Quality Policy

S.A.L.F. S.p.A. top management considers essential for the strategic development of the company, to establish and maintain a quality system in compliance with UNI EN ISO 9001: 2015 and UNI EN ISO 13485: 2016, the European Directives 93/42/EEC and subsequent amendments, Legislative Decree 219/06 and subsequent amendments, the Legislative Decree 193/06 and subsequent amendments and the European Directives concerning medicines, Part 820 of Title 2 1 of the Code of Federal Regulation (CFR) Quality System Regulations (QSR), Canadian Medical Device Regulation SOR/98/282, Therapeutic Goods Regulations 2002, to guarantee:

1) the quality of drugs, medical devices and services in a way to:

- fulfill effectiveness and efficiency customer expectations although not expressed;
- Comply with the product specifications and standards applicable in the field of drugs and medical devices;
- Lead to business results expected;

2) its responsiveness to the needs of the Company, in particular:

- Customer satisfaction, environmental protection, human and animal health, safety of people and property;

3) the evolution of the corporate culture of continuous improvement and total quality in the company.

To this end the S.A.L.F. S.p.A. has prepared a quality system with the involvement of all staff, which sees its application throughout the development of drugs and medical devices from the design of the manufacturing process until its distribution and use.

4) To achieve the objectives described above, the company management undertakes:

- to plan strategies for improvement;
- To involve all staff through constant training and information activities, also optimizing the response time to change;
- To involve all customers by collecting and examining their complaints, demands and proposals;
- To set up an organizational structure targeted implementation of what was expressed;
- To provide the necessary human and material resources;
- To exert a constant monitoring of the implementation of what was expressed in the Quality Manual;
- a periodically verify the compliance of the system to the company policy and make the organizational changes and techniques necessary for the pursuit of this objective.

5) S.A.L.F. S.p.A. top management, aware that the quality policy must be understood, implemented and supported at all levels of the company, **is committed to provide adequate information and to involve all staff through:**

- Providing evidence of the company's policy for quality;
- Communications and updated information that are hung on the bulletin board of the quality;
- Updating indexes of quality, keeping informed staff;
- The set performance targets and support by appropriate means their pursuit;
- The promotion of initiatives to collect suggestions from all staff and targeted improve customer satisfaction, internal security and environmental protection;
- Activation of training courses on concepts and aspects of application of Total Quality, GMP, GVP, norms relating to drugs and medical devices and the UNI EN ISO 9001: 2015 and 13485: 2016.

Cenate Sotto, 02th January 2019

S.A.L.F. SpA Top Management

S.A.L.F. S.p.A. Laboratorio Farmacologico
Fondata nel 1921

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