



Introduction of a New Proprietary PET Drug in a Changing Manufacturing Environment

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Florbetapir F 18 (^{18}F AV-45)

- In development for imaging beta-amyloid deposits in the brain – now in Phase 3
- Clinical trials supported by multiple collaborating manufacturers/manufacturing sites
- Initial challenge:
 - installation of CTM manufacture into commercial operations focused on FDG
 - new equipment/process/procedures/ documentation
- Training, training, training
- Successfully achieved – IND and USP <823>

Commercial manufacturing environment

- Changing from USP <823> to 21 CFR Part 212

New product:

- NDA submission and eventual commercial production before December 2011
- Processes/procedures/documentation consistent with regulatory compliance and efficient operations
- Planning for operations under 21 CFR Part 212