

with compounding pharmacies before contracting out for compounding medicines. They both said if there was an independent audit organization used by the compounding pharmacies with FDA- and state agency–approved standards used for their audits, their quality reviews would be cut at least in half. Having such a service and producing audit results upon demand would be a great sales and marketing capability with prospective customers.

There are a lot of items that will need to be defined, such as the go-forward process if significant audit findings are discovered, the response times to audit findings, the sharing of the information from the audits, which could infringe on improper disclosure of proprietary information, etc. However, the companies that take the initiative to institute such a program should and would be held in high esteem by the regulators—as I found out firsthand with Frito-Lay, AIB International, and the FDA. As one senior executive of a big state board of pharmacy said on June 16, “Such a program would be awesome!”

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Exclusive of cGMP but inclusive of drug quality and safety are two other groups of practices: good laboratory practices (GLP) and good clinical practices (GCP).

Good laboratory practices are defined as “regulations put in place in the 1970’s that establish standards for the conduct and reporting of nonclinical laboratory studies and are intended to assure the quality and integrity of safety data submitted to FDA.”¹⁰ These regulations form a quality system of management controls for (in our case) compounding pharmacies and their supply chain partners to ensure the uniformity, consistency, reliability, reproducibility, quality, and integrity of chemical (including pharmaceuticals) nonclinical safety tests, from physiochemical properties through acute to chronic toxicity tests.¹²

Good clinical practices are defined as international ethical and scientific quality standards for the design, conduct, monitoring, recording, auditing, analysis, and reporting of studies. These standards ensure that the data reported are credible and accurate, and that subjects’ rights and confidentiality are protected.¹³ GCP are more applicable for clinical trials, so let’s focus on GLP, as they relate to regulatory agency audits of compounding pharmacies.