



Quality Policy

To satisfy our customers, EUROIMMUN US, along with its parent company EUROIMMUN AG (a PerkinElmer company), manufactures, distributes and provides support for in-vitro diagnostic products of high quality in accordance with their intended use. Quality, Consistency, Safety, Performance, and Value are our key elements to sustainability and commitment to meet and exceed the customer requirements, and global regulatory requirements.

Management is responsible for ensuring all employees understand and abide by the Quality Policy and it is the responsibility of the employees to perform their duties diligently in concordance with the Quality Policy. The Management and the Staff of EUROIMMUN US is understanding and dedicated to our customers' needs by meeting or exceeding expectations of on-time product delivery, service & support.

EUROIMMUN US Management has established a comprehensive Quality Management System that meets all the requirements of the statutes of US FDA 21CFR § 820 and ISO 13485:2016. Our Quality Management system is designed to meet and adapt to changing needs while ensuring a process of continuing compliance and quality improvement.

In accordance with the statements above, the Management of EUROIMMUN US has defined the following Quality Objectives with regards to assuring quality.

1. To manufacture and distribute/sell in vitro diagnostic test kit(s) for autoimmune diagnostics; and to distribute/sell in vitro diagnostic products (instruments, test kits and software) of consistently high quality and innovation potential in accordance with their intended use.
2. To fulfill or exceed customers' wishes and regulatory requirements to ensure consistent provision of services under the aspect of optimized costing and competitive advantage.
3. To skillfully train and advise customers and provide support when needed.
4. To protect users and patients through assured performance characteristics of the test systems with due consideration to risk management and information on residual risks that cannot be eliminated.
5. To build up partnerships with suppliers, customers and other business partners with the aim of continuously improving product quality and delivery.
6. To continuously improve quality by avoiding errors, minimizing sources of errors and optimization of influencing factors.



Hamid Erfanian, Chief Executive Officer

8/9/2021

Date:



QM signature

8/9/2021

Date:

