IND Resource Information

United States IND regulations: 21 CFR 312:

https://www.ecfr.gov/cgi-bin/text-idx?SID=68e2fa9951d8de6da7c1ca1fc2578fb2&mc=true&node=pt21.5.312&rgn=div5

IND content and format: 21 CFR 312.23:

https://www.ecfr.gov/cgi-bin/text-idx?SID=68e2fa9951d8de6da7c1ca1fc2578fb2&mc=true&node=pt21.5.312&rgn=div5#se21.5.312_123

Definition of a drug - Section 201(g)(1) of the FD&C Act:

- A substance recognized by an official pharmacopoeia or formulary.
- A substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.
- A substance (other than food) intended to affect the structure or any function of the body.
- A substance intended for use as a component of a medicine but not a device or a component, part or accessory of a device.
- Biological products are included within this definition and are generally covered by the same laws and regulations, but differences exist regarding their manufacturing processes (chemical process versus biological process.)

and Section 351 of the Public Health Service Act (42 U.S.C. 262):

- The term "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

Definition of a device - Section 201(h) of the Federal Food Drug & Cosmetic (FD&C) Act:

- an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:
    - recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
    - intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
    - intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

Pre-IND Meetings with FDA:

Draft Guidance for Industry: Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products Guidance for Industry (March 2015)

Guidance for Industry: IND Meetings for Human Drugs and Biologics: Chemistry, Manufacturing, and Controls Information (May 2001)

Electronic submissions:

Section 745A(b) to the FD&C Act requires Sponsors to submit product information electronically:

May 5, 2017: All NDA, ANDA, and certain BLA submissions

May 5, 2018: All IND submissions

Guidance for Industry: Providing Regulatory Submissions in Electronic Format — Submissions Under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act (December 2014)

Electronic Records Management:

21 CFR Part 11:

https://www.ecfr.gov/cgi-bin/text-idx?SID=fb8111fce02ae445605c8425f39ef495&mc=true&node=pt21.1.11&rgn=div5

Guidance for Industry: Part 11, Electronic Records; Electronic Signatures – Scope and Application (August 2003)

Guidance for Industry: Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR Part 11 – Questions and Answers (July 2017)