

Biogen Specific Teaching Material

CFR – Code of Federal Regulations





Questions & Answers

CFR – Code of Federal Regulations

1. What is the Code of Federal Regulations (CFR)?

CFR – Code of Federal Regulations

1. The codification of the general and permanent rules and regulations (sometimes called administrative law) published in the Federal Register by the executive departments and agencies of the federal government of the United States.

2. What does the "c" in "cGMP" indicate?

2. That the FDA expects companies to be aware of revisions and observe current practices.

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3. What regulations do 21 CFR Parts 210 and 211 describe?

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3. The regulations for current Good Manufacturing Practices (cGMP).

4. What is another important source of federal law in the United States, in addition to the United States Code?

4. The Code of Federal Regulations.

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5. Which parts of 21 CFR are especially important to practices at Biogen?

5. Parts 210 and 211: current Good Manufacturing Practices (cGMP), Part 11: Electronic Records, Electronic Signatures.

Thank you for your attention!

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