

# GMP Policy

Good Manufacturing Practices (GMP), refers to the practice of complying with a set of regulations and guidelines, enforced by national and international regulatory agencies, that provide guidance concerning the manufacturing, testing, holding and distribution of active pharmaceutical ingredients (APIs), chemical intermediates used to produce APIs, medicinal (drug) products, cosmetics, food, food /feed additives, dietary supplements and medical devices.

These activities are subject to an authorization issued by a Competent Authority and the holder of such an authorization is legally obliged to comply with the principles and guidelines of good manufacturing practices in order to maintain the authorization.

The purpose of GMP regulations is ultimately to protect the patient or consumer from ineffective, unsafe, impure and/or poor quality products by a systematic and consistent approach to manufacturing based on an appropriate system for managing quality.

This policy applies to all of these product types manufactured within Lonza's manufacturing and distribution organization under these regulations and guidances.

Lonza sites must, as a minimum follow these covering regulations and guidelines where we manufacture and sell our products. Individual sites can incorporate additional guidances that are appropriate for them into their Quality Management Systems (QMS).

As required by the GMP regulations and guidelines, our products are manufactured according to a documented QMS, based on the principles defined in these regulations/guidelines, to ensure they meet appropriate specifications and are consistently produced in accordance with quality attributes appropriate for their intended use in pharmaceutical, food/feed and cosmetic applications.

It is the responsibility of Lonza Management to ensure this policy is followed at all involved sites. The final authority concerning any GMP issue is with the Head of Corporate Quality and accountability for compliance with this policy is with the Heads of the respective legal entities.

**Richard Ridinger**  
Chief Executive Officer

**Phillip Batchelor**  
Head of Corporate Quality