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

- SA shall release the CS by adding it to the «CS Log» and inform HPVD about the approval of the system.

5. Monitoring of Software

a) User feedback and error reports by developers are monitored by SA for relevant occurrences that may affect the organization.

b) New version updates are implemented and the «CS Log» is updated accordingly. If necessary, a revalidation is carried out.

6. Decommissioning of Software

a) In case it is decided to decommission a CS, evaluate possible effects and document the actions in the «CS Log».

7. Coding of CS

a) The ID number of CS starts from 01. The subsequent serial numbers shall be 02, 03 and so on.

VI. ANNEXURE

R01F-SOP-IT-002 «CS Validation» form

R02T-SOP-IT-002 «CS Log»

VII. INTERNAL REFERENCES

None.

VIII. REVISION HISTORY, APPROVALS

Issuance Date	Revision Number	Summary of Revisions
24-Sept-2023	00	New SOP
Written by: HPVD PharmExpert LLC	Reviewed by: QAM PharmExpert LLC	Approved by: Director PharmExpert LLC