

Quality

We are committed to developing, manufacturing, commercializing, and supplying high-quality, safe, effective and reliable products, placing patients and consumers at the centre of all quality-related decisions, throughout the entire product lifecycle, in full compliance with applicable regulatory, quality, and food safety requirements.

Our Pharmaceutical Quality System, aligned with ICH Q9 and ICH Q10, is designed to proactively manage risks to product quality, patient safety, and product integrity. It integrates scientific knowledge, quality risk management, and data integrity principles, and enables continual improvement through performance monitoring, audits, and key quality indicators.

For Consumer Health Care (CHC) products, we ensure that quality systems and controls are commensurate with their intended use, market requirements, and applicable GMP, GxP, and food safety standards, guaranteeing consistent product quality, safety, label compliance, and consumer trust according to Food Safety Globally recognized standards.

Data integrity is a fundamental pillar of our Quality System. We ensure that all GxP and quality-relevant data are accurate, complete, legible, contemporaneous, original, and attributable (AL-COA+), supporting reliable decision-making, regulatory compliance, and patient and consumer safety.

Quality is a shared responsibility of all employees and partners, who are expected to act with integrity and accountability, actively supporting, maintaining, and continuously improving the effectiveness of the Quality Management System. Through a strong Quality and Patient-Centric Mindset, we ensure that patient safety, consumer protection, customer expectations, and regulatory compliance are consistently met while supporting innovation, operational excellence, and sustainable business growth.

This Quality policy applies to all pharmaceutical, CHC products and services, whether established or innovative, and to all activities across the global Alfasigma organisation.