I. PURPOSE

This Standard Operating Procedure (SOP) describes the procedure for validation of Computerized Systems (CS) used in the PharmExpert LLC (Pharmex) to avoid erroneous systems affecting the safety, quality and performance of its services.

II. SCOPE

This procedure shall apply to requirements for initial and periodic validations of CSs.

III. RESPONSIBILITIES

Role	Responsibility
Head of Pharmacovigilance Department (HPVD)	• Providing to SA necessary information for preliminary assessment
System Administrator (SA)	• Determination an impact of software to quality system • Validation of CSs • Approval of validation report
Quality Assurance Manager (QAM)	• Determination an impact of software to quality system • Approval of validation report

IV. DEFINITIONS

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

Good automated manufacturing practice (GAMP) – a set of guidelines for manufacturers and other automation users follow to maintain operational efficiency and reliability.

Validation – confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use can be consistently fulfilled. [FDA 21 CFR 820.3 (z)]

Process validation – establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications. [FDA 21 CFR 820.3 (z)(1)]

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

V. PROCEDURE

A. General Specification

1. ISO 13485:2016 requirement