

SWGDRUG GLOSSARY

These definitions were developed and adopted by the SWGDRUG Core Committee from a variety of sources including The United Nations Glossary of Terms for Quality Assurance and Good Laboratory Practices.

Accreditation Procedure by which an accreditation body formally recognizes that a laboratory or person is competent to carry out specific tasks.

Accreditation Body Independent science-based organization that has the authority to grant accreditation.

Accuracy: Trueness and precision compose accuracy.

Analysis Technical operation to determine one or more characteristics of, or to evaluate the performance of, a given product, material, equipment, physical phenomenon, process, or service according to a specified procedure.

Analyst A designated person who:

Examines and analyses seized drugs or related materials, or directs such examinations to be done.

Independently has access to "open" (unsealed) evidence in order to remove samples from the evidence for examination.

As a consequence of such examinations, signs reports for court or other purposes.

Audit A review conducted to compare the various aspects of the laboratory's performance with a standard for that performance.

Blank Specimen or sample not containing the analyte.

Calibration Set of operations that establishes, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material measure, and the corresponding known values of a measurand.

Certified reference material (CRM) A reference material, one or more of whose property values have been certified by a technical procedure, accompanied by or traceable to a certificate or other documentation that has been issued by a certifying body.

Certifying body Independent science-based organization that has the competence to grant certification.

Chain of custody Procedures and documents that account for the integrity of a sample by tracking its handling and storage from its point of collection to its final disposition.

Controls Samples used to determine the validity of the calibration, that is, the linearity and stability of a quantitative test or determination over time. Controls are either prepared from the reference material (separately from the calibrators, that is, weighed or measured separately), purchased, or obtained from a pool of previously analyzed samples. Where possible, controls should be matrix-matched to samples and calibrators.

Control Sample A standard of comparison for verifying or checking the finding of an experiment.

Correlated techniques Correlated techniques are those that have the same fundamental mechanism of characterization. For example, this would prevent the choice of two gas chromatographic tests both based on a partition mechanism (e.g. Methylsiloxane and phenylmethylsiloxane) or two thin layer chromatographic systems both based on an adsorption mechanism.

Deficiency of analysis Any erroneous analytical result or interpretation, or any unapproved deviation from an established policy or procedure in an analysis.

False positive Test result that states that a drug is present when, in fact, such a drug is not present in an amount less than a threshold or designated cut-off concentration.

Health & safety manager A designated person who is responsible for maintaining the laboratory health and safety program (including an annual review of the program) and who monitors compliance with the program.

Independent test result Result obtained in a manner not influenced by any previous results on the same or similar material.

Laboratory Facilities where analyses are performed by qualified personnel using adequate equipment.

Limit of Detection: Limit of detection (LOD) is the smallest measured content from which it is possible to deduce the presence of the analyte with reasonable statistical certainty.

Limit of Quantitation: The limit of quantitation (LoQ) is the lowest concentration of analyte that can be determined with an acceptable level of precision and trueness.

Linearity: Defines the ability of the method to obtain test results proportional to the concentration of analyte.

Method Detailed, defined procedure for performing an analysis. See Procedure.

Procedure Specified, documented way to perform an activity.

Proficiency testing Ongoing process in which a series of proficiency samples, the characteristics of which are not known to the participants, are sent to laboratories on a regular

basis. Each laboratory is tested for its accuracy in identifying the presence (or concentration) of the drug using its usual procedures.

Qualitative analysis Test that determines the presence or absence of specific drugs in the sample.

Qualitative test See **Qualitative analysis**

Quality assurance (QA) System of activities whose purpose is to provide, to the producer or user of a product or a service, the assurance that it meets defined standards of quality with a stated level of confidence.

Quality assurance manager A designated person who is responsible for maintaining the quality management system and who monitors compliance with the program.

Quality management That aspect of the overall management function that determines and implements the quality policy.

Quality manual Document stating the general quality policies, procedures and practices of an organization.

Quantitative analysis Procedure to determine the quantity of drug present in a sample.

Quantitative test See **Quantitative analysis**

Range Set of concentrations of analyte in which the error of a method is intended to lie within specified limits.

Reference material Material or substance one or more properties of which are sufficiently well established to be used for calibrating an apparatus, assessing a measurement method, or assigning values to materials.

Repeatability: Closeness of the agreement between the results of successive measurements of the same measurand carried out under the same conditions of measurement.

Report Document containing a formal statement of results of tests carried out by a laboratory.

Representative sample Statistically, a sample that is similar to the population from which it was drawn. When a sample is representative, it can be used to make inferences about the population. The most effective way to get a representative sample is to use random methods to draw it. Analytically, it is a sample that is a portion of the original material selected in such a way that is possible to relate the analytical results obtained from it to the properties of the original material.

Reproducibility Closeness of agreement between the results of successive measurements of the same analyte in identical material made by the same method under different conditions, e.g. different operators and different laboratories and considerably separated in time.

Robustness The robustness of an analytical procedure is a measure of its capacity to remain unaffected by small, but deliberate variations in method parameters and provides an indication of its reliability during normal usage.

Sample A portion of the whole material to be tested. Statistically, it is a set of data obtained from a population.

Sampling Analytically, the whole set of operations needed to obtain a sample, including planning, collecting, recording, labeling, sealing, shipping, etc. Statistically, it is the process of determining properties of the whole population by collecting and analyzing data from a representative segment of it.

Selectivity Extent to which a method can determine particular analyte(s) in a mixture without interference from the other components in the mixture. A method that is perfectly selective for an analyte or group of analytes is said to be specific.

Specificity See **Selectivity**.

Standard operating procedures (SOPs) A written document which details the method of an operation, analysis, or action whose techniques and procedures are thoroughly prescribed and which is accepted as the method for performing certain routine or repetitive tasks.

Supervisory chemist A designated person who has the overall responsibility and authority for the technical operations of the drug analysis section.

Technical/assistant analyst A person who analyses evidence, but does not issue reports for court purposes.

Technical support personnel A person who performs basic laboratory duties, but does not analyze evidence.

Test See **Analysis**

Traceable Ability to trace the history, application, or location of an entity by means of recorded identification. See also Chain of custody.

Traceability The property of a result of a measurement whereby it can be related to appropriate standards, generally international or national standards, through an unbroken chain of comparisons

Trueness: The closeness of agreement between the average value obtained from a large set of test results and an accepted reference value.

Uncertainty: Parameter associated with the result of a measurement, that characterizes the dispersion of the values that could reasonably be attributed to the measurand.

Validation Confirmation by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled.

Verification Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled. (Method works in your lab as well as where it was validated.)

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