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## Standard Operating Procedure

# Validation of Commercial Off-the-Shelf (COTS) Computer Systems



This is an example of a Standard Operating Procedure. It is a proposal and starting point only. The type and extent of documentation depends on the process environment. The proposed documentation should be adapted accordingly and should be based on individual risk assessments. There is no guarantee that this document will pass a regulatory inspection.

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## 1. PURPOSE

Software and computer systems should be validated for compliance and business reasons. Validation helps to generate accurate, reliable and consistent analytical results. This SOP gives guidelines on how to validate computer systems.

## 2. SCOPE

Validation of computer systems that have an impact on product quality. Validation includes all life cycle phases from system planning to retirement. The focus is on validation of commercial off-the-shelf systems. Exceptions to this procedure are possible but should be based on risk assessment and justified, documented and approved by operation's management and QA.

## 3. GLOSSARY/DEFINITIONS

Item	Explanation
Validation	"Establishing documented evidence, which provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specification". (Source: "FDA Guidelines on General Principles of Validation", March 1986)
DQ	Design Qualification
IQ	Installation Qualification
OQ	Operational Qualification
PQ	Performance Qualification
URS	User Requirement Specification
FS	Functional Specification
GAMP	Good Automated Manufacturing Practice (Forum). The GAMP Forum exists to promote the understanding of the regulation and use of computer and control systems within the pharmaceutical manufacturing industry.