

Third-party suppliers

In accordance with health authority requirements and expectations, all third parties with whom Novartis does business, and who provide goods or services that fall within the scope of GxP, including Good Manufacturing Practice (GMP) or Good Distribution Practice (GDP), undergo a formal and rigorous assessment, qualification and monitoring process. The way we oversee quality processes are in place is by requiring all our suppliers to have GMP certifications in place and follow GMP rules. Furthermore, we require our Tier 1 suppliers to ensure that their suppliers (Tier 2) are certified and compliant.

Beyond Tier 1 suppliers (Tier 2+), we follow GMP regulations on outsourced activities which allow for the certification of subcontracted activities (covering all supplier tiers) to be delegated, providing it is contractually defined which party has the GMP responsibilities for each activity, thus ensuring this remains within the requirements of the Marketing Authorization for the product concerned. Following this guidance, we ask from our suppliers to contractually define responsibilities for each activity, thus ensuring Tier 2+ supplier certification.

Our oversight is further enabled by our audits. This includes initial and periodic audits of facilities and quality management processes, with normally more than 1 000 audits of third-party GxP, both direct (Tier 1) and indirect (Tier 2+), performed each year.

Clear definitions, specific expectations, requirements, obligations and responsibilities are described in the [Novartis Third Party Code \(PDF 0.4 MB\)](#) and quality agreements are specific to the type of product or service provided.

[Novartis Third Party Code \(371 KB\)](#)

All third parties providing materials, products or services manufactured to GxP standards are required by regulation to have their own quality assurance department and a formal training process. Novartis routinely assesses the capability and effectiveness of third-party training programs during audits, to confirm suitability of the provided service or product. Where transfer of product or technology occurs from Novartis to a third party, full knowledge transfer and associated technical skills training (e.g., quality-critical parameters, process steps) are provided by Novartis. The extent of the training varies according to the complexity and risk of the associated product and process technology. In the case of complex situations involving personal medicine, Novartis utilizes a robust multi-step process with specialized training.

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