Novartis Technical Operations

Novartis Quality Management System

Regulations within the pharmaceutical industry and relationship of ICH Q10 to regional GMP requirements, ISO standards, and ICH Q7

Regulations within the pharmaceutical industry

The Novartis Quality Management System as described in the Novartis Quality Manual is based on international health authority regulatory requirements, also known as "cGxP", a collection of quality guidelines, standards and regulations that ensure that our products are safe, efficacious and meet their intended use throughout their lifecycle, such as:

- Drug discovery: current Good Laboratory Practice (cGLP)
- Drug trials: current Good Clinical Practice (cGCP)
- Manufacturing: current Good Manufacturing Practice (cGMP)
- Distribution: current Good Distribution Practice (cGDP)
- Storage: current Good Storage Practice (cGSP)

Throughout the development and commercialization phases, different sections of the cGxP apply and certification to the corresponding requirements are mandated by the relevant authorities.

Accordingly, all operations are routinely inspected by respective health authorities against relevant cGxP requirements and certified to enable the continued supply of our products to patients.

Relationship of ICH Q10 to regional cGMP requirements, ISO standards, and ICH Q7

- The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) brings together the regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of drug registration[1].
- ICH aims to achieve greater harmonization worldwide to ensure that safe, effective, and high-quality medicines are developed and registered according to ICH guidelines, which are based on scientific consensus between regulatory and industry experts.
- ICH Q10 describes a comprehensive model for an effective quality management system for the pharmaceutical industry, referred to as the Pharmaceutical Quality System. It provides a framework to[2,3]:
  - Establish, implement and maintain a system that is able to deliver high-quality products

  - Develop and use effective monitoring and control systems for process performance and product quality
  - Identify and implement appropriate quality improvements to fulfil quality needs consistently

- ICH Q10 demonstrates industry and regulatory authorities' support for an effective pharmaceutical quality system to enhance the quality and availability of medicines around the world in the interest of public health. Implementation of ICH Q10 throughout the product lifecycle should facilitate innovation and continuous improvement and strengthen the link between pharmaceutical development and manufacturing activities[2,3].

- The model is based on the International Standards Organization's (ISO) quality concepts and includes applicable Good Manufacturing Practice (GMP) regulations. It complements ICH Q8 "Pharmaceutical Development" and ICH Q9 "Quality Risk Management" guidelines[2,3].

All Novartis operations involved in manufacturing pharmaceutical products can only operate if a cGMP certificate is issued by the relevant external health authorities. 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 European Medicines Agency (EMA) in Europe or the Food and Drug Administration (FDA) in the US[2,3].

Regulators and governments build on ISO standards to develop better regulations, thanks to the involvement of globally recognized experts[4].

All Novartis operations involved in the development and manufacture of medical devices are certified against ISO 134855 (ISO 13485-2016 "Medical devices — Quality management systems — Requirements for regulatory purposes"[4]).

As illustrated above, there is a strong link between the harmonized standards and legal requirements established by authorities and the certifications required to develop, manufacture and approve a product for commercialization.

Conclusion

For the manufacture of medical devices, we hold the relevant certifications from ISO and other notified bodies. For all manufacturing, supply and distribution of Novartis pharmaceutical products, we hold the relevant manufacturing licenses and GMP/GxP certificates issued by the appropriate health authorities (FDA, EMEA, WHO, SwissMedic). These confirm after inspection that our duties, including our quality management systems, comply with their regulatory requirements.

References

1. https://www.ich.org/
2. https://www.ema.europa.eu/en/documents/scientific-guideline/international-conference-harmonisation-technical-requirements-registration-pharmaceuticals-human_en.pdf
3. https://www.fda.gov/media/71553/download
4. https://www.iso.org/benefits-of-standards.html
5. https://www.iso.org/standard/59752.html