1. **Scope**

Applicable to all Amgen Inc. and subsidiary or affiliated company 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**

It is Amgen’s policy to comply with all regulations and laws worldwide relating to Adverse Event or Experience (AE), Other Safety Findings and Product Complaint (PC) reporting (collectively known as “Reportable Events”). All Covered Persons are responsible for reporting Reportable Events to the appropriate unit (see section 'How to Report' below) within one business day of learning of the event. It is Amgen’s mission to serve patients, and prompt and accurate reporting of Reportable Events is critical to protecting the health and safety of patients who use Amgen’s products around the world. Amgen will train all Covered Persons on the requirements of this Policy annually.

It does not matter whether the reportable event is thought to be caused or not thought to be caused by taking an Amgen product – all AEs, Other Safety Findings and PCs must be reported. You must still report a reportable event even though it is listed in the approved company prescribing information as a possible side effect. In addition, Covered Persons may learn of Reportable Events during business transactions (e.g., a sales call) or non-business events (e.g., a social event) and all must be reported per the requirements of this Policy.

Additionally, Covered Persons who engage vendors to conduct activities that may collect AEs, Other Safety Findings or PC information (e.g., market research, patient support programs and arrangements with specialty pharmacies) are responsible for ensuring prior to initiation of the engaged service that contracts contain appropriate language requiring reporting of Reportable Events to Amgen and that vendors are trained on these reporting requirements. Managers of Covered Persons must supervise their direct reports with respect to compliance requirements and activities within this policy.

This Policy does not apply to formal data collection processes such as clinical trials or observational studies with formal protocols in place to collect, analyze, and report AEs, Other Safety Findings and PCs. If in doubt whether the Policy applies, Covered Persons should report Reportable Events.
### Definitions:

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<tr>
<th>Term</th>
<th>Definition</th>
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| **Adverse Event or Adverse Experience (AE)** | An AE is any untoward medical occurrence in a patient administered an Amgen product and which is not necessarily caused by the Amgen product. An AE can therefore be any unfavorable and unintended sign (e.g., an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, combination product, or medical device, whether or not considered related to the product.  
  This includes:  
  - Any clinically significant worsening of a pre-existing condition;  
  - An AE that has been associated with the discontinuation of the use of a product; and  
  - Any lack or loss of intended effect.                                                                                                               |
| **Other Safety Findings**                  | For the purposes of this Policy the following are considered Other Safety Findings regardless of whether they are associated with an AE and they must be reported to Amgen:  
  - Use of an Amgen product while pregnant and/or breast feeding  
  - Accidental or intentional medication errors or overdose of an Amgen product,  
  - Misuse, where the Amgen product is intentionally and inappropriately used including misuse for illegal purposes  
  - Abuse, which is, intentional excessive use of an Amgen product  
  - Transmission of an infectious agent through a contaminated Amgen product  
  - Occupational exposure to an Amgen product (e.g., a Healthcare Provider is splashed with medicinal product while preparing an injection)  
  - Reports of patient “death” after exposure to an Amgen product where no other details are provided (e.g. fatal outcomes)  
  - Off-label use of an Amgen product (e.g. a product is intentionally used to treat a condition for which the product is not indicated). However, consistent with Amgen Policy on Communications with Members of the U.S. Healthcare Community regarding off-label use discussions, US |
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<tr>
<td>Commercial field staff</td>
<td>Should not collect information regarding off-label use; such discussions should be referred to Medical Information.</td>
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<tr>
<td>US Commercial field staff</td>
<td>Are required to report information regarding AEs associated with OLU.</td>
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<td>Product Complaint (PC)</td>
<td>A PC includes any written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a drug, combination product, or device after it is released for distribution to market or clinic by either Amgen or by distributors and partners for whom Amgen manufactures the material. This includes all components distributed with the drug such as packaging, drug containers, delivery system, labelling, inserts, etc. Examples include:</td>
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<td>- Device that is damaged or broken</td>
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<td>- Bent or dull needles</td>
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<td>- Missing or illegible labeling</td>
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<td>- Inability of customer to administer the product</td>
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<td>- Product with an unexpected color, appearance, or particles</td>
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<tr>
<td>Reportable Events</td>
<td>Reportable events per this policy include, AEs, Other Safety Findings and PCs.</td>
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**How to Report**

Report information on AEs, Other Safety Findings and PCs to your local Amgen Medical Information/Safety office. Contact numbers for local Medical Information/Safety offices are posted on the Amgen Website. Alternatively, Covered Persons may contact corporate headquarters using the following contact numbers:

**Amgen Medical Information/Global Patient Safety**

Phone: 8-447-3505 or +1-800-772-6436 (+1-800-77-Amgen)

Your reporting obligations are met by directly calling Reportable Events into the appropriate office within one business day. Your obligations are not met by entering the Reportable Events in business reports, such as call notes, emails to your manager, internal social media sites, etc.

Covered Persons should try to obtain details that will assist Amgen in its follow-up, e.g., a patient identifier, such as date of birth or initials, a description of the Reportable Events, the Amgen product
implicated, and reporter contact details. If available, please obtain the lot number on the product pack used, also. Please note that any information collected about an individual person or persons must comply with applicable privacy and data protection laws and regulations, along with Amgen policies. If you have any questions or require direction, contact your local Amgen affiliate’s data protection officer or the Amgen Privacy Office.

Information about Reportable Events must be kept confidential. Covered Persons should not discuss any information concerning a reportable event with anyone except the reporting person or entity, supervising staff, staff in Global Patient Safety, Medical Information staff, Amgen Operations staff, and the Law Department, unless otherwise directed.

3. Covered Persons Responsibility for Compliance

Every Covered Person worldwide is required to follow (1) the Amgen Code of Conduct, (2) laws and regulations applicable in the relevant jurisdictions, 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.

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 requirements to perform their job functions, and (3) supervise their direct reports with respect to compliance requirements and activities.

If Amgen determines that any Covered Person has violated this Policy, related standards, procedures or controls, applicable laws or regulations, or any governance documents, appropriate disciplinary measures will be taken, up to and including immediate termination of employment, to the extent permitted by applicable laws. The following is a non-exhaustive list of possible disciplinary measures to which Covered Persons may be subject (subject to applicable law): oral or written warning, suspension, removal of job duties/responsibilities, demotion, reduction in compensation, and/or termination of employment.

Subject to applicable 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 wrongdoing to governmental authorities. Nothing in this Policy changes the at-will nature of employment at Amgen, its affiliates or subsidiaries, where applicable. Amgen may also terminate the services or work engagement of non-employee Covered Persons for violation of this Policy.