

GMP Policy

1 Brief Introduction

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/feed dietary ingredients and supplements, medical devices and combination products.

2 Scope

This policy applies to all product types manufactured within Lonza's manufacturing and distribution organization and to all Lonza employees engaged in GMP activities.

3 Definitions

For purposes of this document, definitions and abbreviations given in CORP-24 apply.

4 Description

Lonza is committed to being a trusted and reliable partner for our customers, delivering safe and effective products and services in an excellent and efficient manner Lonza accomplishes this by:

- Adhering to applicable regulatory requirements and building effective industry networks to stay abreast of evolving regulations and industry best practices
- Fostering a strong Compliance and Quality culture through the organization where collaboration is naturally embedded on a daily basis
- Integrating GMP and quality management principles into our business processes and decision-making practices
- Building quality into the product lifecycle, ensuring adequate GMP levels through the stages of the product lifecycle
- Designing innovative facilities and processes right from the start
- Providing tailored training and developing our skilled and experienced staff
- Performing regular internal audits focusing on compliance and continuous improvement
- Sharing best GMP practices and applying learnings from Health Authority inspections across all Lonza sites, nurturing a learning culture and enabling compliance

Pierre-Alain Ruffieux

Chief Executive Officer

Oliver Schlaefli

Head Global Quality

