

Appendix I Quality Assurance Standards

1. Medical institutions must assign the authorized personnel to handle the following matters :
 - 1.1 Oversee production operations 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.
 - 1.2 Examine and approve or reject components, containers, closures, in-process materials, packaging materials, labeling, and finished dosage forms to ensure compliance with procedures and specifications.
 - 1.3 Approve or reject, before implementation, any initial specifications, methods, processes, or procedures, and any proposed changes which are demonstrated that does not adversely affect the identity, strength, quality, or purity of any PET drug.
 - 1.4 Review production records. If errors have occurred, or a production batch or any component of the batch fails to meet any of its specifications, personnel must determine the need for an investigation, conduct investigations when necessary, and take appropriate corrective actions.
2. Medical institutions must establish and follow written quality assurance procedures.
3. Medical institutions should prepare, review, approve and distribute all PET drug documents according to written procedures.
4. Medical institutions should conduct the quality risk management, which should be applied proactively and retrospectively through a systematic process for the assessment, control, communication and review of risks to the quality of the PET drugs.