# Audit program

To maintain compliance with our quality and safety standards and to support the continuous improvement of our QMS, Novartis has a robust and independent audit program that covers the product lifecycle.

The audit program is governed by global procedures and covers Novartis internal sites and functions as well as suppliers. The scope of each audit depends on the type of operations conducted. The frequency of audits is based on activities performed and applicable risk assessments. The Novartis quality audit program normally conducts more than 900 audits per year covering internal functions, sites and external suppliers in areas including Good Manufacturing Practice (GMP), Good Clinical Practice (GCP), Good Laboratory Practice (GLP) and pharmacovigilance.

An annual audit plan is established to take into account audit frequency and assessed risks. Audits are performed by certified auditors. The subsequent audit report is reviewed and approved independently and distributed to the auditee (internal function, manufacturing site or external supplier) who is responsible for submitting a corrective and preventative action plan which, upon agreement, is implemented. The audit is closed when all actions in the plan have been completed.

| | 2022 | 2023 | 2024 |
|---|---|---|---|
| **Total audits executed**[1] | 1 034 | 926 | 809 |
| **Internal**[2] | 106 | 81 | 94 |
| **External**[3] | 928 | 845 | 715 |

References:

1. The reduction in the number of audits is primarily due to the divestment of Novartis divisions, manufacturing network and supplier consolidation.
2. Total number of audits that are performed on facilities owned by Novartis
3. Total number of audits that are performed on GxP suppliers to Novartis

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