

Glossary

Term	Meaning
Acceptance criteria	The criteria a system must meet to satisfy a test or other requirement (PDA Technical Report 18)
Boundary value	A minimum or maximum input, output or internal data value, applicable to a system (PDA Technical Report No. 18)
Branch testing	Execution of tests to assure that every branch alternative has been exercised at least once
Change control	A formal monitoring system by which qualified representatives of appropriate disciplines review proposed or actual changes that might affect a validated status to determine the need for corrective action that would assure that the system retains its validated state
COTS Software	Commercial off the shelf software applications that are used as is or can be configured to specific user applications by “filling in the blanks” without altering the basic program
Commissioning	Activities to put a computerised system into proper operation
Computer hardware	Various hardware components in the computer system, including the central processing unit, printer, screen and other related apparatus
Computer system	Computer hardware components assembled to perform in conjunction with a set of programs, which are collectively designed to perform a specific function or group of functions
Computer related system	One or more computerised systems and the relevant operating environment
Computerised system validation	Establishing documented evidence which provides a high degree of assurance that a specific computer related system will consistently operate in accordance with predetermined specifications

Computerised system	A computer system plus the controlled function which it operates
Computerised system specification	A document or set of documents that describe how a computerised system will satisfy the system requirements to the computer related system
Controlled function	A process and any related equipment controlled by a computer system
Design specification	A specification that defines the design of a system or system subcomponents
Developer	The company or group responsible for developing a system or some portion of a system
Firmware	A software program permanently recorded in a hardware device such as a chip or EPROM
Functional requirements	Statements that describe functions, a computer related system must be capable of performing
Functional specification	Statements of how the computerised system will satisfy functional requirements of the computer related system
Functional testing	A process for verifying that software, a system or a system component performs its intended functions
Installation Qualification (IQ)	Documented verification that all key aspects of hardware and software installation adhere to appropriate codes and the computerised system specification
Ongoing evaluation	The dynamic process employed after a system's initial validation to maintain its validated state
Operating environment	Those conditions and activities interfacing directly or indirectly with the system of concern, control of which can affect the system's validated state
Operating system	A set of software programs provided with a computer that function as the interface between the hardware and the applications program
Operational Qualification (OQ)	Documented verification that the system or subsystem operates as specified in the computerised system specifications throughout representative or anticipated operating ranges
Path testing	Execution of important control flow paths throughout the program
Performance Qualification (PQ)	Documented verification that the integrated computerised system performs as intended in its normal operating environment, <i>i.e.</i> that computer related system performs as intended
Policy	A directive usually specifying what is to be accomplished
Process	Structured activities intended to achieve a desired outcome

Qualification protocol	A prospective experimental plan that when executed is intended to produce documented evidence that a system or subsystem has been qualified properly
Standard Operating Procedure	Instructions that specify how something is to be accomplished
Structural integrity	Software attributes reflecting the degree to which source code satisfies specified software requirements and conforms to contemporary software development
Structural verification	An activity intended to produce documented assurance that software has the appropriate structural integrity
User	The company or group responsible for the operation of the system
Validation plan	A document that identifies all systems and subsystems involved in a specific validation effort and the approach by which they will be qualified and the total system will be validated; includes the identification of responsibilities and expectations
Vendor	The company or group responsible for developing, constructing and delivering a system or part of a system