



Manufacturing of Positron Emission Tomography Radiopharmaceutical Products

Section 2

Regulatory Framework for Positron Emission Tomography (PET) Drugs

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Regulation of PET Drugs

- FDA issued final rule for CGMP for PET drugs (21 CFR part 212) in the Federal Register of December 10, 2009 (74 FR 65409).
- FDA also announced the availability of a guidance entitled “PET Drugs—Current Good Manufacturing Practice (CGMP)”.



Effective Date of PET Regulations

- The 21 CFR part 212 regulation is effective December 12, 2011.
 - The regulation will become mandatory for PET drug production on this day.
- After this date, a sponsor must have submitted a new drug application (NDA) or abbreviated new drug application (ANDA) for any PET drug product marketed for clinical use in the United States.



Scope of CGMP Regulations

- After Dec 12, 2011, PET drugs marketed under an approved new drug application (NDA) or an approved abbreviated new drug application (ANDA) must be produced in accordance with the requirements in 21 CFR 212.
- Producers of investigational PET drugs (IND, Investigational New Drug) and research PET drugs (RDRC, Radioactive Drugs Research Committee) will have Option to follow the requirements in part 212 **or** to produce PET drugs in accordance with USP Chapter <823> “Radiopharmaceuticals for Positron Emission Tomography— Compounding,” (USP 32/NF 27) (2009).



Current Regulation for PET Drug Production

- Under section 501(a)(2)(C) of the Act, a compounded PET drug is adulterated unless it is produced in compliance with the USP's PET drug compounding standards and the official monograph for the particular PET drug.
- As per the Modernization Act (section 121(b)), section 501(a)(2)(C) of the Act will expire after Dec 11, 2011 and be replaced by the CGMP requirements described on the previous slide.



Current Requirements for Investigational Studies

- All human investigational / research studies must be performed:
 - Under an IND (21 CFR 312)
 - As RDRC approved study (21 CFR 361)



Regulatory Framework

Section 2, Part 1

- Current Good Manufacturing Practice (CGMP) for PET Drugs: 21CFR 212
- CMC Requirements for an Investigational New Drug Application (IND)
- Content and Format of CMC in a New Drug Application (NDA) – PET Drugs
- Considerations for PET Abbreviated New Drug Application (ANDA)



User Fees

Waiver, Reduction, Refund or Questions

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New Drug CMC Questions?

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