

Combino Pharm Environmental Management System

Introduction

The Head of Malta Operations, together with the Environmental Protection Health and Safety (EPHS) Manager is responsible for the provision of the necessary resources to ensure the effective implementation of the established processes. An **Organisational Chart** is in place to ensure that all processes that affect the environment are realized in an efficient and structured manner at all times. The latest version of this document is available at the Human Resources (HR) Department.

Environmental Policy

- Protect the environment, minimise the impact of our activities on it and prevent pollution.
- Comply with laws, norms, regulations and other applicable environmental requirements.
- Train, raise awareness and involve our personnel in the implementation of this commitment and motivate them to carry out these objectives.
- Reduce the use of halogenated and other solvents, effluents and waste generated in the processes, energy consumption and emissions, as long as it is technologically and economically feasible to do so without compromising the quality of our product.
- Reduce, reuse or recycle waste by recovering solvents or raw materials, using waste as a by-product and managing packaging materials, among other actions, as long as it is technologically and economically feasible to do so without compromising the quality of our product.
- Periodically establish quantifiable environmental objectives, develop plans with the necessary environmental targets to permit the achievement of these objectives, and implement methods of control and follow-up.
- Advise our customers on the proper handling, from an environmental point of view, of our products.
- Inform suppliers and subcontractors of our environmental practices so that these can be applied during works carried out in our facilities.
- Continuously improve environmental management to ensure the improvement of environmental performance.

Roles and Responsibilities

Lines of authority are visually represented within the **Organisational Chart**, whilst specific responsibilities of each key role have been documented within **Job Descriptions**, the latest versions of which are available at the HR Department.

With the objective of ensuring the implementation and the maintenance of the EMS, as well as to accomplish the set objectives and targets, personnel will adopt different levels of environmental authority, jurisdiction and responsibility following the criteria below.

Ultimately, the Head of Malta Operations together with the relevant support of the EPHS Manager shall ensure that the principles governing this EMS are endorsed and upheld at all times.

Objectives and Targets

Combino Pharm has established implemented and documented environmental objectives and targets at various functional organization levels, but mostly concentrated around the Production Department which is the major contributor to the significant environmental aspects. The objectives and targets are SMART and consistent with the Environmental Policy and include commitments to prevent pollution, compliance to legislation and continual improvement. These objectives and targets are established and reviewed on a quarterly basis.

Competence and Awareness

SOP M98711 (Procedure for training of personnel) and **SOP M98713** (Procedure for the transmission of personnel training needs), Combino Pharm ensures that on a yearly basis, all its employees are sufficiently trained, informed and instructed to support the EMS.

Combino Pharm shall ensure that personnel performing tasks for it, or on its behalf, having the potential to cause significant environmental damage, are competent on a basis of appropriate training, education and experience, as follows:

1. Combino Pharm Personnel

The identification of training needs is determined by the corresponding Head of Department, and it takes into account:

- Awareness:
 - To raise the personnel awareness of the importance of accomplishment of the company's Environmental Policy, and the procedures and requirements of the EMS;
 - To point out the consequences of not complying with the environmental standards;
 - To point out the benefits of proper environmental behaviour.
- Training:
 - Significant environmental aspects related to each post;
 - Degree of responsibility in the continuation of procedures.

2. External personnel

The identification of the training and information needs of personnel is carried out by the Head of Human Resources and a Head of Department of the corresponding subcontractor, and takes into account:

- The possible environmental impact of the activities of the subcontracted personnel;
- The duration of such activities.

Training records are kept on file by the HR Department, together with the results of the corresponding training evaluations.

An evaluation of the experience, information, training and awareness of Combino Pharm personnel is carried out to ensure the competence of each individual, especially those who carry out tasks directly related to environmental management.

Operational Control

Combino Pharm ensures that all activities, processes and services which may cause significant environmental impact are carried out through documented operational standards. The responsibility of such activities falls on the Departments in which they occur. Those activities which may cause deviations from the environmental policy, objectives or targets will especially require such operational control.

Documented operational control instructions must exist, defining how the activities and methods for establishing inspection and control are to be carried out for the following aspects which may have certain environmental effects:

- Waste;
- Effluent;
- Prevention of leaks and spillages;
- Activities of research and development;
- Storage of products and their transport;
- Laboratories

All the elements of operational control and the installations of the pollution reduction facilities, which may be employed, will be duly monitored and verified and will be used for preventative maintenance to ensure their proper operation.

Emergency Preparedness and Response

Combino Pharm identifies and responds to potential accidents and emergency situations and prevents and reduces environmental impact which may be associated with those situations through its **Emergency Plan**.

The situations and/or events not included in the **Emergency Plan** or which need to be included will be developed in specific procedures.

Combino Pharm examines and checks its **Emergency Plan** and response procedures whenever it is necessary and, in particular after an emergency situation has occurred.

Monitoring, Measurement, Analysis and Evaluation

The Head of Engineering is responsible for the calibration of production equipment which could potentially affect the environment.

The EPHS Manager is responsible to periodically carry out monitoring and measurement of the key characteristics of the operations and activities which could have a significant impact on the environment, including operational control, follow up actions, inspection and checking of the conformity with the set environmental objectives and targets.

Equipment which is subject to control programmes has a described method of calibration, acceptance criteria and procedure of use and is included in the **Preventive Maintenance Programme**.

Combino Pharm has a **Calibration Calendar** established for this equipment, as well as a record of previous calibrations which have been carried out.

Calibration records must be kept for a minimum of six (6) years.

The EPHS Manager is responsible to plan periodic environmental internal audits of all departments which contribute to the implementation of the procedures according to the EMS. Such audits are a main source of information for the initiation of corrective actions.

Internal auditing may be contracted to an external company if it is considered necessary. As long as the audit follows standard practices, there will be no standard format of how the audit will be carried out.

Management Review

The EMS is reviewed by Management on a periodic basis. During such reviews, the following issues will be considered and discussed:

- Summary of non-conformances and the respective corrective and preventive actions;
- Review of the suitability of the Environmental Policy;
- Review of environmental performance indicators;
- Evaluation of accomplishment of the objectives and targets;
- Follow up of the actions established by the previous Management Review Meeting;
- Recommendations for improvement;
- Objectives for the next period.