CFR – Code of Federal Regulations

Your Objectives:

At the end of this lesson "CFR – Code of Federal Regulations" you should be able to identify and apply CFR as appropriate.

The **Code of Federal Regulations** (**CFR**) is 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.

In addition to the United States Code, the Code of Federal Regulations is another important source of federal law in the United States.

While the United States Code usually only contains laws passed by the United States Congress in the normal legislative process, the Code of Federal Regulations includes federal government regulations. These are published chronologically in the Federal Register and summarized once a year in the Code of Federal Regulations. 21 CFR and the prescriptions in ICH 7 - 11 are particularly important for food and pharmaceuticals.

The following parts of 21 CFR are especially important to practices at Biogen: Parts 210 and 211: current Good Manufacturing Practices (cGMP) Part 11: Electronic Records, Electronic Signatures. These regulations set forth the minimum standards to ensure the safety and purity of food and drug products manufactured in the US.

21 CFR Parts 210 and 211 describe the regulations for current Good Manufacturing Practices (cGMP). Because the FDA continually interprets and revises GMP based on industry practices, new technology, and other observations, the lower case "c" indicates that the FDA expects companies to be aware of revisions and observe current practices.

Subpart A--General Provisions
§ 211.1 - Scope.
§ 211.3 - Definitions.

Subpart B--Organization and Personnel
§ 211.22 - Responsibilities of quality control unit.
§ 211.25 - Personnel qualifications.
§ 211.28 - Personnel responsibilities.
§ 211.34 - Consultants.

§ 211.134 - Drug product inspection.
§ 211.137 - Expiration dating.

Subpart H--Holding and Distribution
§ 211.142 - Warehousing procedures.
§ 211.150 - Distribution procedures.

Subpart I--Laboratory Controls
§ 211.160 - General requirements.
§ 211.165 - Testing and release for distribution.
§ 211.166 - Stability testing.
§ 211.167 - Special testing requirements.
§ 211.170 - Reserve samples.
§ 211.173 - Laboratory animals.
§ 211.176 - Penicillin contamination.

Subpart J--Records and Reports
§ 211.180 - General requirements.
§ 211.182 - Equipment cleaning and use log.
§ 211.184 - Component, drug product container, closure, and labeling records.
§ 211.186 - Master production and control records.
§ 211.188 - Batch production and control records.
§ 211.192 - Production record review.
§ 211.194 - Laboratory records.
§ 211.196 - Distribution records.
§ 211.198 - Complaint files.

Subpart K--Returned and Salvaged Drug Products
§ 211.204 - Returned drug products.
§ 211.208 - Drug product salvaging.

Additional information: http://academy.gmp-compliance.org/guidemgr/files/1-1-1.PDF