

1. Scope

Applicable to all Amgen staff members, consultants, contract workers, and temporary staff worldwide (“Covered Persons”). Consultants, contract workers, and temporary staff are not Amgen employees, and nothing in this Policy should be construed to the contrary.

2. Policy

The pharmaceutical/biotech industry is governed by various laws and regulations in the U.S. and other countries with respect to Good Clinical Practices (“GCP”), Good Manufacturing Practices (“GMP”), and Good Laboratory Practices (“GLP”) (collectively, “Good Operating Practices” or “GxP”), among other practices.

It is Amgen’s policy to comply with all applicable laws and regulations regarding its research, development and manufacturing activities, including GxP. This Policy sets forth the requirements that govern research, development, and manufacturing in a regulated environment.

General Principles

Amgen functions with GxP operations must, as applicable:

- Establish GCP policies and procedures to ensure the generation of valid and reliable clinical data and results, safeguard the health of human study subjects, and comply with applicable laws and regulations.
- Establish GLP policies and procedures to ensure the generation of valid and reliable preclinical safety and other data and comply with applicable laws and regulations.
- Establish GMP policies and procedures to ensure appropriate controls are in place for the manufacturing, processing, packing and holding of drug products; that the safety, integrity, purity and quality of drug products are maintained; and to ensure compliance with applicable laws and regulations.
- Establish governance documents to ensure compliance with applicable laws and regulations related to other areas of compliance, such as “controlled substances” and the use of laboratory animals in research.

Covered Persons must comply with functional governance documents relating to this Policy.

Overall GxP Systems and Controls

To ensure that Amgen’s operational activities are based on sound scientific and quality principles that safeguard patient health and safety, and comply with applicable laws and regulations, Amgen GxP operational functions will have the following systems and internal controls in place:

- Written policies and procedures
- Training on procedures tailored to the appropriate functional area
- Mechanisms to periodically assess and test compliance with applicable requirements and Amgen policies
- Processes for document creation and retention

- Validation policies, including procedures to ensure relevant electronic records and electronic signatures comply with, as applicable, 21 CFR Part 11 and other similar international regulations
- Processes for the design, development, validation and lifecycle management of computer related systems including IT infrastructure, business systems, laboratory systems, laboratory instruments, and process control systems operating in GxP regulated areas.
- Processes for reporting, investigating, and escalating alleged noncompliance from regulatory requirements or Amgen policies and procedures, where appropriate
- Processes for conducting and/or responding to internal and external audits
- Processes for handling and responding to regulatory inspections and investigations
- Process for escalating GxP compliance issues to appropriate levels of management
- Provision of adequate resources to ensure that each operational function can comply with Amgen policies and procedures

Other Areas of Compliance Obligations

Amgen functions with GxP operations must, as applicable, develop and maintain policies and procedures to address the handling of “controlled substances” (e.g., narcotics and psychotropics) that are regulated by the U.S. Drug Enforcement Administration and similar bodies in other jurisdictions, in the course of Amgen’s scientific research, development and manufacturing.

Amgen believes that research using animals is necessary to advance biomedical knowledge and provide improvements in healthcare. Covered Persons working with animals in research or sponsoring external animal use must comply with the Research & Development Laboratory Animal Care and Use Policy.

3. Additional Information

Covered Persons Responsibility for Compliance

Every Covered Person worldwide is required to follow (1) the Amgen Code of Conduct, (2) all applicable laws and regulations, and (3) Amgen governance documents applicable to him or her, including without limitation, those relating to this Policy. Covered Persons should exert due diligence in preventing violations of such laws, regulations, and governance documents. Covered Persons must refer to the governance documents in effect for the geographic area in which they work, or for which they are responsible, or request guidance from their manager or compliance representative with responsibility for that geographic area. See Section 4, below, for a non-exhaustive list of governance documents related to this Policy. The term “governance documents” in this Policy means Amgen’s written policies, standards, procedures, business practices, and manuals.

Amgen expects its managers to (1) be familiar with (or take appropriate steps to become familiar with) the laws, regulations, and Amgen governance documents applicable to the activities they manage or supervise, (2) ensure their direct reports have appropriate training on compliance issues to perform their job functions, and (3) supervise their direct reports with respect to compliance requirements and activities.

If Amgen determines that any Amgen staff member has violated this Policy, applicable laws or regulations, or any governance documents, appropriate disciplinary measures will be taken, to the extent permitted by local laws. The following is a non-exhaustive list of possible disciplinary measures to which Amgen staff members may be subject (subject to local laws): oral or written warning; suspension; removal of job duties/responsibilities or demotion; reduction in compensation; and termination of employment.

Amgen

GLOBAL CORPORATE COMPLIANCE POLICY

RESEARCH, DEVELOPMENT, AND MANUFACTURING IN A REGULATED ENVIRONMENT POLICY

Subject to local laws, Amgen reserves the right to take whatever disciplinary or other measure(s) it determines in its sole discretion to be appropriate in any particular situation, including disclosure of the wrongdoing to governmental authorities. Nothing in this Policy changes the at-will nature of employment at Amgen, its affiliates or subsidiaries, where applicable.