

QUALITY POLICY OF MANA PHARMA, S.L. (MD/ IPS)

To comply with this Quality Policy, **MANA PHARMA, S.L.** has Quality Management Systems implemented and maintained throughout the Organization, which define the context to carry out the Importation Activity and Authorized Representative in Europe of **Medical Devices, Medical Devices for In Vitro Diagnostics, Non-Medical Devices included in Annex XVI of Regulation (EU) 2017/745 and Devices and Instruments Used for Permanent, Semi permanent or Tattooing of the Skin by Invasive Techniques not Considered Medical Devices. Products (IPS Activity)**, all based on the applicable Legislation, such as **Regulation (EU) 2017/745, Regulation (EU) 2017/746, Regulation (EU) 2022/2236, Royal Decree 192/2023, Royal Decree 1662/2000, EN ISO 13485: 2016/ A11:2021, ISO 9001: 2015** and any other applicable regulations.

Sanitary Scope (General) (IPS Activity):

- Importation, Storage, Distribution, Export, and Authorized Representation in Europe, of **Medical Devices, Medical Devices for In Vitro Diagnostics, Non-Medical Devices listed in Annex XVI of Regulation (EU) 2017/745, Devices and Instruments Used for Permanent, Semi-Permanent Make-up or Tattooing of the Skin by Invasive Techniques not Considered Medical Devices.**, with which **MANA PHARMA, S.L.** carries out operations, in the development of its professional activities..

ISO 9001:2015 Scope (IPS Activity):

Importation, Storage, Distribution, Export and Authorized Representation services in Europe, of:

- Medical devices:
 - Non-active and active implantable medical devices in general.
 - Active and non-active healthcare products in general.
- IVD medical devices:
 - Reagents and reagent products, calibrators and control materials in general.
 - IVD medical products in general.
- Non-medical medical devices according to current regulations.
- Devices for permanent and semi-permanent make-up.

Scope EN ISO 13485:2016/ A11:2021 (IPS Activity):

Importation, storage, distribution, export and Authorized Representation services in Europe, of:

- Medical devices:
 - Non-active and active implantable medical devices in general.
 - Active and non-active healthcare products in general.
- IVD medical devices:
 - Reagents and reagent products, calibrators and control materials in general.
 - IVD medical products in general.

Our purpose, to provide service to society through our commitment to its health and well-being, excludes justifying any means to achieve it. The result, however beneficial it may be, does not justify the use of inadequate resources, even if they are sometimes present in the economic and commercial world where we carry out our business activity. **MANA PHARMA, S.L.** must be prepared to make some sacrifices, knowing that by doing so it will be preserving what is essential to it: its integrity.

We wish to be recognized, within a competitive market, as a responsible company; that the recipients of our services can trust our values; that our suppliers recognize us for our honesty, for being faithful to our word. And that everyone who joins this project shares our position and manifests it in their work. We want it to be understood that our economic activity is at the service of the person, of the common good, and although inherent to the business activity there is economic benefit, **MANA PHARMA, S.L.** preserves its integrity, helping to the realization of our project of health and welfare of society.

The scope of action of **MANA PHARMA, S.L.** is focused on the supply, distribution and export of medicines (of which, in some cases **MANA PHARMA, S.L.** is a TAC Laboratory and/or Local Representative), Medical Devices and pharmaceutical products in general, as well as materials and equipment, and also in the import of Medical Devices, all this wide range of materials being used by the Clients in the development of their professional activities (all of them related to the health and wellness sector). Customers are national and international, public and private. Most of our customers are located in developing countries.

It is important to mention the outstanding health activity carried out by **MANA PHARMA, S.L.** in the national territory, related to Medicines in Special Situations (MSE), in connivance with the Health Authorities, thus contributing to alleviate the lack of supply of medicines that occur in our country. In addition, **MANA PHARMA, S.L.** distributes medicines in Spain from European TAC Laboratories that have placed their trust in us, acquiring **MANA PHARMA, S.L.** the role of Local Representative before the Spanish Health Authorities.

We have consistently maintained, and continue to maintain, that the characteristics of our company are very peculiar. Our entrepreneurial being brings added value, insofar as the beneficiary of our activity is the society, and ultimately, the health sector.

Our purpose is to generate and maintain solid relationships with our clients, based on trust, offering a quality service at competitive prices. To this end, we are committed to complying with all legal and regulatory requirements, as well as the requirements of our Customers and Suppliers, or those we have subscribed to internally.

This would not be possible without our valuable personnel, qualified professionals who attend to our customers in a personalized way, to consider not only their current needs, but also to anticipate their future expectations, favouring communication and creating the necessary structure for continuous improvement.

Our commitment extends to our suppliers, who are selected and evaluated in terms of their service and quality in order to provide our customers with the maximum guarantee.

All those of us who work in management positions in the company have a greater responsibility, directly proportional to the position we occupy, to comply with and ensure that the Quality Policy is complied with. But all of us who work at **MANA PHARMA, S.L.** are responsible for putting it into practice.

It only remains for me to thank you for your involvement and your commitment to put into practice what is stated here, and to contribute to make it a reality for others.

Sincerely regards,

Katayun Manavi Tabatabai
General Manager
MANA PHARMA, S.L.
In Madrid, on 10/06/2024