§ 212.2 What is current good manufacturing practice for PET drugs?

Current good manufacturing practice for PET drugs is the minimum requirements for the methods to be used in, and the facilities and controls used for, the production, quality assurance, holding, or distribution of PET drugs intended for human use. Current good manufacturing practice is intended to ensure that each PET drug meets the requirements of the act as to safety and has the identity and strength, and meets the quality and purity characteristics, that it is supposed to have.

§ 212.5 To what drugs do the regulations in this part apply?

(a) Application solely to PET drugs. The regulations in this part apply only to the production, quality assurance, holding, and distribution of PET drugs. Any human drug that does not meet the definition of a PET drug must be manufactured in accordance with the current good manufacturing practice requirements in parts 210 and 211 of this chapter.

(b) Investigational and research PET drugs. For investigational PET drugs for human use produced under an investigational new drug application in accordance with part 312 of this chapter, and PET drugs produced with the approval of a Radioactive Drug Research Committee in accordance with part 361 of this chapter, the requirement under the act to follow current