



QUALITY POLICY

Version 02, 30/09/2024

PETSIAVAS commits to improving and protecting patients by providing high quality and reliable products, in the fields of pharmaceuticals, medical devices, nutritional supplements and cosmetics.

Top Management has established and supports a Quality System, adjusted to the individual requirements of each product category, always in compliance with current legislation and its directions.

General directions

1. Focus on patients and consumers
2. Meeting patient expectations regarding Quality
3. Full compliance with the respective Regulatory Requirements
4. Quick and effective response to concerns regarding Quality, either by patients or Competent Authorities and Institutions
5. Integrated plan-do-check-act approach (PDCA)

The Quality System is certified according to the applicable standards per field:

- Good Manufacturing Practice (EU-GMP) for the Pharmaceutical Department
- Good Distribution Practice (EU-GDP) for the Pharmaceutical Department
- ISO 9001:2015 for the Surgical & Hospital and Health Care Departments
- ISO 14001:2015 for the Surgical & Hospital and Health Care Departments
- ISO 13485:2016 for the Surgical & Hospital and Health Care Departments
- Ministerial Decision 1348/2004 for the distribution of Medical Devices

The Company aims for a zero quality defect policy, with the following measures:

- Effort to constantly improve processes
- Regular review of products and the System, as applicable
- Continuous process verification, as applicable
- Risk assessment by use of suitable tools (FMEA)
- Supplier and subcontractor evaluation
- Qualification and calibration of critical equipment
- Regular monitoring of critical environmental conditions
- Validated production, storage, distribution and control procedures
- Investigation of all deviations and non-conformities
- Investigation of all quality complaints
- Implementation of corrective and preventive actions depending on the root cause
- Regular and continuous personnel training in quality procedures and matters
- Internal audits to verify the proper implementation of the Quality System

For the proper operation of the Quality System, the Company has established an autonomous Quality Assurance Department, separate from other departments, to maintain and constantly improve the System and supervise implementation.

R. Anastasopoulos
General Manager