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# 50+ FDA ACRONYMS THAT MATTER TO YOUR BUSINESS

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Must-know terminology for  
FDA-regulated environments.

# Deciphering the Language Your Business Needs to Succeed

As a global leader  
in environmental and  
industrial measurement,  
Vaisala understands  
that knowledge truly  
is power.

If you work in the pharmaceutical, biotech or medical device industries, you know the importance of complying with U.S. Food and Drug Administration regulations. Whether you lead research and development of new therapies, manage a manufacturing facility, or oversee storage and distribution of regulated drugs and devices, understanding the FDA's Title 21 regulations is your best assurance of compliance. Moreover, it's your employer's best safeguard against any enforcement actions that could result from a Title 21 violation.

But recognizing the critical importance of FDA regulations, and understanding those regulations fully, are not the same. In fact, the deeper you delve into FDA Title 21, the more likely you are to become confused and frustrated, especially by the abbreviations and acronyms that are so much a part of regulatory language.

That's why we developed this guide, *50+ FDA Acronyms that Matter to Your Business*. You'll find definitions, helpful insights, and links to additional resources for more than 50 acronyms that are fundamental to achieving Good Manufacturing Practices and FDA compliance within the life sciences industry. We encourage you to keep the guide handy and share it with colleagues. Ideally, it will make the process of achieving FDA compliance easier and more efficient for you and your organization.

From 75 years of experience as a global leader in environmental and industrial measurement, Vaisala understands that knowledge truly is power. Welcome to your guide to understanding the FDA acronyms that matter most to your business.

## **Important Note**

The purpose of this document is to provide readers a basic explanation of commonly used industry and FDA regulatory jargon as it relates to good manufacturing practices. The acronym and initialism descriptions are not legal definitions, and the list is not all-inclusive. For complete official or legal definitions, please consult with an attorney or regulatory affairs professional specializing in FDA laws and regulations.

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### Drug applications

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- CMC** chemistry, manufacturing, and controls
- DMF** drug master file
- IND** Investigational New Drug application
- NCE** new chemical entity
- NDA** New Drug Application
- NME** new molecular entity
- RM** raw material

### FDA centers and offices

- CBER** Center for Biologics Evaluation and Research
- CDER** Center for Drug Evaluation and Research
- CDRH** Center for Devices and Radiological Health
- CFSAN** Center for Food Safety and Applied Nutrition
- CVM** Center for Veterinary Medicine
- DO** District Office
- FDA** Food and Drug Administration
- HHS** U.S. Department of Health and Human Services
- IB** Inspections Branch
- NIH** National Institutes of Health
- OCC** Office of Chief Counsel
- OGC** Office of General Counsel
- OI** Office of Investigations
- OIG** Office of Inspector General
- ORA** Office of Regulatory Affairs

### Laws, regulations, guidance documents, compendia

- CFR** Code of Federal Regulations
- CGMP** Current Good Manufacturing Practice
- CGTP** Current Good Tissue Practice
- CPGM** Compliance Program Guidance Manual
- FDCA** Food, Drug, and Cosmetic Act

- FD&C Act** Food, Drug, and Cosmetic Act
- FOI** freedom of information
- FOIA** Freedom of Information Act
- FR** Federal Register
- GLP** Good Laboratory Practice
- GMP** Good Manufacturing Practice
- GTP** Good Tissue Practice
- ICH** International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
- IOM** Inspections Operations Manual
- ISO** International Organization for Standardization
- QSR** Quality System Regulation
- USP-NF** United States Pharmacopeia – National Formulary

### Quality related

- ALCOA** Attributable, Legible, Contemporaneous, Original, Accurate
- CAPA** corrective and preventive action
- DQ** design qualification
- IQ** installation qualification
- OOS** out of specification
- OQ** operational qualification
- PQ** performance qualification
- PV** process validation
- QA** quality assurance
- QC** quality control
- QS** quality system
- QU** quality unit
- SOP** standard operation procedure
- VMP** validation master plan

### Contract organizations

- CMO** Contract Manufacturing Organization
- CRO** Contract Research Organization

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# INSPECTION FORMS AND RELATED ITEMS

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# 482

(Form FDA 482)  
Notice of Inspection form

## DEFINITION

Section 704(a)(1) of the FD&C Act authorizes the FDA to enter and inspect any factory, warehouse, or establishment in which food, drugs, devices, tobacco products, or cosmetics are manufactured, processed, packed, or held for introduction into interstate commerce.

## IMPLICATIONS

Section 704(a)(1) of the FD&C Act gives the FDA broad inspection duties. Prior to inspection, the FDA must present appropriate credentials and written notice (that's the Form FDA 482). Inspection must occur at reasonable times, within reasonable limits, and within

a reasonable manner, as determined by the FDA. The act also permits the FDA to enter any vehicle used to transport or hold food, drugs, devices, tobacco products, or cosmetics. Placing such products in the trunk of your personal vehicle is not off limits to the FDA.

## RESOURCES

Inspection Reference, Guides & Field Activities

Investigations Operations Manual – Chapter 5: Establishment Inspections

SEC. 704. [21 USC §374] Factory Inspection

# 483

(Form FDA 483)  
Inspectional Observations form

## DEFINITION

The FDA will issue a Form 483 when their investigators observe any significant objectionable conditions during an inspection. The conditions are cited when, in an investigator's judgment, the observed conditions or practices indicate that an FDA-regulated product has violated the federal Food, Drug, and Cosmetic (FD&C) Act or other FDA regulations.

## IMPLICATIONS

Form 483 alone doesn't constitute a final FDA determination of whether any condition violates the FD&C Act or any relevant regulations. The Establishment Inspection Report (EIR), also prepared by the FDA investigator, includes further inspectional evidence. The FDA will consider the overall situation presented in the 483 and EIR to determine what further action, if any, is appropriate.

When a company doesn't follow a guidance document (a nonbinding outline of the FDA's current thinking on a topic) inspectors cannot cite that omission as an observation.

Some say that the FDA follows an unwritten policy that they must issue a 483 at each inspection. That's false. And receiving a 483 isn't necessarily a bad thing. Identifying violations, correcting them, and learning how to avoid them often make a company better.

## RESOURCES

Form FDA 483: Frequently Asked Questions

# 484

(Form FDA 484)  
Receipt of Samples form

## DEFINITION

Receipt for samples taken during FDA inspection.

## IMPLICATIONS

If an FDA inspector removes any samples during inspection, he or she must provide the manufacturer with a receipt describing them. The manufacturer should also retain an

identical sample to analyze. If all goes well, the results obtained by the FDA will be the same as those obtained by the manufacturer.

## RESOURCES

SEC. 704. [21 USC §374] Factory Inspection

# EIR

Establishment Inspection Report

## DEFINITION

A written narrative report that accurately describes the FDA investigator's inspection findings.

## IMPLICATIONS

This detailed report is available by request through the FOI (Freedom of Information) office at the FDA. The district office (DO) should provide the investigated establishment with a copy. If you do not

receive yours, ask for one. Since it's public information, anyone can request a copy of an EIR through FOI. Confidential and proprietary information are redacted.

## RESOURCES

Establishment Inspections



# NAI

No Action Indicated

## DEFINITION

No objectionable conditions or practices were found during FDA inspection (or, the level of significance of the documented objectionable conditions does not justify further FDA action).

## IMPLICATIONS

An NAI entry on a report is good news for the manufacturer, indicating the inspector didn't document any objections to company practices.

## RESOURCES

Establishment Inspection Report

# OAI

Official Action Indicated

## DEFINITION

An OAI classification occurs when an investigation reveals significant objectionable conditions or practices warranting regulatory action [for example, a warning letter (WL)] to address the manufacturer's lack of compliance with statutes or regulations.

## IMPLICATIONS

Typically, an inspector makes an OAI classification only if a form FDA 483 has been previously issued and the documented evidence supports further action. Next, an inspector issues an Establishment Inspection Report (EIR) to document one or more

out-of-compliance systems that should be classified OAI. From there, District Offices (DO) may issue warning letters to notify firms of violations, to solicit voluntary corrections, and to provide for the initial phase of formal agency regulatory actions.

## RESOURCES

Establishment Inspection Report

# UL

untitled letter

## DEFINITION

An untitled letter is an initial correspondence from the FDA to a regulated industry that cites violations that do not yet meet the threshold of regulatory significance of a warning letter. An untitled letter does not include the warning letter's mandate to promptly correct a violation that could result in enforcement action.

## IMPLICATIONS

The FDA is under no legal obligation to warn individuals or firms about violations before moving to enforce the regulation. However, after an inspection, the FDA may provide an individual or firm an opportunity to take voluntary and prompt corrective action before

it initiates enforcement. If you were inspected and it didn't go well, receiving an untitled letter or a warning letter shouldn't be a surprise. And you should take corrective action accordingly.

## RESOURCES

Warning and Untitled Letters – Background

# VAI

Voluntary Action Indicated

## DEFINITION

Objectionable conditions were found and documented at the inspection, but neither the FDA center nor District Office is prepared to take or recommend any regulatory (advisory, administrative, or judicial) actions, such as a warning letter, since the objectionable conditions do not meet the threshold for regulatory action.

## IMPLICATIONS

If the “Inspection Conclusion” indicates VAI, this is not as good as no action indicated (NAI), but not as bad as official action indicated (OAI).

## RESOURCES

Establishment Inspection Report

# W L

warning letter

The FDA generally is under no legal obligation to warn individuals or firms about violations before taking enforcement action.

## DEFINITION

An FDA notification that a manufacturer has significantly violated a federal regulation.

The warning letter identifies the violation, such as poor manufacturing practices, false claims of product performance, or incorrect directions for use. The letter also makes clear that the company must correct the problem and provides directions and a timeframe for the company to inform the FDA of its plans for correction. The FDA then checks to ensure that the company's solutions are adequate.

## IMPLICATIONS

The FDA may give individuals and firms a chance to take voluntary and prompt action to correct an FD&C Act violation before they initiate an enforcement action. This opportunity to comply with the law comes in the form of a warning letter or an untitled letter.

Warning letters apply to violations that may lead to enforcement action if not promptly and adequately corrected. Untitled letters do not include the enforcement warning because

they apply to violations that don't meet the threshold of regulatory significance.

The FDA generally is under no legal obligation to warn individuals or firms about violations before taking enforcement action. If your FDA inspection didn't go well, receiving an untitled or warning letter is likely.

There is no need to make a freedom of information (FOI) request to access regulatory letters. The FDA makes them public on its Web site, [fda.gov](http://fda.gov).

## RESOURCES

Warning and Untitled Letters – Background

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# DEVICE APPLICATIONS

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# 510(k)

premarket notification

## DEFINITION

Any company wanting to market a Class I, II, or III device intended for human use, and not requiring a Premarket Approval (PMA), must submit a 510(k) to the FDA unless the device is exempt from 510(k) requirements of the Food, Drug, and Cosmetic Act. The term “510(k)” comes from the section of the FD&C Act that addresses premarket notification (PMN) requirements. Though PMN is the FDA’s official term for the 510(k), the latter use prevails in regulatory matters.

## IMPLICATIONS

Before marketing a device, each submitter must receive a letter from the FDA indicating the device’s substantial equivalence (SE) to a predicate device and stating that the new device can be marketed in the United States. This letter “clears” the device for commercial distribution.

A claim of substantial equivalence does not mean the new and predicate devices must be identical. The FDA determines substantial equivalence by examining a product’s intended use, design, energy used or delivered, materials,

chemical composition, manufacturing process, performance, safety, effectiveness, labeling, biocompatibility, standards, and other characteristics, as applicable.

Note that if the device goes through the PMA process it is “approved” by the FDA for marketing. To some, “cleared” and “approved” may be a technicality, but the differences are significant, since the 510(k) standard for safety and effectiveness depends on SE, while the PMA standard requires an independent demonstration of safety and effectiveness.

## RESOURCES

[21 CFR 807 Subpart E](#)

[Premarket Notification \[510\(k\)\]](#)

[Overview of 510\(k\) Clearances](#)

[510\(k\) Premarket Notification Database](#)

# IDE

## Investigational Device Exemption

### DEFINITION

An IDE allows an investigational device to be used in a clinical study to collect safety and effectiveness data required to support a PMA or a 510(k) submission to the FDA. Clinical studies with devices of significant risk must be approved by the FDA and by an Institutional Review Board (IRB) before the study can begin. Studies with devices of nonsignificant risk require only the IRB's approval before the study can begin. An IDE, similar to the Investigational New Drug (IND) application, allows for an unapproved (uncleared) medical device to be shipped for interstate commerce.

### IMPLICATIONS

The criteria for determining whether an IDE is needed are quite different from determining whether an IND is required. For an IDE, the device's risk level — exempt, significant risk, or nonsignificant risk — is taken into consideration. For an IND, the investigation cannot involve any factor significantly increasing the risks (or decreasing the risk

acceptability) associated with the use of the drug product.

However, the IND and IDE application both contain, among other similarities, a description of the methods, facilities, and controls used for the manufacture, processing, packing, storage, and installation of the device.

### RESOURCES

21 CFR 812



# PMA

## Premarket Approval

The PMA application is the most stringent type of device marketing application required by the FDA.

### DEFINITION

PMA is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of causing illness or injury. The PMA application is the most stringent type of device marketing application required by the FDA. The applicant must receive FDA approval of its PMA application prior to marketing the device.

### IMPLICATIONS

A PMA application is often compared to a New Drug Application (NDA). The similarities are in the amount and level of data required of them to demonstrate safety and efficacy to the FDA,

and both applications must be approved by the FDA before marketing of the products can begin.

### RESOURCES

21 CFR 814

Premarket Approval (PMA)

PMA Approvals

Premarket Approval (PMA) Database

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# DRUG APPLICATIONS

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# NDA

(Form FDA 356h)  
New Drug Application

## DEFINITION

The NDA application is the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing in the United States. Since 1938, every new drug has been the subject of an NDA before approval for shipment in interstate commerce.

The chemistry, manufacturing, and controls section of the NDA describe the composition, manufacture, and specification of the proposed drug substance and product. Data gathered during animal studies and human clinical trials of an IND become part of the NDA.

One of the goals of the NDA is to provide enough information to permit the FDA to determine whether the methods used in manufacturing the drug and the controls used to maintain the drug's quality are adequate to preserve the drug's identity, strength, quality, and purity.

## IMPLICATIONS

Each NDA can contain tens of thousands of pages of data, information, and documents. Before electronic data storage and transmission became the norm, NDAs were submitted — in triplicate — on paper. The volume and logistics of storage and retrieval became so unwieldy that the FDA now requires electronic submission of all NDAs. The law also requires payment of a user fee with each NDA submission. In FY 2012, an

original NDA including clinical data requires a user fee of \$1,841,500.

Did you know that signing a Form FDA 356h is signing a contract with the federal government? In bold type on the bottom of the second page of the form it states, "WARNING: A willfully false statement is a criminal offense. U.S.C. Title 18, Sec. 1001."

## RESOURCES

21 CFR 314

New Drug Application Introduction

# ANDA

Abbreviated New Drug Application

## DEFINITION

An ANDA is an application used specifically to obtain marketing approval for generic drugs. Its genesis is the Waxman-Hatch Amendments (Drug Price Competition and Patent Term Restoration Act of 1984).

## IMPLICATIONS

A generic drug is identical, or bioequivalent, to a brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use. The active ingredients in generic drugs are chemically identical to their branded

counterparts and must meet Current Good Manufacturing Practices (CGMP) in their manufacturing, processing, handling, packaging, and controls, as with all drug products. If CGMP is not followed, these drugs are, by definition, adulterated.

## RESOURCES

[Summary of Drug Price Competition and Patent Term Restoration Act of 1984](#)

[Waxman-Hatch Amendments](#)

[What Are Generic Drugs?](#)

# API

active pharmaceutical ingredient

Some patients claim that generic products either don't work or make them ill. Typically, it's the inactive ingredients that cause such problems, not the API.

## DEFINITION

Any substance or mixture of substances used in manufacturing that becomes an active ingredient in the drug product. APIs furnish pharmacological action or other direct effects in the diagnosis, cure, mitigation, treatment, or prevention of disease, or affect the structure and function of the body.

## IMPLICATIONS

Today, many drug products (prescription and over-the-counter) are available as generics, helping to keep down the cost of medication. The API in a generic drug product is exactly the same API in its brand version, but the excipients (inactive ingredients) may differ.

Some patients claim that generic products either don't work or make them ill. Typically, it's the inactive ingredients that cause such problems, not the API. So it's possible for consumers not find treatment success with another manufacturer's generic version.

## RESOURCES

CPGM 7356.002F Active Pharmaceutical Ingredients: Process Inspection

Guidance for Industry: Manufacturing, Processing, or Holding Active Pharmaceutical Ingredients

Guidance for Industry: Q7A Good Manufacturing Practice for Active Pharmaceutical Ingredients

# BLA

biologics license application

## DEFINITION

The BLA is a request for permission to put a biologic product into interstate commerce. As with any other drug, a biological product's clinical trials are conducted under an Investigational New Drug application (IND), and the Form FDA 356h is used to seek marketing approval. The Center for Biologics Evaluation and Research (CBER) regulates these products.

## IMPLICATIONS

Good Manufacturing Practices apply to biological products as well. If CGMP is not followed in the manufacturing, processing, handling, packaging, and controls for biological products, they are by definition adulterated, and the BLA will be denied.

## RESOURCES

21 CFR 600

BLA Process

# CMC

chemistry, manufacturing, and controls

## DEFINITION

The section of an Investigational New Drug application (IND) describing the composition, manufacture, and control of the drug substance and product, including placebo, labeling, and environmental analysis. The FDA requires that the CMC contain sufficient information to ensure the proper identification, quality, purity, and strength of the investigational drug. The amount of information needed to make that assurance will vary with the phase of the investigation, the proposed duration of the investigation, the dosage form, and the amount of information otherwise available.

## IMPLICATIONS

The CMC proscribes the acceptable limits and analytical methods you must apply to ensure the identity, strength, quality, and purity of the drug substance. And while the CMC does not as clearly define drug stability, it does require information sufficient to support drug substance and drug product stability during

toxicological studies and planned clinical studies.

Note that the words “identity, strength, quality, and purity” also appear in Good Manufacturing Practice (GMP) regulations as well as the Food, Drug, and Cosmetic (FD&C) Act.

## RESOURCES

21 CFR 312.23(a)(7)

21 CFR 314.50(d)(1)

Guidance for Industry: INDs for Phase 2 and Phase 3 Studies. CMC Information

# DMF

drug master file

When a DMF is submitted to the FDA, it's not reviewed until it's referenced in support of an application.

## DEFINITION

A DMF is a submission to the FDA that the holder may use to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs. The submission of a DMF is not required by law or FDA regulation. A DMF is submitted solely at the discretion of the holder. The information contained in the DMF can also support other applications (such as an IND, an NDA, or an ANDA), or another DMF.

## IMPLICATIONS

What makes the DMF so useful is that only the DMF holder and the FDA see its contents. This means, for example, that a contract manufacturer does not have to divulge its confidential or proprietary processes, equipment, and tests to its customers. This information goes directly to the FDA in support of the manufacturer's application.

Of note: When a DMF is submitted to the FDA, it's not reviewed until it's referenced in support of an application. At that point the FDA reviews it and provides comments to the DMF holder. If deficiencies require attention, the DMF holder must satisfactorily address them before the FDA will regard it in support of an application. The DMF holder does not have to share these deficiencies, corrections, or timelines for

correction to the application sponsor. This process can delay, for example, the review and approval of a marketing application submitted by an NDA sponsor.

There are five types of DMFs:

*Type I:* Manufacturing Site, Facilities, Operating Procedures, and Personnel

*Type II:* Drug Substance, Drug Substance Intermediate, and Material Used in Their Preparation, or Drug Product

*Type III:* Packaging Material

*Type IV:* Excipient, Colorant, Flavor, Essence, or Material Used in Their Preparation

*Type V:* FDA Accepted Reference Information

## RESOURCES

Guideline for Drug Master Files



# IND

Investigational New Drug application

Did you know that signing a Form FDA 1571 is signing a contract with the federal government?

## DEFINITION

Current federal law requires drug sponsors to obtain New Drug Application (NDA) approvals before they transport or distribute a drug across state lines. Because the sponsoring company, academic organization, or individual will probably want to ship the investigational drug to clinical investigators in many states, it must seek an exemption from that legal requirement. The Investigational New Drug application (IND) is the means through which the sponsor technically obtains this exemption from the FDA.

## IMPLICATIONS

The IND application process was first implemented in 1962 as part of the Kefauver-Harris Amendments to the Food, Drug and Cosmetic (FD&C) Act. Partly in response to public concern over Thalidomide birth defects, the amendments included new requirements to prove drug effectiveness and safety, control clinical trials, and tighten quality assurance during drug manufacturing (*Food and Drug Review* 46, no. 11).

An IND application must contain information in three broad areas: pre-clinical studies (animal pharmacology and toxicology), manufacturing information, and clinical study protocol.

Did you know that signing a Form FDA 1571 is signing a contract with the federal government? In bold type on the bottom of the second page of the form it states: "WARNING: A willfully false statement is a criminal offense. U.S.C. Title 18, Sec. 1001."

## RESOURCES

21 CFR 312

Investigational New Drug (IND) Application

IND Overview

# NCE

new chemical entity

## DEFINITION

An NCE is a drug that contains no active moiety already approved by the FDA. An active moiety is the molecule or ion (excluding those appended portions of the molecule that cause the drug to be an ester, salt, or other noncovalent derivative of the molecule) responsible for the physiological or pharmacological action of the drug substance. See also NME.

## IMPLICATIONS

Marketing exclusivity is available for NCEs, which by definition are innovative. The FDA grants a five-year period of marketing exclusivity to NDAs for products containing chemical entities never previously approved by FDA either alone or in combination. The term “new chemical entity” appears in the

FDA’s Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) as one of the patent and exclusivity terms. In the same reference, the terms “active ingredient” and “active moiety” are synonymous.

## RESOURCES

21 CFR 314.108

Orange Book

# NME

new molecular entity

## DEFINITION

A NME is an active ingredient never before marketed in the United States in any form. See also NCE.

## IMPLICATIONS

The FDA has indicated that the current term “new chemical entity” was based on the “new molecular entity” designation in the FDA’s internal classification system in operation at the time of the Hatch-Waxman amendments to the FD&C Act. Neither the term “new chemical

entity” nor the term “active moiety” actually appear in the FDCA statute. However, “new chemical entity” appears in 21 CFR 314.108. Drug manufacturers may still encounter the NME acronym in FDA publications, but it’s synonymous with the current “NCE.”

## RESOURCES

Drugs@FDA Glossary

# RM

raw material

An RM can be either an active or inactive ingredient.

## DEFINITION

“Raw material” means any ingredient intended for use in the manufacture of a drug substance or drug product, including those that may not appear in that product. An RM can be either an active or inactive ingredient.

## IMPLICATIONS

The active ingredient(s) and the inactive ingredients (i.e., raw materials) make up a finished drug product. (People sometimes confuse the terms “drug substance” and “drug product.” The drug *substance* is the active ingredient. The drug *product* is the finished dosage form. For example, acetaminophen is the drug substance in Tylenol Tablets. But Tylenol Tablets are the drug product.)

An active ingredient is any component of a drug product intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of humans or other animals. Active ingredients include some components that may undergo

chemical change during manufacturing and be present in the drug product in a modified form intended to furnish the specified activity or effect.

An inactive ingredient (excipient) is any component of a drug product other than the active ingredient. Excipients include the components that keep the tablet together; help it dissolve in the stomach; add flavor, color, coating, or bulk to a tablet; lubricate the tablet press; or aid in mixing and blending. Inactive ingredients can be just as important as the active ingredients, since the wrong excipient can impair delivery of the active ingredients to the patient.

## RESOURCES

21 CFR 210.3

Inactive Ingredient Database

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# FDA CENTERS AND OFFICES

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# FDA

Food and Drug Administration

## DEFINITION

The FDA's origin goes back to 1848. It was 1930 when the agency was renamed The Food and Drug Administration. The modern regulatory functions of the FDA began in 1906 with the passage of the Pure Food and Drug Act. Its jurisdiction encompasses most food products (other than meat and poultry); human and animal drugs; therapeutic agents of biological origin; medical devices; radiation-emitting products for consumer, medical, and occupational use; cosmetics; and animal feed.

## IMPLICATIONS

The FDA enforces the Food, Drug, and Cosmetic (FD&C) Act. If you manufacture, market, or transport any product under FDA authority, it has jurisdiction to regulate those activities. In addition to conducting its own reviews, approvals, and monitoring, the FDA also follows media reports, receives information from individuals and companies, and conducts inspections that

can uncover FD&C Act violations. Violators can be penalized with fines, incarceration, disqualification, debarment, negative press, and other consequences. Companies report competitors to the FDA; employees report on their own companies. However, the FDA should not be viewed as "big brother." It's protecting and promoting public health as best it can with limited resources.

## RESOURCES

[FDA Home Page](#)

[History of FDA](#)

## FDA CENTERS AND OFFICES

**CBER** Center for Biologics Evaluation and Research. CBER is the Center within the FDA that regulates biological products for human use under applicable federal laws, including the Public Health Service Act and the Federal Food, Drug and Cosmetic Act. CBER protects and advances the public health by ensuring that biological products are safe and effective and available to those who need them. CBER also provides the public with information to promote the safe and appropriate use of biological products.

**CDER** Center for Drug Evaluation and Research. CDER performs an essential public health task by making sure that safe and effective drugs are available to improve the health of people in the United States. As part of the FDA, CDER regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. This work covers more than just medicines. For example, fluoride toothpaste, antiperspirants, dandruff shampoos, and sunscreens are all considered “drugs.”

**CDRH** Center for Devices and Radiological Health. CDRH regulates firms that manufacture, repackage, relabel, and import medical devices sold in the United States. In addition, CDRH regulates radiation-emitting electronic products (medical and nonmedical) such as lasers, x-ray systems, ultrasound equipment, microwave ovens, and color televisions.

**CFSAN** Center for Food Safety and Applied Nutrition. CFSAN promotes and protects the public’s health by ensuring that the nation’s food supply is safe, sanitary, wholesome, and honestly labeled, and that cosmetic products are safe and properly labeled.

**CVM** Center for Veterinary Medicine. CVM regulates the manufacture and distribution of drugs, devices, and food additives given to, or used on, pet animals, poultry, cattle, swine, and minor animal species.

**DO** District Office. The DO is considered the basic field operating unit of the FDA. It covers investigative, compliance, analytical, and administrative functions, as well as responsibilities in consumer affairs and state contract management.

**FDA** Food and Drug Administration. An agency within the Department of Health and Human Services. The FDA protects and promotes public health through the regulation and supervision of food safety, tobacco products, dietary

supplements, prescription and over-the-counter pharmaceutical drugs, vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices, veterinary products, and cosmetics.

**HHS** Health and Human Services. HHS is the cabinet-level department under which the FDA is a part.

**IB** Inspections Branch. The IB is the part of the DO responsible for conducting field inspections.

**NIH** National Institutes of Health. The NIH is the nation’s medical research agency supporting scientific studies that turn discovery into health. Its mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce the burdens of illness and disability.

**OCC** Office of Chief Counsel. The OCC is the Food and Drug Division of the HHS Office of General Counsel. Its litigators handle both civil and criminal enforcement cases, and defend challenges to provisions of the FDCA, the implementing regulations, and FDA policies, initiatives, and decisions.

**OGC** Office of General Counsel.

**OI** Office of Investigations. The Office of Investigations (OI) is responsible for conducting and coordinating investigative activities related to fraud, waste, abuse, and mismanagement in HHS programs and its operations, including wrongdoing by applicants, grantees, and contractors, or by HHS employees in the performance of their official duties. The OI reports to the attorney general when OIG has reasonable grounds to believe federal criminal law has been violated.

**OIG** Office of Inspector General

**ORA** Office of Regulatory Affairs. The ORA is the lead office for all FDA field activities. It also leads import, inspection, and enforcement policy. ORA supports the five FDA Product Centers by inspecting regulated products and manufacturers, conducting sample analysis on regulated products, and reviewing imported products offered for entry into the United States. ORA also develops FDA-wide policy on compliance and enforcement and executes the FDA’s import strategy and food protection plans.

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# REGULATIONS, GUIDANCE DOCUMENTS, LAWS, COMPENDIA

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# CFR

Code of Federal Regulations

## DEFINITION

The CFR is the codification of the general and permanent rules published in the Federal Register by the executive departments and agencies of the federal government. It is divided into 50 titles that represent broad areas subject to federal regulation. Title 21 of the CFR is reserved for rules of the Food and Drug Administration.

## IMPLICATIONS

CFR regulations are interpretations of the statutory law and are legally binding. Turn to the CFR to read the Current Good Manufacturing Practice (CGMP) regulations to understand how to conform to them. Further, the FDA publishes guidance documents that

contain its current thinking on a particular topic. These documents are not legally binding for you or the FDA. You still must comply with CFR Title 21.

## RESOURCES

[About the CFR](#)

[CFR – Title 21 – Food and Drugs](#)

[Search CFR Title 21 Database](#)

# GMP or CGMP

Good Manufacturing Practice or Current Good  
Manufacturing Practice

## DESCRIPTION

Current Good Manufacturing Practice for finished pharmaceuticals (21 CFR 312.211) ensures that drugs meet the Food, Drug, and Cosmetic (FD&C) Act requirements for safety, and meet the identity, strength, quality and purity characteristics that they purport or are represented to possess.

## IMPLICATIONS

The FD&C Act deems a drug adulterated unless the methods used in its manufacture, processing, packing, and holding, and the facilities and controls used in those processes, conform to current Good Manufacturing Practice as described above. The final rule amending the GMP regulations appeared

in the Federal Register on March 28, 1979, which presents public comments submitted to the FDA, and the FDA's responses. It's an excellent reference to help you understand the FDA's rationale for each element of the GMP regulations.

## RESOURCES

21 CFR 211

Guidance for Industry: Quality Systems Approach to Pharmaceutical CGMP Regulations

Guidance for Industry: CGMP for Phase 1 Investigational Drugs

Federal Register Notice. Final rule. CGMP in Manufacture, Processing, Packaging, or Holding of Human and Veterinary Drugs

Guidance for Industry: Q7A Good Manufacturing Practice for Active Pharmaceutical Ingredients

# GTP or CGTP

Good Tissue Practice or Current Good  
Tissue Practice

## DEFINITION

CGTP requirements govern the methods used in, and the facilities and controls used for, the manufacture of human cells, tissues, or cellular or tissue-based products (HCT/Ps) in a way that prevents the introduction, transmission, or spread of communicable diseases by HCT/Ps. Communicable diseases include, but are not limited to, those transmitted by viruses, bacteria, fungi, parasites, and transmissible spongiform encephalopathy agents.

## IMPLICATIONS

The CGTP regulations are relatively new, taking effect in 2005. An entire section of the GTP regulations addresses environmental control and monitoring, specifically temperature and humidity control.

## RESOURCES

21 CFR 1271

Draft Guidance for Industry: CGTP

# CPGM

Compliance Program Guidance Manual

If you are responsible for compliance or inspections, familiarity with CPGMs can be extremely valuable.

## DEFINITION

The FDA's Compliance Program Guidance Manuals provide instruction to personnel for evaluating industry compliance with the federal Food, Drug, and Cosmetic Act and other laws administered by the FDA. The FDA's compliance programs are organized by the following areas: Center for Biologics Evaluations and Research, Center for Devices and Radiological Health, Center for Drug Evaluation and Research, Center for Food Safety and Applied Nutrition, and Center for Veterinary Medicine.

## IMPLICATIONS

Participating in an FDA compliance program does not create or confer any rights for or on any person and does not operate to legally bind the FDA or public. However, these programs may grant the applicant an alternative approach to satisfy the requirements of the applicable statutes and regulations.

If you are responsible for compliance or inspections, familiarity with CPGMs can be extremely valuable as preparation for an FDA inspection, since they describe in detail what inspectors look for, how they look for it, and why.

## RESOURCES

Compliance Program Guidance Manual

# FD&C Act or FDCA

Food, Drug, and Cosmetic Act

## DEFINITION

The first comprehensive federal consumer protection law was the 1906 Food and Drugs Act, which prohibited misbranded and adulterated food and drugs in interstate commerce. The enactment of the 1938 Food, Drug, and Cosmetic Act tightened controls over drugs and food, included new consumer protection against unlawful cosmetics and medical devices, and enhanced the government's ability to enforce the law. This law, as amended, is still in force today.

## IMPLICATIONS

In 1937, in an attempt to make sulfanilamide (a bad-tasting antibacterial medication) more palatable, its manufacturer, S.E. Massengill, added it to a sweet-tasting solvent, diethylene glycol. The company was not aware that diethylene glycol is toxic to humans, but did not test it prior to marketing. Elixir of Sulfanilamide caused 107 deaths, including many children, as soon as it went on the market. This was the tragic incident that led to the enactment of the FD&C Act. The FDCA required firms to prove that any new drug was safe before it could be marketed. It also

created the New Drug Application (NDA) process that's still in use today.

In 1962 the FD&C Act was amended in response to another tragedy. Thalidomide, manufactured by Wm. S. Merrill Co., was being tested in the United States for use as a treatment for morning sickness during pregnancy. This product was teratogenic, causing numerous birth defects. The 1962 amendment required that efficacy had to be proven in addition to safety.

## RESOURCES

Reference Edition of the FD&C Act

# FOIA and FOI

Freedom of Information Act and freedom of information

## DEFINITION

The FOIA is a federal law that allows for the full or partial disclosure of previously unreleased information and documents controlled by the United States government. The act defines agency records subject to disclosure, outlines mandatory disclosure procedures, and grants nine exemptions to the statute. It was signed into law on July 4, 1966, and went into effect the following year.

## IMPLICATIONS

The 1996 amendments to the FOIA mandate publicly accessible “electronic reading rooms” for indexed and searchable FOIA-response materials and other information. On the FDA’s Web site is an index to the electronic reading room. It contains categories of frequently requested FDA documents.

Before submitting a FOIA request, check to see if the information you’re looking for is already available on the FDA Web site. If it is, it’s free. New FOIA requests require search and review processing fees ranging from under

\$25 to almost \$100, depending on the grade level of the FDA employee filling the request. Then there’s a copying charge of 10 cents per page. Of course, FDA fees are always subject to change.

The FDA maintains a log of all FOI requests. If you prefer to remain anonymous (perhaps when researching a competitor, for example), use a third party to make the request for you. Specialized companies and law firms often provide these services.

## RESOURCES

Freedom of Information

Electronic Reading Room

# FR

Federal Register

## DEFINITION

The Federal Register is the official journal of the United States government. Published daily, it includes most of the routine publications and public notices of government agencies.

## IMPLICATIONS

The FR contains proposed new rules and regulations, final rules, changes to existing rules, and notices of meetings and judicial proceedings. Proposed rules are published in the FR for public comment before they are finalized. An important element of the FR is the preambles to final rules. It's here that you can read the FDA's reasons for accepting or rejecting arguments submitted during the public comment period. This helps in understanding the interpretation of the new

rules. In one example from the FR preamble to the Current Good Manufacturing Practices regulations, several cited public comments asserted that the phrase "good state of repair" is vague and subject to varying interpretation. The FDA disagreed, saying that the phrase means that buildings must be in good repair so drug products processed within them aren't adversely affected. Such insight into the regulator's mind can help businesses navigate the process.

## RESOURCES

Search Federal Register

<http://www.accessdata.fda.gov/scripts/oc/ohrms/index.cfm>

# GLP

Good Laboratory Practice

Even though the GLP regulations address analytical testing, their focus is on nonclinical studies to support safety data.

## DEFINITION

GLP regulations were put into effect in 1981 to ensure adequate quality control for nonclinical (animal) studies and to provide an adequate degree of consumer protection. The regulations specify minimum standards for the proper protocol and conduct of safety testing and contain sections on facilities, personnel, equipment, standard operating procedures, test and control articles, quality assurance, records and reports, and laboratory disqualification.

## IMPLICATIONS

GLP applies to the conduct of all nonclinical laboratory studies that support or are intended to support applications for research or marketing permits for products regulated by the FDA, including food and color additives, animal food additives, human and animal drugs, medical devices for human use, biological products, and electronic products. Compliance with GLP regulations is intended to ensure the quality and integrity of the safety data filed pursuant to the FD&C Act.

Some researchers mistakenly think that GLP applies to analytical laboratory testing. Even though the GLP regulations address analytical

testing, their focus is on nonclinical studies to support safety data.

When manufacturers submit a nonclinical laboratory study to the FDA to support applications for research or marketing permits, they must include a statement attesting to their study's compliance with GLP. Noncompliance requires the submission of a statement of rationale. Some researchers believe that "GLP-like" is close enough. The FDA has responded that no such thing exists and a study is either GLP-compliant or it's not.

## RESOURCES

21 CFR 58

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=58>

GLP Q&A

<http://www.fda.gov/downloads/ICECI/EnforcementActions/BioresearchMonitoring/UCM133748.pdf>



# ICH

International Conference on Harmonisation  
of Technical Requirements for Registration  
of Pharmaceuticals for Human Use

## DEFINITION

ICH is a joint initiative involving both regulators and research-based industry representatives of the European Union, Japan, and the United States in scientific and technical discussions of the testing procedures required to assess and ensure the safety, quality, and efficacy of medicines.

## IMPLICATIONS

The objective of ICH is to increase international standardization of technical requirements to ensure that safe, effective, and high-quality medicines are developed and registered in the most efficient and cost-effective manner.

ICH publishes guidance documents covering four areas: quality, safety, efficacy, and multidisciplinary. These guidance documents are aimed at eliminating duplication in the development and registration processes so that a single set of studies can be generated to

demonstrate the quality, safety, and efficacy of a new medicinal product.

ICH has also developed the Common Technical Document (CTD), which describes the common format for preparing a well-structured application for submission to regulatory authorities. The ICH has taken this a step further and developed the electronic CTD (eCTD), which allows for the electronic submission of the CTD from applicant to regulator.

## RESOURCES

ICH Official Web Site  
<http://www.ich.org/>

# IOM

Inspections Operations Manual

## DEFINITION

The IOM is the primary source regarding FDA policy and procedures for field investigators and inspectors. It directs the conduct of all fundamental field investigational activities. Adherence to this manual by agency personnel is paramount to ensure quality, consistency, and efficiency in field operations.

## IMPLICATIONS

If you keep in mind the purpose of the FDA's Office of Regulatory Affairs (ORA), compliance becomes more an important responsibility than a burdensome obligation. Its vision: All food is safe; all medical products are safe and effective, and the public health is advanced and protected. Its mission: Protect consumers and enhance public health by

maximizing compliance of FDA-regulated products and minimizing risk associated with those products.

Manufacturers with regulatory matters before the FDA might consider accessing the IOM (link below) to get an inside look at how its policies and procedures work in practice.

## RESOURCES

Inspections Operations Manual  
<http://www.fda.gov/ICECI/Inspections/IOM/default.htm>

# ISO

International Organization for Standardization

## DEFINITION

ISO is the world's largest developer and publisher of international regulatory standards. Its status as a nongovernmental organization serves as a bridge between the public and private sectors, enabling a consensus on solutions that meet both the requirements of business and the broader needs of society.

## IMPLICATIONS

More than 260 technical committees make up the ISO, each one focusing on a specific topic. There are over 90 international classifications for standards, and copies of them and other

ISO publications are available for purchase in the United States from the American National Standards Institute (ANSI) in Washington, D.C.

## RESOURCES

ISO Official Web Site

# QSR

Quality System Regulation

## DEFINITION

In the medical device world, Current Good Manufacturing Practices (CGMP) requirements appear in the QSR. These requirements govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use. They are intended to ensure that finished devices will be safe and effective and otherwise comply with the FD&C Act.

## IMPLICATIONS

Keep in mind, just as with drugs, not complying with CGMP or QSR by definition deems the device adulterated. The manufacturer of an adulterated device may be subject to regulatory actions by the FDA.

## RESOURCES

21 CFR 820

Presentation: Quality System Regulation 21 CFR 820 – Basic Introduction

Medical Device Quality Systems Manual

Federal Register. Medical Devices: CGMP

# USP- NF

United States Pharmacopeia-National  
Formulary

## DEFINITION

The United States Pharmacopeia–National Formulary (USP–NF) is a book of public pharmacopeial standards. It addresses medicines, dosage forms, drug substances, excipients, medical devices, and dietary supplements.

Monographs for drug substances and preparations are featured in the USP. Monographs for dietary supplements and ingredients appear in a separate section of the USP. Excipient monographs are in the NF.

## IMPLICATIONS

Drug products listed in the USP–NF must comply with the monographs for those products. That means those products must conform to all specifications, be tested according to the specified directions, and be labeled and packaged in compliance with the standards. Products labeled USP but not meeting the requirements and specifications

of the USP are considered adulterated, misbranded, or both. If your product appears in the USP and does not meet the USP specifications, you must label it to show how the drug differs from the compendial (established) product. Viewing the contents of the USP–NF requires a paid subscription.

## RESOURCES

Official Web Site of the USP–NF

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# QUALITY RELATED

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# ALCOA

Attributable, Legible, Contemporaneous,  
Original, Accurate

## DEFINITION

For data to be accepted as reliable, valid, and usable by the researcher, it should meet certain fundamental elements of quality, whether collected or recorded electronically or on paper. Data should be attributable, legible, contemporaneous, original, and accurate.

## IMPLICATIONS

This acronym was first used by the FDA in bioresearch monitoring inspections. Since the concept can be applied to all data, it has gained popularity beyond bioresearch monitoring.

## RESOURCES

Bioresearch Monitoring – Inspectional

# CAPA

corrective and preventive action

## DEFINITION

*Corrective action:* Action taken to eliminate the cause of a detected nonconformity or other undesirable situation.

*Preventive action:* Action taken to eliminate the cause of a potential nonconformity or other undesirable potential situation.

NOTE: Preventive action is taken to prevent occurrence, whereas corrective action is taken to prevent recurrence. (ISO 9000:2005)

## IMPLICATIONS

Prevention and correction are two of the most important elements of an effective quality system. A company should maintain a system for implementing preventive actions and corrective actions resulting from the investigation of complaints, product rejections, nonconformances, recalls, deviations, audits, regulatory inspections and findings, and trends from process performance and product-quality monitoring. FDA inspectors should apply

a structured approach to the investigation process, with the objective of determining the root cause of the nonconformity. The level of effort, formality, and documentation of the investigation should be commensurate with the level of risk. CAPA methodology should result in product and process improvements and enhanced product and process understanding.

## RESOURCES

Guidance for Industry – Q10 Pharmaceutical Quality System

Corrective and Preventive Actions



PV

process  
validation

DQ

design  
qualification

IQ

installation  
qualification

OQ

operational  
qualification

PQ

performance  
qualification**DEFINITIONS**

*Process validation:* documented evidence that the process, operated within established parameters, can perform effectively and reproducibly to make an ingredient or product meeting its predetermined specifications and quality attributes.

*Design qualification:* documented verification that the proposed design of the facilities, equipment, or systems are suitable for the intended purpose.

*Installation qualification:* documented verification that the equipment or systems, as installed or modified, comply with the approved design, the manufacturer's recommendations, and/or user requirements.

*Operational qualification:* documented verification that the equipment or systems, as installed or modified, perform as intended throughout the anticipated operating ranges.

*Performance qualification:* documented verification that the equipment and ancillary systems, as connected together, can perform effectively and reproducibly based on the approved process method and specifications.

**IMPLICATIONS**

The FDA prefers manufacturers apply prospective validation (validation documented before a new process is implemented or before applying for FDA approval). Manufacturers can conduct concurrent validation when they don't have data from replicated production runs because they've

produced only a limited number of batches. Retrospective validation is acceptable for well-established processes that have operated without significant changes to the ingredient or product quality resulting from changes in raw materials, equipment, systems, facilities, or the production process.

**RESOURCES**

Guidance for Industry – Process Validation: General Principles and Practices

ICH Q7 GMP for API

# OOS

out of specification

## DEFINITION

OOS results include all test results that fall outside the specifications or acceptance criteria established in drug applications, drug master files (DMFs), official compendia, or by the manufacturer. The term also applies to all in-process laboratory tests that are outside of established specifications.

## IMPLICATIONS

In the 1990s, the way the FDA and pharmaceutical companies approached OOS was entirely different. The FDA held that when a test batch fails it should be rejected. Then Barr Laboratories challenged that position, saying because of the chance of lab error, it

should have the chance to confirm or refute an OOS finding. In 1993, the courts were unwilling to accept the FDA's perspective on OOS and sided with Barr. This led to the FDA reinterpreting how OOS results are handled.

## RESOURCES

Guidance for Industry: Investigating OOS Test Results for Pharmaceutical Production

Barr Laboratories vs. FDA

QA

quality  
assurance

QC

quality  
control

QS

quality  
system

QU

quality  
unit**DEFINITIONS**

*Quality assurance:* the planned and systematic activities that ensure a food, drug, or device will be processed and produced with consistency, meeting all analytical and performance specifications within and between batches. QA primarily involves (1) review and approval of all procedures related to production and maintenance; (2) review of associated records; and (3) auditing, performing, and evaluating trend analyses.

*Quality control:* the steps taken during the generation of a product or service to ensure it meets requirements and the product or service is reproducible. QC usually involves (1) assessing the suitability of incoming components, containers, closures, labeling, in-process materials, and the finished products; (2) evaluating the performance of the manufacturing process to ensure adherence to proper specifications and limits; and (3) determining the acceptability of each batch for release.

*Quality system:* formalized business practices that define management responsibilities for organizational structure, processes, procedures, and resources needed to fulfill product and service requirements, customer satisfaction, and continual improvement. Under a quality system, it's normally expected that the product and process development units, the manufacturing units, and the QU will remain independent.

*Quality unit:* a group organized within an organization to promote quality in general practice by ensuring the various operations associated with all systems are appropriately planned, approved, conducted, and monitored. The QU has the authority to create, monitor, and implement a quality system.

**IMPLICATIONS**

The guidance document referenced below is a must-read for anyone involved in pharmaceutical manufacturing, quality, and regulations. It integrates quality systems and risk management with the goal of encouraging industry to adopt modern and innovative manufacturing technologies. One of the key

concepts of this guidance document is quality by design. The guidance document is intended to bring together the Good Manufacturing Practice regulations (for which the last major revision was in 1978) and our current understanding of quality systems. Much has changed over that time.

**RESOURCES**

Guidance for Industry: Quality Systems Approach to Pharmaceutical CGMP Regulations

# SOP

standard operating procedure

The FDA defines “shall” as a requirement. This is different from “should,” which indicates a recommendation only.

## DEFINITION

An SOP is a detailed written instruction aimed explicitly at achieving uniformity in the performance of a specific function. Good Manufacturing Practices (GMPs) are classic SOPs.

## IMPLICATIONS

The drug GMP regulations include numerous references to the requirement of “written procedures,” or SOPs. Note the use of the word “shall,” below. The FDA defines “shall” as a requirement. This is different from “should,” which indicates a recommendation only.

*Some SOP examples from 21 CFR 211:*

There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include all requirements in this subpart. These written procedures, including any changes, shall be drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by the quality control unit. [211.100(a)]

Written procedures describing the warehousing of drug products shall be established and followed. [211.142]

There shall be a written testing program designed to assess the stability characteristics of drug products. The results of such stability testing shall be used in determining appropriate storage conditions and expiration dates. The written program shall be followed. [211.166(a)]

The device GMP regulations also make clear that SOPs shall be written. For example, “Where process controls are needed they shall include: Documented instructions, standard operating procedures (SOPs), and methods that define and control the manner of production.” (21 CFR 820.70)

## RESOURCES

21 CFR 211: Current Good Manufacturing Practice for Finished Pharmaceuticals

# VMP

validation master plan

## DEFINITION

The VMP is the foundation of a company's Good Manufacturing Practice validation program. It's a comprehensive plan that should include process validation; facility and utility qualification and validation; equipment qualification; cleaning; and computer validation.

## IMPLICATIONS

A VMP should define the validation program implemented at all manufacturing facilities. During an FDA inspection, inspectors typically compare individual validation records with the requirements of the VMP. When an inspection reveals noncompliance with a company's own VMP, the inspector may cite that as an observation on the 483, and it may show

up on a subsequent warning letter. Often 21 CFR 211.22 (responsibilities of the quality-control unit) and 211.100 (written procedures; deviations) are cited as the unmet regulations. In cases of continued poor compliance, the FDA has seized drug products and ingredients from manufacturers.

## RESOURCES

Quality System Information for Certain Premarket Application Reviews

21 CFR 211

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# CONTRACT ORGANIZATIONS

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# CMO

Contract Manufacturing Organization

## DEFINITION

An organization that serves the pharmaceutical, biotechnology, and medical device industries and provides clients with comprehensive services from product development through manufacturing.

## IMPLICATIONS

Companies without their own development or manufacturing capabilities can greatly benefit from the expertise of CMOs. Their fees may be high, but if time is money, a CMO can

significantly reduce the time spent moving through the process—from development through manufacturing for commercial distribution.

# CRO

Contract Research Organization

## DEFINITION

CROs that provide support services to the pharmaceutical and biotechnology industries in the form of outsourced pharmaceutical research (for both drugs and medical devices). CROs range from large, international full-service organizations to small, niche specialty groups and can move a new drug or device from its conception to FDA marketing approval, freeing the sponsor from staffing for these services.

## IMPLICATIONS

CROs provide valuable services in drug and device development, especially for clinical trials, protocol development, data monitoring, statistical analysis, and marketing application

submissions. Some CROs specialize in particular medical areas or aspects of the clinical research process, while others are a “one stop shop.”



# INDEX

- 356h** New Drug Application
- 482** Notice of Inspection form
- 483** Inspectional Observations form
- 484** Receipt of Samples form
- 510(k)** premarket notification
  
- ALCOA** Attributable, Legible, Contemporaneous, Original, Accurate
- ANDA** Abbreviated New Drug Application
- API** active pharmaceutical ingredient
  
- BLA** biologics license application
  
- CAPA** corrective and preventive action
- CBER** Center for Biologics Evaluation and Research
- CDER** Center for Drug Evaluation and Research
- CDRH** Center for Devices and Radiological Health
- CFR** Code of Federal Regulations
- CFSAN** Center for Food Safety and Applied Nutrition
- CGMP** Current Good Manufacturing Practice
- CGTP** Current Good Tissue Practice
- CMC** chemistry, manufacturing, and controls
- CMO** Contract Manufacturing Organization
- CPGM** Compliance Program Guidance Manual
- CRO** Contract Research Organization
- CVM** Center for Veterinary Medicine
  
- DMF** drug master file
- DO** District Office
- DQ** design qualification
  
- EIR** Establishment Inspection Report
  
- FDA** Food and Drug Administration
  
- FDCA** Food, Drug, and Cosmetic Act
- FD&C Act** Food, Drug, and Cosmetic Act
- FOI** freedom of information
- FOIA** Freedom of Information Act
- FR** Federal Register
  
- GLP** Good Laboratory Practice
- GMP** Good Manufacturing Practice
- GTP** Good Tissue Practice
  
- HHS** U.S. Department of Health and Human Services
  - IB** Inspections Branch
  - ICH** International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
  - IDE** Investigational Device Exemption
  - IND** Investigational New Drug application
  - IOM** Inspections Operations Manual
  - IQ** installation qualification
  - ISO** International Organization for Standardization
  
- NAI** No Action Indicated
- NCE** new chemical entity
- NDA** New Drug Application
- NIH** National Institutes of Health
- NME** new molecular entity
  
- OAI** Official Action Indicated
  
- OCC** Office of Chief Counsel
- OGC** Office of General Counsel
- OI** Office of Investigations
- OIG** Office of Inspector General
- OOS** out of specification
- OQ** operational qualification
- ORA** Office of Regulatory Affairs
  
- PMA** Premarket Approval
- PQ** performance qualification
- PV** process validation
  
- QA** quality assurance
- QC** quality control
- QS** quality system
- QSR** Quality System Regulation
- QU** quality unit
  
- RM** raw material
  
- SOP** standard operation procedure
  
- UL** untitled letter
- USP-NF** United States Pharmacopeia – National Formulary
  
- VAI** Voluntary Action Indicated
- VMP** validation master plan
  
- WL** warning letter

## Vaisala: Measure, Monitor, and Validate in Life Science Environments

The world's leading pharmaceutical and biotechnology companies rely on Vaisala technologies, systems, and people to monitor, measure, and validate temperature, humidity, differential pressure, and other critical parameters in their highly demanding controlled and regulated environments.

Learn more about how Vaisala helps life sciences customers achieve good manufacturing practices and compliance within FDA-regulated environments, or register for one of our free GMP webinars and seminars, at [Vaisala Life Science](http://Vaisala Life Science) ([www.vaisala.com/lifescience](http://www.vaisala.com/lifescience)). Or [contact us](#) today.