

MMV QUALITY POLICY

MMV, an organization responsible for development of pharmaceutical products is committed to the discovery and development of safe and effective pharmaceutical products in compliance with current regulatory requirements.

It is the policy of MMV that all drug discovery and development activities are based on sound scientific data generated in compliance with internationally recognized standards and guidelines. In order to achieve this MMV's operations comply with the following principles:

- The rights of clinical study volunteers are protected
- The operation of a well defined Quality Management System (QMS)
- Ensuring operations are current, effective and in compliance with the Company policies and with current standards and good practices for GLPⁱ, GCPⁱⁱ, GMPⁱⁱⁱ and GDP^{iv}
- Ensuring that all staff are trained not only in the operations which they are required to perform, but also in the principles of quality and appropriate good practices as required
- Developing good relationships with third party suppliers who consistently meet our requirements
- Ensuring that documentation is continuously controlled, complies with MMV processes and systems and is suitable for worldwide regulatory filings including ICH^v regions
- The development and implementation of programmes of continuous improvement for quality systems in order to secure continued confidence in the safety, quality and efficacy of the medicines that we develop

Applicable guidelines include ICH guidelines for GCP, GMP, GLP and GDP. MMV works with partners and contract organizations that are committed to the same quality principles. Contracts and agreements will be maintained which clearly define responsibilities in order to assure product quality, safety and efficacy comply with regulatory requirements.

MMV has put in place a QMS to ensure that this policy is achieved. The MMV Quality Manual describes the QMS and defines management responsibilities including the ongoing review of its effectiveness.

ⁱ Good Laboratory Practice

ⁱⁱ Good Clinical Practice

ⁱⁱⁱ Good Manufacturing Practice

^{iv} Good Distribution Practice

^v International Conference on Harmonization