ESG Index: Quality

Product quality and patient safety

We maintain a robust quality system with harmonized processes and procedures, in compliance with external regulatory requirements and standards. We continually monitor and adhere to new regulations from health authorities and other regulators for both marketed products and investigational molecules, with health authorities and other regulators conducting regular inspections of our facilities. We conduct thorough investigations when deviations, out-of-specification and/or failure of our manufacturing processes to meet our quality standards, current Good Manufacturing Practices (cGMP) and other applicable regulations occur.

Relevant links and disclosures

- Progress (PDF 5.0 MB)
- Novartis quality website
- Novartis Quality Management System (QMS)
- Novartis Quality Policy (PDF 0.2 MB)
- Audit program
- Product and patient safety training
- Reporting side effects for Novartis products

Other information

- Regular external product/service safety audits (see below):
  - We maintain a robust quality system with harmonized processes and procedures. These include providing integrated medical safety evaluations and benefit-risk assessments as well as monitoring the quality and safety of in-market and investigational products. This quality system is compliant with regulatory requirements and standards. Further, we are regularly subject to health authority inspections, which additionally ensure regulatory compliance and the highest product quality at our manufacturing sites.
- Extent and scope of product quality and safety training for employees:
  - All internal and third-party personnel are required to take mandatory Safety and Quality (cGxP) trainings before executing a GxP relevant task.
  - Throughout the product lifecycle, all our operations require a cGxP certificate issued by the relevant health authorities, with a robust Quality Management System in place that incorporates all the relevant legal requirements and associated standards, including ISO. Against this background, regulators require we are able to prove that our employees are qualified, through education, training or experience, to perform any assigned task which has an impact on product quality or patient safety.
  - We have a very robust quality and safety training process (initial and continuous training) for our employees and we are regularly audited on our training procedures. Examples of topics covered in initial training for all employees include: Product Quality Reporting (adverse events), Information Management and Responsible Record Keeping, Novartis Group Quality Management Escalation, GxP on-boarding and HSE.
  - Global annual GxP quality trainings consist of at least two trainings that are applicable to all

functions and may address current regulatory changes or internal requirements within Novartis. These trainings support the qualification of employees and should be added to the training curricula of the target audience (new hire and on-boarded). Functions and sites may choose to have further specific training programs in addition. This is documented in the annual training plan.

- Regulatory Inspections
  - To ensure product quality, we maintain a robust quality management system for our medicines in full compliance with requirements from health authorities and other regulators, who conduct regular inspections of our facilities. In 2024, 124 inspections took place at our facilities, all of which were found to be acceptable.
  - Inspections by the US FDA:
    - FDA total inspections: 9
    - FDA warning letters: 0
    - FDA Form 483: 4
    - FDA recalls: 1
  - Inspections
    - Inspections related to clinical trial management and pharmacovigilance: 21
    - Number of FDA OAI (official action indicated) classifications: 0
    - Number of FDA VAI (voluntary action indicated) classifications: 0

Falsified medicines

Falsified medicines are a growing global problem. The Pharmaceutical Security Institute reported a 10% increase in pharmaceutical crime incidents worldwide in 2022 – to the highest number of incidents recorded in a single year. At Novartis, our priority is to protect patient health and safety through quick authentication and reporting of falsified medicines to health authorities and the WHO.

Relevant links and disclosures

- Progress (PDF 5.0 MB)
- Position on Falsified and Counterfeit Medical Product (PDF 0.2 MB)

List of links present in page

1. https://prod1.novartis.com/esg/index/quality
2. https://prod1.novartis.com/sites/novartis_com/files/novartis-integrated-report-2024.pdf#page=38
3. https://prod1.novartis.com/about/quality
4. https://prod1.novartis.com/about/quality/novartis-quality-management-system-qms
5. https://prod1.novartis.com/sites/novartis_com/files/novartis-quality-commitment.pdf
6. https://prod1.novartis.com/about/quality/audit-program
7. https://prod1.novartis.com/about/quality/product-and-patient-safety-training
8. https://www.report.novartis.com/
9. https://prod1.novartis.com/sites/novartis_com/files/novartis-integrated-report-2024.pdf#page=39
10. https://prod1.novartis.com/sites/novartis_com/files/falsified-counterfeit-medical-products-07-2019.pdf