Basic Laboratory Methods in a Regulated Environment

THE U.S. CODE OF FEDERAL REGULATIONS: ORGANIZATION AND ACCESS

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This document explains how the United States Code of Federal Regulations is organized and how to access it through the internet.

The **Code of Federal Regulations** (CFR) is a codification of the general and permanent rules of the Federal Government [1]. The CFR contains the complete and official text of the regulations that are enforced by federal agencies. The CFR is organized as follows:

- The CFR is divided into 50 **titles** that represent broad areas subject to Federal regulations.
- Each title is divided into **chapters** that are assigned to various agencies issuing regulations pertaining to that broad subject area.
- Each chapter is divided into **parts** covering specific regulatory areas.
- Large parts may be subdivided into **subparts**.
- Each part or subpart is then divided into **sections** -- the basic unit of the CFR.
- Sometimes sections are subdivided further into paragraphs or subsections. Citations pertaining to specific information in the CFR will usually be provided at the section level.

An example of a typical CFR citation is 21 CFR 211.67(a). To interpret this:

- The number 21 is the CFR **title** [2]. The broad subject area is Food and Drugs.[3]
- The number 211 is the **part**. Part 211 is entitled *Current Good Manufacturing Practice for Finished Pharmaceuticals*.
- The number .67 refers to a particular **section**. This section is about Equipment cleaning and maintenance.
- The (a) is the first paragraph or subsection within the section.

There are various ways to access the portions of the CFR relating to the manufacture of pharmaceuticals by using the web: [4]

The FDA web site includes a copy of 21CFR parts 210 and 211 at this address: http://www.fda.gov/cder/dmpq/cgmpregs.htm. You will also find links to other useful regulatory information at this site.

Another site that publishes come of the FDA regulations is a commercial site hosted by *The GMP Institute* http://www.gmp1st.com/index.htm. This site includes the following useful items:

- You can purchase inexpensive booklets from the GMP Institute that contain the text of the GMP

regulations.

- You can also go to their web site to link to the cGMP regulation 21 CFR Parts 210 and 211 for the drug industry.

- They also have links to the regulations for the medical device industry (21 CFR Part 820), the food industry (21 CFR Part 110) and the blood products industry (21 CFR Part 606).

- This site also has an inclusive list of guidance documents from the FDA.

- The Preamble for the current Good Manufacturing Practices as published in the September 29, 1978 issue of the Federal Register, can also be found on their web site. The Preamble is an interesting document that contains comments from the public relating to the GMP regulations and the official response to those comments.

Footnotes:

[1] This explanation of the CFR is based largely on information from the National Archives and Records Administration web site. This government web site explains what the Federal Register is and provides access to government documents (http://www.archives.gov/).

[2] Each of the titles of the CFR is assigned to a specific agency. The following link is a list of Government agencies and their relevant CFR Titles, Subchapters or Chapters.
(http://www.access.gpo.gov/nara/cfr/parallel/alphabetical_list.pdf)

[3] Title 21 contains three Chapters that relate to Food and Drugs. Often the Chapter and Subchapter are not cited, but the citation in the example here is found under Chapter 1. The agency that is responsible for compliance with Chapter 1 is The Food and Drug Administration (FDA). The other Chapters are controlled by other federal agencies. Chapter 1 has seven subchapters and 1299 Parts. Subchapter C covers regulations for General Drugs. Other Subchapters within this Chapter cover regulations for Food, Food additives, and other products regulated by FDA.

[4] Federal regulations are first published in the **Federal Register** (FR) by the executive departments and agencies of the Federal Government. The Federal Register is a legal newspaper published every business day by the National Archives and Records Administration (NARA). It contains Federal agency regulations; proposed rules and notices; and Executive orders, proclamations and other Presidential documents. The Federal Register informs citizens of their rights and obligations and provides access to a wide range of Federal benefits and opportunities for funding. The CFR is kept up-to-date by the daily Federal Register. For the most up-to-date information, these two publications must be used together to determine the latest version of any given rule. When a Federal agency publishes a regulation in the Federal Register, that regulation usually is an amendment to the existing CFR in the form of a change, an addition, or a removal.