

What of course counts is that the compounded medicine is sterile in the vial or container when the physician or nurse administers it to the patient.

Good Manufacturing Practices: The Foundation to Ensure a Safe and Sterile Environment

Earlier in the book I referred to current good manufacturing practices. So what exactly are good manufacturing practices? According to the FDA, good manufacturing practices are practices recommended by the FDA to authorize and control the licensing, manufacturing, and sale of pharmaceutical drugs and food products. These practices combine to provide the minimum requirements that (in our case) pharmaceutical compounding drug manufacturers and compounding pharmacies must meet to ensure that the compounded drugs do not pose a safety risk to patients and are of high quality.⁸ The FDA's good manufacturing practices are extensive in nature. There is a whole process to be GMP certified with the FDA (and it could be an entire book unto itself).

Using information from the FDA website⁸ and input received from several calls with FDA representatives, I have developed a list of foundational principles that GMP evolve around:

- Controlled environmental conditions to prevent cross-contamination of a pharmaceutical compounding drug product with other drug or proscribed material that may cause the compounded drug to be unsafe for consumption and a risk to patients. (This is an area in which the New England Compounding Center (NECC) apparently failed. It is also an area that should have been a top priority for the FDA and the Massachusetts Board of Pharmacy because many officials have cited the presence of a cardboard recycling center in close proximity to the NECC compounding facility as a potential hazard. Used cardboard has a high propensity to absorb moisture and bacteria.)
- Cleanliness. Compounding pharmacies and manufacturers must maintain a clean, sanitized manufacturing and compounding area.
- Process mapping and process modeling of the entire compound manufacturing and compounding processes. These processes must be clearly defined to employees and supply chain partners. They must also be validated vis-à-vis the compounded product specifications (as PCCA does with its suppliers). This can be a huge job to keep current!