



## The J. Molner Company Quality Policy

Quality and professionalism are integral parts of The J. Molner Company's business principles and are the cornerstone of ensuring high levels of customer satisfaction and patient safety. By maintaining operational excellence, we ensure the long-term sustainability of our business. Each person at The J. Molner Company is responsible for ensuring the quality of our activities and compliance with this policy.

The aim of The J. Molner Company quality system is to:

- Ensure that GMP requirements are met on a daily basis for all performed activities.
- Ensure that the needs of customers, regulatory authorities, and other certification organizations are met.
- Ensure customer satisfaction with our products and services.
- Ensure that The J. Molner Company drug products continuously meet the standards for quality, safety and effectiveness.

Therefore, the objectives of the quality system are to:

- Ensure the continued development, implementation, and maintenance of the quality system and to continually seek improvements in the effectiveness of the quality system.
- Report results accurately and unambiguously in a timely manner; seek improvements in the service and products provided to customers.
- Meet customer requirements for performed service and testing activities for turn-around time, sample collection, reliability of service, and reporting.
- Ensure all activities are performed by suitably trained and qualified staff and provide opportunities for staff to extend their knowledge and competency and gain relevant professional qualifications.
- Ensure equipment used is fit for purpose, properly maintained and calibrated, and where possible, measurements are traceable to recognized standards.
- Ensure full traceability throughout the sample handling process and ensure sample handling procedures and environmental conditions do not affect the results.
- Ensure the test methods selected are up to date and fully validated as fit for purpose to ensure the accuracy and reliability of our test results.
- Use internal audits, external proficiency, and other checks to ensure the quality system continues to comply with requirements; ensure problems are investigated promptly, the root cause established, and effective action taken to prevent a recurrence.
- Monitor subcontractors and suppliers to ensure quality standards are maintained in line with established quality agreements and GMP guidelines.
- Ensure through quality system and vendor qualification activities that the manufacturing, testing, shipping and distribution of all The J. Molner Company finished drug products meet the predefined quality, safety and efficacy standards.

- Implement and continuously improve our pharmacovigilance activities by monitoring, assessing, and mitigating risks associated with pharmaceutical products throughout their lifecycle. By maintaining robust systems for adverse event reporting, signal detection, and risk management, we safeguard patient health, comply with regulatory requirements, and ensure product quality and safety.
- Ensure that all reported customer complaints regarding product quality are addressed and the effectiveness, or safety concerns are systematically documented, evaluated, and resolved promptly for all The J. Molner Company drug products.
- Ensure that changes impacting drug products are implemented in a controlled manner, with careful assessment of their potential impact to ensure compliance, effectiveness, and safety.
- Continually assess risks and opportunities in relation to all company GMP related activities in order to give assurance that the management system is achieving its intended results.



Jason Grenfell-Gardner  
Chief Executive Officer

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This version cancels and replaces all previous Quality policy statements