Current Good Manufacturing Practice (CGMP) Regulations

(May 2023): Immediately in Effect Guidance for Industry: Testing of Glycerin, Propylene Glycol, Maltitol Solution, Hydrogenated Starch Hydrolysate, Sorbitol Solution, and other High-Risk Drug Components for Diethylene Glycol and Ethylene Glycol (/media/167974/download)

FDA ensures the quality of drug products by carefully monitoring drug manufacturers' compliance with its Current Good Manufacturing Practice (CGMP) regulations. The CGMP regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. The regulations make sure that a product is safe for use, and that it has the ingredients and strength it claims to have.

The approval process for new and generic drug marketing applications includes a review of the manufacturer's compliance with the CGMP. FDA assessors and investigators determine whether the firm has the necessary facilities, equipment, and ability to manufacture the drug it intends to market.

Code of Federal Regulations (CFR) (https://www.ecfr.gov/cgi-bin/ECFR?page=browse)

FDA's portion of the *CFR* is in Title 21, which interprets the *Federal Food, Drug and Cosmetic Act* (/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-cgmp-regulations)and related statutes, including the Public Health Service Act. The pharmaceutical or drug quality-related regulations appear in several parts of Title 21, including sections in parts 1-99, 200-299, 300-499, 600-799, and 800-1299.

The regulations enable a common understanding of the regulatory process by describing the requirements to be followed by drug manufacturers, applicants, and FDA.

- 21 CFR Part 314 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=314) For FDA approval to market a new drug.
- 21 CFR Part 210 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=210.1). Current Good Manufacturing Practice in Manufacturing Processing, packing, or Holding of Drugs.

BioNTech-Pfizer Exhibit 1273
BioNTech SE and Pfizer Inc. v. ModernaTX, Inc. IPR2023-01359

- 21 CFR Part 211 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=211). Current Good Manufacturing Practice for Finished Pharmaceuticals.
- 21 CFR Part 212 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=212). Current Good Manufacturing Practice for Positron Emission Tomography Drugs.
- 21 CFR Part 600 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=600). Biological Products: General.

The following pages provide more information with respect to regulations for particular product types and manufacturing considerations:

- Field Alert Reports (for NDAs and ANDAs) (/drugs/surveillance/field-alert-reports)
- Biological Product Deviation Reports (for BLAs) (/about-fda/about-center-drug-evaluation-and-research/cder-biological-product-deviations)

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