guidelines.

One time we had an unannounced visit by the FDA. An auditor called one hour before arriving at one of our facilities. When he arrived, we welcomed him, brought him to the conference room, gave him a cup of coffee, and provided him with copies of our AIB audits for the past year. We proceeded to discuss with him our challenges, and brought in the people who were instrumental in maintaining a food-safe environment and addressing any findings that were identified in the AIB audits. He proceeded to do his audit, came back with “all is well,” and was on his way.