Quality, environment and safety policy

The Senior Management of S.A.L.F. S.p.A. has considered it essential since 2000, for the strategic development of the company, to establish and maintain a Quality System compliant with the UNI EN ISO 9001:2015 and UNI EN ISO 13485:2016 standards, the European Directives 93/42 / EEC and subsequent amendments, the Legislative Decree 219/06 and subsequent amendments, to Legislative Decree 193/06 and subsequent amendments and the European Directives concerning medicinal products, Part 820 of title 2 1 of the code of Federal Regulation (CFR) Quality System Regulation (QSR), Canadian Medical Device Regulation SQR/98/282, Therapeutic Goods Regulations 2002, Brazilian Resolution RDC 16 2013, RDC 23 2012 e RDC 67 2009, MHLW Ministerial Ordinance 169. For the same reasons, the Senior Management of S.A.L.F. S.p.A., in 2012, decided to start and maintain an environmental management system compliant with the UNI EN ISO 14001 standard and certified by a third party and a safety management system organized in accordance with OHSAS 18001.

The Management Systems are therefore able to guarantee:
the quality of drugs, medical devices and services so that:
- effectively and efficiently satisfy customer expectations even if not expressed;
- comply with the product specifications and applicable regulations concerning drugs and medical devices;
- lead to the desired business results;

their compliance with the needs of the Company, in particular:
- customer satisfaction,
- the protection of the environment and the prevention of pollution, human and animal health, the safety of people and things to ensure that the workplace is safe and as risk-free as possible.

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

To this purpose, the S.A.L.F. S.p.A. has set up a Quality, Environment and Safety Management System with the involvement of all personnel, which sees its application to all the activities that take place throughout the production site of S.A.L.F. S.p.A., in the entire development of drugs and medical devices starting from the design of the manufacturing process up to its distribution and use.

To achieve the objectives described above, the company management demonstrates leadership and commitment to management systems by promoting, developing and supporting them. In particular, it undertakes:
- to analyze one's own organization and its context;
- to plan improvement strategies, integrating the requirements of management systems into the organization's business processes;
- to involve all personnel, raising awareness and guiding and supporting people to contribute to the effectiveness of management systems, through constant information and training activities, aimed at professional improvement and management of company activities not only for the quality aspect, but also for risk prevention and health protection and for limiting environmental impact and preventing pollution;
- to analyze and take into consideration the needs and expectations of the relevant stakeholders (including mainly customers, suppliers, partners, employees, local communities, national and local public control bodies and authorizations), integrating them into their own systems management as mandatory and / or voluntary requirements;
- to set up an organizational structure aimed at implementing what has been expressed;
- to provide the human resources, workspace, infrastructure, machinery and necessary tools;
- to constantly monitor the implementation of the requirements defined in the documented Management System information;
- to periodically verify the compliance of the Systems with the company policy and to make the organizational and technical changes necessary to pursue this objective;
- to comply with the current regulations regarding environmental protection and safety at work and any agreements signed with third parties.

The Senior Management of S.A.L.F. S.p.A. aware that the quality, environment and safety policy must be understood, implemented and supported at all company levels, is committed to providing adequate information and involving all personnel also through:
- giving evidence of the company policy for quality, the environment and safety through its publication on the company website and thus making it available to all interested parties.

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- up-to-date communications and information that are hung on the quality - environment - safety notice board
updating the quality, environment and improvement objectives, keeping personnel informed as far as applicable;
- to set qualitative and environmental objectives and targets and to support them with adequate means to pursue them;
- promoting initiatives aimed at collecting suggestions from all personnel and aimed at improve customer satisfaction, internal security and environmental protection;
- the activation of training courses on the concepts and application aspects of Total Quality, GMP, GVP of the laws on drugs and medical devices, of UNI EN ISO 9001 and UNI EN ISO 13485, UNI EN ISO 14001 and for compliance with the mandatory standards for the prevention of pollution and for the safety and health protection of its employees.

Objectives S.A.L.F. S.p.A. for the next five years are:

• Strategy:
Constantly focus on innovation
The sector must remain that of the sterile, but the products must change, the technologies refine, the skills increase, the organization adapt;
Growth at ALL levels to improve not only technical but also managerial and relational skills
Clear roles and responsibilities with equally clear corporate and function objectives, necessarily shared, with defined times;
Individual objectives aligned with company objectives;
Constant, rigorous and punctual checks of the "bar" level.

• Structure:
Movements in the packaging area
New office building
Creation of new vial filling areas
New laboratory area

• Shopping:
Solution bearer and promoter: antenna always aimed at AQ - PROD - CQ - COMM to capture needs and propose solutions

• Commercial area:
New foreign branch (s) starting from UK;
Promotion of new divisions with different markets products
(e.g. dentistry, beauty and leisure)

• Production, maintenance, engineering:
Introduction Mes for management control and continuous improvement of dashboards and cash flow control.
Preventive maintenance programming from manuals and predictive maintenance
Spare parts warehouse brought within the company.
Greater and better interaction with the office purchases to control expenses in a timely manner and organizing the material at best.
Starting from the "Process Department" (CI-Team) for the control and supervision of the process through measurements, statistical analysis, operational management of the plants, over time we arrive at the creation of a "Project Department" (P-Team) for the design of " machines "or parts of customized machines

• Quality:
Integration of staff and office efficiency through maximum integration with production QA, IT, PRO and CI-Team.
Bringing the laboratory to an increasingly advanced level, with adequate equipment and ever greater skills.
Expansion of spaces

• Logistics:
Introduction of one or more vertical warehouses.
Automation of systems in use (trilateral and end of line)

• Administration, Finance and Control:
Introduction Mes for management control and continuous improvement of dashboards and cash flow control.

• Research and development:
Need for an R&D manager able to collect market suggestions, promote projects with precise time objectives, evaluate and verify their progress by coordinating PROD - CQ - AQ - REG - COMM
with the aim of presenting at least 5 new dossiers per year.

• Regulatory:
Clear and well-defined objectives of products to be registered in equally defined times, always favoring the time element by identifying, if and when necessary, third parties to which to delegate any operations that are not "critical" or "confidential".
Start of certification of medical devices according to the new Medical Devices Regulation (EU) 2017/745 (MDR).

• Human resources:
Presence and constant updating of social media in order to facilitate HR recruiting by focusing on new talents and passion.
New functions to grow: legal office, R&D innovation, energy management, external relations, marketing, general secretariat
Increase the attractiveness of the company:
By meeting employee expectations
By acting on those levers (e.g. social responsibility, welfare etc.) that make the workplace more attractive in the eyes of potential candidates
Rewarding merit and performance without exception.

• ICT:
Constant increase in computerization: wiring of the entire production for quality and quantity control in real time
(MES, warehouse discharges and various dedicated programs).
Constant data processing in collaboration with PRO and the CI-Team.
Introduction of new technologies (AI, machine learning, augmented reality ...)
Cybersecurity

• Environment, health and safety:
Solutions aimed at introducing green processes and products or improving them.
Launch of ISO 45000 certification
Actions aimed at improving welfare and the working environment

• CI TEAM:
Creation of a team for "continuous improvement" consisting of an interdisciplinary CI-Team (AQ - IT - PRO - MAN - CQ - CdG) but with independent staff capable of initiating and managing projects for continuous improvement and technical and organizational innovation (eg lean, 5S, 6 sigma etc...).
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Cenate Sotto, 30th August 2021

SALF SPA Management