QUALITY POLICY

INTRODUCTION
This policy is intended to demonstrate that POLIFARM d.o.o. (POLIFARM thereafter) has the ability, integrity and resources to perform required activities.

The procedures for maintaining quality system are described in Standard Operating Procedures (SOPs) that provide precise instructions on how to perform and document the relevant activity.

This quality policy covers all those activities that fall under the responsibility of POLIFARM.

The general manager is responsible for the local quality system, but implementation of these systems and quality per se is the responsibility of each director, manager, supervisor and employee.

ROLES AND RESPONSIBILITIES
General Manager supports establishment (resource allocation), implementation and maintenance of quality policy.
Roles and responsibilities are defined in a separate document (Organizational Chart).

Each position within the organizational chart is covered by a job description or a function description. Job contracts are signed by the staff member and by the general manager, indicating that they are both aware and agree to the scope of activities described therein.
Personnel must have appropriate educational qualification, training and experience or suitable combination of these factors to enable them to perform their duties.

CONFIDENTIALITY
The confidentiality of commercial information shall be respected all the times. Proprietary rights and intellectual property rights shall be protected and respected. Personnel will make every effort to protect information stored in electronic format or on magnetic media or in any other computerized format. Personnel will make every effort to adhere to relevant data protection law.

QUALITY MANAGEMENT
Quality commitment is based on the following principles:

- Recognition that all applicable national and international legislation and regulations, in particular guidelines regarding medicinal products, must be put into force and implemented for the benefit of the company, all employees, and the patients. Continuous improvement and updating to new technical or scientific or legal requirements and techniques is a principle.

- Team-based working principles and provision of adequate training for all local employees in order to improve skills and broaden the knowledge base to the benefit of the company, the employee and the patient.

QUALITY MANAGEMENT REVIEW
Quality Management Review is carried out at least annually by the general manager and other employee's, as necessary and required. The meeting minutes which are mandatory, are approved by the general manager. The minutes include a list of open issues with agreed corrective and preventive actions.

QUALITY MANAGEMENT SYSTEM DOCUMENT CHANGE CONTROL
POLIFARM should establish and maintain a system for the control of all documentation related to the quality system, e.g. standard operating procedures.
The document control system should ensure that documents are authorized by appropriate persons prior to issue and that only current versions are held by the nominated individuals. A record of all relevant local documents and document owners should be maintained. The system should ensure that superseded documents are withdrawn from use. Superseded documents should be retained for an appropriate and defined period.
The documentation system should ensure that any changes to documents are made in a controlled manner and are properly authorized. There should be a means of identifying changes in individual documents.

QUALITY IMPROVEMENT, CORRECTIVE & PREVENTIVE ACTION (CAPA)
POLIFARM should establish and maintain a system of quality indicators, organized and defined. In particular these indicators should address, although not necessarily be limited to: timeframes for response to external or internal complaints, management review results, amount and quality of training provided to local personnel and efficacy of the CAPA program including external audit and/or inspection follow-up. The CAPA procedure requires a route cause analysis, corrective action plan or action plan for implementation of the required actions and an assigned staff member responsible for the implementation. Where CAPA items are not resolved by their implementation date, a new date is assigned and if this date is also not met, the item is brought to the attention of the general manager at the next management review meeting.
Corrective action applies to revising or replacing processes so that they will produce conforming products or services. Action intended to correct a process so as to eliminate or reduce the cause of nonconformities may be classified as a corrective action.

LOCAL RECORDS
00It is essential to maintain quality records not only to conform to the regulations but to also aid management in reviewing the effectiveness and making decisions on how to improve it. The records that are maintained also demonstrate that processes and services are according to standards. Records must be stored in conditions to facilitate their preservation and ready access by appropriate personnel. The records are retained for at least 10 years or as specified in individual SOPs.
The quality records that are maintained include but are not limited to:

- Quality Management System documentation
- Document Change Request
- Audit Reports and Management Reviews
- Customer Complaints
- Personnel Records/Training records/Job Descriptions
- Receipt documents of spontaneous AE-Reports
- Promotional/Advertisement material

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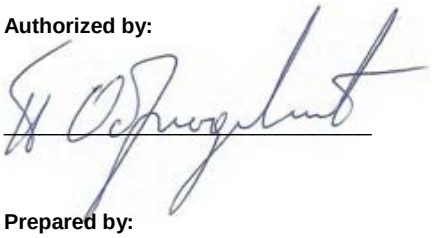

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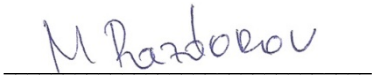

DOCUMENT REVISION HISTORY

Effective Date	Version Number	Reason for Revision
07.10.2013.	1.0	N/A
13.01.2020.	2.0	Change of Key Persons
01.02.2022.	3.0	Change of Logo Design