Quality Manual

ISO 9001:2015

Quality Management System

PharmExpert LLC

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This QM reviews once in 3 years. Earlier review/actualization is subject if there is a major change in the processes described in the QM.

1. SCOPE

Pharmex has developed and implemented a QMS to demonstrate its ability to consistently provide services that meets clients and applicable regulatory requirements, and to address customer satisfaction through the effective application of the PV System, including continual improvement and the prevention of nonconformity.

QMS ensures that our quality objectives, policies and procedures are embedded into our daily operations and are adhered to at all times.

The QMS of PV system in Pharmex includes a QM, summary of structures, Standard Operation Procedures (SOP) and processes to achieve the quality objectives (¶ 6.2).

Since our business is international, the manual and all related documented information has been prepared in English language.

2. NORMATIVE REFERENCES

2.1 External References

External references are collected in the «Normative References» (R01T-SOP-QA-002).

2.2 Internal References

SOP-QA-003 «Pharmacovigilance Glossary»

SOP-HR-001 «Human Resources Management

SOP-HR-002 «Training»

SOP-PV-001 «Adverse Event Processing»

SOP-PV-006 «Literature Monitoring»

SOP-PV-012 «Safety Communication to HCPs_non-HCPs»

SOP-PV-015 «Service agreements»

SOP-PV-017 «Handling of RA Requests»

SOP-QA-001 «GDocP

SOP-QA-002 «SOP on SOP»

SOP-QA-004 «Non-Conformity Management»

Procedure – specified way to carry out an activity or a process.

Quality management system (QMS) – a part of a management system with regard to quality.

Quality manual (QM) – specification for the QMS of an organization.

Quality planning – part of quality management focused on setting quality objectives and specifying necessary operational processes, and related resources to achieve the quality objectives.

Quality policy – policy related to quality.

Quality system (QS) – the sum of all aspects of a system that implements quality policy and ensures that quality objectives are met.

Quality system of a pharmacovigilance system – the organizational structure, responsibilities, procedures, processes and resources of the PV system as well as appropriate resource management, compliance management and record management.

Risk – effect of uncertainty.

Risk-benefit balance –an evaluation of the positive therapeutic effects of the MP in relation to the risks, i.e. any risk relating to the quality, safety or efficacy of the MP as regards patients' health or public health.

Top management – person or group of people who directs and controls an organization at the highest level.

For other terms and definitions refer to the SOP-QA-003 «Pharmacovigilance Glossary».

4. CONTEXT OF THE ORGANIZATION

4.1 Understanding the Organization and its Context

Pharmex has determined external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its QMS.

Assigned employees of Pharmex monitors and reviews information about these external and internal issues and top management perform analysis.

The internal issue of the Pharmex's environment includes:

- Organizational structure
- Infrastructure
- Resources (material and human) to achieve the stated objectives

Internal factors are related to the knowledge and results of the work of Pharmex. These factors are of a strategic nature and can have both a positive and a negative impact on the activities of internal factors and are taken into account when providing services in the field of PV.

The external elements of the Pharmex environment include: