East Syracuse, NY, US

The Syracuse site has 35,000L Drug Substance manufacturing, storage, and quality control capabilities. The facility is fully GMP operational with clinical and commercial capabilities.

As of today, the facility received multiple product approvals from more than 60 different global regulatory bodies including FDA, EMA, PMDA, and MFDS

INSPIRED BY SCIENCE...EMBRACING DIVERSITY...FOSTERING TALENT...CONNECTING LIVES

SmartSearch Plus+ Search Operators:

Note: *All Search Operators must be in CAPITAL LETTERS *

NEAR → finds one term next to another term, 8 words apart by default or (x) words away as in NEAR(x) contained in (a) PDF Guidance or (b) 21 CFR

e.g. 'Quality' NEAR 'supplier' – same as ('Quality' NEAR 'supplier') –

finds PDF Guidances or 21 CFRs where 'quality' is next to 'supplier' 8 words apart

AND → finds ALL terms BOTH contained in (a) PDF Guidance or (b) 21 CFRs clause

e.g. 'Quality' AND 'supplier', ('Quality' 'supplier')
finds PDF Guidances or 21 CFRs where 'quality' AND 'supplier' are both found

OR → 1 of 1 ***) 21 CFRs clause***

finds PDF Guidance or 21 CFRs clauses where 'quality' or 'supplier' is found

Wildcard '' → finds words that contain any character after leading characters speficified contained in (a) PDF Guidance or (b) 21 CFRs clauses*

Postmarket NEAR device Guidance

SmartSearch Filters

FDA Regulation (21 CFR/Guidance)

CFR (3)

FDA Agency (CBER/CDRH/CDER)

Select value

FDA Search Results Shown Below

[FDA Regulation (21 CFR/Guidance) ="CFR"]

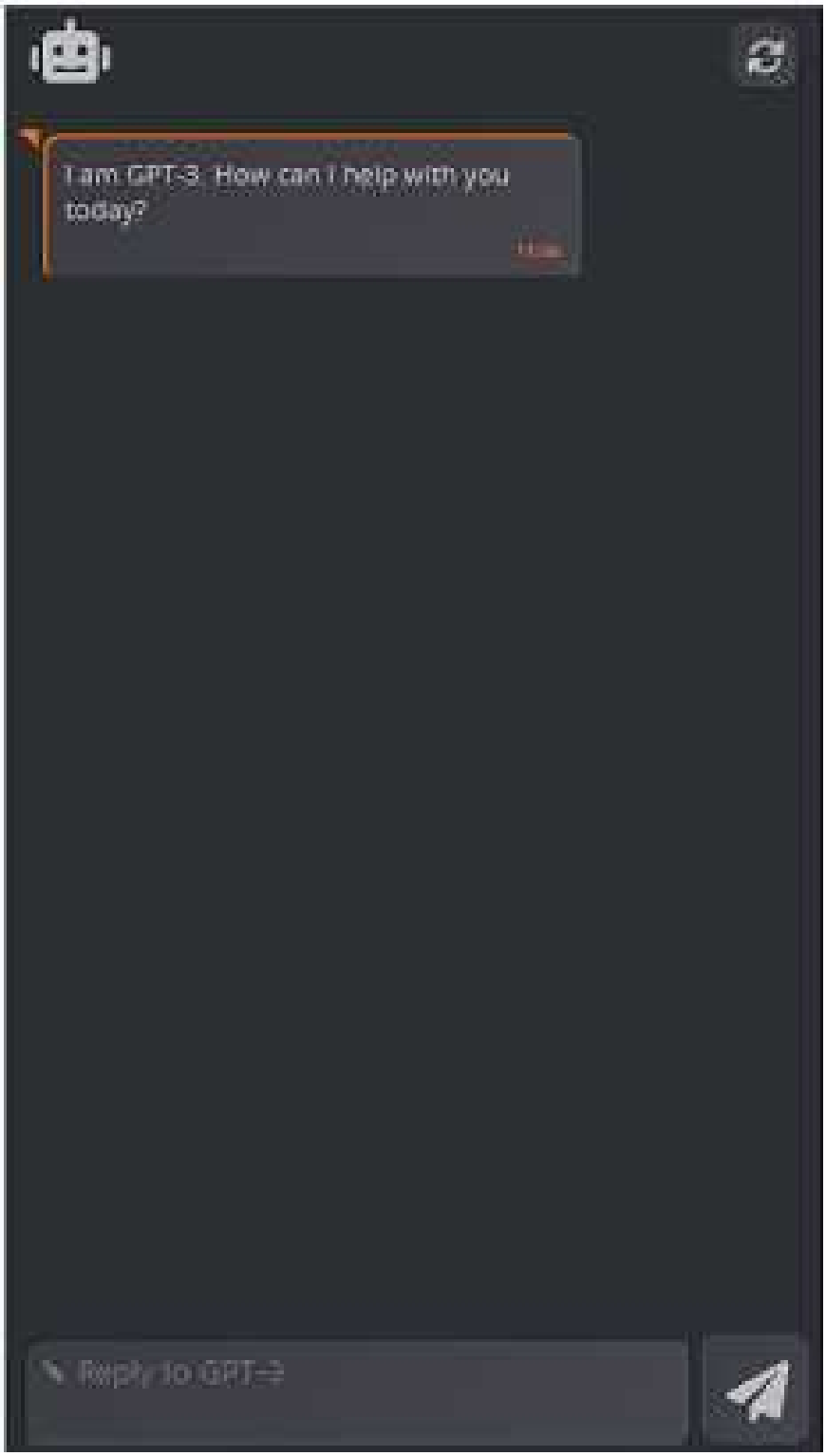
3 results for '***Postmarket NEAR device Guidance*** '

Click to Sort SmartSearch Results

Subpart C - Postmarket Surveillance Plan
How long must I conduct postmarket surveillance of my device?
Sec. 822.15

Subpart A - General Provisions
How do you define the terms used in this part?
Sec. 822.3(l)

Subpart B - Notification
How will I know if I must conduct postmarket surveillance?
Sec. 822.5



ChatGPT-3.5 Tubo Temporarily Disabled