UNIT -3

CODE OF FEDERAL REGULATIONS

❖The CODE OF FEDERAL REGULATIONS (CFR) is the codification of the general and permanent rules and regulations published in the Federal Register by the executive departments and agencies of the Federal Government of the United States.

❖The first edition of the CFR was published in 1938.Beginning in 1963 for some titles and for all titles in 1967, the Office of the Federal Register began publishing yearly revisions.

- The CFR is published by the Office of the Federal Register, an agency of the National Archives and Records administration (NARA).
- The CFR is divided into 50 titles that represent broad areas subject to federal regulations

- Each volume is updated yearly and issued on a quarterly basis.

Title 1-16	1st January
Title 17-27	1st April
Title 29-41	1st July
Title 42-50	1st October

Each title is divided into chapters, which usually bears the name of the issuing agency.
Each chapter is sub-divided into parts that covers specific regulatory areas.
Large parts may be sub-divided into sub-parts. All parts are organized in sections.

Ex.14 CFR 121.313 (Title 14, Part 121, Section 313).

The *color* of each set of volume is changed every year.

Title 21

Food and Drugs

- 21 CFR consists of 1499 parts.
- Title 21 of the CFR is reserved for rules of the Food and Drug Administration.
- Governs food and drugs within the United States for the FDA, DEA, and the ONDCP.

  Chapter I — Food and Drug Administration

  Chapter II — Drug Enforcement Administration

  Chapter III — Office of National Drug Control Policy

Chapter I — Food and Drug Administrations

- Most of the Chapter I regulations are based on the Federal Food, Drug, and Cosmetic Act.
- Notable sections:
  - 11 Electronic records and electronic signature related.
  - 50 Protection of human subjects in clinical trials.
  - 54 Financial Disclosure by Clinical Investigators.
  - 56 Institutional Review Boards that oversee clinical trials.
  - 58 Good Laboratory Practices (GLP) for nonclinical studies.

- The 100 series are regulations pertaining to food.
  - ✓101, especially 101.9 — Nutrition facts label related
  - ✓(c)(2)(ii) — Requirement to include trans fat values
  - ✓(c)(8)(iv) — Vitamin and mineral values
  - ✓106-107 requirements for infant formula
  - ✓111 *seq.* cGMPs for Dietary Supplements
  - ✓170 food additives
  - ✓190 dietary supplements

- **The 200 and 300 series are regulations pertaining to pharmaceuticals**

✓202-203 Drug advertising and marketing

✓210 et seq. cGMPs forpharmaceuticals

✓310 et seq. Requirements for newdrugs

✓328 et seq. Specific requirements for over-the-counter (OTC)drugs.

- **The 500 series are regulations for animal feeds and animal medications:**

✓510 *et seq.* New animaldrugs

✓556 Tolerances for residues of drugs in food

- **The 600 series covers biological products.**

✓601 Licensing under section 351 of the Public Health Service Act

✓606 *et seq.* cGMPs for human blood and blood products

- **The 700 series includes the limited regulations on cosmetics.**

✓ 701 Labeling requirements

- **The 800 series are for medical devices.**

✓803 Medical Device Reporting

✓814 Premarket Approval of Medical Devices

✓820*seq.* Quality system regulations (analogous to cGMP, but structured like ISO)

✓860 *et seq.* Listing of specific approved devices and how they are classified.

- **The 900 series covers mammography quality requirements.**
- **The 1000 series covers radiation-emitting device**

✓ (e.g. cell phones, lasers, x-ray generators); requirements enforced by the Center for Devices and Radiological Health.

- **The 1100 series includes**

✓ The definition of "tobacco product" to be subject to the Federal Food, Drug, and Cosmetic Act as amended by the Tobacco Control Act.

•1240 Rules promulgated under 361 of the Public Health Service Act on interstate control of communicable disease, such as:

✓ Requirements for pasteurization of milk

✓ Interstate shipment of turtles as pets.

- ✓ Interstate shipment of African rodents that may carry monkeypox.

Sanitation on interstate conveyances.

Chapter II — Drug Enforcement Administration

- Notable sections:
  - ✓ 1308 — Schedules of controlled substances
  - ✓ 1308.11 — List of Schedule I drugs
  - ✓ 1308.12 — List of Schedule II drugs
  - ✓ 1308.13 — List of Schedule III drugs
  - ✓ 1308.14 — List of Schedule IV drugs
  - ✓ 1308.15 — List of Schedule V drugs

Chapter III

✓1405 Governmentwide requirements for drug-free workplaces