

audits should be both scheduled and unscheduled, and incorporate the FDA and state board of pharmacy audit templates, current good manufacturing practices, and good laboratory practices. As mentioned before, a lot of particulars need to be defined to launch such a service, such as the need for a mobile lab to do quick tests (ScanRDI Lite?) and knowledge transfer sessions. In the foreseeable future, some firm will launch this service because the good compounding pharmacies will want to exceed the FDA and state regulatory agency guidelines while providing life-saving and life-enhancing drugs to patients. PCCA is well poised to lead the industry in providing this service.

SUMMARY

Pharmacy compounding in the supply chain world is a bridge between Titles I and II of the Drug Quality and Security Act. There are three main parts to this supply chain: from doctor prescription/patient demand to ingredients, from ingredients to compounding pharmacies, and from compounding pharmacies to patients in need of the compounded medicines.

We reviewed PCCA in depth, covering order aggregation and supplier sourcing, order placement to PCCA receipt of bulk ingredients, and compounding pharmacy order-fill processes. We reviewed the compounding pharmacies to patients part of the supply chain, and at a very high level discussed clean rooms for sterile compounding of drugs.

We also reviewed current good manufacturing practices in some depth. Additionally, we proposed for the compounding pharmacies to seek out an accredited independent audit firm (i.e., AIB International) to do self-audits at the highest standard of both FDA audits and state board of pharmacy audits. We briefly discussed good laboratory practices and good clinical practices. We ended the chapter with a review of Eagle Analytical Services and their support of compounding pharmacies. These services utilize state-of-the-art technology and range from testing samples and formulas to providing feedback techniques to pharmacists at compounding pharmacies.

It only takes one New England Compounding Center and a lack of current good manufacturing practices and good laboratory practices to produce real and present danger to patient safety. The compounding pharmacy supply chain by and large appears to have safe controls and good