§ 212.5

and has the identity and strength, and
meets the quality and purity charac-
teristics, that it is supposed to have.

§ 212.5 To what drugs do the regula-
tions 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 in-
vestigational new drug application in
accordance with part 312 of this chap-
ter, and PET drugs produced with the
approval of a Radioactive Drug Re-
search Committee in accordance with
part 361 of this chapter, the require-
ment under the act to follow current
good manufacturing practice is met by
complying with the regulations in this
part or by producing PET drugs in ac-
cordance with Chapter 823, “Radio-
pharmaceuticals for Positron Emission
Tomography—Compounding.” May 1,
2009, pp. 365-369, 32d ed. of the United
States Pharmacopeia (USP) National
Formulary (NF) (USP 32/NF 27) (2009).
The Director of the Federal Register
approves this incorporation by ref-
ERENCE in accordance with 5 U.S.C.
552(a) and 1 CFR part 51. You may ob-
tain a copy from the United States
Pharmacopeial Convention, Inc., 12601
Twinbrook Pkwy., Rockville, MD 20852,
Geeta M. Tirumalai, 301-816-8352, e-
mail: gt@usp.org, Internet address:
You may inspect a copy at the Food and
Drug Administration Biosciences Li-
brary, 10903 New Hampshire Ave., Sil-
ver Spring, MD, 20993-0002, 301-796-3504,
or at the National Archives and
Records Administration (NARA). For
information on the availability of this
material at NARA, call 202-741-6030, or
go to http://www.archives.gov/
federal_register/code_of_federal_regulations/
ibr_locations.html.

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Subpart B—Personnel and
Resources

§ 212.10 What personnel and resources
must I have?

You must have a sufficient number of
personnel with the necessary ed-
ucation, background, training, and ex-
perience to perform their assigned func-
tions. You must have adequate re-
sources, including facilities and equip-
ment, to enable your personnel to per-
form their functions.

Subpart C—Quality Assurance

§ 212.20 What activities must I perform
to ensure drug quality?

(a) Production operations. You must
oversee production operations to en-
sure that each PET drug meets the re-
quirements of the act as to safety and
has the identity and strength, and
meets the quality and purity charac-
teristics, that it is supposed to have.

(b) Materials. You must examine and
approve or reject components, con-
tainers, closures, in-process materials,
packaging materials, labeling, and fin-
ished dosage forms to ensure compli-
ance with procedures and specifi-
cations affecting the identity, strength,
quality, or purity of a PET drug.

(c) Specifications and processes. You
must approve or reject, before imple-
mentation, any initial specifications,
methods, processes, or procedures, and
any proposed changes to existing speci-
fications, methods, processes, or proce-
dures, to ensure that they maintain
the identity, strength, quality, and pu-
rity of a PET drug. You must dem-
onstrate that any change does not ad-
versely affect the identity, strength,
quality, or purity of any PET drug.

(d) Production records. You must re-
view production records to determine
whether errors have occurred. If errors
have occurred, or a production batch or
any component of the batch fails to
meet any of its specifications, you
must determine the need for an inves-
tigation, conduct investigations when
necessary, and take appropriate correc-
tive actions.

(e) Quality assurance. You must es-
establish and follow written quality as-
surance procedures.