

Product and patient safety training

The importance of patient safety was highlighted in our 2021 materiality assessment, with both internal and external stakeholders identifying it as the most material topic for our company.

We have a very robust quality and safety training process (initial and continuous training) for our associates and we are regularly audited on our training procedures. Examples of topics covered in training for all employees include: product quality reporting (adverse events), information management and responsible record keeping, Novartis Group quality management escalation and GxP on-boarding.

We require all employees involved in manufacturing, supply and distribution to undergo at least two annual trainings on quality standards. Employees can also take additional training relevant to their specific role or worksite.

All associates in Novartis Technical Operations (manufacturing arm of Novartis) complete their initial role-specific training to ensure they can safely and compliantly perform their tasks, prior to performing them independently. All Novartis employees (including contractors) in manufacturing and quality assurance are continuously trained to maintain the skills and knowledge needed to manufacture medicine safely, compliantly and effectively. Examples of these trainings include: aseptic operator, enhanced third-party oversight, data integrity, investigation certification program and quality management systems.

All third parties providing materials, products or services to GxP standards are required by regulation to have their own quality assurance department and a formal training process.

Continuing training is a Principle of GMP regulations asked by all regulators. Hence, our suppliers operating under GMP rules are also required to have continuing training. Additionally, Novartis asks its suppliers to comply with ICH (International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use) and PICS (Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme).

Novartis routinely assesses the capability and effectiveness of third-party training programs during audits, to confirm suitability of the provided service or product. We monitor adherence to the regulatory requirements for training as part of our GMP audit process for our GMP suppliers.

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