# Novartis quality management system (QMS)

The Novartis Quality Management System (QMS) (PDF 0.2 MB) is a structured and documented approach describing how Novartis addresses external health authority (e.g., Food and Drug Administration (FDA) in the US, European Medicines Agency (EMA) in Europe) regulatory requirements and other relevant standards and guidelines (e.g., ISO standards for medical devices) to help ensure quality processes, products and services. Our QMS is built on the principles defined by the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) and documented in the ICH Q10 Pharmaceutical Quality System guideline. It provides a systematic and risk-based approach to consistently and efficiently achieve product safety and quality.

All Novartis operations involved in the manufacturing of pharmaceutical products can only operate if a Good Manufacturing Practice (cGMP) certificate is issued by the relevant external health authorities. Therefore for 100% of the manufacture, supply and distribution of our pharmaceutical products, we hold the relevant manufacturing licenses and GMP/GxP certificates issued by the appropriate external health authorities – for example the FDA, the EMA, the WHO and SwissMedic – that confirm after inspection, that our duties, including our quality management systems, comply with their strict regulatory requirements.

In addition, NVS Technical Operations including global functions, and manufacturing sites are ISO 9001 Certified by BSI (British Standards Institute) (PDF 1.1 MB) Certification body with the scope Manufacture of Pharmaceuticals. ISO 9001 certification is internationally recognized and demonstrates our adherence to globally accepted standards for quality management. It is a testament to our relentless pursuit of delivering exceptional pharmaceutical products while consistently meeting and exceeding customer expectations.

Harmonized standards (e.g., ICH Q10) are generally adopted by authorities as requirements to achieve such certification. The ICH Q10 framework is integrated in regional GxP requirements, for example, by the EMA in Europe or the FDA in the US.

The QMS facilitates innovation and continuous improvement, and strengthens the link between development and manufacturing activities throughout product development, manufacturing and distribution. Our QMS includes monitoring and implementation of industry and regulatory trends, periodic reviews of our processes and products, monitoring of key quality indicators, risk assessments, quality management reviews, audits, inspections and self-inspections. Insights gathered from these activities feed into the development of our quality strategy and quality plan.

The Novartis QMS and the Novartis Quality organization, including management responsibilities, are described in the Novartis Quality Manual and are based on FDA, EMA, other international health authority regulatory requirements, the ISO 9001:2015 and ICH. All relevant Novartis functions and manufacturing sites (as well as suppliers) must adhere to the requirements described in the Novartis Quality Manual.

The Novartis Quality organization, led by the Head of Global Quality who reports functionally to the CEO, is an independent function that is responsible for the development, implementation and maintenance of the Novartis QMS. It consists of a formal organization, as well as advisory and decision-making bodies and is responsible for both quality assurance and quality control throughout Novartis. The Head of Global Quality regularly briefs the Executive Committee of Novartis and the Audit and Compliance Committee of the Novartis Board of Directors.

In order to develop, manufacture and supply pharmaceutical products, Novartis is inspected and certified by the relevant external health authorities in the countries where we operate. This ensures we comply with external health authority regulations and standards.

We have in-house testing specifications detailed for each product and raw material. GMP guidelines require test specifications and quality control testing for all drug products and materials used in the manufacturing process before they can be released to market and customers. This includes in-process testing, release testing, shelf-life acceptance criteria, pharmacopoeial testing and periodic or skip lot testing and apply throughout the lifecycle of a medicinal product.

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