

GMP Policy

Good Manufacturing Practice (GMP) is a set of regulations and guidelines that provide guidance concerning the manufacturing, holding and distribution of active pharmaceutical ingredients (APIs), chemical intermediates used to produce APIs, medicinal (drug) products, food and food/feed additives. These products must be manufactured under a controlled system for managing quality to ensure they meet appropriate specifications and are consistently produced in accordance with quality standards appropriate for their intended use.

During the manufacture of Lonza products, the company places the highest priority on the safety and health of the consumers of our products and as such, places the highest emphasis on ensuring that each product has the correct identity, quality and purity characteristics that it purports, or is represented, to possess. This GMP Policy applies to the manufacture of APIs intended for human or veterinary use, API intermediate materials, including materials/products used in clinical trials, dietary supplements, vitamins, food and other feed/ food additives required to be compliant with GMP, using the following production methods

- chemical synthesis
- extraction
- cell culture / fermentation
- recovery from natural sources

Manufacture includes the receipt of materials, production, packaging, repackaging, labelling, relabelling, quality control, release, storage and distribution.

Manufacturing processes for APIs and API intermediate materials must comply with the International Conference on Harmonisation Guide, ICH Q7A, entitled Good Manufacturing Guide for Active Pharmaceutical Ingredients, which is recognised by many regulatory bodies worldwide including those from the European Union, USA, Japan, Switzerland and Canada, as well as being compliant with the regulatory requirements, where these are defined, of the destination countries to be supplied with a specific product.

Manufacturing processes for food and feed/food additives must comply with the US Food & Drug Administration current Good Manufacturing Practice (GMP) regulations for foods (Title 21 Code of Federal Regulations, part 110) as well as the appropriate food GMP standards pertaining to the country of manufacture.

It is the responsibility of all involved personnel at any level to apply this policy and to act immediately if a risk of violating this policy is detected. The final authority concerning any GMP issue is with the Head of Corporate Quality and accountability for compliance with this policy is with the head of the respective legal entities.



Richard Ridinger
Chief Executive Officer