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I. PURPOSE

This Standard Operating Procedure (SOP) describes the procedure for Information Security Policy at PharmExpert LLC (Pharmex) is to ensure protection of the confidentiality, integrity and availability of Information Assets and Information Systems, whether electronic, manual, voice or data, either owned and operated, or accessed.

II. SCOPE

This procedure shall apply to all Pharmex's personnel involved in business processes.

III. RESPONSIBILITIES

Role	Responsibility
Director	• Providing the company with all resources for implementation of Information Security Policy
Pharmex's personnel	• Protection of Pharmex's information; its Information and Communications Technology (ICT) systems and other assets, and maintaining their operation, confidentiality, availability and integrity • Ensure information (in all formats) is protected from adverse impact on its integrity, availability, unauthorized disclosure, amendment or destruction • Read, understand and comply with the security requirements identified in this SOP
System Administrator (SA)	• Create users and edit or delete roles or records within the system • Integrity of the information and for ensuring the correct access by user • Follow any system or network specific requirements • Escalate permissions or privileges • Use an administrator account to perform non-administrator tasks
Quality Assurance Manager (QAM)	• Compliance monitoring

IV. DEFINITIONS

Abbreviations used in the text are spelled out on its first mention.

Pharmex's personnel – staff of Pharmex and outsourced Local Contact Persons responsible for PV (LCPPV) in the countries of responsibility.

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

V. PROCEDURE

A. General Specification

1. Security Principles

The Security Principles define Information Security as the application of control measures to protect the confidentiality, integrity and availability of systems and services:

- Confidentiality – information is only accessed by those who have been authorized to do so for legitimate purposes.
- Integrity – accuracy and completeness of information and information processes is maintained so that it can be trusted.
- Availability – authorized users have access to information when and where it is needed.

2. Information Subject

a) Information subject to this SOP includes, but is not limited to:

- electronic information stored on computers, disks, any other electronic storage media;
- information transmitted by electronic means, including incoming and outgoing emails, message transmissions through mobile phone applications or messengers, video conferencing, telephone traffic;
- hard copy information including paper records, whiteboards, briefing boards and notice boards;
- Spoken information.

b) An information system includes elements of the following:

- Physical environment (e.g. buildings, equipment, cables, etc.).
- Information and data.
- Software and hardware.
- Operational Service provision (what the system is there is achieve).
- Human resources (users).

B. Process

1. Computer User Accounts

a) Processes for allocating, amending and removing user access rights are set out by the SA on order of Director.

b) In order to log on as a SA, personnel must be an authorized administrator and be in possession of system logon credentials allocated to them.

c) SA appoints by Director.

d) SA can be IT specialist or any other Pharmex’s personnel with appropriate knowledge.